Pyrolytic carbon metacarpal-phalangeal implants. Medium-term follow-up

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Purpose. To assess the medium-term effect of pyrolytic carbon metacarpophalangeal arthroplasty on pain relief, ROM increase and hand function, as well as the incidence and type of complications observed. We also set about evaluating the reduction on ulnar deviation and the patients' degree of satisfaction.
Materials and methods. This was a retrospective study of 28 pyrolytic carbon metacarpophalangeal prostheses implanted into 16 patients at the Valladolid University Hospital by one single surgeon, with a mean follow-up of 39 months.
Results. Pain decreased by 6.3 points, ROM increased by 21.5° and function improved by 23%. Low incidence of intra– and postoperative complications. Ulnar deviation decreased by 10°, while patient satisfaction stood at 7.1 points.
Conclusions. The prosthesis under study showed good medium-term levels of resistance and biocompatibility. Pain decreased and ROM increased, making it possible for patients to carry out their elementary activities. Intra– and postoperative complications were few and patients were satisfied. Periprosthetic osteolysis was observed in a few cases, but it has not got worse and has remained asymptomatic. The prosthesis presented hereby seem to us the best option available at present to address early to mid-stage chronic disease of the metacarpophalangeal joint, especially in young RA patients and in patients with OA.

Key words: *metacarpophalangeal implants, pyrolytic carbon.*

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Prótesis metacarpofalángicas de carbón pirolítico. Seguimiento a medio plazo

Objetivo. Evaluar a medio plazo en los pacientes con artroplastia metacarpofalángica de carbón pirolítico la disminución del dolor, el incremento del arco de movilidad, la funcionalidad de la mano, así como la incidencia y tipos de complicaciones. Valorar la disminución de la desviación cubital y el grado de satisfacción del paciente.
Material y método. Estudio retrospectivo de 28 prótesis metacarpofalángicas de carbón pirolítico, en 16 pacientes en el Hospital Clínico Universitario de Valladolid por un mismo cirujano, con un seguimiento medio de 39 meses.
Resultados. Disminución del dolor en 6,3 puntos. Incremento de 21,5° del arco de movilidad. Incremento del 23% de funcionalidad. Escasa incidencia de complicaciones intra y posquirúrgicas. La desviación cubital disminuyó en 10° y la satisfacción de los pacientes fue de 7,1 puntos.
Conclusiones. Hemos observado a medio plazo una buena resistencia y biocompatibilidad de la prótesis. El dolor disminuyó, así como aumentó el arco de movilidad posibilitando las actividades básicas de los pacientes. Las complicaciones intra y posquirúrgicas son escasas, y los pacientes se encuentran satisfechos. Estamos expectantes con la evolución de algunas imágenes osteolíticas periprotésicas pese a que no han evolucionado en el tiempo y son asintomáticas. Las prótesis que presentamos nos parecen hoy en día la mejor opción en patologías crónicas destructivas de las articulaciones metacarpofalángicas no demasiado evolucionadas, sobre todo en reumáticos jóvenes y en pacientes con artrosis.

Palabras clave: *prótesis metacarpofalángicas, carbón pirolítico.*

From the beginning of the 20th century many materials and designs have been used in the treatment of metacarpal-phalangeal (MCP) conditions, but none of them showed good strength or biocompatibility levels. Up to now, the standard reference has been Swanson's silicone prosthesis[1-3], which has offered the best results in spite of the significant Lumber of complications and undesired effects (like siliconitis) it has been associated with.

The use of pyrolytic carbon as a material for MCP arthroplasties constitutes a novelty in Spain. In fact our Department of Orthopedic and Trauma Surgery was one of the first ones to adopt it. This means that as yet very few medium to long-term studies have been published on this prosthetic material.

