RETROSPECTIVE ANALYSIS OF

CLINICAL AND RADIOLOGICAL OUTCOME OF EXETER CEMENTED TOTAL HIP ARTHROPLASTY

2000 - 2010

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE RULES AND REGULATIONS FOR THE M.S. DEGREE (BRANCH-II) ORTHOPAEDIC SURGERY EXAMINATION OF THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY TO BE HELD IN APRIL, 2015

CERTIFICATE

This is to certify that this dissertation titled **"RETROSPECTIVE ANALYSIS OF CLINICAL AND RADIOLOGICAL OUTCOME OF EXETER CEMENTED TOTAL HIP ARTHROPLASTY FROM 2000 TO 2010"** is a bonafide work done by**DR. A. ARUN SHANKAR**in the Christian Medical College, Vellore in partial fulfillment of the rules and regulations of the TamilNadu Dr. M.G.R. Medical University for the award of M.S. Degree (Branch-II) Orthopaedic Surgery under the supervision and guidance of **Prof. ALFRED JOB DANIEL** during the period of his post-graduate study from JUNE 2013 to MARCH 2015.

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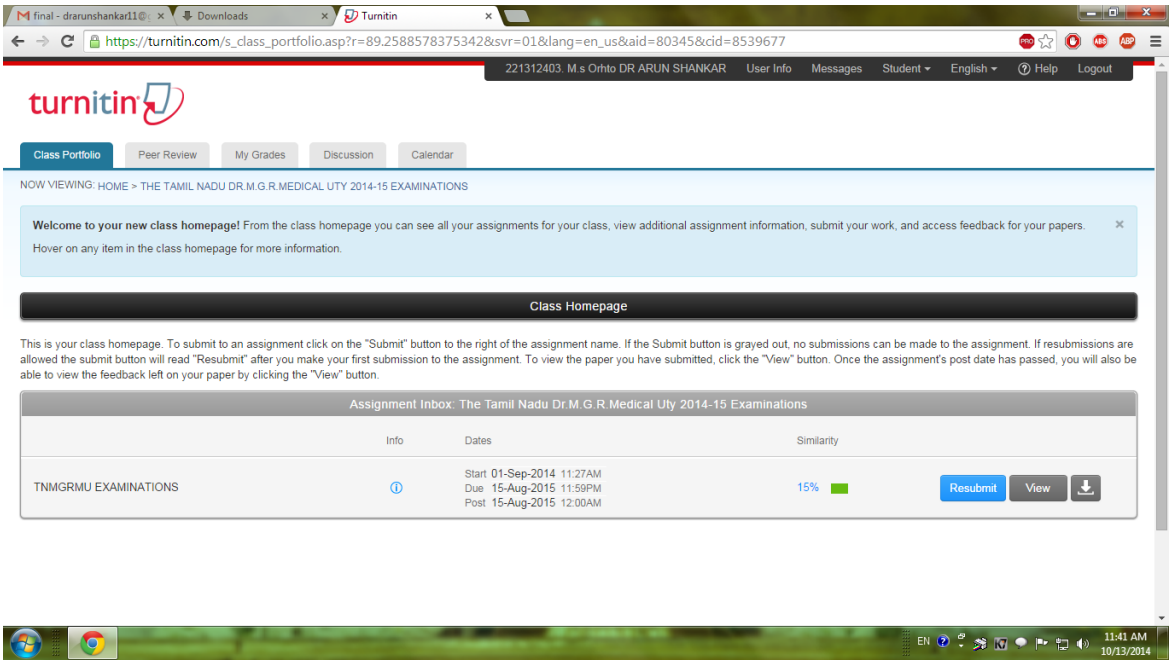
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Sub: **Fluid Research grant project:**
Retrospective analysis of clinical and radiological outcome of Exeter cemented total hip arthroplasty from 2000 to 2010.
Dr. A. Arun Shankar, Dr. Alfred Job Daniel, Dr. Thomas Mathai, Orthopaedics, CMC, Vellore.

Ref: IRB Min.No.8845 [OBSERVE] dated 07.04.2014

Dear Dr. A. Arun Shankar,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
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Dear Dr. A. Arun Shankar,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Retrospective analysis of clinical and radiological outcome of Exeter cemented total hip arthroplasty from 2000 to 2010." on April 7th 2014.

The Committees reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae' of Drs. A. Arun Shankar, Alfred Job Daniel, Thomas Mathai.
3. No of documents 1-2

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on April 7th 2014 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

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Fluid Grant Allocation:

A sum of 41,000/- INR (Rupees Forty One Thousand only) will be granted for 2 years.

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD.,MNAMS.,DNB(Endo),FRACP(Endo),FRCP(Edin),FRCP(Glasg)
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Cc: Dr. Alfred Job Daniel, Orthopaedics, CMC, Vellore.

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ACKNOWLEDGEMENT

I have great pleasure in thanking my teacher and guide**Prof. Alfred Job Daniel**, Professor and Head of the Department of Orthopedic Surgery – Unit III, Christian Medical College for permitting me to use the clinical materials and for his valuable advice and encouragement in preparing this dissertation.

