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Evaluation of new version of Mecbio hip resurfacing prosthesis

Mecbio kalça yüzey yenileme protezinin yeni versiyonunun değerlendirilmesi

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Objectives: The aim of this preliminary study was to compare clinical outcomes of the modern version of the Mecbio resurfacing arthroplasty prosthesis which is custom-designed for each patient with the older prototype which has three sizes.

Patients and methods: Between 2003 and 2008, 20 patients with hip disorders who underwent a total of 21 arthroplasties with the modern version or prototype prosthesis were included in the study. The prototype was used for the first 15 procedures, while the modern version was used for the last six procedures. The modified lateral approach was performed on all patients. Clinical and radiological examination were also performed by two experienced surgeons. Cortical changes of the calcar were evaluated by comparison of the thinner layer of the medial cortex with thickened one within 5 cm below the lesser trochanter. The patients were also clinically evaluated by the Harris Hip Score. The mean follow-up was three years (range, 2 to 5 years).

Results: There was a significant improvement in the Harris Hip Score following surgery compared to baseline between the groups ($p<0.05$). There was a significant increase in the prototype group (0.14±0.06 to 0.23±0.07, $p<0.0001$) and modern version group (0.15±0.07 to 0.25±0.03, $p=0.0020$) in terms of the thinner cortex and thickened cortex in the prototype group (0.21±0.06 to 0.28±0.06 $p<0.0001$) and modern version group (0.25±0.07 to 0.29±0.05, $p=0.0156$). There was no significant difference in terms of radiological measurements between the groups.

Conclusion: The results suggest that excellent clinical and radiological outcomes can be obtained with both the prototype and modern version prosthesis.

Key words: Birmingham hip resurfacing prosthesis; custom-designed; hip resurfacing arthroplasty; total hip arthroplasty.

Amaç: Bu öncül çalışmanın amacı, Mecbio yüzey yenileme artroplasti protezinin her hastaya özel tasarlanmış yeni versiyonu ve üç ebatta mevcut olan eski prototipin klinik sonuçlarını karşılaştırmaktır.

Hastalar ve yöntemler: Çalışmaya 2003 ve 2008 yılları arasında kalça bozukluğu olan ve modern versiyon ve prototip protez ile toplam 21 artroplasti yapılan 20 hasta dahil edildi. İlk yapılan 15 işlemde prototip kullanılırken, son altı işlemde modern versiyon kullanıldı. Tüm hastalara modifiye edilmiş lateral yaklaşım uygulandı. İki deneyimli cerrah tarafından klinik ve radyolojik değerlendirme yapıldı. Kalkarda görülen kortikal değişiklikler, medial korteksin ince tabakasının küçük trokanterin 5 cm aşağısındaki kalın tabakayla karşılaştırılması ile değerlendirildi. Ayrıca hastalar Harris Kalça Skoru ile de değerlendirildi. Ortalama takip, üç yıldı (dağılım 2-5 yıl).

Bulgular: Her iki grubun cerrahi sonrası Harris Kalça Skorunda başlangıca kıyasla anlamlı bir iyileşme vardı ($p<0.05$). İnce korteks açısından prototip grubunda (0.14±0.06-0.23±0.07, $p<0.0001$) ve modern versiyon grubunda 0.15±0.07-0.25±0.03, $p=0.0020$) ve kalın korteks açısından prototip grubunda (0.21±0.06-0.28±0.06, $p<0.0001$) ve modern versiyon grubunda (0.25±0.07-0.29±0.05, $p=0.0156$) anlamlı bir artış vardı. Gruplar arasında radyolojik ölçümler açısından anlamlı bir fark yoktu.

Sonuç: Çalışma sonucu, hem prototip hem de modern versiyon protezler ile mükemmel klinik ve radyolojik sonuçların elde edilebileceğini göstermektedir.

Anahtar sözcükler: Birmingham kalça yüzey yenileme protezi; özel tasarlanmış; total kalça artroplastisi; kalça yüzey yenileme artroplastisi.

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Total hip arthroplasty has been greatly improved since it was first devised, but loosening still remains a problem.[1] To avoid this problem, hip resurfacing[2] or thrust plate prostheses[3] were developed.

We have a new prosthesis design, the Mecbio hip resurfacing prosthesis, which is based and press-fitted on the femoral head and neck, rather than just the head.[4] The purpose of this preliminary study was to evaluate the outcomes of patients who received the prototype or modern type prosthesis.

