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To assess the 2-year clinical and radiologic results with an entirely HA-coated total hip replacement, with an emphasis on periprosthetic bone remodelling

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Abstract
Total hip arthroplasty (THA) is one of the most successful surgical procedures that has been introduced and today over 1.5 million THA's are performed annually in the world. The development of THA in the 60's by Sir John Charnley represents a milestone in orthopaedic surgery. The most common indication for THA is primary osteoarthritis, a degenerative disorder of the cartilage and the surrounding tissues. However, 8-9% of the THA's performed sooner or later need to be re-operated. Revision arthroplasty is a challenging procedure, costly and with a less reliable outcome. The main reason for failure leading to revision is aseptic loosening. Both mechanical and biological effects act in the loosening process, the dominating factor may be one or the other, depending on a number of circumstances, including implant design, fixation mode and technique, as well as biologic factors unique to the individual. Our purpose of this study is to determine the performance of, and periprosthetic bone response to hydroxyapatite (HA)–coated hip implant at least 2 years after insertion. This is both prospective & retrospective study of patients operated with uncemented fully HA coated THR in our institute, Sample size taken is 30 patients of institute who have undergone uncemented fully HA coated THR. We have taken Patients with un cemented fully HA coated THR done, At least 2 year back in hospital as a Inclusion criteria. In exclusion criteria we have excluded Patient with uncemented partially HA coated THR and Patients with anterior thigh pain before operation. Our procedure of study was Clinical follow up of patients pre-op, immediate post op, 12months & 24 months using anterior thigh pain. Radiological follow up through x-rays at pre-op, immediate post op, 12 months & 24 months. Anteroposterior radiographs of the pelvis and femurs cantered over the pubis, and lateral views of the femurs were standardized by using the same film quality, developing process, exposure, target distance, magnification, and field and keeping the leg in the same position. The linear measurements were made by a calliper and corrected for magnification of the radiographs, using the diameter of the head of the femoral component as reference. Femoral zonal analysis was performed on the anteroposterior radiographs as described by Gruen *et al.* and on the lateral radiographs according to Johnston *et al.* spot welds that is diaphyseal endosteal bone formation were noted in both anteroposterior and lateral x-rays. Subsidence of the stem was measured by the vertical distance from the lateral shoulder of the prosthesis to the superior tip of the greater trochanter or to the tip of the lesser trochanter. Varus or valgus migration was determined by measuring the angle made by the intersection of a line through the midstem of the prosthesis and a line through the midshaft of the femur as seen on the anteroposterior radiograph. End point of study was completion of clinical and radiological follow up of 30 patients.
Results shown by this study reviews 38 hips in 30 patients who were followed up for a average of 32 months (range 24- 96 months). There were 22 male and 8 female patients. The average age was 41years (range, 14-55 years). The diagnosis was AVN in 28 hips, Ankylosing spondylitis in 7 hips, Fracture neck femur in 2 hips, Koch's in 1 hip. 6 hips had undergone prior procedures, including osteosynthesis of femoral neck fracture. Clinically Result shows Hip function rose to a near-normal level during the first year, and this result was maintained throughout the study. At 2 years, only 1 patient complained of vague, uncharacteristic hip pain, unrelated to walking. No patient suffered from thigh pain.

Keywords: Total hip arthroplasty (THR), cementless arthroplasty, Periprosthetic bone density, hydroxyapatite (HA)–coated hip implant, HA-coated total hip replacement

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Introduction
Total hip arthroplasty is a very successful reproducible procedure and an excellent treatment to eliminate pain and restore function in a diseased hip for both the short-term and long-term period. An extensive body of literature documents both functional improvement and high rates of long term survivorship for this procedure.

As a result both indications and expectations for total hip arthroplasty have continued to broaden as new advances are incorporated.

The ability of hydroxyapatite (HA) to bond directly to bone quickly and strongly has been used by plasma spraying of HA coatings on hip prostheses. Preliminary reports on HA-coated hip prostheses are limited but mostly encouraging. The clinical effect of coating limitation is uncertain, and because the major problem with cementless prostheses has been loosening, extensive coating that may increase fixation seems more rational.

