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Short to Early-Mid Term Clinical Outcomes and Survival of Pyrocarbon Shoulder Implants: A Systematic Review and Meta-Analysis

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Abstract

Background: The appropriate surgical treatment option for young and active patients undergoing shoulder arthroplasty for arthritis remains questionable. Pyrolitic carbon (pyrocarbon) has been shown to improve implant longevity and decrease wear when in contact with cartilage or bone. The present systematic review aimed to evaluate clinical and radiological outcomes as well as the survivorship of pyrocarbon shoulder implants.

Methods: The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed. A systematic search was performed using the MEDLINE, EMBASE and Cochrane Library databases. All the studies dealing with the use of pyrolitic shoulder implants were pooled, data of interest were extracted and statistically analyzed through meta-analysis.

Results: A total of 9 studies were included for a total of 477 shoulders treated. The overall mean rate of survival of the implants was $93.4 \pm 5.8\%$ and $80\% \pm 26.5\%$ at 2 years and final follow up, respectively, while resulting $82.4\% \pm 22.1\%$ and $92.3\% \pm 3.5\%$ for PISA (pyrocarbon interposition shoulder arthroplasty) and hemi-arthroplasty/hemi-resurfacing, respectively.

Conclusions: Pyrolitic carbon shoulder implants showed good survivorship and clinical outcomes at an early to early-mid-term follow-up. More studies and better-designed trials are needed in order to enrich the evidence on long-term outcomes and comparison with other shoulder replacement options for young and active patients.

Level of Evidence: IV.

Keywords

shoulder hemi-arthroplasty, shoulder replacement, pyrolitic carbon, hemi-arthroplasty

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Introduction

The treatment of end-stage arthritis in the young (<60 years) and active population remains controversial. Shoulder arthroplasty represents the only reliable option even with its not completely satisfying results in terms of clinical and radiological outcomes.[1,2] Reverse shoulder arthroplasty rarely finds its indication in the young and active patients due to the increased risk of implant loosening and osteolysis and the lack of revision options.[3]

The use of total shoulder arthroplasty showed promising outcomes but also an high ratio of revision due to an early glenoid loosening or symptomatic erosion,[4,5] while shoulder hemi-arthroplasty (HA) has commonly been indicated for young and active patients with an acceptable status of the glenoid even though literature highlighted significative early complications such as glenoid erosion and functional loss.[6]

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Several therapeutic options have been proposed to resurface the glenoid using meniscal allograft, capsular interposition or synthetic membrane. They often ended up as being a nonvalid option due to their mid to long-term biomechanics properties and wear.[7,8] The discovery of a new material that could improve the implant longevity and reduce the glenoid impact and erosion on these kind of patients remains challenging. Pyrolitic carbon (pyrocarbon), with its modulus of elasticity similar to the diaphyseal bone and high biomechanical tolerance, has been proved to have better tribological properties than metal sliding against bone and cartilage without causing pain or damage.[9,10]

For this reason, pyrocarbon is commonly used in hand and wrist arthroplasty, as well as in other surgeries, for its proven proprieties in improving implant longevity and producing little or no cartilage and bone wear.[11,12] Over the past years, this material has been used in different shoulder implants: as a humeral head coating for HA and hemi-resurfacing systems or for the pyrocarbon interposition shoulder arthroplasty (PISA). PISA consists of a spherical graphite core coated with a pyrocarbon bearing surface, freely positioned in a reamed cavity in the proximal humerus, and directly articulating with double mobility against the glenoid and the humerus.

The purpose of this systematic review and meta-analysis was to analyze the clinical evidence available in relation to the pyrocarbon shoulder implants. The main focus was to determine clinical, radiological success, and survivorship of the different types of implants.

Materials and Methods

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines have been utilized to carry out this systematic review.[13] The PRISMA statement is composed of a 27-item checklist relating to review contents and a 4-phase flow chart of the study selection process.