PATIENTS AND METHODS

The study included 20 patients (12 males, 8 females; mean age 51.8 years; range 35.3 to 72.1 years) with hip disorders who underwent a total of 21 arthroplasties between 2003 and 2008. In the initial 15 procedures (7 for avascular necrosis with one patient with having bilateral avascular necrosis, 7 for osteoarthritis, and 1 for femoral neck fracture) the prototype prosthesis was used. This prosthesis was press-fitted by an experienced operator who needs to adjust the appropriate size and the position of the original neck-shaft angle. In the remaining six procedures (2 for avascular necrosis, 3 for osteoarthritis, and 1 for acetabular dysplasia) the modern type prosthesis which is custom made was used. The mean follow-up duration after surgery was three years (range, 2 to 5 years). The study was approved by the Institutional Review Board of The Taichung MetroHarbor Hospital, Taiwan. All patients signed an informed consent statement. The Mecbio hip resurfacing prosthesis was approved and received a medical device certificate from the State Food and Drug Administration of the People's Republic of China.

The modified lateral approach was used for all patients.[5] In the modern type Mecbio resurfacing arthroplasty procedures, following exposure of the hip joint, the femoral head was dislocated and a custom-made neck guide (I) was fixed along the neck contour by using at least two screws (Figure 1). The femoral head was partially cut and removed by using a reciprocating saw from the horizontal slit of the neck guide (I). The femoral neck was retracted inward away from the operative field for good exposure of the acetabulum following removal of the neck guide (I) (Figure 1). A fenestrated metal-back cup of the same size as the reamed area was pressed in the prepared acetabulum which had been reamed. The bone debris taken from the cut head was filled between the fenestrated metal-back cup and self-locked inner cup (UHMWPE - Ultra-high molecular weight polyethylene under ISO-5834 standard offered by Perplas Medical, Lancashire, UK). In addition, the inner cup was firmly fixed by two screws on the fenestrated metal-back cup. However, in 15 cases the conventional metal-back cup was used. In these cases, the acetabular cup was covered with gauze to avoid falling debris. Thereafter, a guide pin was inserted in the central hole of the neck guide (I) and another guide pin was drilled in the upper hole of the neck guide (I) when the neck guide (I) was put on again (Figure 1). Then the neck guide (I) was removed again, but the central and upper guide pins were left in place. The neck guide (II) was then put on along with two guide pins. The neck cortex was decorticated by tapping the neck guide (II) which has a sharp cutting edge (Figure 1). After removal of the neck guide (II), a custom-made anatomic neck press-fit resurfacing (made of CoCr Cast under ISO-5832 standard offered by Doncasters Medical Technologies,

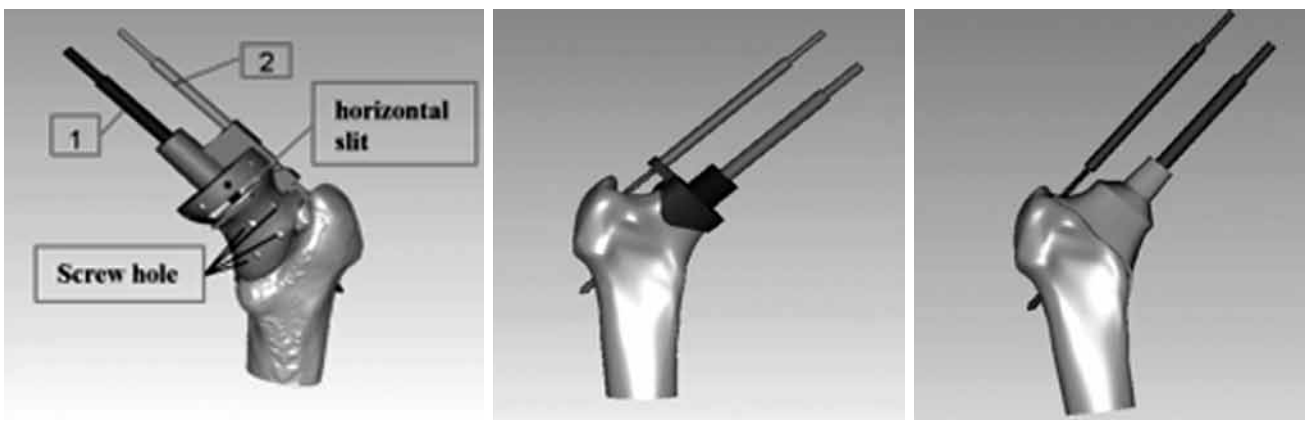

Figure 1. The procedures of assembly of the modern Mecbio resurfacing arthroplasty prosthesis. Fixation of the neck guide (I), re-approximation of the neck guide (I), insertion of the central (1) and anti-tension guide pin (2).

