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RESEARCH ARTICLE

EARLY RESULTS OF LARGE CERAMIC HEAD ON HIGHLY CROSS LINKED POLYETHYLENE CEMENTLESS TOTAL HIP REPLACEMENT IN YOUNG ADULTS.

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Key words:-
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Abstract

This study study was conducted on 20 patients undergoing total hip replacements due to various hip pathologies in adults aged from 20 to 55 years . All patients who had undergone noncemented THR using 36-mm ceramic femoral heads and highly cross-linked polyethylene liners were identified . Indications for use of a ceramic femoral head were young (aged 55 years or younger) and/or active patients. The study excluded any patient with any dislocations, acetabular fractures, infections, or any revision or reoperation as indications for hip joint replacement.

All the patients of the study were subjected to the following after an informed consent

1) Full history taking.

2) Clinical assessment , To correlate radiographic readings with patient satisfaction and clinical symptoms, the patients answered a questionnaire, concerning pain and patient satisfaction according to Harris hip score.

3) Radiographic assessment.

Duration of the study was 18 months, Preoperative clinical assessment and harris hip score and radiological evaluation and the same protocol for each visit post operatively

The results showed that The Harris Hip Score increased from a preoperative mean of 38.2 points to 94.2 points.And range of motion improved from mean 122.35 to 204.15° after 18 months follow-up. These values are higher than those of two other comparable running studies with 28 mm femoral head.

Increasing the femoral head size increase the stability and range of motion of the hip joint in THA but with convensional bearing surfaces this cause increased wear rate and decrease the longivity of the prothesis. With new articulatig bearing surfaces as ceramic on highly cross linked poly ethylene we can get the benefit of increasing the head size and increase the longivity of the joint prothesis specially in young adults.

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Introduction:-

Total hip arthroplasty is one of the most successful and cost effective surgical interventions in medicine, relieving pain and restoring function of hip joint. Improvements in septic prophylaxis, implant fatigue strength and osteointegration have made wear and the biologic response to the subsequent particulate debris the weak link in the long term success of total joint arthroplasty . [(1)] (**Heisel C , et al , 2004)**

Wear of ultra-high molecular weight polyethylene(UHMWPE) prostheses in total joint arthroplasty produces billions of submicron particles annually that may cause a foreign body response leading to extensive bone resorption and gross loosening of the components. Improving the wear resistance of polyethylene, and as a result, reducing the number of particles released to the periarticular tissues, could extend substantially the clinical lifespan of total joint replacements. Effort to improve the wear performance of UHMWPE led to the development of cross-linked ultrahigh molecular weight polyethylenes (XLP) that are resistant to this type of wear by minimizing surface orientation. (**Engh CA Jr , et al , 2006)**

Reducing wear guarantees the longer survivorship of the implants by reducing the osteolysis and aseptic loosening. Thus, the need for improved bearing surfaces in total hip arthroplasty (THA) has led to the development and study of alternative bearing materials. [(3)] (**Baker DA , et al , 2003)**

Ceramics were introduced in total hip arthroplasty to address the problems of friction and wear that were reported with metal on polyethylene articulations. Thus remarkable sliding characteristics and wettable material could limit wear debries generation and provide longer lifetime of the artificial hip. Extensive clinical study shows that alumina is the best used in young and active patients. [(4)] (**Willmann G., et al , 2000)**

Smaller prosthetic head sizes are linked to a higher rate of prosthesis dislocations, whereas larger heads did show a higher resistance against dislocation . Since dislocation is still a major concern in total hip Arthroplasty, any mean to reduce the dislocation rate is an attractive option per se. In former times gaining higher resistance against dislocation by using larger head sizes had to be trade-off against the higher rate of debris associated with larger heads. With the advent of hard-on-hard bearing like ceramic-on-ceramic and metal-on metal large diameter heads have become applicable without additional drawbacks and therefore the use of larger diameters has become more popular. The rate of dislocation could be reduced dramatically by this mean in accordance with former clinical experience. [(5)] (**Amstutz HC, et al , 2004)**

As soon as highly cross-linked polyethylene has become available the use of large diameter head has become even more popular, a real boom has started. One has to point out that by using larger diameter heads articulating against cross-linked polyethylene a remarkable part of the gain in debris reduction is lost again. So, in arthroplasties with polyethylene there is still this trade-off between stability and debris. Larger head sizes have also become popular because of the increased range of motion. [(6)] (**Geller JA, et al , 2006)**

Subject and Methods:-

Subject selection:-

The study was conducted on 20 patients undergoing total hip replacements due to various hip pathologies in adults aged from 20 to 55 years .