Pyrolytic carbon has been used since 1969 in millions of cardiac valve prostheses with very good fatigue strength levels. There is experience of the use of this material in MCP prostheses implanted in baboons that showed both biomechanical and biochemical compatibility and good levels of fatigue strength[4]. After this success, the short and medium term results of MCP pyrolytic carbon prostheses were studied in humans with satisfactory results[5,6]. Pyrolytic carbon prostheses are formed by the deposition, onto a graphite base, of the carbon released after subjecting hydrocarbonated gas to high temperatures (1.300 °C). This material is comprised by crystals in 2 dimensions of graphite and in 3 dimensions of diamond, which furnishes it with certain strength and elasticity properties.

These prostheses are indicated in patients in the early stages of rheumatoid arthritis with good bone stock, like young rheumatoids, and in post-traumatic osteoarthritis.

The purpose of this study was to make medium-term a clinical and radiographic review of patients implanted with a pyrolytic carbon prosthesis in a MCP joint between 2000 and 2003, and to determine the patients' degree of satisfaction.

MATERIAL Y MÉTODO

This is a medium-term retrospective observational study that included all patients subjected to a MCP pyrolytic carbon arthroplasty between June 2000 and February 2003. The total number of patients was 16, and the total number of prostheses implanted was 28. All patients were operated on at the Valladolid University Hospital by one same surgeon. The prosthesis used (Ascension®) was an uncemented resurfacing-type implant, with a hemispherical head and compensated stems (fig. 1); there were 5 possible sizes (10, 20, 30, 40 and 50). We reviewed the clinical history and then asked patients to visit the hospital for a clinical examination and the performance of both static and dynamic radiographs.

Figure 1. *View of the Ascension® metacarpal-phalangeal pyrolytic carbon prosthesis.*

Mean age of patients was 59 years (34-74) at the time of surgery. Of the 16 patients, 7 were male (43.7%) and 9 female (56.2%), 15 were right-handed (93.7%) and 1 was left-handed (6.2%). Twenty-three prostheses (82.1%) were placed in the patients' dominant hand, whereas the five remaining ones (17.8%) were placed in their non-dominant hand.

Eleven patients had rheumatoid arthritis, and they were subjected to 22 arthroplasties (78.5% of all prostheses implanted). These patients had had a mean evolution of 14.8 years since their rheumatoid condition was first diagnosed (range: 7-20 years). Of the 11 rheumatoid patients, 9 presented with moderate-severe joint destruction and the 2 remaining ones had a mild destruction; 8 of the 11 patients presented with a moderate-severe subluxation of the joint.

Four patients had been diagnosed with osteoarthritis six years before and given conservative treatment; these were implanted 5 prostheses (17.8% of total) (4 prostheses in the third MCP joint and one in the fourth); radiographically they presented with subluxation and joint destruction.

One patient presented with post-traumatic osteoarthritis of 4 years' evolution; he was implanted a prosthesis in the fourth MCP joint (3.5%): he presented significant radiographic joint destruction (figs. 2A y B).

Of the 16 patients, 11 were operated on their right hand, 2 on their left hand and 3 patients were operated on both hands. The number of prostheses placed in each MCP joint as well as the prosthetic sizes used for each joint are summarized in table 1. The largest Lumber of prostheses were placed in the second MCP joint (46.4%), and the most frequently used size was 30 (75%).

In 2 patients, 4 MCP arthroplasties were performed, of which those in the second and third rays were made of pyrolytic carbon and those in the fourth and fifth rays were made of silicone, since these were the digits that had most severe ulnar deviation (figs. 3A y B). In one patient, all four prostheses used were made of pyrolytic carbon (figs. 4A, B y C). All patients were alive at the time of carrying out this study and all of them were reviewed.