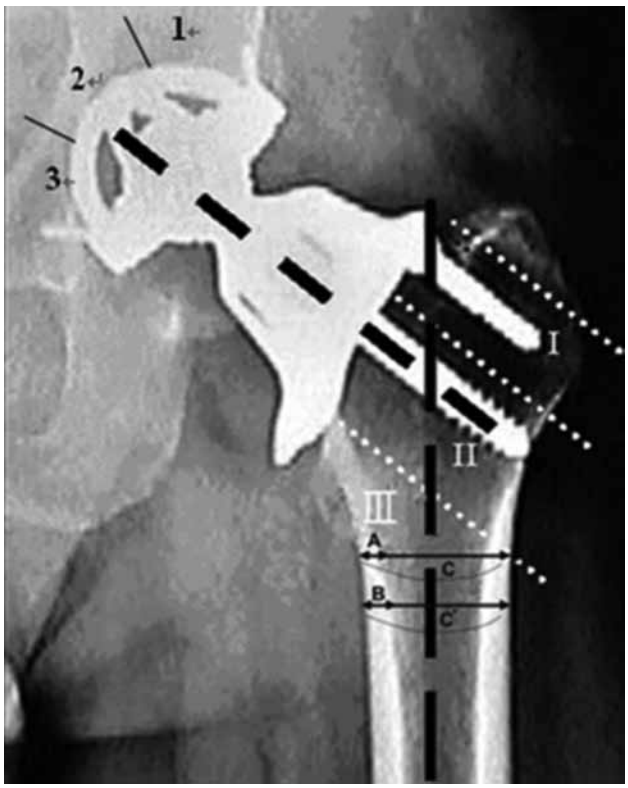

Figure 2. Definition of radiological zones of the acetabular and femoral components, neck-shaft angle, thinness and thickness of calcar density, 5 cm below the lesser trochanter.

Birmingham, UK) was tapped along with the two guide pins (Figure 1). A central screw and anti-tension screw were fixed following removal of the guide pins. The whole prosthesis was now assembled and the wound was closed in layers.

All patients were examined radiologically and clinically by two experienced surgeons. The positions of the femoral and acetabular components were evaluated radiologically by measuring the comparison of the neck-shaft angle, cortex changes of the calcar before and after the operation, and radiolucent lines. The defined zone of femoral component was divided between the anti-tension screw and central screw, and between the central screw and saddle of the design, just above the calcar. The definition of the radiological zones of the acetabulum and femoral neck is shown in figure 2.

The cortex change of the calcar was evaluated by comparison with the thinner and thickened cortex of the medial cortex, within 5 cm below the lesser trochanter. Measurements were made by two experienced staff before the operation and least six months after the operation as A, A′ and B, B′ respectively (Figure 2). A refers to the thinner cortex within 5 cm below the lesser trochanter before the operation, A′ refers to the same cortex measured at least six months after the operation, B refers to the thickened cortex within 5 cm below the lesser trochanter before the operation, and B′ refers to the same cortex measured least six months after the operation. All of A, A′ and B, B′ will be the numerator and the distance which is measured from the same site to draw a line, perpendicular to the shaft axis, will be the denominator as C and C′, before and after the operation (Figure 2).

The patients were also clinically evaluated using the Harris hip score (HHS). The HHS questionnaires were sent to all patients before and at least six months after the operation. All questionnaires were returned. The HHS can range from zero points (worst outcome) to 100 points (best outcome).

Results are expressed as the mean and standard deviation. The non-parametric Wilcoxon signed rank test was used for paired data and the Wilcoxon rank sum test was used for independent data. Data were analyzed using SAS 9.0 (SAS Institute Inc., Cary, NC). All p values were two-sided and were considered significant if p was less than 0.05.

