Follow-up of total hip replacement using domestic prosthesis in 33 hips*☆

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Supported by: the Science and Technology Development Project of Jilin Province, No. 200905164*

Received: 2010-04-16
Accepted: 2010-06-12
(20100416002/G)

Chang F, Yu QW, Liu GY, Qu Y, Zhang JZ, Wang JC. Follow-up of total hip replacement using domestic prosthesis in 33 hips. Zhongguo Zuzhi Gongcheng Yanjiu yu Linchuang Kangfu. 2010;14(30): 5682-5685.

[http://www.crter.cn http://en.zglckf.com]

Abstract

BACKGROUND: Total hip replacement has been widely used in the treatment of severer hip diseases in China. However, most of prostheses are designed according to Caucasian osteometric measurements, whether those prostheses are suitable for Orientals is still in dispute. It is emerging to design prostheses for Orientals, there are few reports addressing therapeutic effect after replacement.

OBJECTIVE: To follow up the long-term results of total hip replacement using domestic designed dual-assembly total hip prosthesis.

METHODS: Totally 30 patients (33 hips) who underwent total hip replacement at the Department of Orthopaedic Surgery, China-Japan Union /Affiliated Hospital of Jilin University, from June 1987 to December 1996, were followed up. The designed dual-assembly total hip prosthesis was produced by Central Iron & Steel Research Institute, which was similar to bipolar prosthesis with a polyethylene acetabular cup. First generation cementing techniques were applied. The average age at the time of the operation was 56.5 years (30–81 years) and the average follow-up period was 8.5 years (5.0–14.4 years). Standard anteroposterior radiographs of the hip and clinical examinations were used to analyze therapeutic efficacy.

RESULTS AND CONCLUSION: The total excellent and good rate was 68.6%. The imaging examination showed that there were 16 hips (48.5%) had aseptic loosening and 11 hips (33%) had heterotrophic bone formation. Additionally, two cases suffered from infection and one case suffered from dislocation. The utilization of prosthesis achieved certain curative effects. However, the design and cement technology have problems due to limitation of conditions, which should be solved in further experiments.

INTRODUCTION

Total hip replacement (THR) is a useful way to treat severe hip diseases. It has made great progress since 1940s and has been widely used all over the world. In China, the operation was being done since early 1960s, but there are still many problems that need to be solved in order to improve the results of the operation. The results of THR in Caucasian patients have been widely published, but there were not so much information about the outcome of THR among Chinese patients, who generally have a smaller body build with different osteometric measurements of the acetabulum and the proximal femur[1-2]. The disease pattern is also different in Chinese patients. Osteoarthritis of the hip joint is uncommon, and avascular necrosis of the femoral head is the most common preoperative diagnosis[3]. This study aims to investigate the results of original hip prosthesis, which was performed at the Department of Orthopaedic Surgery, China-Japan Union/Affiliated Hospital of Jilin University, and to identify the main factors that influenced the outcome of the operation.

SUBJECTS AND METHODS

Design

A case analysis.

Time and setting

Patients in the Affiliated Hospital of Jilin University from June 1987 to December 1996 were followed up.

Subjects

A total of 197 patients had primary total hip arthroplasty were included. The implant that we used was an original type made in China (Central Iron & Steel Research Institute, Beijing, China). It includes three parts: the acetabular part, the middle free part and the femur part (Figure 1). The prosthesis looks like a bipolar prosthesis with a polyethylene cup. First generation cementing techniques were applied and the cement was made in China (Tianjin Synthetic Material Research Institute, Tianjin, China). The cement was hand mixed without porosity reduction and then thumb packed into the acetabulum and the femoral medullary canal. Then, the prosthesis was implanted. Prophylactic antibiotic was given for 5 to 10 days. Average blood transfusion was 400 mL per patient.