Eligibility Criteria

Studies written in English, Italian, French, Spanish, and German were eligible for inclusion. Only peer-reviewed journals were considered, and randomized controlled trials (RCTs), prospective, and retrospective comparative studies and case series were included. Exclusion criteria were reviews of the literature, expert opinions, and studies that did not evaluate pyrocarbon interposition shoulder implants. The eligibility criteria were studies with at least 10 adult subjects recruited. All studies had to relate outcomes after pyrocarbon implants shoulder arthroplasty.

Information Sources and Search

An electronic systematic search of CINAHL, EMBASE, PubMed, and the Cochrane Central Registry of Controlled Trials was carried out by two reviewers, in order to identify eligible studies. Inter-rater reliability for study eligibility was measured using the kappa (κ) statistic. A κ of 0 to 0.2 represents slight agreement, 0.21 to 0.40 fair agreement, 0.41 to 0.60 moderate agreement, and 0.61 to 0.80 substantial agreement. A value >0.80 is considered almost perfect agreement, according to the guidelines of Landis and Koch.[14] The search was executed on 10 February 2022. The utilized search strings were: ((Pyrocarbon [MeSH Terms]) AND Shoulder Arthroplasty[MeSH Terms]) ; (((Shoulder arthroplasty [MeSH Terms]) AND Pyrocarbon [MeSH Terms]) AND Implants) AND outcomes.

Study Selection

Once the duplicates had been removed, relevant articles from the electronic search were retrieved in full text and evaluated. A manual search of the bibliography of each published study was performed, in order to find relevant articles that could potentially have been missed. Reviews, systematic reviews and meta-analyses were also retrieved and read, in order to broaden the search to include studies that might have been missed. The remaining articles were analyzed by two reviewers, to exclude studies not fulfilling the eligibility criteria. The reviewers were not blinded to the authors, year, and journal of publication. Studies eligible for inclusion were categorized by study type, according to the Oxford Centre for Evidence-Based Medicine (www.cebm.net). The following categories were utilized: case report, RCT and case series.

Data Collection Process

Two assessors independently extracted data from eligible studies using a data extraction form that was predefined according to the protocol. For each study, we extracted the criteria concerning the epidemiological characteristics of participants (age and sex), and assessment of results (revisions, reoperations, type of implant, implant survival, radiological assessments, pre-operative constant score, postoperative constant score). Revision involves removing at least a component of the implants that were inserted during primary surgery with or without replacing them with new components, while reoperation included resurgery without interfering with the implant. Data were analyzed using R software (2020; R Core Team). The primary endpoint was the rate for implant survival after pyrocarbon shoulder interposition replacement surgery. We also stratified the implant final survival, revision, and reoperation rate, as well as the functional scores and glenoid radiological erosion in relation to the different type of implant. The I^2 index was used to measure the heterogeneity of results within the included studies. Substantial heterogeneity was defined as $I^2 > 75\%$. The mean rate of revision was calculated with a 95% confidence interval (CI). We realized a forest plot of the results (Figure 1).