Periprosthetic bone density change is a common finding in total hip arthroplasty (THA). It has been suggested that when bone loss is excessive, it can compromise the long-term clinical performance of the prosthesis. Periprosthetic bone loss was first observed around failed cemented femoral stems; it was related to aseptic loosening, and it was named “cement disease”.

Methods

This is both prospective & retrospective study of patients operated with uncemented fully HA coated THR in our institute.

Definitions used as reference

- **Bone ingrowth:** It is the term used to describe biological response when new bone tissue is found in direct contect with the surface of non-cemented implant. Synonym bone ongrowth, osseointegration, biological ingrowth.
- **Bone remodelling:** It refers to mechanically adaptive changes in bony architecture.
- **Spot weld:** endosteal new bone formation bridging from cortical bone and in apposition of implant surface, seen as densification on radiographs.
- **Pedestal formation:** Radiological endosteal densification at the tip of stems, partially or completely bridging the medullary canal. synonym tip sclerosis
- **Reactive lines:** radiological endosteal densification parallel to the lining of the implant, normally with in millimeter distance from implant surface. synonym: radiodence line, radioopaque line, sclerotic line, cortical line.
- **Subsidence of the stem:** Measured by the vertical distance from the lateral shoulder of the prosthesis to the superior tip of the greater trochanter or to the tip of the lesser trochanter.
- **Varus or valgus migration:** Determined by measuring the angle made by the intersection of a line through the midstem of the prosthesis and a line through the midshaft of the femur as seen on the anteroposterior radiograph.
- **Stress shielding**: Osteopenia occurring in bone as the result of removal of normal stress from the bone by an implant.

Sample size taken is 30 patients of institute who have undergone uncemented fully HA coated THR. We have taken Patients with uncemented fully HA coated THR done, At least 2 year back in hospital as an Inclusion criteria. In exclusion criteria we have excluded Patient with uncemented partially HA coated THR and Patients with anterior thigh pain before operation.

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Results

This study reviews 38 hips in 30 patients who were followed up for a average of 32 months (range 24- 96 months). There were 22 male and 8 female patients. The average age was 41years (range, 14-55 years). The diagnosis was AVN in 28 hips, Ankylosing spondylitis in 7 hips, Fracture neck femur in 2 hips, Koch’s in 1 hip. 6 hips had undergone prior procedures, including osteosynthesis of femoral neck fracture. Clinically Result shows Hip function rose to a near-normal level during the first year, and this result was maintained throughout the study. At 2 years, only 1 patient complained of vague, uncharacteristic hip pain, unrelated to walking. No patient suffered from thigh pain.

Femoral Radiographic Results

- Stem subsidence or loosening was not seen in any case.
- 5 stems had been inserted into the varus whereas 4 in valgus position.

Alignment	Hips	Percentage (%)
Central	29	76%
Varus	5	13%
Valgus	4	11%
Total	38	100%

- 10 stems had not been completely buried in the femoral bone, so that 6 mrn of the HA coated part protruded above the calcar resection level. Within the first 2 years, new bone grew up as far as 4 mm along 6 of these prostheses (Fig. 1).
  Figure (1) showing new bone formation in calcar region.
- Decrease in calcar height was not seen in any case. Rounding of the calcar started at 6 months in 12 hips, at 1 year in 8 hips, and at 2 years in 2 hips, whereas the remaining 10 calcars showed no rounding.
- We regularly found cancellous bone remodeling in the proximal femur, resulting in trabecular reorientation. In addition, diaphyseal endosteal bone formation with so-called spot welds was found in all cases (Fig. 2). This formation was first seen at 6 months in 19 hips, at 1 year in 12 hips, and at 2 years in 5 hips.