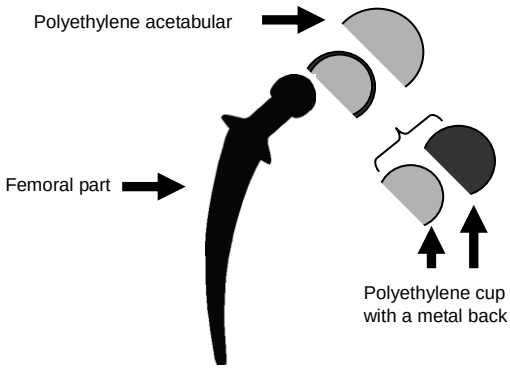

Figure 1 The implant comprises the acetabular part, the middle free part and the femur part. The acetabular part and the femur part were made of polyethylene and metal, respectively. The middle part was composed of two cups: a metal one in the acetabular side and a polyethylene one in the femur side. Two cups were fixed to each other and the middle part can move freely between the actabular part and the femur part

Methods

Totally 33 hips in 30 patients were reviewed. Among

them, 17 patients (19 hips) were followed up via telephone, 7 patients (7 hips) by letter, and 6 patients (7 hips) by home visit. All the patients had physical and radiographic examinations. The average age of the patients at the time of the operation was 56.5 years (30–81 years) and 11 (12 hips) of them were under 50 years of age. There were 16 male and 14 female patients. The disease was bilateral in 3 cases, on the right side in 14 cases, and on the left side in 13 cases. The preoperative diagnoses were avascular necrosis of femoral head (15 hips), femoral neck fracture (13 hips), osteoarthritis (2 hips), post-traumatic arthritis (2 hips) and rheumatoid arthritis (1 hip). The average follow-up period was 8.5 years (5.0–14.4 years). All subjects gave informed consent for participation in this study.

Main outcome measures

The Beijing score system (Table 1) was used for clinical evaluation. The score system was originated in Beijing in 1982[4]. It is similar to that of Charnley score to some extent although the point in Beijing system is higher. The score system includes items for pain, function, and range of motion. Each item has 6 points of score and the total score is 18 points. The score of 16–18 points is excellent, 13–15 is very good, 10–12 is good, 7–9 is fair, 4–6 is poor and 0–3 is very poor. Patients who received 13–18 points are considered satisfied with the operation. Standard anteroposterior radiographs of the hips and proper clinical examinations were also carried out. Loosening was diagnosed using the evaluation system published in Campbell's operative orthopedics[5]. Ectopic bone formation was recorded using the classification system of Brooker[6].

Table 1 Beijing score system

Level	Pain		Joint function					Degree of motion
	Degree	Requirements of acesodyne	Gait and distance	Support	Squat and sit	Stairs	Independent movement	
6	None	None	Normal	None	Freely	Freely	Entirely independent	> 211°
5	Slight after activity	None	Slight limp in long distance	None	Sit freely, ability to squat	No need of handrail	With efforts	160°–210°
4	Greater increased after activity	Occasionally minor dosage of acesodyne	Moderate limp	One cane	Ability to sit upright, inability to squat	Need handrail	With efforts except trimming toenail	101°–160°
3	Pain limits activity	Increased dosage of acesodyne	Walk with severe limp	One crutch or two canes	Sit with difficulty, inability to squat	Move with difficulty	Limited movement, cannot trim toenail	61°–100°
2	Increased pain inhibits activity	Occasionally increased strength acesodyne	Limited movement even indoors	A pair of crutch	Sit for short period of time, inability to squat	Incapable	Need assistant	31°–60°
1	Increased pain severely inhibits activity	Strong dosage of acesodyne	Wheelchair or bedridden	Bedridden	Unable to do either	Incapable	Incapable	0°–30°

RESULTS

Follow-up results

The overall results of the clinical score were showed in Table 2.

Table 2 The clinical score at the time of follow-up (Hip)

Score	Total	Male	Female	Age < 50 yr	Follow up > 10 yr
16–18	12	5	7	2	3
13–15	10	6	4	3	2
10–12	4	2	2	2	1
7–9	5	3	2	3	2
4–6	2	1	1	2	2
Total	33	17	16	12	10

A disaccord between the clinical symptoms and radiographic findings was noted. Some patients had severe symptoms without any significant change in the radiograph, and some patients had obvious bone resorption in the radiograph but manifested few clinical symptoms. Though the radiographic loosening rate was relatively high, the clinical score was not very low (Figure 2). Most of them had a score higher than 13 points and the total satisfactory rate was 68.6%. In younger patients (< 50 years old), the loosening rate seems to be different because the satisfactory rate was only 41.7%. There was no difference in the clinical score between male and female.

a: Before operation b: After operation c: 7 yr after operation

Figure 2 Aseptic loosening

Representative case

Case 1: a 56 years old man, who suffered from a femoral neck fracture. Seven years after the operation, sinking, osteolysis and heterotrophic bone formation could be seen. The clinical score was 17, and there were no clinical problems (Figure 2).