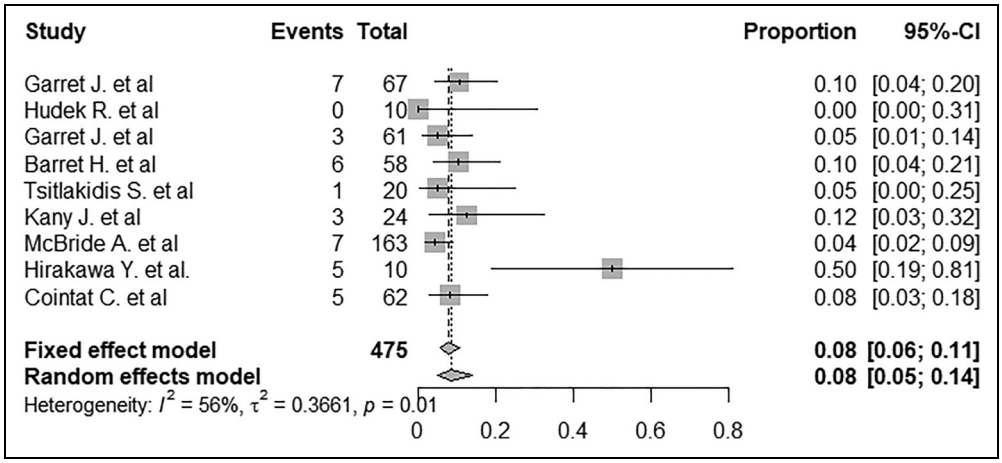

Figure 1. Forest plot on the overall revision rate.

Table 1. Study Details.

Study	Year of publication	Study type	Level of evidence	Mean follow up (months)	Number of of patients (shoulders)	Women/men	MINORS
Garret et al	2017	Case series	IV	49.7 ± 7.3	67 (67)	30:25	14/16
Hudek et al	2017	Case series	IV	42.8 ± 15	10 (10)	6:4	10/16
Garret et al	2018	Case series	IV	25.9 ± 3.3	61 (61)	20:41	11/16
Barret et al	2019	Case series	IV	47 ± 15	56 (58)	25:31	13/16
Tsitlakidis et al	2020	Case series	IV	24.3 ± 8.1	19 (20)	11:8	12/16
Kany et al	2020	Case series	IV	36 (NR)	- (24)	16:8	12/16
McBride et al	2021	Retrospective cohort comparison	III	72 (NR)	- (163)	139:24	20/24
Hirakawa et al	2021	Case series	IV	48.5 (NR)	10 (10)	NR	10/16
Cointat et al	2021	Case series	IV	33 (NR)	62 (64)	20:44	13/16

Quality of the Studies

The quality of included studies was evaluated using the MINORS (Methodological Index for Nonrandomized Studies) score (Table 1). Two authors performed this evaluation, which included a discussion to reach a consensus in case of disagreement.

Results

A total of 45 studies were found in the electronic search; of these, 9 were eligible for inclusion in this systematic review. No more studies were identified as relevant through the manual search. In total, 8 out of 9 studies were retrospective case series, one study was a retrospective cohort comparison (inter-rater agreement K value = 0.91). The study selection process is shown in Figure 2. Study details are summarized in Table 1. The main indication for arthroplasty was primary shoulder osteoarthritis. Other indications included chondrolysis after arthroscopy, rheumatoid arthritis, avascular necrosis, post-traumatic arthritis and postinstability arthritis. Four studies examined PISA implant, 4 studies examined pyrocarbon HA implant while only 1 study examined pyrocarbon hemi-resurfacing. A total of 477 shoulders were included in the 9 studies, mean age 52.5 years (range 44–58 years), treated for average follow up of 42.1 ± 14.6 months (Table 2).

Methodological Quality

In order to evaluate methodological quality of the included studies, MINORS score have been assessed. Average value was 11.9, although 1 comparative study was evaluated on a 24-point scale and not on a 16-point scale. This study had a MINORS score of 20.

Implant Survival

The mean rate of implant survival was extracted at 2 years and at the last collected follow up (final follow up). These results where extracted and calculated according to a random effect model. Only 4 studies reported this parameter at 2-year follow up where the mean survival was 94.5 ± 5.2%. All of the studies investigated implant survival at the final follow up. It ranged from 50% to 100% with an