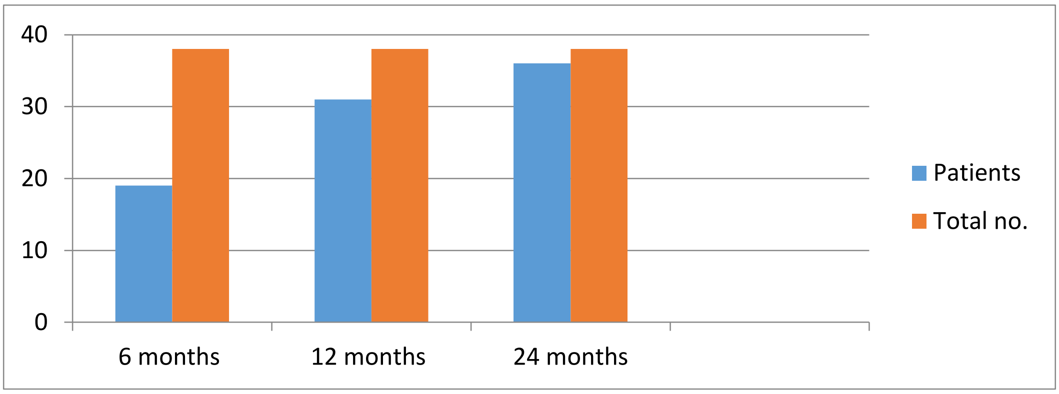


Fig 2: showing multiple spot-weld formation at 2 years.

Table 2. Showing spot-weld formation in femoral stem with time

	Patients	Percentage (%)
6 months	19	50%
12 months	12	32%
24months	5	13%
Total	36	95%

- The endosteal bone density increased until 2 years.
- Considerable trabecular bone formation was noted at the tip of the stem found in 6 hips (Fig. 2). The cancellous bone always connected the tip to the nearest cortex (Fig.3) or to both in case of the tip being centered in the femoral canal. Four femurs with valgus stems developed cortical thickening in zones 4 and 5. This thickening was first seen at 1 year, slightly increasing throughout the study. The tips of these stems were lying against the endosteal cortex, causing a bony reaction with cortical thickening (Fig. 3). In 2 cases calcar was fractured, both of them being secured with wire loops, healed uneventfully.

  Figure (3) showing pedestal (black arrow) and spot-weld formation.
- Stem subsidence or loosening was not found in any of these cases.
- In the anteroposterior view, 32 hips showed stress shielding which was present throughout the follow up (Fig 4). In the lateral view, 32 femurs showed decrease in bone density. No correlation was found between decreased bone density and stem size, canal fill, sex, age, or body weight.

  Figure (4) showing stress shielding both in calcar and greater trochantric region

Table 3: Showing % of stress shielding noted on x-rays:

Stress shielding	Patients	Percentage (%)
Present	32	84%
Absent	6	16%

- Radiopaque double lines were seen along the proximal part of 5 femoral stems, always locatedboth in zone 1 (Fig. 5). The lines were present till 2 years of follow up. The mean length of the lines in zone 1 was 4mm. The width was aorund 1mm. We found no association between the development of proximal radiopaque double lines and sex, age, body weight, stem size, canal fill, or polyethylene wear.

  Figure (5) showing radiopaque line formation.

Discussion

This is a study of a prospectively and retrospectively collected series of hip arthroplasty using a tapered, titanium, Hydroxyappatite coated hip stem. The concept of osseointegration is related to a high degree of direct bone-implant contact without intervening soft tissue, as ascertained by microscopic evaluation. Intimate radiologic bone-implant contact is essential however does not guarantee of bone fixation; a thin layer of fibrous tissue can be concealed in the interface. The surrounding of a prosthesis by a radiopaque double line correlates histologically with a fibrous tissue layer between implant and bone. In such cases, the development of clinically significant failure is inevitable. Migration of an implant that is bonded to bone is hardly possible. Cementless prostheses surrounded by an extensive radiopaque double line (so-called fibrous fixation) or revealing measurable migration or subsidence should be considered loosenings because they have not achieved the intentional direct bone-implant contact. Loosening should be separated into primary nonintegration and loosening of implants previously bonded directly to bone. The femoral implant evaluated in this study has been shown to perform quite well historically and in this group of patients, it developed osseointegration with clear evidence in all cases of endosteal spot welds and trabecular bridging. There were no cases of aseptic loosening, with a stable bone response demonstrated reliably at greater than 2 years of follow-up. There was no evidence of subsidence or component migration, indicating that implant stability was achieved early and reliably. The results of this study are comparable to those reported by Rokkum and Reigstad. In their review of 94 consecutive cases, with careful radiographic and clinical follow up, there was no observed stem subsidence or loosening in any case. They regularly found cancellous bone remodeling in the proximal femur, with preservation of the osseous architecture. The Proximal osteolysis was minimal and distal osteolysis absent, despite a high rate of acetabular failure in their study.

