Comparative meta-analysis of pyrocarbon and silicone for joint replacement surgery

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**Abstract**

**Objective:** To investigate the efficacy and complications that might be associated with pyrocarbon compared with silicone in patients undergoing joint replacement surgery.

**Methods:** The full-text papers about the clinical efficacy of pyrocarbon and silicone were retrieved from multiple databases. Review Manager version 5.0 was adopted for meta-analysis and analyses of sensitivity and bias.

**Results:** Ultimately, we studied 232 patients across eight studies that met the eligibility criteria. The meta-analysis suggested a significant difference between the pyrocarbon and silicone groups in terms of the Disabilities of the Arm, Shoulder, and Hand (DASH) score (standard mean difference (SMD) = 1.48; 95% CI [0.97, 1.99]; P = .009; P for Heterogeneity < .00001; I<sup>2</sup> = 63%); Visual Analogue Score (VAS) (SMD = 1.68; 95% CI [1.36, 1.99]; P < .0001; P for heterogeneity = 0.01; I<sup>2</sup> = 61%), and the abnormal radiolucent line (RR = 6.66; 95% CI [3.19, 13.89]; P < .0001; P for heterogeneity = 0.87, I<sup>2</sup> = 0%); and ossification development (RR = 0.90; 95% CI [0.56, 1.44], P = .66; P for heterogeneity = 0.94, I<sup>2</sup> = 0%).

**Conclusion:** This study showed that pyrocarbon might be an efficient material compared with silicone for joint replacement surgery, but resulted in poorer functional and pain outcomes compared with silicone.

**Abbreviations:** CFPEEK = carbon fiber reinforced polyether ketone composite, CIs = confidence intervals, RR = Odds Ratios, VAS = Visual Analogue Score.

**Keywords:** joint replacement surgery, pyrocarbon, silicone, treatment

1. Introduction

Hip arthroplasty has become a widely accepted treatment for hip osteoarthritis, hip fracture, and femoral head necrosis in the elderly. Through joint replacement, pain can be eliminated, the deformity can be corrected, joint function can be restored to a certain extent, and the quality of life can be greatly improved.<sup>[1–3]</sup> Joint prosthesis material should display good biocompatibility and be able to replace the physiological function of the human hip joint within its lifetime.<sup>[4–6]</sup> From the original muscle fascia to the use of ivory and other biomaterials and today’s broad use of metal, ceramics, and polymeric composite materials, it is recognized that hip prosthetic materials have met varying treatment needs, at least to a certain extent. Nevertheless, with scientific and technological advances, it is found that people have higher expectations of wear and tear resistance, stability, and service life of hip prostheses.

Since carbon represents one of the major elements of the human body, carbon materials have inherent biocompatibility compared with other materials.<sup>[7–9]</sup> Glassy carbon materials were used initially but were abandoned due to insufficient strength. At present, the main application of carbon is the use of carbon-fiber-reinforced polyether ketone composite (CFPEEK).

Silicone double-trunk hinge prosthesis not only maintains joint clearance, joint alignment through collagen scar tissue, and retention of joint movement, it can also greatly improve joint mobility through the hinge design.<sup>[10–13]</sup> The biggest difference between double-stem hinge implants and single-stem implants is their greater range of motion, and the dorsal opening of the hinges provides a larger dorsal flexion angle.

There are several articles comparing pyrocarbon and silicone, among which various research designs, inclusion and exclusion criteria, and selected measurements have been explored.<sup>[3–6]</sup> Proubasta et al<sup>[3]</sup> supported the use of pyrocarbon, while Zahiri et al<sup>[5]</sup> suggested silicone for joint replacement surgery. Since the choice of material for joint replacement remains controversial, a comprehensive meta-analysis was applied to evaluate the clinical efficacy and possible complications that might be associated with the use of pyrocarbon and silicone in joint replacement surgery.
2. Methods

All analyses were based on previously published studies; thus, no ethical approval and patient consent were required.

2.1. Searched databases and strategies

The literature was searched in PubMed, Embase, and the Cochrane Central Register of Controlled Trials databases after the year 2000. Two independent investigators carried out the initial search, deleted duplicate records, screened the titles and abstracts for relevance, and identified the publications for exclusion from further analysis or requiring further assessment. Next, we reviewed the full-text articles for possible or likely inclusion. We also manually checked the references of the retrieved articles and previous reviews to identify additional eligible studies. The following keywords were selected:

1. pyrocarbon;
2. silicone;
3. joint transfer.

The key words were used in all possible combinations to obtain the maximal number of articles. To obtain more relevant research and a higher degree of accuracy, the reference list of each retrieved article was also reviewed.

2.2. Inclusion and exclusion criteria

Studies were included if:

1. They were considered randomized trials or case-control studies.
2. They compared pyrocarbon and silicone.
3. They involved patients receiving joint transfer surgery.