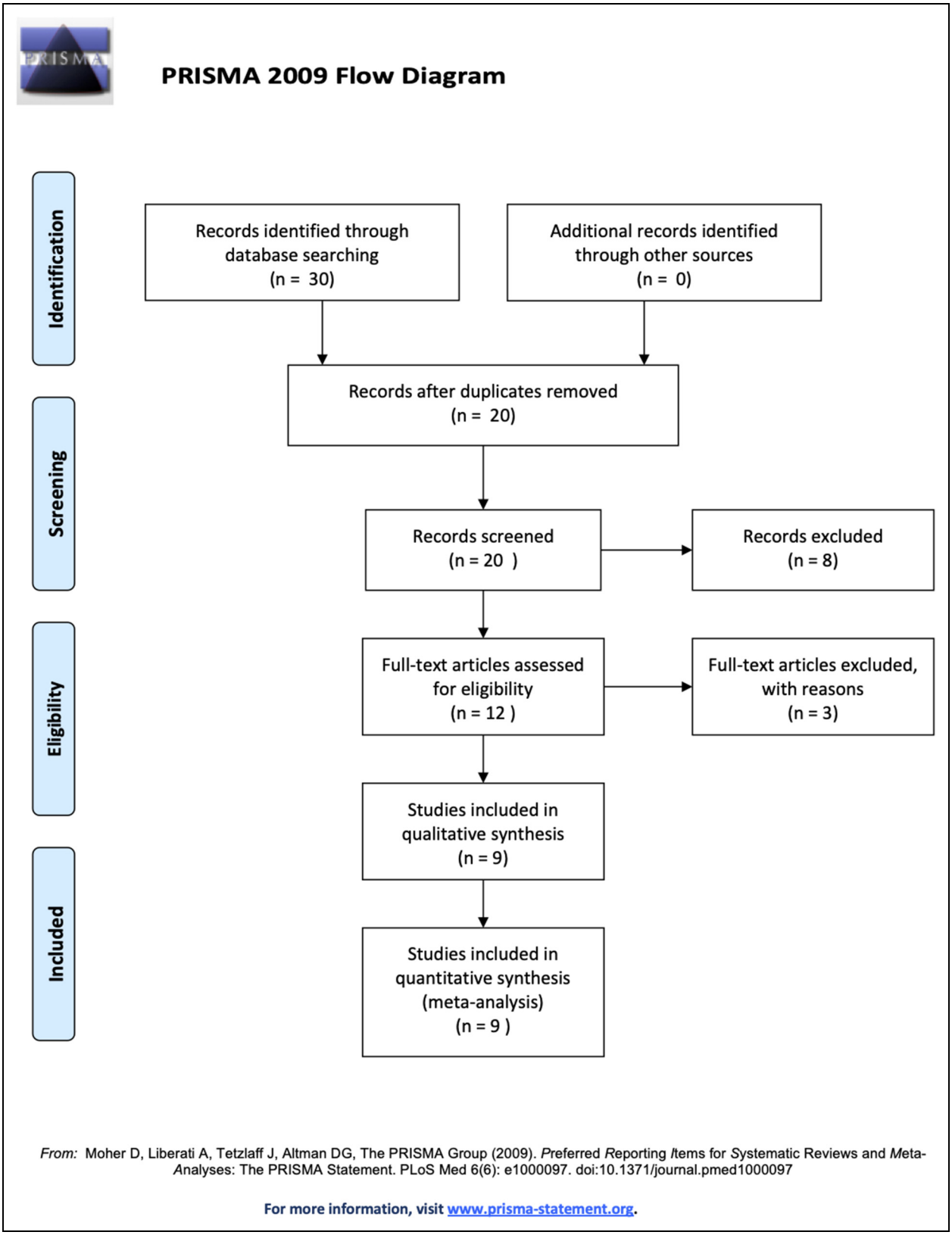

Figure 2. PRISMA flow chart of the study selection process.

Table 2. Main Outcome Rates.