In a retrieval analysis of this implant, Tonino et al found that all 5 stems were well fixed in the femur, and there was a significant evidence of both distal and proximal osseointegration. Although the relative contribution of the hydroxyapatite coating to the success of this implant cannot be determined by this study, there is considerable clinical and experimental evidence suggesting that such coatings enhance initial fixation and ultimate osseous integration. Comparative studies have indicated advantages of HA-coated implants over noncoated implants of similar design, with HA-coated femoral stems achieving more reliable bony fixation, better evidence of spot welds, and less subsidence than porous control groups.

The tapered geometry of this implant may also have played a significant role in the osseous integration and bone adaptation that was observed in this study. Long-term success has been documented with other tapered stems, without hydroxyapatite coating. Comparison of early postoperative with long-term radio-graphs, however, does demonstrate preservation of bone architecture, with similar appearance of bone quality, both early and late. In addition, the complete absence of thigh pain noted in this group of patients may be related to this favourable bone response without significant hypertrophy or remodeling. It has been documented that despite the high rate of acetabular wear, there were no cases of significant femoral osteolysis. There was no distal osteolysis; when present, lysis was confined by a sclerotic zone to the proximal zones of the implant and was not progressive. It is likely that the circumferential and complete coating of the implant conferred upon it a resistance to progressive and distal manifestations of osteolysis.

The most striking clinical finding in our study was the absence of thigh pain, which is often seen both in proximally and in fully porous-coated stems as well as in proximally HAcoated stems, even with histologically verified bone ingrowth. Mismatch between the modulus of elasticity of the bone and prosthesis and diaphyseal endosteal irritation by an unstable stem have been proposed as causes of thigh pain. Thigh pain seems to be eliminated with the entirely HA-coated stem, probably because of comprehensive diaphyseal bonding.

This study documents the success of this tapered, titanium, HA-coated femoral stem in a consecutive series of unselected cases with no failure of fixation or aseptic loosening though stress shielding was present in majority of cases. The implant was found to perform with equal success across a wide range of pathologic entities, patient profiles, and bone types. Although the relative contributions of the surface coating, the implant geometry, and the surgical technique of compaction broaching cannot be established by this study, it is clear that this combination of features resulted in a durable and reliable femoral construct for this group of patients. Further documentation of the performance of this device into the second decade of service and beyond will be necessary to determine if these favorable results are maintained.

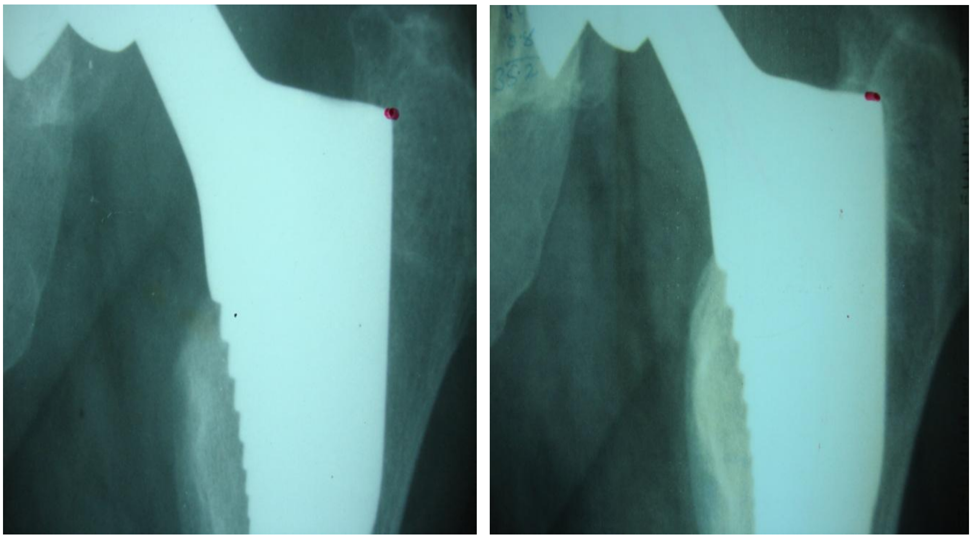
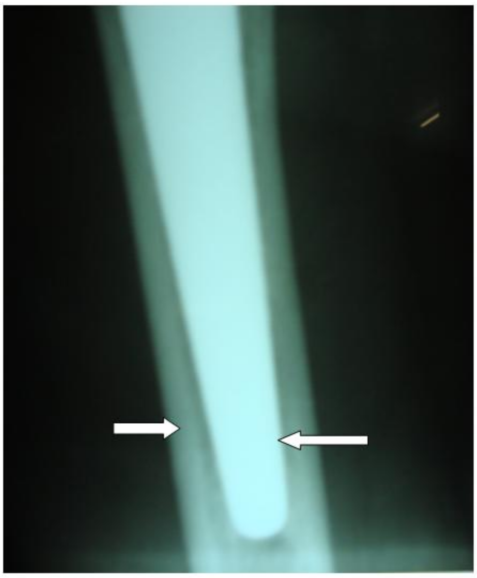