I sincerely thank **Dr. Thomas Mathai** ,Associate professor, Department of Orthopedic Surgery – Unit III for his guidance and encouragement throughout this study.

I am also grateful to other faculty members of the Department and my post-graduate colleagues who helped me in all possible ways in this project.

I also thank my family members for their unstinting support in preparing this thesis.

ABSTRACT

TITLE OF THE ABSTRACT : RETROSPECTIVE TITLE ANALYSIS OF CLINICAL AND RADIOLOGICAL OUTCOME OF EXETER CEMENTED TOTAL HIP ARTHROPLASTY. 2000 - 2010.

DEPARTMENT : ORTHOPAEDICS UNIT III.

NAME OF CANDIDATE : DR.A.ARUN SHANKAR.

DEGREE AND SUBJECT : M.S.ORTHOPAEDICS.

NAME OF GUIDE : Prof.Alfred Job Daniel.

Objectives :

To analyse the clinical and radiological outcome of Exeter cemented total hip arthroplasty.

Methods :

1. Clinical outcome was analysed with Harris Hip Score.
2. To analyse the Radiological outcome as follows.
    a. Immediate post op Cement mantle thickness.
    b. Cement filling within the medullary canal.
    c. Orientation of femoral prosthesis within the cement mantle.
    d. Follow up xrays for radiological features of loosening.
3. Pearson Chi square test and Fischers exact test were used to correlate the significance among the variables.

Results :

1. In our study of 47 hips we had excellent - 65.96% ; Good- 21.28% ; Fair – 8.51% and poor- 4.26% results.

2. There were no cases of femoral stem loosening (0%) , 1 case (2.1%) of acetabular cup loosening and 1 case of dislocation (2.1%).

3. There was significant correlation between cement thickness and Gruen's loosening zones.

4. There was no significant correlation between cementing technique and orientation of stem with proximal femoral resorption and loosening in Gruens zones.

5. Second generation of cementing technique produced 82.92% grade A; 14.89% grade B; 0% in grade C and 2.13% grade D which also did not have a correlation with stem revision.

INDEX

AIMS OF THE STUDY

The aims of the study are

1. To analyse the functional outcomeof Exeter cemented total hiparthroplasty.

2. To analyse the Radiological outcome by evaluating the following parameters.

    a. Immediate post-opx-rays for cement filling, cement thickness and orientation of femoral prosthesis within the femoral canal.

    b. Subsidence of femoral stem within the cement mantle.

3. Analyse the loosening of femoral prosthesis.

INTRODUCTION

ANATOMY OF HIP JOINT

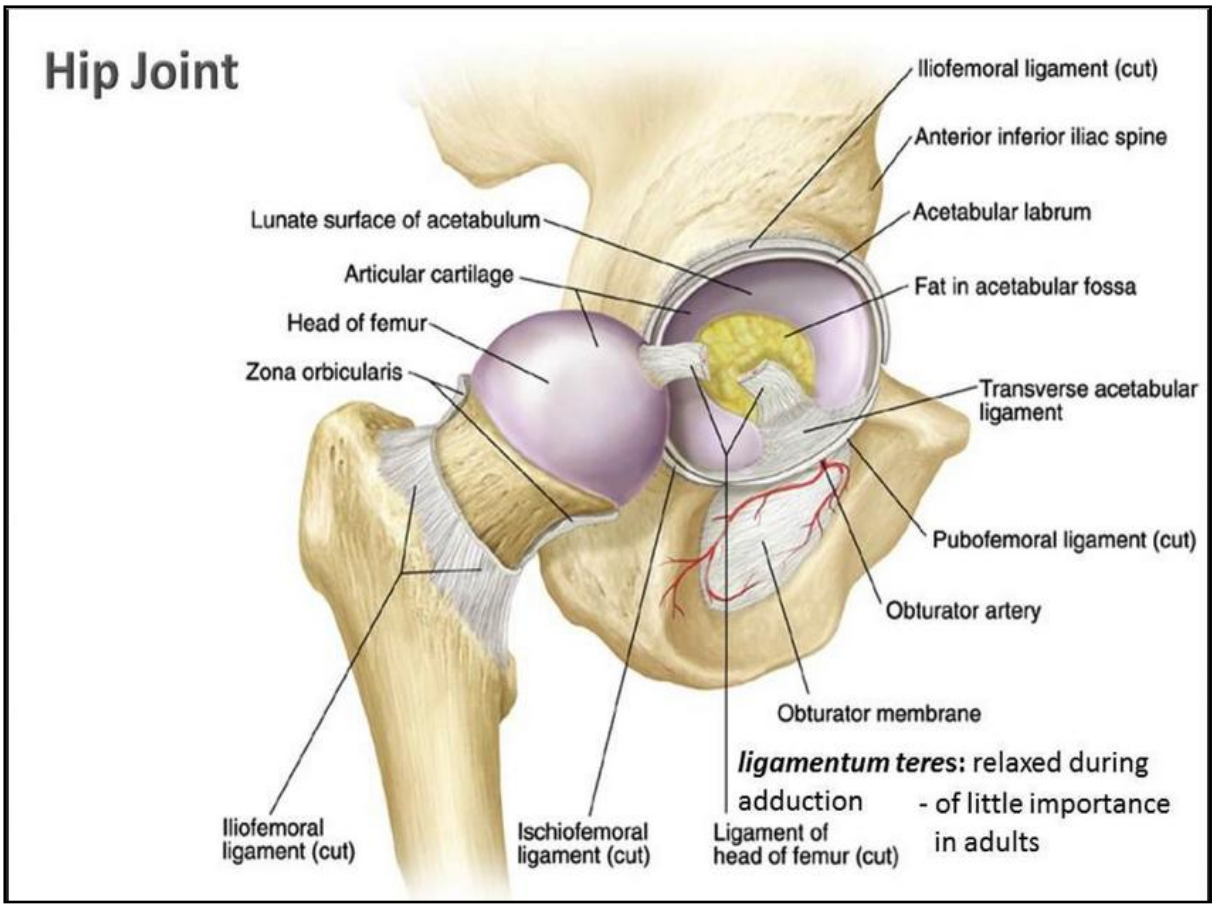
The hip joint is ball and socket synovial joint, ball formed by the femoral head and socket formed by acetabulum. It is also called as femoro-acetabular joint a primary connector between the axial skeleton and lower limbs. Hip joint serves as both static and dynamic stabiliser of the body during locomotion and transmits body weight to lower limbs.