RESULTS

The overall results, including both clinical and radiological values, are shown in Table 1. The mean pre- and postoperative HHSs for the prototype and modern resurfacing prostheses were 38.9, 94.5, and 39.2, 93.8, respectively. There was a significant difference in the HHS from before to after the operation for both

TABLE I

The performance of two types of Mecbio hip resurfacings

	Prototype (n=15)			Modern type (n=6)			
	Before	After	p^a	Before	After	p^a	p^b
Harris hip score	38.9±13.3	94.5±11.1	<0.0001*	39.2±12.5	93.8±8.5	0.0313*	<0.0001*
Neck-shaft angle	146.8±7.5	146.7±9.1	0.6803	148.4±3.7	151.1±2.6	0.1011	0.7003
Thinner cortex	0.14±0.06	0.23±0.07	<0.0001*	0.15±0.07	0.25±0.03	0.0020*	0.6084
Thickened cortex	0.21±0.06	0.28±0.06	<0.0001*	0.25±0.07	0.29±0.05	0.0156*	0.0927

MHP: Mecbio hip resurfacing; a: Comparison between before and after intragroup; b: Comparison between intergroup difference; * p<0.05 statistically significant difference.

the prototype and modern type prostheses ($p<0.0001$ and $p=0.0313$, respectively). There was improvement in the HNS regardless of the model used but there was no significant change in the neck-shaft angle from before to after the operation for either the prototype or modern type prosthesis.

In the evaluation of calcar density, the total mean values of the thinner and the thickened cortex before and after the operation were 0.1, 0.2 and 0.2, 0.3, respectively (Table 1). There was significant change in calcar density with either the assessment of the thinner or thickened cortex, according to both observers from before to after the operation (both $p<0.0001$). There was a significant difference in the assessment of the thinner cortex change or the thickened cortex change from both A and B observers with either the prototype or modern type prosthesis ($p<0.0001$, $p=0.0020$, and $p<0.0001$, $p=0.0156$). However, there was no difference between the prototype and modern type in the neck-shaft angle or calcar change for either thinner or thickened cortex. That is to say, generally there was a significant difference in the HHS before and after the operation for both the modern type and prototype prosthesis. There were no significant differences in neck-shaft angle or thinner and thickened cortex between the modern type and prototype. This indicates that calcar density is increased in both modern type and prototype Mecbio resurfacing arthroplasty prosthesis.

There were no patients who had radiolucent shadow over the acetabular component but there was a patient who received the prototype prosthesis who had radiolucent appearance over zone I and zone II of the femoral component. However, this patient was satisfied with his physical condition. Figure 3 shows example radiographs before and after the surgery of patients who received prototype (right hip) and modern type (left hip) prostheses. Both patients were satisfied with their physical condition at five years

Figure 3. Radiographies before and after surgery for patients who received the prototype prosthesis (a 52-year-old male) or modern type prosthesis (a 35-year-old female).

later for the prototype prosthesis and at two years later for the modern type prosthesis (Figure 4). Their bone density in the calcar region was increased significantly.

DISCUSSION

In our study, short-term follow-up which averaged three years showed excellent clinical and radiological outcomes for both the prototype and modern type Mecbio hip resurfacing prostheses. With both devices there was significant improvement in the HHS from before to after surgery while there was no significant change in neck-shaft angle. With both the prototype and modern type of prosthesis calcar density appeared to be increased. No patients had radiolucent shadow over the radiolucent component and the one patient who had radiolucent component over zones I and II of the femoral component was satisfied with his physical condition.

Conventional hip arthroplasty has been performed for many years and long-term studies show satisfactory results.[6-8] However, resurfacing arthroplasty preserves more bone stock for possible revision arthroplasty and therefore provides an additional benefit, especially for younger, more active patients. In addition, it not only provides bone stock for possible revision arthroplasty, but can resolve certain hip conditions such as extra-articular disorders or retained instrumentation in the proximal aspect of the femur which cannot be successfully treated with conventional arthroplasty.[9] Importantly, short- and mid-term studies comparing resurfacing arthroplasty with conventional arthroplasty indicate that the clinical outcomes from resurfacing arthroplasty are at least as good as those from using the conventional technique.[10,11]

Although the currently used Birmingham hip resurfacing prosthesis or Conserve plus hip resurfacing prosthesis have produced satisfactory outcomes in mid-term follow-up studies, a possible complication is periprosthetic fracture of the femoral neck which is probably caused by multiple factors, including surgical technique, patient activity, or high strain around the component base.[12-17] Shimmin and Back[18] found that femoral neck fracture occurs in 1.46% of cases. To overcome the problems associated with other types of resurfacing prostheses we used a different hip resurfacing prosthesis which is a custom-made, anatomic press-fit neck model.[19-21] The initial prototype design, which was made in only three sizes, emphasizes press-fitting. A problem with the prototype is that there are risks involved when using it because the correct positioning is largely dependent on the experience of the surgeon. However, the advanced modern type was designed to have an exact press-fitted anatomic neck which was obtained from approximately 1-mm slice computed tomography (CT) scans from the femoral head to the intertrochanteric region before the operation. The digital imaging and communications in medicine (DICOM) data of CT images were transferred to three-dimensional software through industry format. The design and supplementary tools are custom made and planning is done before the operation. The accurate position of the central screw is determined by objective measurement using a radiogram. Therefore, neither varus nor valgus position of the central screw is possible due to operator error. The preoperative planning procedures make it unlikely that any errors will occur during the positioning of the modern type prosthesis. In the radiological follow-up analysis of this study, there was a significant increase in calcar density with both the prototype and modern type,