Decision of total hip replacement was based on clinical and radiological evaluation in cases of hip osteoarthritis,complicated fracture neck femur and advanced stages of avascular necrosis of femoral head.
Patients were 14 males and 6 females
primary hip replacements 13 right side and 7 left side
body mass index ranging from 22.67 to 34.07
all cases done with posterior approach to hip joint.

Patients demographics and preoperative data:-

1- **Gender**

The study included 14 male patients (70%) and 6 female patients (30%)

2- **Age, height, weight, BMI**

Mean age was 38.85 years, weight 73.95 Kg, height 169.15 cm and BMI 24.99 kg/cm2.

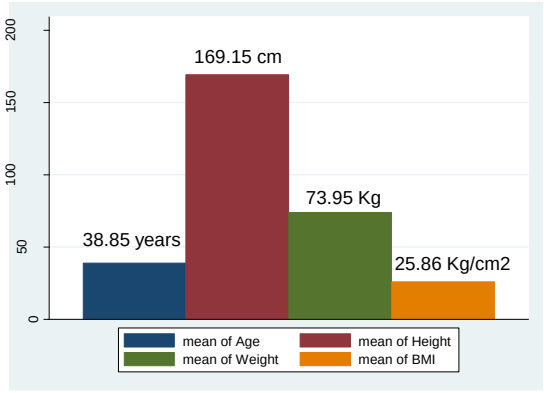

Figure (1):- Bar chart of the mean age, height, weight and BMI

3- **Pre-operative Diagnosis:**

Preoperative diagnoses were osteoarthritis (65%), AVN (20%), dysplasia (10%) and ankyloses (5%)**.**

Diagnosis	Frequency	Percent	Cum.
Osteoarthritis	13	65	65
AVN	4	20	85
Dysplasia	2	10	95
Ankylosis	1	5	100
Total	20	100	

Table (1) preoperative patients' diagnoses

Inclusion criteria:-

All patients who had undergone noncemented THR using 36-mm ceramic femoral heads and highly cross-linked polyethylene liners were identified . Indications for use of a ceramic femoral head were young (aged 55 years or younger) and/or active patients.

Exclusion criteria:-

The study excluded any patient with any dislocations, acetabular fractures, infections, or any revision or reoperation as indications for hip joint replacement.

Methods:-

All the patients of the study were subjected to the following after an informed consent

1) Full history taking.

2) **Clinical assessment**

To correlate radiographic readings with patient satisfaction and clinical symptoms, the patients answered a questionnaire, concerning pain and patient satisfaction according to Harris hip score.

3) **Radiographic assessment:**

Radiographic measurements were based on anteroposterior conventional radiographs of the pelvis and anteroposterior hip/upper femoral radiographs showing the entire femoral component. These radiographs were taken the day after the operation,six weeks post operative ,six months post operative ,one year post operative , eighteen months and two years post operative .

Duration of the study was 18 months. Preoperative clinical assessment and harris hip score and radiological evaluation and the same protocol for each visit post opeatively.

Operative technique:-

Standard Posterior approach to hip joint and using same implants (cementless acetabular penical cup size from 54 to 60 , marathon highly cross linked polyethylene acetabular liner ,delta ceramic head size 36 and corail stem)

Fig (2):- The hip implants

Post operative:-

anteroposterior conventional radiographs of the pelvis and anteroposterior hip/upper femoral radiographs showing the entire femoral component. These radiographs were taken the day after the operation.

mobilization from bed first day post operative , using walker .
Discharge almost between 4 to 6 days post operative with clear instructions for how to mobilize from bed and walk.

First follow up visit:-
after two weeks from surgery date for wound checking and removal of stitches.