ACETABULUM:

The acetabular socket is horse shoe shaped deepened by the surrounding fibrocartilaginous structure labrum, which is deficient inferiorly at the acetabular notch. The acetabulum is formed by three bones ilium,pubis and ischium , Y shaped growth plate fused at triradiate cartilage around age of 14-16 yrs. The peculiar anatomy of acetabulum helps to contain the femoral head within it and smooth slippery gliding surface of both the articular surfaces of acetabulum and femoral head formed by the hyaline cartilage and lubricant synovial fluid helps in locomotion. There is non articulating part in the acetabulum from which ligamentumteres arises and helps in stabilisation and supplying nutrition to a part of femoral head.

FEMORAL HEAD

Ball shape of femoral head helps to contain itself within the acetabulum. It is also lined with smooth hyaline cartilage and the lubricant synovial membrane helps in free gliding of femoral head within the acetabulum. The ligamentumteres which attaches to femoral from within the acetabulum helps in stabilisation and gives nutrition. The femoral head is attached to shaft by femoral neck, which is anteverted to shaft by 15 to 20 degrees. The neck shaft angle ranges 120 +/- 5 degrees, neck shaft angle more than 130 degrees is coxavalga and less than 120 degrees is coxavara.



LIGAMENTOUS AND CAPSULAR ANATOMY

The ligaments and capsule surrounding the hip gives additional stability. The capsule is formed by interwinging of three ligamentous entities.

1. Iliofemoral ligament.
2. Pubofemoral ligament.
3. Ischiofemoral ligament.

HISTORICAL REVIEW

1840 - Carnochan, New York used wooden block between the damaged ends of hip joint

1860 - AugusteStanislasVerneuil, Paris performed the first soft tissue hip interposition

1890 - Gluck introduced an Ivory ball and socket joint fixed to bone with Nickel-plated screws

1919 - Delbet used Rubber femoral head for femoral neck fractures

1925 - Marius N Smith Peterson, Boston introduced the Moldarthroplasty

1936 - Vitallium, an alloy of cobalt-chromium introduced

1938 - Philip Wiles - first Total Hip Arthroplasty with a metal-on-metal prosthesis made of stainless steel

1939 - Bohlman and Austin T.Moore used a 12-inch long Vitallium femoral head prosthesis in a patient with Giant Cell Tumour of the proximal femur

1939 - Frederick R. Thompson of New York – Thompson prosthesis

1946 - Judet brothers designed the Acrylic short stemmed prosthesis

1946 - Edward J. Haboush, New York used “Fast setting Dental acrylic” to glue prosthesis to bone

1950 - Sven Kiaer introduced bone cement

1952 - Gaenslen introduced metallic acetabular cup used for acetabular cup arthroplasty with reshaped femoral head

1955 - McBride introduced metallic acetabular cup used along with Thompson prosthesis

1957 - Urist - Vitalliumacetabular socket used along with Thompson femoral prosthesis

1957 - Aufrancreported 1000 cup arthroplasties performed at the Massachusetts General Hospital

1958 - John Charnley develops Low Friction Arthroplasty (LFA) using Polytetrafluoroethylene (PTFE)

1962 - Sir John Charnley- The first cemented metal-on-polyethylene hip replacement at the WrightingtonHospital in England using cemented high-density polyethylene

(UHMWPE) socket and monoblock cemented femoral stem with head size of 22.225 mm. The stem was polished and manufactured out of EN58J stainless steel.