Study	Mean age	Diagnosis	Type of Implant	Revisions/ reoperations (%)	Implant survival (2-year follow up)	Radiological assessment
Garret et al	49.3 ± 12.0	42 (63%) primary OA, 13 (19) avascular necrosis and 12 (18%) with secondary OA postinstability or postfracture	PISA	10.5%/ 3%	89.5% (90%)	- Glenoid erosion: 0.9% - Tuberosity thinning: 0.4% - Medialization of the humerus: 1.3% - Decrease of subacromial space: 0.6% - Humeral sclerotic bone densification line around the implant: 50%
Hirakawa et al	55.2 ± NR	7 (70%) primary OA, 1 (10%) fracture sequelae, 1 (10%) osteonecrosis, 1 (10%) with secondary OA	PISA	50%/ 0%	50% (90%)	- Glenoid erosion: 50% - Tuberosity thinning: 40% - Superior migration of the implant's center of rotation: 50%
Hudek et al	55.6 ± 12.9	10 (100%) avascular necrosis	PISA	0% / 10%	100% (NR)	- Glenoid erosion: 90% - Tuberosity thinning: 60% - Humeral sclerotic bone densification line around the implant: 100% - Superior migration of the implant's center of rotation: 80% - Inferior migration of the implant's center of rotation: 10%
Barret et al	52 ± 13	18 (31%) primary OA, 16 (28%) fracture sequelae, 3 (5%) osteonecrosis, 15 (26%) secondary OA, 2 (3%) rheumatoid arthritis, 4 (7%) revision of failed arthroplasty	PISA	10%/ 3%	90% (NR)	- Glenoid erosion: 78% - Tuberosity thinning: 48% - Humeral sclerotic bone densification line around the implant: 22% - Superior migration of the implant's center of rotation: 67% - Posterior subluxation: 12% - Anterior subluxation: 9%
Tsitlakidis et al	52.8 ± 10.8	14 (70%) primary OA, 4 (20%) osteonecrosis, 2 (10%) with rheumatoid arthritis	Hemi-arthropalsty	5.5%/ 0%	94.5% (NR)	- Glenoid erosion: 5% - Tuberosity thinning: 0% - Humeral sclerotic bone densification line around the implant: 0% - Superior migration of the implant's center of rotation: 10%

(continued)

Table 2. Continued.

Study	Mean age	Diagnosis	Type of Implant	Revisions/ reoperations (%)	Implant survival (2-year follow up)	Radiological assessment
Kany et al	44 ± NR	12 (50%) primary OA, 10 (41%) postinstability OA	Hemi-arthropalsty	12.5%/ 8%	87.5% (NR)	-
Cointat et al	53 ± NR	20 (31%) primary OA, 13 (20%) fracture sequelae, 13 (20%) osteonecrosis, 15(23%) with secondary OA, 3 (5%) rheumatoid arthritis	Hemi-arthroplasty	8.1%/ 0%	91.9% (100%)	- Glenoid erosion: 70%
Garret et al	57.9 ± 13.3	37 (61%) primary OA, 11 osteonecrosis, 11 (18%) with secondary OA, 2 (3%) with rheumatoid arthritis	Hemi-arthropalsty	5.7%/ 0%	95.3% (NR)	- Glenoid erosion: 13%
McBride et al	-	(8.9%) primary OA	Hemi-resurfacing	4.3%/-	95.7% (97.9%)	-

Abbreviation: PISA, pyrocarbon interposition shoulder arthroplasty; OA, Osteoarthritis; NR, Not Reported.

overall mean of 88.3% ± 14.9%. PISA and HA resulted in 82.4% ± 22.1% and 92.3% ± 3.5%, respectively. The overall rate of revision was 8.0% (95% CI; 6%-11%). I^2 index was 56% (Figure 1), while the overall rate of reoperation was 2% (95% CI; 1%-5%). I^2 index was 14% (Figure 3). Differential analysis also found 17.6% ± 22.2% and 7.9% ± 3.3% rates of revision and reoperation for PISA while 4% ± 4.2% and 2% ± 4% respective rates for HA.