Second follow up visit: after six weeks with clinical assessment and radiological evaluation.
1- clinical assessment by history taking and application of **harris hip score .**
2- Radiological assessment:

Radiographic evaluation of hip replacement
Initial placement of the prosthetic components should mimic the normal positions of the native acetabulum and femoral head and neck. Specific anatomical landmarks and measurements are used to verify correct placement. In the initial evaluation of hip arthroplasties, the following elements are assessed:
1 Leg length
2 Horizontal centre of rotation
3 Acetabular inclination
4 Femoral stem positioning

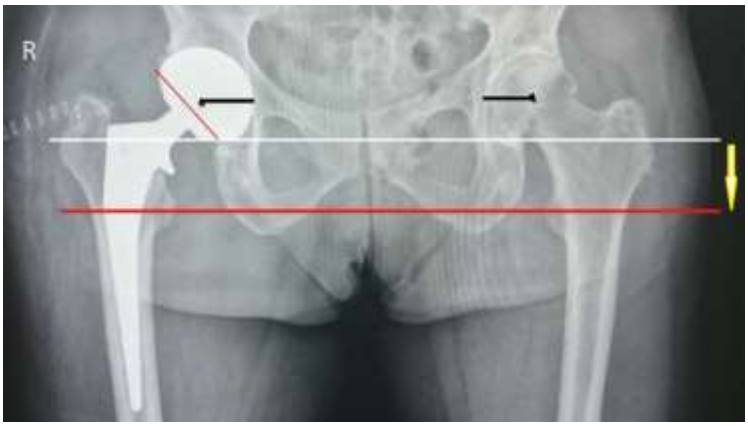

Fig (3):- X ray post operative evaluation post THA

Cementless components:-
Assessing the initial fixation of cementless components is more difficult than those with cement. The initial postoperative radiograph is unlikely to show any obvious bony defects. Assessing fixation is really only possible on follow up radiographs as the native bone shows more reactive change to non-cemented prosthesis. One common

finding in cementless components is a thin isolated radiolucent band (< 2 mm) around the rough surface of the prosthesis. This lucency is frequently well delineated by a thin sclerotic margin and if non-progressive after two years this finding is considered normal. Though suboptimal, this appearance indicates fibrous ingrowth and is thought to provide sufficient stability.

Fig (4):- Evaluation of follow up x ray in THA

The remaining follow up results were done after six months, one year and 18 months, with judging the same parameters clinical and radiological.

Results:-

Changes in Harris Hip Score

Variable	Patients Number	Mean	Std. Dev	Min	Max
Pre-op	20	38.2	12.26	15	55
6 weeks	20	80.1	9.1	67	93
6 months	20	92.95	6.1	76	99
12 months	20	94	5.6	76	99
18 months	20	94.2	5.5	76	99

Table (2):- shows the preoperative Harris score and mean score postoperative at 6 weeks, 6 months, 12 months, 18 months

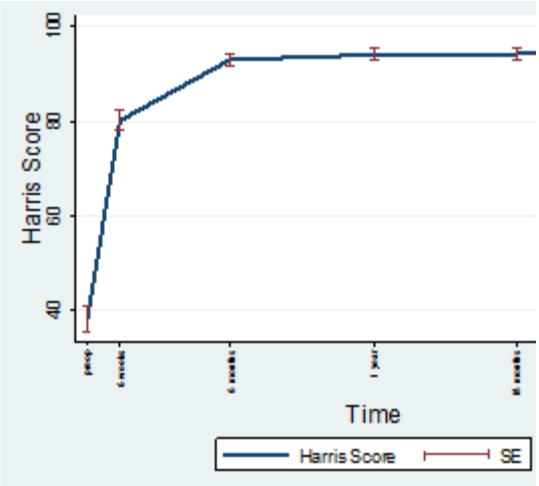

Figure (5):- Mean change in Harris Score over the follow up time

Significance of Harris score change over time

	Coefficient	Std.Err	z-statistics	p-value	[95% Conf. Interval]
6 weeks	41.9	1.196	35.02	<.0001	39.6 - 44.2
6 months	54.75	1.196	45.76	<.0001	52.40 - 57.1