1963 - McKee and Watson-Farrar -Metal-on-metal articulation with a modified Thompson femoral head prosthesis and a chrome-cobalt metal socket fixed with cement.

1963 - Stanmore hipdeveloped - Department of Biomedical Engineering, Instituteof Orthopaedics, Stanmore. Femoral component made of cast cobalt-chromium- molybdenum alloy (Alivium) with a 25 mmor 35 mm diameter head and the acetabular componentis made of high molecular weight RCH 1000 polyethylene.

1964 - Ring prosthesis – Acetabular cup with a long threaded stem and a modified Moore's prosthesis as femoral stem

1969 - Ling and Leeintroduced the collarless polished double tapered Exeter stem (Stryker, Newbury, UK)

1970 - Pierre Boutin used alumina cup and alumina ceramic head attached to a metal stem

1970 - Stanmore hip modified to matte stem

1972 - Stanmore hip again modified tonarrow smooth, straight stem with a 25-mm head and an ultra-high molecular weight polyethylene cup

1972 - Pierre Boutin - Femoral component entirely made of ceramic

1972 - Alumina ceramic heads articulating with UHMWPE in Japan

1980 - Silane cross-linked HDPE – Wrightington Hospital

1992 - Sedel introduced a new Alumina ceramic-on-ceramic design

1995 - Muller – Cobalt chrome alloy pairings

BIOMECHANICS OF HIP JOINT

The hip joint is the second largest weight bearing joint in the body next to knees. It is most stable ball and socket jointfurther strengthened by ligaments and muscles surrounded by it. It is subjectedto higher physiological loads and so more prone to develop arthritis whicheventually needs intervention in the form of total hipreplacement.

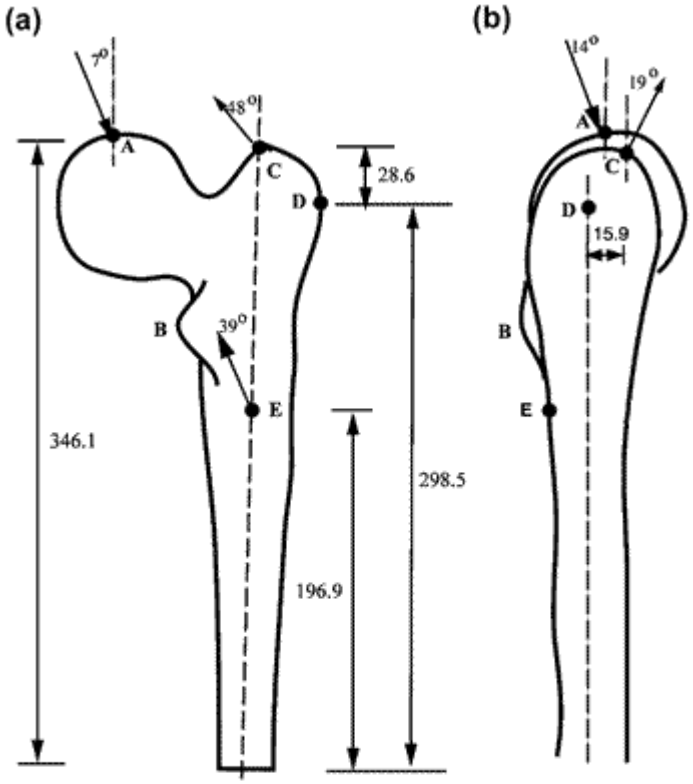


Figure 2.
(a) Posterior and **(b)** lateral views. Point of action and direction of hip joint and muscle force vectors for toe-off case (right femur, length unit: mm). A = joint contact, B = lesser trochanter, C = abductor muscle (gluteus minimus), D = abductor muscle (gluteus medius), and E = adductor muscles (superior fibers of adductor magnus).

The basic understanding of bi o-mechanics of hip joint is necessary to reduce the joint reaction force and thereby increasing the longevity of the implant by reducing the wear rate.

i) BIO-MECHANICS: the science that deals with study of forces (internal or external) acting on the living body .

ii) TORQUE : A measurement of force causing rotation and defined as product of magnitude of force and the perpendicular distance from the fulcrum moment arm (MA).

TORQUE = F × MA

LEVER:

- any rigid segment that rotates around a fulcrum

A lever system exists whenever two forces are applied to a lever in way that produces opposing torques.

In a Lever system,

- the force producing the resultant torque is effort force (EF).
- the force creating an opposite torque is resistance force (RF).
- EFFORT ARM (EA)- the moment arm for EF.
- RESISTANCE ARM (RA) – the moment arm for RF.

The body weight is the force applied to the lever arm which extends from centre of gravity of body to the centre of femoral head . Abductor muscle acts on the lever arm which extends from the lateral aspect of greater trochanter to the centre of femoral head. This exerts equal moment to hold pelvis in level in one – legged stance and also exerts moment to tilt the pelvis to the same side on walking.