Figure 4. Follow-up radiographic images for the same patients in figure 3 at five-year follow-up of the prototype prosthesis and at two-year follow-up of modern type prosthesis.

which means that natural physiologic weight bearing occurred in accordance with Wolff's law.[9]

Although the prototype model was developed earlier in 1992, at that period of time in China follow-up was difficult because China was an underdeveloped country. However, we noticed that there was increased bone density over the calcar region in the earlier experience, which was compatible with the results of laboratory testing. Therefore, we planned a complete study from 2003 to 2008. Although the femoral neck of the Mecbio hip resurfacing prosthesis is mechanically stronger than that of the Birmingham hip resurfacing prosthesis, their device also seems to have a possible complication of fracture of the femoral neck which did not happen in the current study. The durability of fixation also needs a longer time to observe. We look forward to carrying out a longer and larger study in the future.

There are several other types of hip prostheses that preserve bone. Two that are resurfacing devices are the Conserve Plus and Wagner. A retrospective study of the Conserve Plus hip resurfacing prosthesis that was based on a minimum of 10 years follow-up (average, 11.7 years) of 100 implantations found that the results were satisfactory in young patients but for comparison with conventional total hip arthroplasty longer follow-up is needed.[20] A study of 100 consecutive Wagner resurfacing hip arthroplasties in which the follow-up duration ranged from 8-10 years found that the outcome of long-term follow-up (range 91-118 months) was poor leading the authors to conclude that follow-up must be for at least eight years to meaningfully evaluate new prosthetic designs.[21] Another type of hip prosthesis is the thrust plate hip prosthesis which totally replaces the femoral head, preserving the femoral neck. This device is not a resurfacing prosthesis. Studies of the thrust plate prosthesis have produced mixed results.[22-25] In a study directly comparing thrust plate prosthesis with conventional total hip arthroplasty no difference was found between the methods in the restoration of biomechanics of the hip, and it was concluded that the results indicated that the thrust plate hip prosthesis does not produce more accurate leg length restoration or femoral *offset* than conventional total hip arthroplasty.[25] The average duration of follow-up in our preliminary study was only three years. A much longer period of follow-up will be needed to compare the outcomes of the Mecbio resurfacing arthroplasty prosthesis with those devices that have been evaluated with mid- and long-term follow-up.

In summary, both the modern type and prototype of the Mecbio resurfacing arthroplasty prosthesis can significantly increase the thinner cortex and thickened cortex in patients and there were no significant differences in radiological measures between the groups. The results of this study indicate that excellent clinical and radiological outcomes can be obtained with both the prototype and modern type Mecbio prosthesis.

