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Original Article

Preliminary analysis on the MD-4® plasma-sprayed titanium acetabular component☆

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ABSTRACT

Objectives: To evaluate the short-term performance of a type of implant manufactured in Brazil.
Methods: This study analyzed a cohort of 60 patients who underwent implantation of MD-4® acetabular components during primary hip arthroplasty procedures performed between January 1, 2010, and August 1, 2012. The patients were studied retrospectively with regard to clinical behavior, stability and radiological osseointegration. The patients were followed up for a minimum of 12 months and a maximum of 42 months (mean: 27) and were evaluated by means of the Harris Hip Score, SF-36 questionnaire and serial conventional radiographs.
Results: All the components were radiologically stable, without evidence of migration or progressive radiolucency lines. On average, the Harris Hip Score evolved from 36.1 to 92.1 ($p < 0.001$) and the SF-36 showed significant increases in all its domains ($p < 0.001$). No differences were observed among patients with osteoarthrosis, osteonecrosis, hip dysplasia or other conditions.
Conclusions: The short-term results showed clinical and radiological signs of stability and osseointegration of the implants, which may represent a predictive factor regarding medium-term survival of this acetabular component.

Análise preliminar do componente acetabular de titânio plasma-spray MD-4®

Palavras-chave:
Osteointegração
Artroplastia de quadril
Prótese de quadril

RESUMO

Objetivos: avaliar o desempenho em curto prazo de um tipo de implante fabricado no Brasil.
Métodos: estudo de uma coorte de 60 pacientes que tiveram componentes acetabulares MD-4® implantados durante artroplastias primárias do quadril, entre 1 de janeiro de 2010 e 1 de agosto de 2012, e foram estudados retrospectivamente com relação ao comportamento

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clínico, à estabilidade e à osteointegração radiológica. Os indivíduos foram acompanhados por 12 meses no mínimo e no máximo 42 (média: 27) e avaliados por meio do Harris Hip Score, do questionário SF-36 e de radiografias convencionais seriadas.

Resultados: todos os componentes estavam radiologicamente estáveis, sem evidência de migração ou de linhas de radioluzência progressivas. Em média, o Harris Hip Score evoluiu de 36,1 para 92.1 ($p < 0,001$) e o SF-36 mostrou incremento significativo em todos os domínios ($p < 0,001$). Nenhuma diferença foi observada entre pacientes com osteoartrose, osteonecrose, displasia do quadril ou outras condições.

Conclusões: os resultados de curto prazo mostraram sinais clínicos e radiológicos de estabilidade e de osteointegração dos implantes, o que pode representar um fator preditivo quanto à sobrevivência em médio prazo do componente acetabular considerado.

Introduction

Over the last 20 years, a large variety of porous surfaces and metallic materials have been used to achieve fixation by means of bone growth (ingrowth) in total joint prostheses for the hip and other joints. The ones most commonly used are composed of titanium or titanium alloys, rough-surfaced chromium–cobalt metal alloys and woven metal fiber. The external coatings of the cups present macro or microporosity, such as that obtained through spraying the surface with titanium (plasma spray) or, more recently, through using trabeculated metal.[1]

Studies on animal models, clinical studies and evidence from implants removed postmortem (retrievals) have demonstrated the capacity of porous surfaces for favoring bone growth through ingrowth and generating osseointegration. They are effective for supplementing or ensuring the primary mechanical stability that is achieved through introducing the implant under pressure (i.e. press-fitting it), with or without adjuvant screws.[2] Weller and Volkmann[3] found that pores of diameters between 50 and 200 μm favored bone ingrowth and noted that spraying with titanium is a method capable of reproducing these parameters.

Absence of early translation of the metal cup is considered to be indicative of good medium and long-term results.[4,5] Bone growth on the porous external surface of the implant is influenced by the size of the pores, properties inherent to the materials and close proximity between the bone and implant.[6] Surface roughness and osteoconductivity of the titanium coating have been correlated with the primary and secondary stability of the implants.[4]

The primary objectives of the present analysis were to investigate the clinical performance, stability and presence of short-term radiological signs of osseointegration of the acetabular component analyzed, and whether there might be any association between the stability and fixation of the cup and the variables of etiological diagnosis, age, positioning and primary stability of the implant. There are no studies in the literature on the performance of the acetabular component analyzed in this series.

Materials and methods

This study was approved by our institution's research ethics committee under the number CEP 408.719. All the individuals selected explicitly agree to participate through a free and informed consent statement.

This was an observational clinical study that examined an initial group of 62 individuals, from which a cohort of 60 individuals was retrospectively evaluated for a minimum period of 12 months and a maximum of 42 months (mean: 27). The MD-4® acetabular component (MDT Ind. Com. Imp. Exp. Implantes Ltda.) was used under uniform conditions by the same surgeon at a regional teaching and referral hospital between January 2010 and August 2012. The acetabular component was used together with a polished cemented femoral nail with a centralizer and a plug to occlude the femoral canal, which were all manufactured in Brazil. A second-generation cementation technique was used.[7] All the individuals received two adjuvant titanium screws. Only two cases were lost during the follow-up.

The MD-4® acetabular component is composed of a hemispherical cup that is manufactured using the 6Al–4V titanium alloy.[8] The external coating of plasma-sprayed titanium has a mean thickness of 150 μm and a mean pore size of 224 μm. The component has three peripheral holes for inserting adjuvant titanium fixation screws and one central (polar) hole for the impaction guide. The insert of ultra-high molecular weight polyethylene is molded by means of a machining process. It has 18 notches and an edge raised by 10°, and it is sterilized by means of gamma rays for use with femoral heads of 22 mm (only for cups of 44–48 mm) and 28 mm (for other measurements).

The cases selected were only affected in a single joint and presented grade IV in the classification of Kellgren and Lawrence for osteoarthrosis.[9] Complete clinical data were registered before the operation and after 6, 12, 18 and 24 months of evolution. Conventional radiographs were obtained before the operation, during the immediate postoperative period, after six weeks of evolution and after 3, 6, 12, 18 and 24 months of follow-up. The clinical and radiological evaluations were made by the senior author. The radiographs were reviewed by a second independent trained observer who was also a