The ratio of length of lever arm of body weight to that of abductor muscle is about 2.5:1 ,so the force exerted by abductor muscle must be 2.5 times of body weight to maintain pelvis level while standing on one leg. The estimated weight on the femoral head in the stance phase

of gait is equal to sum of forces created by the abductor and body weight and it is 3 times the body weight.(47)

CHARNLEY'S CONCEPT:

The main concept was to shorten the lever arm of body weight by deepening the acetabulum and lengthening the lever arm of the abductor by reattaching the greater trochanter laterally. By this moment produced by the body weight is decreased and counter balancing force of abductor muscle is also decreased.(2).

In an arthritic hip the ratio of the lever arm of body weight to that of abductor will be 4:1. So the length of both the lever arm is surgically changed to make the ratio 1:1.

Currently the principle of medialization is given away in order to preserve the subchondral bone in the pelvis and trochanteric osteotomy is not done to preserve the abductor muscle power. This principle is restored by altering the head and stem offset.

Total hip replacement is one of the successful operations widely done all over the World for various diseases. Evolution of arthroplasty started in 1981 by Gluck T German orthopaedic surgeon who used Ivory forununitedfracture neck of femur, followed by Dr.Austin Moore (1899 – 1963) an American surgeon, who reported the firstMetallic replacement surgery usingvitallium.

The real success of arthroplastybegan with Sir John Charnley'slow friction arthroplasty.The advent of ultra-high molecular weight polyethylene and bone cement in 1962 made an enormous change in total hip arthroplasty.

Exeter hip system was developed inthe UnitedKingdomduring Charnley's era. It is a cemented hip system with a highly polished double tapered design of the stem. With newer insight of the biomechanics of hip joint bearing systems, modular heads,new varieties of

cement, improved cementing techniques and new approaches, this implant gives excellent results.

Exeter hips give equal results when compared with Charnley's originalarthroplasty results. The present study is to analyse the survivorship of Exeter hip system done in our institute in Department of Orthopaedics Unit III 2000 – 2010,with a minimum follow up of 36 months and a maximum follow up of 135 months.

REVIEW OF LITERATURE

EVOLUTION OF TOTAL HIP ARTHROPLASTY:

The first total hip arthroplasty was done in 1930 byDr Philip WilesFromMiddlesex hospital. GK McKee a trainee ofDr. Philip further developed the prototype of uncemented total hip replacements from 1940 to 1950. Haboushintroduced implant fixation with polymethyl methacrylate.McKee's total hip replacement was widely used, and these implants initially relieved pain but led to early failure due to loosening.(1)

Stanmore hip was implanted first in 1963 and later modified in 1970 as matte finished stem, 25mm head with ultra-high molecular polyethylene cup. At the same time Muller developed curved and straight stem with 32mm head. He also introduced Muller SL (self-locking) with a principle of fixing the largest stem tightly in femoral canal.

CHARNLEY'S ERA: 1960 (Low friction arthroplasty)

Increased rate of loosening led Charnley to analyse and explain thathigher frictional torque at the joint and synovial lubrication alone were not adequate to reduce the friction. Increased rate of loosening led Charnley to develop the concept of low friction arthroplasty.

He initially used Teflon plate, but eventually failed due to wear and this further made him to use different size of heads. He initially thought that larger femoral heads led to higher volumetric poly wear and so he used smaller heads; but it caused undesirable side effects like linear penetration and compromised stability. Charnley'sclose relation with a Dental school at University of Manchestor led him to consider using acrylic cement used by the dentists for affixing the implant to bone.(2).

Charnley finally settled on a design of total hip arthroplasty,which was cemented high density socket made of polyethylene and monoblock cemented femoral stem and head size of 22.225mm. This stem was made of EN58J highly polished stem. Charnley's first

cemented metal on poly arthroplasty was done in 1962 at theWrightington hospital, England.(2).

Charnley's stem has evolved over four generations,the first generation was the original flat back, the second generation was round back,thirdgeneration was cobra flanged and the latest is taper slip C – stem.

FOUNDATION OF EXETER HIP SYSTEM:

Exeter hip system is the most commonly done cemented total hip arthroplasty all over the world. It was designed in Princess Elizabeth orthopaedic hospital by Prof.Robin Ling,an orthopaedic surgeon at Exeter, United kingdom,andDr.Clive Lee, an engineer from the Exeter University.

Exeter hips were first implanted in 1970 as total hip arthroplasty with metal on plastic. It has now crossed 40 years with more than 1 million arthroplasties all over the world by the end of 2010. Exeter hips are suitable for all age groups with varied diseases with success rate of 95% taking endpoint as loosening.