Functional Outcomes and Patients Satisfaction

The rate of patient satisfaction with surgery was reported in 4 studies[15–17] with a mean of 86.3% ± 5.7%. Different scores were applied to evaluate clinical outcomes. The Constant-Murley score was the most administered (8 out of 9 studies). Its mean resulted 31.2 ± 10% before surgery, while at the final follow up increased to 69.9 ± 4.4%. Also, differential analysis found a mean of 26.9% ± 13.2% and 64% ± 6.6% for pre-constant and post-constant scores related to PISA, while 35.7% ± 7.4% and 73.4% ± 2.3% pre-constant and post-constant scores related to HA. Moreover, several scores were used to evaluate pain, so they could not be statistically studied. All the extracted constant scores and rates of overall satisfaction are summarized in Table 3. Only 2 works investigated rates of return to work and sports[18,19] with a resulting mean of 82.5% and 89%, respectively.

Radiological Assessments

Seven studies analyzed radiological assessments through the study of X-rays at 2-year follow up. All of these studies found glenoid erosion with an overall mean of 43.8% ± 37.2%. Glenoid erosion was assessed through the evaluation of pre-operative compared with follow up's X-rays at different time points. Differential analysis found glenoid erosion in 54.7% ± 39.6 and 29.3% ± 35.4% for PISA and HA, respectively. Only 5 studies found tuberosity thinning with a mean of 29.7 ± 27.8%, while humeral sclerotic bone densification line around the implant had a mean of 43 ± 34%. The remaining radiological assessments are summarized in Table 2.

Discussion

Total shoulder arthroplasty and HA have been more extensively performed in recent years for a variety of reasons, most commonly to reduce pain in patients with advanced osteoarthritis and proximal fractures. The optimum treatment of shoulder arthritis in the young patients represents a challenge for the orthopedic surgeons worldwide. This is due to the specific needs of this kind of patients: high-performance demand and longevity of the implant. This systematic review aimed to evaluate the survivorship, as well as the clinical and radiological short to early-midterm outcomes, of the pyrocarbon interposition shoulder implants. To our knowledge this

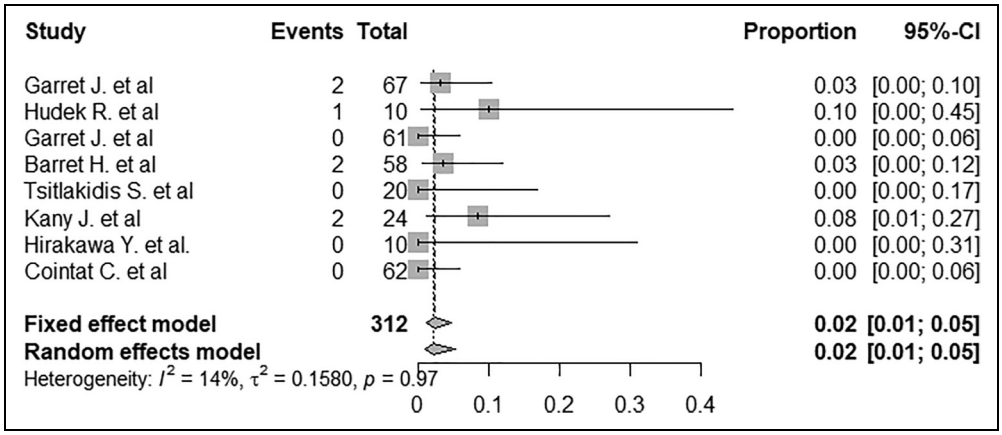

Figure 3. Forest plot on the overall reoperation rate.

Table 3. Functional and Satisfaction Results at Final Follow Up.