1 year	55.8	1.196	46.64	<.0001	53.4- 58.1
18 months	56	1.196	46.81	<.0001	53.7 -58.345
2 years	56	1.196	46.81	<.0001	53.7 - 58.3
sigma_u | 6.8					
sigma_e | 3.8					
rho | 0.76					

Table (3) Significance of Harris score change over time

Interpretation of the table

- Changes of the postoperative scores are highly significant from the baseline (p-value <.0001).
- The average increase in the score at the 6 weeks visit was 41.9 from the preoperative measures. The average increase in the score at the 6th month visit was 54.75 from the preoperative measures. The average increase in the score at 1 year was 55.8 from the preoperative measures. The increase in 18month and 24 months' score was similar and equals to 56 above the baseline visit.
- The score follows normal distribution with Standard deviation of 6.8
- The estimated unexplained within patient variation of the score was 3.8
- 76% variation of the score across the patients can be attributed to patient level difference.

Factors affecting Harris score change:-

We tested if the Harris score change is affected by patients gender, age, preoperative diagnosis or side of the surgery and we didn't find significant difference between subgroups.

	Coefficient	Std.Err	z- statistics	p-value	[95% Conf. Interval]
Gender	-1.14	5.28	-0.22	.829	-11.49- 9.21
Age	-0.045	.33	-0.14	-0.69	-.69 - 0.60
Side of lesion	0.011	5.28	.00	.998	-10.34- 10.37
Preop diagnosis	-2.27	3.1	-0.73	0.46	-8.34 - 3.8

Table (4):- shows the effect of the preoperative value on changes of Harris score postoperative

- Three patients had moderate improvement of Harris score from 21,22,23 to 88 postoperatively and as the model shows the change of postoperative Harris score was not significantly related to the preoperative patients characteristics but it was mainly attributable to the preoperative patients level difference. One case showed fair improvement of Harris score and this patient had preoperative diagnosis of ankyloses and low preoperative score of 15.

Range of Motion

Variable	Mean	Std. Dev	Min	Max
Preop range of motion	122.35	19.8	99	161
Range of motion at 18 months	204.15	7.69	189	214

Table (5):- shows the range of motion measured preoperatively and 2 years postoperatively (Mean, standard deviation, minimum and maximum)

- Mean pre-operative range of motion score was 122.35 and standard deviation 19.8 (min 99 and max 161). At 18 months follow up the mean score was 204.15 and SD 7.69 (min 189 and max 214).

Significance of range of motion score change overtime

	Coefficient	Std.Err	z-statistics	p-value	[95% Conf. Interval]
18 months	81.8	3.5	23.2	<.0001	74.9- 88.7
sigma_u | 10.1					
sigma_e | 11.2					
rho | 0.45					

Table (6):- Significance of range of motion score change overtime

Interpretation of the table:

- Changes of the postoperative scores are highly significant from the baseline (p-value <.0001).
- The average increase in the score at the 18 months visit was 81.8 from the preoperative measures.
- The score follows normal distribution with Standard deviation of 10.1
- The estimated unexplained within patient variation of the score was 11.2
- 45% variation of the score across the patients can be attributed to patient level difference.

Factors affecting range of motion score change:-

We tested if the range of motion change is affected by patients' gender, age, preoperative diagnosis or side of the surgery and we didn't find significant difference between subgroups.

	Coefficient	Std.Err	z- statistics	p-value	[95% Conf. Interval]
Gender	5.19	17.8	.29	.7	-29.6- 40
Age	.02	1.03	.02	.99	-2.01- 2.05
Side of lesion	3.04	16.9	.12	.9	-31.17- 35.24
Preop diagnosis	-6.5	10.5	-0.61	.54	-27.1 -14.1

Table (7):- Preoperative patient's factors and their effect on the postoperative change in the range of motion

Range of Flexion

Variable	Mean	Std.Dev	Min	Max
Range of flexion preoperative	72.45	6.24	63	82
Range of flexion at 18 month postoperative	108.1	2.36	104	112

Table (8):- shows the mean of range of flexion measured preoperatively and at 18 months postoperatively