Figure 2. (A) *Pre-operative x-ray in a patient who had suffered a traumatic amputation of the second and third fingers and who presented with post-traumatic osteoarthritis in the fourth metacarpal-phalangeal joint. (B) X-ray follow-up three years post-op.*

Table1. Prosthesis size and its relationship with the metacarpal-phalangeal joint operated

Joint	Size 10	Size 20	Size 30	Size 40	Size 50	Total
Índex	0	0	10	3	0	13
Middle	0	1	8	2	0	11
Ring	0	1	2	0	0	2
Little	0	0	1	0	0	1
Total	0	2	21	5	0	28

Surgical technique and post-operative control

All patients were operated with locoregional anesthesia. As regards the surgical technique, the guidelines laid down by Beckenbaugh[7] were followed. We followed 8 main steps:

1. A longitudinal skin incision was performed if one or more prosthesis were placed; a transverse incision was made if all for MCP prostheses were implanted.

2. The approach followed the radial margin of the extensor mechanism.

3. An incision was made to open the MCP capsule, sparing the collateral ligaments if intact, and exposing the joint surfaces (fig. 5).

4. Introduction of the alignment device to conduct a bone resection of 2-4 mm in the metacarpal and of 1-2 mm in the proximal phalanx. This resection was carried out with a saw, through the guide and distal to the attachment of the collateral ligaments (figs. 6A y B).

5. Medullary reaming, taking into account that the size of the prosthesis is determined by the medullary canal of the proximal phalanx and not of the metacarpal (fig. 7).

6. Trial with plastic components to determine joint dynamics and stability.

7. Placement of the uncemented prostheses, by means of impaction.

Figure 3. *(A) Pre-op x-ray of a rheumatoid patient with articular destruction of the 4 metacarpal-phalangeal joints. (B) Follow-up at 3 years post-op following pyrolytic carbon arthroplasties in the second and third fingers, and silicone arthroplasties in the fourth and fifth fingers.*

Figure 4. *(A) Pre-operative x-ray of a patient with destruction of the 4 metacarpal-phalangeal joints. (B) Intraoperative view following a pyrolytic carbon arthroplasty of the 4 metacarpal-phalangeal joints. (C) X-ray follow-up of the 4 pyrolytic carbon arthroplasties, 30 months after surgery.*

8. Plane-by-plane closure, accompanied by a plication of the radial side of the extensor mechanism in rheumatoid patients who required recentering.

No patient required to be hospitalized for this surgery. After the operation, patients were placed in a plaster palmar splint for 3 weeks; at that point a clinical and x-ray review was carried out and dynamic immobilization was prescribed for 8 weeks on average. Patients were referred to the rehabilitation department, where they received a mean of 30 sessions.

Figure 5. *Longitudinal incision, opening of the capsule and exposure of the joint in a patient with third metacarpal-phalangeal joint osteoarthritis.*

Figure 7. *Phalangeal medullary reaming determines the size of prosthesis to be used.*

Assessment of results

Following physical therapy, clinical and x-ray reviews were carried out at 3 months, 6 months and every year since. Pain was evaluated by means of an analog scale out of a total of 10 points. Range of motion was assessed clinically and radiologically. Ulnar deviation was assessed clinically. Functional improvements were determined by studying the patients' ability to perform activities of daily living. Patient satisfaction was assessed by means of an analog scale out of 10 points.

RESULTS

Mean follow-up of these patients was 39 months. The mean pain score was 7.5 points pre-op and 1.2 points at the moment of carrying out this study, a decrease of 6.3 points (i.e. an 84% reduction of pre-op pain levels). ROM increased by 21.5° overall; mean MCP extension was –23° pre-op and –10° post-op; mean flexion was 50° pre-op and 58.5° post-op. We observed a mean 10° reduction in ulnar deviation in patients with rheumatoid arthritis. Preoperatively only 50% of patients had some function in their hand; postoperatively this figure rose to 83%. The degree of patient satisfaction was 7.1/10 points on average, and 75% of patients claimed that they would undergo the surgery again.