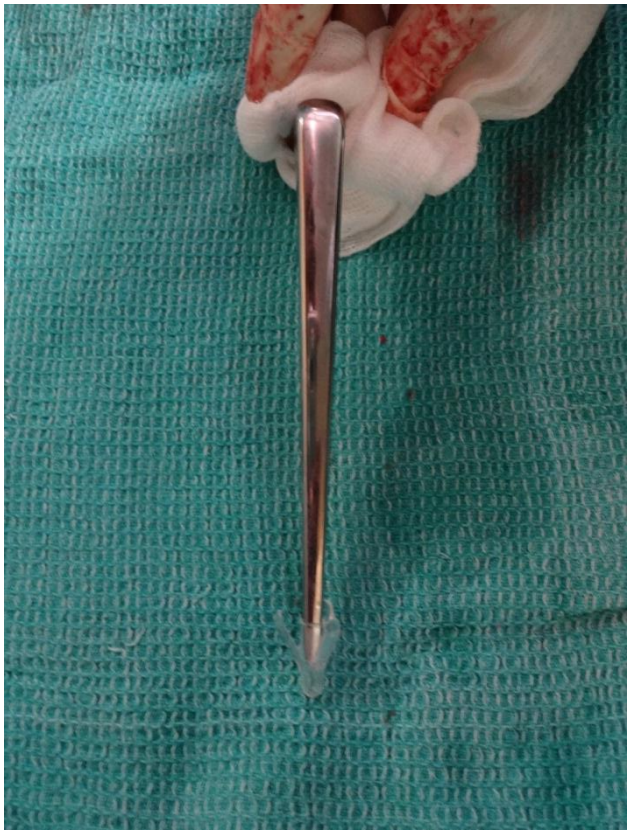
FEMORAL STEM DESIGN: (TAPER SLIP PRINCIPLE)

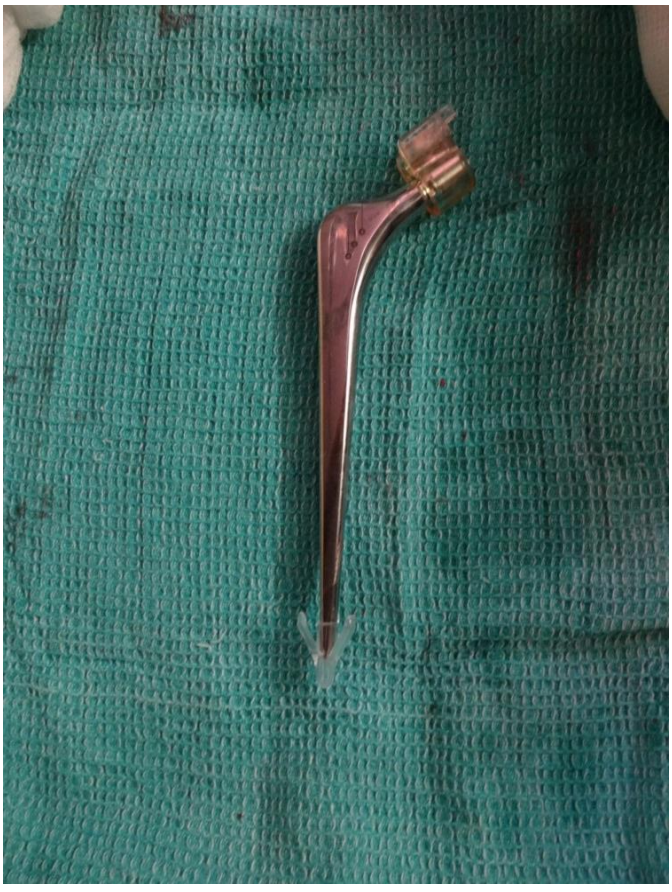
Exeter stem is highly polished double tapered stem. The original stem was made of Stainless steel EN58J and was made of two sizes- standard and lightweight. The design of the stem is in such a way as to utilize the inherent time dependent property of bone cement to improve stability, uniform load transmission and restoration of patient anatomy.