- Mean preoperative range of flexion score was 72.45 and standard deviation was 6.24 (min 63 and max 82) and the mean postoperative score improved to 108.1 and SD was 2.36 (min 104 and max 112)

Significance of the change of the flexion range:

Flex range	Coefficient	Std.Err	z-statistics	p-value	[95% Conf. Interval]
18 months	35.65	1.19	29.89	<.0001	33.31- 37.99
sigma_u | 2.83					
sigma_e | 3.77					
rho | 0.36					

Table (9) Significance of the change of the flexion range

Interpretation:-

- Changes of the postoperative scores are highly significant from the baseline (p-value <.0001).
- The average increase in the score at the 18 months visit was 35.65 from the preoperative measures.
- The score follows normal distribution with Standard deviation of 2.83
- The estimated unexplained within patient variation of the score was 3.77
- 36% variation of the score across the patients can be attributed to patient level difference.

Factors affecting Flexion range score change:-

We tested if the flexion range change is affected by patients' gender, age, preoperative diagnosis or side of the surgery and we didn't find significant difference between subgroups.

	Coefficient	Std.Err	z- statistics	p-value	[95% Conf. Interval]
Gender	.094	7.00	.01	.99	-13.64- 13.8
Age	.061	.437	.14	.89	-.795- .917
Side of lesion	.463	7.01	.07	.94	-13.27 – 14.2
Preop diagnosis	-.087	4.1	-.02	.98	-8.14 – 7.97

Table (10):- Factors affecting Flexion range score change

Radiological follow up and postoperative complications:

- Radiological follow up by plain x-ray showed no progressive radiolucency or change in position of components in all cases.
- Postoperative dislocation was not reported in any patients
- Superficial wound infection was reported in 2 cases (10%) and occurred in the first 2 weeks postoperatively. The infection was fully recovered with antibiotics according to culture and sensitivity and with daily wound dressing.
- No other complications were reported.

Discussion:-

Regarding different bearing surfaces combinations and head sizes in total hip replacements many studies were done

As compared to other puplished papers in hip replacement field , these considered to be good results.

1- **Early results and differences in clinical outcome of 32 and 36mm ceramic on ceramic articulation done by M.Jovanovic , C.Warzecha ,Muschika and F.Hoffmann** and presented in10th EFORT Congress 3 - 6 June 2009, Abstract P380, Vienna Austria

Results:-

- With increasing head size, there is less chance of component-on component impingement and therefore a decreased risk of chipping and breaking. Furthermore femoral heads with 28 mm diameter have higher complication rates compared to heads with a diameter equal to or larger than 32 mm.
- Patients with femoral heads of 32 mm and 36 mm diameter have excellent and comparable clinical results.
- The Harris Hip Score increased from a preoperative mean of 49 points to 96 points.
- Range of motion improved to 218° and flexion angle to 110° after two years follow-up. These values are higher than those of two other comparable running studies with 28 mm femoral head. [7] **(M.Jovanovic, 2009)**

Another study for ceramic on highly cross linked poly ethylene:

2- Ceramic on highly cross-linked Polyethylene in cementless Total Hip Arthroplasty by J.-S. Kang and K.-H. Moon published in 12th BIOLOX® Symposium Seoul, Republic of Korea September 7 - 8, 2007:

Thirty six patients (42 hips) underwent cementless total hip arthroplasty using a porous-coated acetabular cup, highly cross linked polyethylene liner (Marathon™), and an extensively porous-coated femoral stem(Anatomic Medullary Locking, AML, Depuy, Warsaw, In, USA). A 28mm alumina head used in all hips. [8] **(J.-S. Kang , et al , 2007)**

Results:-

Clinical results The average Harris hip score was 92.3(range, 76-100) points at the final followup. Hip scores at last follow-up were; excellent in 28 out of 39 hips (71.8%), good in 8 (20.5%) hips and fair in 3(7.7%) hips. The prevalence of thigh pain was 23.7%(4 hips) initially and the pain disappeared 3 years after surgery in all hips.