Declaration of conflicting interests

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REFERENCES

1. Huber M, Reinisch G, Trettenhahn G, Zweymüller K, Lintner F. Presence of corrosion products and hypersensitivity-associated reactions in periprosthetic tissue after aseptic loosening of total hip replacements with metal bearing surfaces. Acta Biomater 2009;5:172-80.
2. Back DL, Dalziel R, Young D, Shimmin A. Early results of primary Birmingham hip resurfacings. An independent prospective study of the first 230 hips. J Bone Joint Surg [Br] 2005;87:324-9.
3. Ünver B, Karatosun V, Günal İ. Rehabilitation of thrust plate prosthesis which is a new approach of the femoral component of total hip arthroplasty. Eklem Hastalik Cerrahisi 2001;12:186-93.
4. SFDA (Sino Food & Drug Administration); Approval No. 3050191. 2003.
5. Hardinge K. The direct lateral approach to the hip. J Bone Joint Surg [Br] 1982;64:17-9.
6. Ranawat CS, Atkinson RE, Salvati EA, Wilson PD Jr. Conventional total hip arthroplasty for degenerative joint disease in patients between the ages of forty and sixty years. J Bone Joint Surg [Am] 1984;66:745-52.
7. Chen CJ, Xenos JS, McAuley JP, Young A, Engh CA Sr. Second-generation porous-coated cementless total hip arthroplasties have high survival. Clin Orthop Relat Res 2006;451:121-7.
8. Wroblewski BM, Siney PD, Fleming PA. Low-friction arthroplasty of the hip using alumina ceramic and cross-linked polyethylene. A 17-year follow-up report. J Bone Joint Surg [Br] 2005;87:1220-1.
9. Mont MA, McGrath MS, Ulrich SD, Seyler TM, Marker DR, Delanois RE. Metal-on-metal total hip resurfacing arthroplasty in the presence of extra-articular deformities or implants. J Bone Joint Surg [Am] 2008;90 Suppl 3:45-51.
10. Marker DR, Strimbu K, McGrath MS, Zywiel MG, Mont MA. Resurfacing versus conventional total hip arthroplasty - review of comparative clinical and basic science studies. Bull NYU Hosp Jt Dis 2009;67:120-7.
11. Sandiford NA, Muirhead-Allwood SK, Skinner JA, Hua J. Metal on metal hip resurfacing versus uncemented custom total hip replacement-early results. J Orthop Surg Res 2010;5:8.
12. Watanabe Y, Shiba N, Matsuo S, Higuchi F, Tagawa Y, Inoue A. Biomechanical study of the resurfacing hip arthroplasty: finite element analysis of the femoral component.

J Arthroplasty 2000;15:505-11.
13. Heilpern GN, Shah NN, Fordyce MJ. Birmingham hip resurfacing arthroplasty: a series of 110 consecutive hips with a minimum five-year clinical and radiological follow-up. J Bone Joint Surg [Br] 2008;90:1137-42.
14. Hing CB, Back DL, Bailey M, Young DA, Dalziel RE, Shimmin AJ. The results of primary Birmingham hip resurfacings at a mean of five years. An independent prospective review of the first 230 hips. J Bone Joint Surg [Br] 2007;89:1431-8.
15. Beaulé PE, Campbell PA, Hoke R, Dorey F. Notching of the femoral neck during resurfacing arthroplasty of the hip: a vascular study. J Bone Joint Surg [Br] 2006;88:35-9.
16. Irvine GB. Femoral neck fractures following Birmingham hip resurfacing. J Bone Joint Surg [Br] 2005;87:1445.
17. Ong KL, Kurtz SM, Manley MT, Rushton N, Mohammed NA, Field RE. Biomechanics of the Birmingham hip resurfacing arthroplasty. J Bone Joint Surg [Br] 2006;88:1110-5.
18. Shimmin AJ, Back D. Femoral neck fractures following Birmingham hip resurfacing: a national review of 50 cases. J Bone Joint Surg [Br] 2005;87:463-4.
19. Tai CL, Lee MS, Chen WP, Hsieh PH, Lee PC, Shih CH. Biomechanical comparison of newly designed stemless prosthesis and conventional hip prosthesis-an experimental study. Biomed Mater Eng 2005;15:239-49.
20. Amstutz HC, Le Duff MJ, Campbell PA, Gruen TA, Wisk LE. Clinical and radiographic results of metal-on-metal hip resurfacing with a minimum ten-year follow-up. J Bone Joint Surg [Am] 2010;92:2663-71.
21. Howie DW, Campbell D, McGee M, Cornish BL. Wagner resurfacing hip arthroplasty. The results of one hundred consecutive arthroplasties after eight to ten years. J Bone Joint Surg [Am] 1990;72:708-14.
22. Buergi ML, Stoffel KK, Jacob HA, Bereiter HH. Radiological findings and clinical results of 102 thrust-plate femoral hip prostheses: a follow-up of 2 to 8 years. J Arthroplasty 2005;20:108-17.
23. Yasunaga Y, Yamasaki T, Matsuo T, Yoshida T, Oshima S, Hori J, et al. Clinical and radiographical results of 179 thrust plate hip prostheses: 5-14 years follow-up study. Arch Orthop Trauma Surg 2011.
24. Karatosun V, Unver B, Gunal I. Hip arthroplasty with the thrust plate prosthesis in patients of 65 years of age or older: 67 patients followed 2-7 years. Arch Orthop Trauma Surg 2008;128:377-81.
25. Karatosun V, Unver B, Gultekin A, Gunal I. A biomechanical comparison of the thrust plate prosthesis and a stemmed prosthesis. Hip Int 2011;21:565-70.