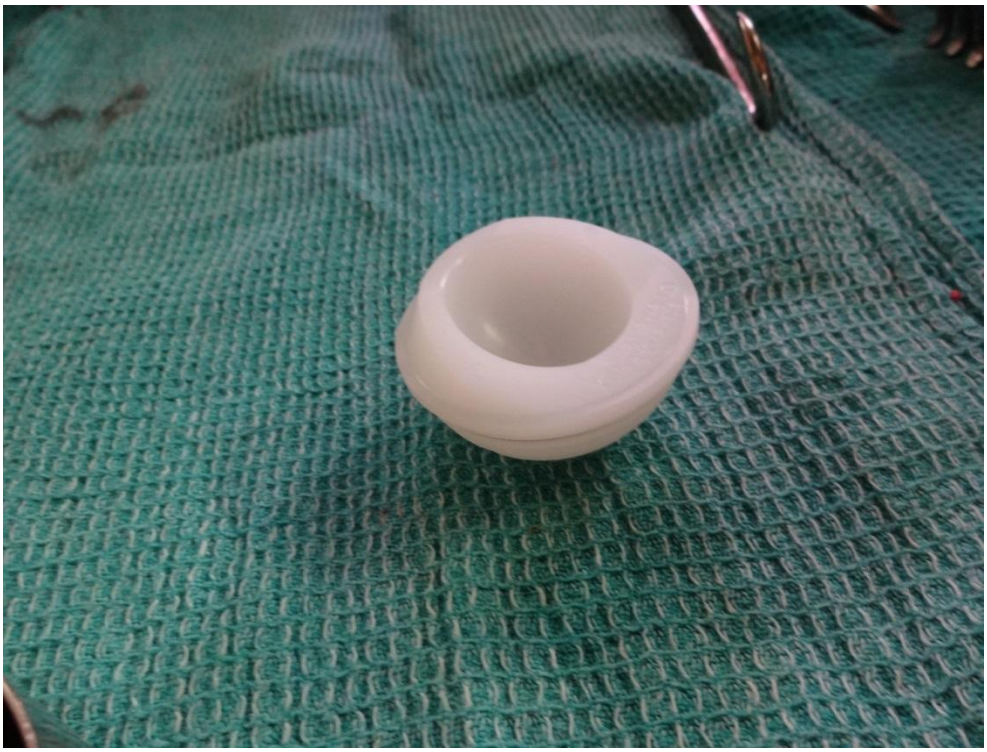
Since 1988 there is an extended availability of the range of stem sizes and offsets. but the basic double tapered stem design is unchanged. Longer stems have been added to

address femoral bone loss in revision surgeries. In 2001 the spigot at the head and neck junction was changed to V40 design for using ceramic bearings.

CHANGE IN DESIGN : 1970 TO 1988.







ADVANTAGE OF TAPER SLIP:

Highly polished double tappered stem subsideswithin the cement mantle to attain a stable position. This made better understanding of biomechanics of taper slip and alsoviscoelastic nature of bone cement. Under constant loading there is slow subsidence of the implant within the cement mantle which gives better stability and helps to prevent proximal bone resorption.

Tight wedging of the implant within the cement mantle induces a compressive stress and prevents shear forces between the implant and the cement (Hoop stress effect). This tight fit not only improves stability but also prevents passage of particulate debris across the cement mantle and prevents aseptic loosening.(4)

FAILURE OF MATT FINISHEXETER STEM:

It was thought that change in surface finish will increase the stabilityof implant. As a result, matt finish stems were introduced by theExeter group. Even original Charnley's polished stem had roughness of Ra 0.01mm and many other designs like grit blasted stem had surface roughness of 1.5mm. This rough surface finish will provide stability by mechanically interlocking with cement mantle and give stability. But undesirably about 10% ofExeter matt finishedimplants in 10 years were revised due to loosening. This led to the conclusion that matt finish tapered stem when subsiding within the cement mantle causesabrasion in the mantle. The metal debris,thus generated pass through the cement stem interface,through the cracks in the cement mantle and reaches the cement and femoral canal interface. This eventually led to increase cytokines level and causes focal osteolysis and aseptic loosening.

Excellent results with highly polished double tapered stem is mainly because of controlled subsidence that occursin stem cement interface and locks itself in a stable position

and prevents the passage of debris and eventually causing osteolysis. Hence in 1986 highly polished tapered stems were reintroduced.(4)

GEOMETRY OF FEMORAL STEM:

1. Shape closed femoral stem.
2. Force closed stem.

SHAPE CLOSED OR COMPOSITE BEAM FEMORAL STEM:

Working philosophy differs with shape closed and force closed designs. Shape closed stems should be made of rigid material and tightly bound to bone. They are not meant for subsiding in the cement mantle. Further the cement material should be well bound to the implant which can be made possible by matt finishing of surface. Collared stem will also act as shape closed because collar blocks the subsidence and transmits the weight distally in the cement mantle. Finite element analysis of composite beam predicts that the stiffer the implant the greater the load sharing occurs. Proximal femur is bypassed and much of the weight is transmitted to the distal part of bone stock. This leads to proximal femur resorption.(5)

FORCE CLOSED OR TAPER SLIP FEMORAL STEM:

Force closed stems are tapered stems which work by taper slip principle.Tapering may be double tapered or it may triple tapered. Surface of force closed stems are highly polished, so that they subside freely in the cement mantle and self locks itself in a stable position. Increased axial force and greater axial load gives tighter fit to stem.

Radial compressive force is transferred to axial bone. The main fundamental engineering implication is that a perfectly bonded stem to cement interface will not allow any stress relaxation until the interface is ruptured. In taper slip relaxation occurs when load is reduced while maintaining the strain. (5)

Long term analysis of first generation Charnley'sflat back design and highly polished Exeter stem has given good outcome which is attributed to taperslip principle. Both the designs subside within the cement mantle. Appearance of both the designs in anteroposterior view is similar but Exeter is tapered in lateral view also.

Subsidence not only depends on the shape of the implant but also the viscoelastic nature of the cement and technique of cementation to allow the implant to subside. Thus in earlier years when finger packing technique was used loosening rates were high.