Case 2: a 70-year-old woman suffered from a femoral neck fracture. This radiograph was taken at the latest follow-up after 10.9 years of the operation. Brooker grade was Ⅳ and

clinical score was 11. The limb's mobility was severely limited, but there was no pain or other discomfort. The patient was unwilling to be treated (Figure 3).

Figure 3 Heterotrophic bone formation

Complications

The most common complication was aseptic loosening. Acetabular loosening was found in 16 components (48.5%) and femoral loosening in 11 components (33.3%). The main symptoms were pain and limited function.

Infection was found in 2 cases. Diagnosis was made by focal puncture and bacterial culture in both cases. One of the patients was infected at 3 years after the operation. The patient was an old, blind, inactive man, unwilling to undergo any treatment even though there was a sinus in his thigh. The other was infected soon after the operation and it was revised. Both of them had greater suffering than any of the other patients. Dislocation was found in one case and the prosthesis was revised.

Heterotrophic bone formation was found in 11 hips (33%), but most of them did not develop severe symptoms, so they did not require revision. The Booker grade was Ⅰ in one case, grade Ⅱ in 3 cases, grade Ⅲ in 5 cases, and grade Ⅳ in 2 cases (Figure 3).

DISCUSSION

Complications

Aseptic loosening

Aseptic loosening was the most common complication of THR. Some of the loosening did not have any symptoms, and some symptoms were not due to loosening, hence, it is difficult to diagnose. At present, the most common method to diagnose is to combine the clinical symptoms and radiographic findings. So, we have to be careful to decide for revision. Though other factors contribute, it has been reported that polyethylene debris was the main reason of aseptic loosening[7]. Since none of our patients had obvious postoperative trauma or the evidence of infection, we thought that the loosing was caused mainly by debris. Polyethylene is the common material of acetabular cup, so it seems that there is no better alternative to avoid the production of polyethylene debris at this time. Furthermore, an effective treatment for this complication was not available except revision. Many researchers are trying to solve the problem by using such techniques as low-friction ion-treated femoral head[8], metal-metal implant and so on[9].

With the recent development of more modern techniques, femoral lysis remains low among patients with cemented femoral components using second or third generation cementing techniques[10]; this suggests that the use of cement with new techniques may protect femur against lysis. The explanation seems to be that cement seals off the femoral cavity and delays the ingress of particulate polyethylene. Iwase *et al*[11] followed up 72 hips of Scan Hip for 10 years, and they found focal osteolysis around the femoral stem in 23 hips (32%) and around the sockets in 8 hips (11%). Other researchers also reported similar results. Compared to these reports, we found that the implant we used has a relatively high focal osteolysis in either the femur component (48.5%) or the acetabular component (33.3%). It might be due to the increased metal-polyethylene interface. The femoral head size has been shown to be an important factor affecting wear. Volumetric wear of polyethylene increases along with an increase in the head diameter. The free middle part was added to gain the merits of both total hip arthroplasty and bipolar prosthesis, but a relatively bigger interface perhaps increased polyethylene particles. Furthermore, a free component may increase the risk of the instability of the hip joint.

Heterotrophic bone formation

Heterotrophic bone formation is a common complication of THR. Since it occurred soon after the operation, the heterotrophic bone formation can be protected to some extent by close monitoring at the early stage of postoperative care. The symptoms of heterotrophic bone formation were not serious and did not cause the patients as much pain as other complications. A few of them required treatment, though the function and range of motion were seriously limited in some cases.

Infection

Infection is not a common complication, but it requires special attention because infection causes failure of the operation. In our study, there was infection in two cases. After infection, methods such as antibiotic cement might be helpful.

Age

Young age is a risk factor for total hip arthroplasty though it was not a contraindication of the operation. Many researchers demonstrated that young and active patients had worse postoperative outcome than the older patients, and some of them pointed that the proper indication should be that even if the operation failed and the implant was excised, the function of the joint should not be worse than that of preoperative state[12]. Some researchers even proposed that the osteoarthritic patients under 55-year-old should not be considered as the indication of THR. In the present series, only 41.7% of the patients below 50-year-old received an excellent or good clinical score.