Fig 1: showing new bone formation in calcar region.



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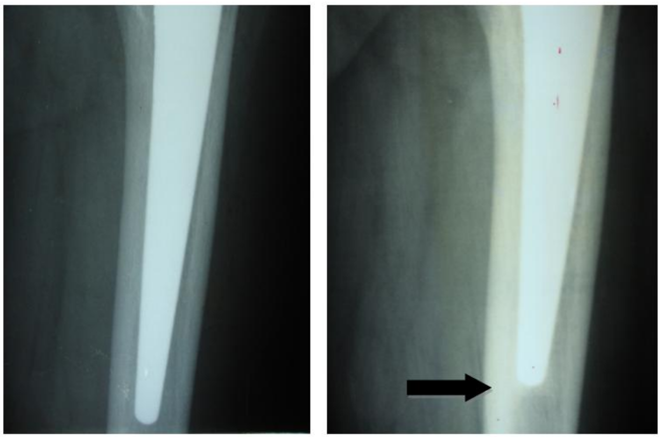
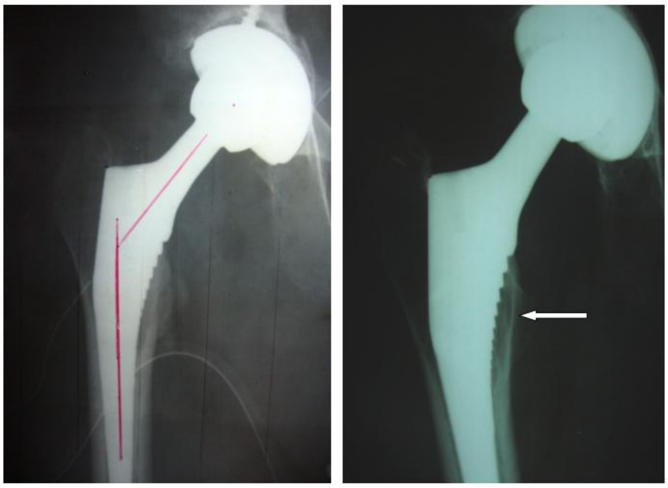


Fig 3: Showing pedestal (black arrow) and spot-weld formation.



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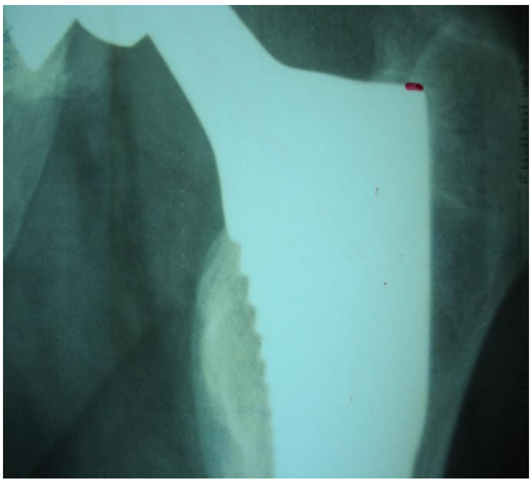

Fig 5: Showing radiopaque line formation.

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