Studies were excluded if:

1. They were case studies/meta-analyses/letters to the editor.
2. Comparison between pyrocarbon and silicone was absent.
3. Patients receiving joint replacement surgery were not included.
4. They were duplicates.

2.3. Data extraction and review

After selection, 2 authors analyzed the studies, and the following data were extracted for the relevant information as follows: article identification (i.e., author, year, and study location), sample characteristics (i.e., the number of patients in each study and their age), the type of intervention (different groups), and the methods used to obtain the relevant results (i.e., the methods used for posture evaluation). Any disagreement was discussed, and a third reviewer was consulted when necessary.

The Cochrane risk of bias assessment tool for non-randomized studies of interventions was individually applied to all selected studies. The risk of bias of each study was rated as “high risk,” “low risk” or “unclear” according to the match level for comparative information that was extracted and the evaluation criteria. Note that the authors strived to be objective during this quality assessment; however, a slight up or down of grading was possible. This manuscript adheres to the applicable EQUATOR guidelines.

2.4. Statistical analysis

Review Manager version 5.0 software (Cochrane Collaboration, 2011) was used to calculate the odds ratios (RR) with 95 percent confidence intervals (CIs). Summary outcomes are described as proportions and 95 percent CIs for the categorical and weighted mean differences (SMD) ± standard deviation (SD) for continuous data. Cumulative response rates in each group were calculated separately by using the sum of the responders and the total number of included patients, and these were reported as proportions and CIs for each individual modality. P < .05 was considered statistically significant. The significance and the extent of statistical heterogeneity were calculated using the Q test and I² index, respectively. Random effects modeling was applied if the P value for the test of heterogeneity was <0.10. Risk ratios were calculated for each analysis with the corresponding 95 percent CIs. Funnel plots were used to detect the possibility of publication bias by evaluating the asymmetry. We also performed sensitivity analyses based on the quality and weight of the trials by sequentially excluding each individual trial.

3. Results

3.1. Search results

A total of 501 articles was initially identified, but eight papers eventually met all inclusion criteria. Figure 1 is a flowchart of identification, inclusion, and exclusion, reflecting the search process and the reasons for exclusion.

3.2. Main features of the studies

This analysis consisted of a total number of 232 patients obtained from 8 randomized trials (14-21) (Table 1). These articles were published from 2011 to 2018. The sample size was between 10 and 43. The study included 119 patients in the pyrocarbon group and 113 in the silicone group.

3.3. Quality assessment

The risk of bias is presented in Figure 2. There was little bias between the pyrocarbon and silicone groups.

3.4. Meta-analysis of the DASH score

All studies examined the DASH score (Disabilities of the Arm, Shoulder, and Hand) (22). All 8 studies, including the 232 patients, showed a statistically significant difference in the DASH score on comparing the pyrocarbon and the silicone group (SMD = 1.48, 95% CI [0.97, 1.99]; P = .009; P for Heterogeneity <0.00001; I² = 63%) (Fig. 3). The DASH score in the pyrocarbon group was higher than that of the silicone group, indicating worse joint function with the pyrocarbon prostheses than with silicone ones.

3.5. Meta-analysis in the context of the Visual Analogue Score (VAS)

The results showed that the VAS score (23) in the pyrocarbon group was higher than that of the silicone group (SMD = 1.68; 95% CI [1.36, 1.99]; P < .00001; P for Heterogeneity = 0.01; I² = 61%) (Fig. 4). These results indicate that the pyrocarbon prostheses were associated with higher pain than silicone ones.

3.6. Meta-analysis of the abnormal radiolucent line

The overall result indicated that the abnormal radiolucent line in the pyrocarbon group was higher than that of the silicone group (RR = 6.66; 95% CI [3.19, 13.89]; P < .00001; P for Heteroge-
neity = 0.87, $I^2 = 0\%$) (Fig. 5). This indicates less effective healing with the pyrocarbon prostheses compared with silicone ones.

### 3.7. Meta-analysis of ossification development

The studies showed no statistical difference between the pyrocarbon and the silicone groups (RR = 0.90; 95% CI [0.56, 1.44]; $P = .66$; $P$ for Heterogeneity = 0.94; $I^2 = 0\%$) (Fig. 6).

### 3.8. Sensitivity analysis

According to the meta-analysis, the heterogeneity of the DASH score was high ($I^2 = 63\%$). As shown in Figure 7, the heterogeneity of the DASH score might have been attributed to the different results found for each study. When the article of Sweets in 2011\cite{20} was excluded, $I^2$ changed to 19 percent.
Table 1
Characteristic of the included studies.