We observed no cases of synovitis reactive to the materials used, nor wound alterations or disruptions to proximal or distal interphalangeal joint mobility resulting from surgery. There were no instances of prosthetic loosening or periprosthetic fractures. We did observe radiographic images of periprosthetic osteolysis of less than 1 mm in 25%

A B

Figure 6. *(A) Introduction of the alignment device for resecting the metacarpal bone. (B) Alignment device for phalangeal bone resection.*

Figure 8. *Detailed view of periprosthetic osteolysis in a proximal phalangeal component.*

of prostheses (7 cases); these did not lead to symptoms or grow larger during follow-up (fig. 8). Only in 2 prostheses (7.1%) did periprosthetic osteolysis exceed 1 mm in thickness; this had no clinical repercussions either.

During surgery there were no vascular, neurological or other complications. The only early complications that appeared postoperatively were 2 phlyctenular lesions caused by immobilization and the dehiscence of two sutures in one patient, which resolved inconsequentially. There were no hematomas, infections, bone fractures, sympathetic reflex dystrophy, prosthetic loosening or immediate prosthetic dislocation. As regards late complications, there was one prosthetic dislocation at 12 months resulting from trauma caused by an effort involving traction and loading on the finger; this was successfully treated by means of closed reduction and immobilization for 3 weeks. There were 9 cases of prosthetic subluxation, all of them in patients with significant preoperative ulnar deviation; none of these presented with clinical symptoms.

In one case, on performing the yearly follow-up x-ray we observed that one of the prosthetic metacarpal stems had broken; we applied conservative treatment, with periodical follow-up, and the patients is currently asymptomatic.

DISCUSSION

One of the most significant findings of this study was the biocompatibility and good tolerance shown by pyrolytic carbon prostheses as compared with other materials like silicone[1-3]. The surgical technique is not complicated and the surgeon can avail himself of sophisticated yet easy-to-use instruments to place the implants with few intra- and postoperative complications[6]. Pyrolytic carbon prostheses being unconstrained, it is always important to spare the soft tissues, especially in rheumatoid patients with a windswept hand. The prosthetic design is highly stable in spite of being unconstrained, which means that there are no dislocations in the immediate post-operative period.

As regards ulnar deviation in patients with rheumatoid arthritis, we observed a slight correction, but the Basic achievement is that the deviation progresses more slowly since the joint destruction caused by the rheumatoid synovitis is arrested. This cosmetic aspect of ulnar deviation is the one that creates greatest disappointment in the rheumatoid patients operated since they normally expect greater levels of correction,

In some rheumatoid patients we managed to ease their symptoms by placing the 2 pyrolytic carbon prostheses on the radial side (second and third rays), which is where most strength, accuracy and mobility are needed for gripping objects, and the 2 constrained silicone prostheses on the ulnar side (fourths and fifth rays) in order to limit ulnar deviation, which tends to be especially severe in these digits.

We should emphasize the favorable evolution of patients with osteoarthritis and post-traumatic arthritis implanted with pyrolytic carbon prostheses. As regards mobility, we have observed greater improvements in patients that followed a correct rehabilitation program both in hospital and at home, since post-op physical therapy is the mainstay of the whole process. Results obtained for pain relief, decrease in ulnar deviation and ROM improvement are similar to those published in similar Studies with these arthroplasties[6].

We would like to stress that in spite of the promising degrees of biocompatibility and osteointegration observed, we shall remain attentive as to the evolution of the periprosthetic lytic images observed in slightly over 30% of our cases. It should be said that no evolution has occurred in the medium-term. The same finding has been reported in similar Studies but no reference is made to its long-term evolution[6].

The purpose of placing an MCP prosthesis —in our opinion and in that of our patients— has been fulfilled since on the whole they have led to an improvement in the two main problems affecting these patients: pain and the inability to perform their activities of daily living.

Overall, patients claim to be satisfied with the results obtained, which seems to indicate that MCP pyrolytic car-

bon prostheses could be considered the best indication currently available for chronic degenerative conditions (osteoarthritis) and for young rheumatoids that have not developed significant ulnar deviation of the fingers or periarticular soft tissue destruction (capsule and ligaments).

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Conflict of interests

The authors have declared to have no conflict of interests.