Others

First generation cementing techniques was applied to the patients in this study. In the present series, good cement mantle could not be achieved in most cases. Many reports have indicated that the first generation cementing techniques lead to unsatisfactory results of the operation. Researches proved that the outcome of second and the third generation cementing techniques were superior to that of the first generation cementing techniques. Wroblewski *et al*[13] studied 59 cemented acetabular components removed at revision and found that 19 of them (32%) showed areas where there was no cement between the rear part of the component and the acetabular bone. These investigators believed that polyethylene particles

could be generated at this interface. Once the acetabular component became loose, the generated particles led to form foreign-body granuloma.

On the other hand, in this series, results of the radiographs showed that there were femoral loosening in 16 hips, acetabular loosening in 11 hips and heterotrophic bone formation in 11 hips. Some of the radiographs showed obvious bone resorption but the patients had either few or no symptoms. This disaccord indicates that radiographic finding is not parallel to the clinical symptoms. Söderman *et al*[14] randomly selected 1 113 patients from the Swedish National Hip Register and found that the results showed no significant correlation between clinical failure and radiographic failure.

Only 2 cases were revised in the present study, obviously fewer than other reports. The reason might be the inappropriate health insurance system in China, which makes it difficult to pay for the revision for some patients and/or some patients perhaps went to other hospitals to do the revision and did not respond to our follow-up.

To improve the result of the operation, a follow-up is very important. Like Sweden's total hip arthroplasty register, we emphasized its necessity in China as well. Some orthopaedic surgeons in China are appealing to establish a total hip arthroplasty register, and expected to be implanted in near future. It will help us to evaluate various aspects of THR, including long-term outcomes.

CONCLUSION

In the present study, the loosening rate was high, but the implant did help some patients in improving their quality of life. Now, we have made better progress in these areas, though there are still some problems need to be solved. By using a new implant, second or third generation cementing techniques, we believe that better results will be achieved.

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国产人工全髋关节置换 33 髋随访*☆

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摘要

背景：全髋置换治疗严重髋关节疾病在国内的应用已越来越多。然而，目前的主流假体都是基于西方人的解剖数据而设计的，是否适合体型相对较小的东方人应用，存在一定争论。针对这一问题，在亚洲，包括中国，针对东方人的假体设计不断出现，但对其疗效观察的数据却并不多见。

目的：随访由国内自行设计制造的双动全髋假体的置换效果。

方法：对 1987-06/1996-12 在吉林大学中日联谊医院/附属临床医院骨科施行全髋关节置换的 33 髋进行随访。所应用假体为北京钢铁研究院设计生产的一种双动式全髋假体，其设计类似于目前的双动股骨头假体之外，再加上一聚乙烯髋臼假体。固定方式为骨水泥固定，采取第一代骨水泥固定技术。假体置换时平均年龄 56.6 岁，平均随访 8.5 年。通过临床评分及 X 射线影像学结果来分析治疗效果。

结果与结论：临床评分总优良率为 68.6%。影像学检查发现髋臼松动 16 髋(48.5%)，股骨假体松动 11 髋(33%)，异位骨化 11 髋(33%)。另外发现感染 2 髋，脱位 1 髋。此假体的应用取得了一定的疗效。但受当时条件所限，该假体在设计、骨水泥技术上都存在一定问题，有待进一步改进。

关键词：全髋关节置换；人工假体；随访；影像学检查；并发症
doi:10.3969/j.issn.1673-8225.2010.30.042
中图分类号: R318　文献标识码: A
文章编号: 1673-8225(2010)30-05682-04

常非，于庆巍，刘光耀，曲扬，张静哲，王金成. 国产人工全髋关节置换 33 髋随访[J]. 中国组织工程研究与临床康复，2010，14(30):5682-5685.
[http://www.crter.org　http://cn.zglckf.com]
(Edited by Li YK, Zhao LJWang L)

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基金资助：吉林省科技厅科技发展计划资助项目(200905164)。

致谢：感谢日本筑波大学的落合直之教授、石井朝夫先生和三岛初先生在本文结果分析上给予的无私帮助。

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