| Study      | Year | Language | Country | Age range (mean) | Groups | n   | Type of research | Years of onset         |
|------------|------|----------|---------|------------------|--------|-----|------------------|------------------------|
| Bellemere  | 2012 | English  | France  | 56.8 ± 6.3       | pyrocarbon | 8   | RCT              | October 2008 to October 2011 |
| Completo   | 2018 | English  | Portugal| 52 ± 12          | pyrocarbon | 5   | Case-control     | January 2012 to December 2017 |
| Daecke     | 2012 | English  | Germany | 64.6 ± 6.1       | pyrocarbon | 21  | RCT              | August 2004 to August 2007   |
| Gledic     | 2017 | English  | France  | 62.3 ± 8.8       | pyrocarbon | 11  | RCT              | January 2008 and December 2015 |
| Mariconda  | 2014 | English  | Italy   | 63.1 ± 11.9      | pyrocarbon | 13  | Case-control     | January 2009 to January 2011  |
| Smec       | 2017 | English  | America | 63.8 ± 6.1       | pyrocarbon | 21  | RCT              | January 2010 to September 2014 |
| Sweets     | 2011 | English  | America | 55.7 ± 6.7       | pyrocarbon | 20  | RCT              | November 2001 to September 2007  |
| Vitale     | 2012 | English  | America | 52.6 ± 9.3       | pyrocarbon | 20  | RCT              | January 2005 to January 2010  |

Figure 2. Assessment of the quality of the included studies: low risk of bias (green hexagons), unclear risk of bias (white hexagons), and high risk of bias (red hexagons).

Figure 3. A forest plot for DASH scores in the pyrocarbon and silicone groups.
3.9. Bias analysis

Funnel plots of the DASH score in the pyrocarbon and silicone groups were performed. All studies are included in the plot. The results showed that the funnel plot had medium symmetry and little publication bias (Fig. 8).

4. Discussion

Previous studies of pyrocarbon and silicone prostheses reported conflicting results.\cite{3-6} Therefore, this meta-analysis aimed to investigate the efficacy and complications that might be associated with pyrocarbon compared with silicone in patients
undergoing joint replacement surgery. The results showed that although pyrocarbon is an efficient material for arthroplasty, silicone results in better functional, pain, and radiological outcomes compared with pyrocarbon, probably resulting in a better quality of life in the patients. The results could provide guidance for the selection of prostheses for joint surgery.

Artificial joint replacement is an effective surgical procedure in the treatment of joint diseases and is widely used in the clinic. There are many kinds of artificial joint prostheses that have certain advantages; however, there are also some insurmountable shortcomings such as electrolysis, corrosion, wear, loosening, bone absorption, sinking of metallic materials, aging, brittleness, and the toxicity of the materials. Carbon fiber composite is a common material for joint replacement. It has many advantages in artificial prosthetic manufacturing, such as high mechanical strength, fatigue resistance, good thermal stability, corrosion resistance, simple forming process, low cost, lightweight, transmission line, and several other attractive properties. In 1965, Swanson performed the first metatarsophalangeal joint replacement with silicone as a joint implant in accordance with Kellers procedure. Two years later, a silicone single-handle first metatarsophalangeal joint implant was introduced to replace the base of the proximal metatarsal bone. After continuous improvement, Swanson formally put forward the term “silica gel prosthesis.” The implant uses a silica gel cap as the gasket to provide ideal conditions for soft tissue stability.

In this meta-analysis, the differences in the DASH score between the pyrocarbon and silicone groups was significant. The score in the pyrocarbon group was higher than that of the silicone group, indicating worse functional outcomes in the pyrocarbon group. In addition, the VAS score was also significantly different between both groups, favoring the silicone group. Those results are in contradiction with the study Foucher et al, who showed that pyrocarbon was a relatively better material than silicone for joint replacement.

When comparing the abnormal radiolucent line between groups, the value in the pyrocarbon group was higher than that found in the silicone group. Differences in ossification development were found to be insignificant. This indicated that pyrocarbon might lead to more adverse events than would silicone. This is supported by Chen et al, who stated that surgery using pyrocarbon exhibited more complications when compared with silicone due in part to the characteristics of the materials.

A strength of this analysis is that low heterogeneities were observed. In addition, according to the funnel plots, no publication bias was observed, which would better support the objectivity and fidelity of our results. Nevertheless, the conclusions on this meta-analysis must be considered within its limitations. First, the outcomes that could be analyzed were limited due to the various assessment tools used in the literature. Future studies could examine additions outcome indicators that could provide a more comprehensive grasp of the differences between pyrocarbon and silicone. Second, published articles in additional areas of study and in other languages could be included, since the heterogeneity might be attributed to both differences in race/ethnicity and geographic area. Third, because the sample size in this research was limited, more articles with greater population sizes could be analyzed in future studies. Fourth, as in all meta-analyses, selection criteria might lead to some important studies being excluded. Fifth, in the present meta-analysis, all included studies favored the silicone group, and it cannot be excluded that some negative results were not published. Sixth, it is possible that specific, selected patients might benefit more from a pyrocarbon prosthesis, but the present study did not allow such analyses.

In conclusion, this study showed that pyrocarbon might be an efficient material compared with silicone for joint replacement surgery but resulted in poorer functional and pain outcomes compared with silicone. Therefore, the use of silicone prostheses could be advocated for joint surgery.
Author contributions
Conceptualization: Cui Yang.
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