Study		Garret et al	Hirakawa et al	Hudek et al	Barret et al	Tsitlakidis et al	Kany et al	Cointat et al	Garret et al	McBride et al
Constant score	Pre	34.1 ± 15.1	30 ± 16.5	7.4 ± NR	36 ± 14	29.7 ± 8.2	46 ± N.R.	36 (26–50)	31.0 ± 15.8	-
	Post	66.1 ± 19.7	65 ± 20.1	64.6 ± 12.9	70 ± 15	73.9 ± 20.3	70 ± N.R.	75 (69–81)	74.8 ± 17.0	-
Patient overall satisfaction		-	87%	90%	90%	-	-		78%	-

represents the first systematic review and meta-analysis on the topic. The main finding was that implants using pyrocarbon have shown a high survival at 2-year (94.5 ± 5.2%) and final (88.3% ± 14.9%) follow ups, associated with an important increase of average constant score compared with pre-operative evaluation (31.2% vs 69.9%). Even though the quality of the published evidence is low, the use of this material as an interface to glenoid bone demonstrates promising results. Direct comparison between pyrolitic carbon and metal interposition was performed in a few studies only.[20,21] McBride et al[21] reported statistically lower revision rates in patients aged <55 years for hemi-resurfacing arthroplasty using pyrocarbon compared with other metal resurfacing or HAs as well as lower revision rates in male patients. Similar results were reported from Kany et al[20] when comparing 10 metal head and 24 pyrocarbon head HAs with a higher revision rate for the metal group (30% vs 17%). In addition, pre-operative constant score increased by 13 points in cobalt-chromium HA and 24 points in pyrocarbon HA, while the subjective shoulder value (SSV), increased by 19% and 34%, respectively. When compared to our study, literature reports similar or even worst results in studies analyzing early-to-midterm outcomes for metal resurfacing HA.[22,23] This factor increases the focus on the long-term follow up comparison, where pyrocarbon presents hypothetical advantages[24] but no clinical or radiological support yet. Levine et al,[1] conducted a longitudinal long-term follow up study where they collected data from 25 shoulders treated with metal resurfacing HA for glenohumeral osteoarthritis. They found a 29% revision rate and less than 80% survivorship at an average length of 17.2-year follow up. In addition, only 25% of patients were satisfied with their outcome. In a study investigating on mid-to-long term outcomes of 31 shoulder HAs, Neyton et al,[25] found 16% at 5-year follow up and 21% at final follow up rates of revision. Our study resulted in a shorter follow up but evident lower revision rates for pyrolitic carbon shoulder implants. Since the relevance of many studies reporting the superior midterm to long-term results of total shoulder arthroplasty in comparison with humeral head replacement for glenohumeral osteoarthritis,[6,23,26,27] investigating on new materials which could increase long-term outcomes for patients treated with shoulder HA results fundamental in order to really point out when and if this treatment should be indicated over total replacement. A subgroup meta-analysis for the different type of implant could not be conducted due to the limited data in the literature, even though mean rates for survivorship (82.4% vs 92.3%) and constant score (63.9% vs 73.4%) resulted higher for HA/hemi-resurfacing in comparison with PISA and lower in terms of revision (17.6% vs 3.2%), reoperation (4% vs 2%) and glenoid erosion (54.7% vs 29.3%). Hemi-resurfacing highlighted the highest rates for survivorship and constant score as well as the lowest for complications but only one study analyzed this type of implant, then no statistically significant data could be extracted. Our study had several limitations. First,

the high heterogeneity between the studies pointed out by our meta-analysis should lead to a critical interpretation of the results. The most relevant limitation is the low evidence level of the included studies as most are level IV studies and the low number of studies available on this topic as well as the difficulty to compare functional and satisfaction outcomes, which was related to the differences in study design. Moreover, the indications for arthroplasty were heterogeneous and an absence of prospective studies with significant groups of control decreased the quality of data. Finally, a lack of subgroup analysis related to the different functional demands of the patients could produce a high risk of bias.

Conclusion

This study underlies a high rate of survivorship and clinical improvements as well as radiological complications at a short to early-midterm follow up in patients treated with pyrocarbon interposition shoulder implants. At the current state of research, pyrocarbon shoulder implants represent a promising therapy to invest on, finding higher clinical rates and lower complications rates for HA when related to PISA. Further research and higher quality studies should be carried out to individuate long-term outcomes and to compare this treatment with other shoulder replacement techniques in order to define where to find their right indication.

Declaration of Conflicting Interests

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