Radiographic results Thirty-five(89.75%) stems had good canal fill. All of these showed bone ingrowth. Four (10.5%) hips had a poor canal fill. Three of these showed bone ingrowth, and one hip showed stable fibrous ingrowth. There was no unstable stem. All acetabular and femoral components were bone-ingrown, and neither pelvic nor femoral osteolysis was identified. The subsequent head penetration, with elimination of the bedding-in wear, resulted in a linear wear rate of 0.032 +/0.02 mm per year. [8] **(J.-S. Kang , et al , 2007)**

Another study comparing Uncemented Total Hip Arthroplasty between Metal on Metal and Ceramic on Polyethylene Bearing Surfaces in Young Patients:

3- Comparison of Uncemented Total Hip Arthroplasty between Metal on Metal and Ceramic on Polyethylene Bearing Surfaces in Young Patients by Y.-H. Kim published in 12th BIOLOX® Symposium Seoul, Republic of Korea September 7 - 8, 2007:

56 hips (43 patients) were enrolled in this study with matched pair variables (28 hips in metal-on-metal and 28 hips in ceramic-on-polyethylene).

Results

Clinical Results The mean Harris hip score was increased from 53.6 points (range, 21 to 77) preoperatively to 94.5 points (range, 89 to 100) at the final follow-up in the metalon-metal group and was increased from 48.4 points (range, 26 to 72) preoperatively to 96.1 points (range, 93 to 100) in the ceramic-on-polyethylene group. There was no patient who showed the thigh pain. [9] **(Y.-H. Kim, 2007)**

Radiographic Results The incidence of bone formation around the femoral stem per Gruen [2] zone at final follow-up . The fixation status of all the femoral component was classified as bone ingrowth according to the method described by Engh et al . No loosening of the femoral stem was observed. [9] **(Y.-H. Kim, 2007)**
In metal-on-metal group, focal osteolysis around the cup at zone 1 was found on the radiograph of one case with the pain appeared at 27 months postoperatively, however, the case is currently under observation until 108 months after operation to see whether the osteolysis progress or not (case 1). The other hip in metal-on-metal group that showed the groin pain at 25 months postoperatively had osteolysis around the cup at zone 2 and proximal femur at zone 7 on the radiograph . There was progressive huge osteolysis around the cup at zone 2 and around the stem at zone 7 with the increasing size and aseptic loosening of the cup as well on the radiograph taken at 63 months postoperatively (case 2). The mean linear and volumetric wear rate of ceramic-on-polyethylene group was 0.08 ± 0.02 mm/yr and 87.42 ± 6.17 mm3/yr, respectively. [9] **(Y.-H. Kim, 2007)**

According to this study, the ceramic-onpolyethylene articulation considered as the safer option as compared with the various other alternative bearings due to the following disadvantages of them. In conclusion, excellent clinical and radiographic results of uncemented total hip arthroplasty with the third generation ceramic-on-polyethylene articulation were obtained in young patients in the mid-term follow-up, especially in terms of no osteolysis, no loosening and very low wear, which means the third generation ceramic-on-polyethylene articulation is the one of the safe options in new articulation systems to reduce wear. However, although the metal-on-metal articulation showed also excellent clinical and radiographic results, early osteolysis probably due to delayed metal hypersensitivity are remained as a concern. [9] **(Y.-H. Kim, 2007)**

Conclusion:-

Increasing the femoral head size increase the stability and range of motion of the hip joint in THA but with convensional bearing surfaces this cause increased wear rate and decrease the longivity of the prothesis.

With new articulatig bearing surfaces as ceramic on highly cross linked poly ethylene we can get the benefit of increasing the head size and increase the longivity of the joint prothesis specially in young adults.

Recommendation:-

Competition between various articulations in order to reduce wear ,improve range of movements and to improve the longevity of THA will be continued through next decades. In that, ceramic-on-polyethylene including recently developed highly cross-linked polyethylene articulation would be remained as a good option for THA especially young and active patients. Further manufacturing and material development, improvements in the processing of ceramic as well as advances in engineering of head-neck articulations and liner design will lead to more favorable clinical results and decrease in the incidence of ceramic fracture and dislocation. In future, it is necessary to perform prospective randomized comparative studies to compare various bearing surfaces in patients matched in age, sex, diagnosis, body mass index, kinds of polyethylene and ceramic head.

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