Cyclical activities of loading and relaxation during rest through the life helps to attain a satisfactory state of proximal femoral bone in Exeter series.(5).

Despite the modern technique of cementation with lavage,medullary plugging, uniform packing of cement with, cementguns and pressurisation, survival rates of 3rd generation dorsal flanged Charnley's stems were low. Hence the need for stronger cement to prevent subsidence for dorsal flanged Charnley's stem.

Principles of composite beam and taper slip are different. Any mixture of two systems will ultimately lead to failure.Thus with matt finish tapered Exeter stem failure was high because of excessive cement mantle abrasion and metal debris generated by subsidence which was necessary for taper slip system.

Hence criteria for radiological failure for a composite beam stem and tapered stemis different and cannot be applied for both.

EXETER ACETABULUM DESIGN:

Both metal backed cups and polyethylene cups were available initially. Metal backed cups were abandoned in 1991 due to the fact it causes lot of metal debris and ultimately leads to loosening.

All polyethylene components have two designs: low profile and high profile based on the thickness in the dome. High profile polyethylene allows greater lateralisation of the femoral head. These cups also haveskirt on the external side to reduce the dislocation. Hence all PolyethyleneExeter cupshave excellent survivorship.(6)

EVOLUTION OF BONE CEMENT:

History of bone cement begun with early 20^{th} century by Otto Rohm,who synthesised polymethylmethacrylate was used in dental practice.In 1936 doughy nature of bone cement was discovered by mixing liquid monomer methylmethacrylate with polymethylmethacrylatepowder.Initially it was used in cranioplasties and later in 1960's Sir John Charnley popularised it by using it in his low friction arthroplasties. Charnley was the first to realise that bone cement can be used in medullary canal to make it act like a grout to give stability of the implant.

Properties of bone cement:

It has 2 components:

1. Liquid – stabiliser hydroquinone prevents polymerisation, activator dimethyl paratoludiene and dye chlorophyll.
2. Powder – initiatordibenzoylperoxide, radio-opacifier zirconium oxide or barium sulphate.
3. It may have antibiotic.

When these two polymers unite it causes an exothermic reactionwherein a temperature of 40 to 47 degrees are produced. This rise in temperature is dissipated to the surrounding structures as it cures.High viscosity cements will have longer working phase and shorter wetting phase. Low viscosity cements will have longer wetting phase and shorter working phase.(7).

FOUR POLYMERISATION PHASES:

1. Mixing phase- lasts 1 minute when powder and liquid homogenises.
2. Waiting phase- several minutes until cement reaches a non-sticky state.
3. Working phase- 2 to 4 minutes when cement is applied it should withstand bleeding pressure otherwise it will lose its strength.
4. Finally hardening takes place.

EVOLUTION OF CEMENTING TECHNIQUES:

Cementing techniques evolved from first generation tofourth generation.Improvement in the cementing technique has evolved toincrease the outcome with various changes in the cementing techniques. Acrylic cements were used by Charnley initially.

1.FIRST GENERATION CEMENTING TECHNIQUE:

1. Hand mixing the cement with bowl.
2. Minimal preparation of femoral canal leaving the cancellous bone.
3. Irrigation of canal and drying it.
4. Digital packing of the cement and prosthesis application.

During 1980's better understanding of the cement property was achieved by reducing the porosity and increasing the fatigue strength.

Pressurisation of the cement to improve the osseous integration and the importance of good cement mantle around the prosthesis was understood clearly.

2.SECOND GENERATION CEMENTING TECHNIQUE:

1. Removal of cancellous bone till endosteal surface.
2. Distal cement restrictor introduction.
3. Pulsatile irrigation,drying of femoral canal .
4. Retrograde insertion of cement using the cement gun.
5. Manual positioning of prosthesis.(8, 9).

3.THIRD GENERATION CEMENTING TECHNIQUE:

1. Porosity reduced by using vaccum centrifugation.
2. Femoral canal preparation, pulsatile lavage irrigation and packing canal with adrenal soaked gauze.
3. Retrograde cementing and pressurisation.
4. Prosthesis insertion using proximal and distal centraliser to ensure uniform cement mantle.(10).

4.FOURTH GENERATION CEMENTING TECHNIQUE:

1. Plugging the canal.
2. Femoral canal preparation and lavaging.
3. Retrograde filling, vaccum mixing and centrifugation.
4. Pressurization and centraliser application.

EVOLUTION OF EXETER CEMENTING TECHNIQUE

The technique of using cement was gradually refined between 1970 and 1980 based on two in vitro studies that had been carried out in Exeter. These showed that by a using a combination of exposure of strong cancellous bone in the femur, thorough pressure washing of the bone surface followed by the subsequent plugging & retrograde filling of the femur with reduced viscosity cement dough and 'closed cavity' pressurisation of the femoral canal, a fourfold increase in the shear strength of the cement-bone interface is produced. The clinical application of such methods was flawed initially by failure to appreciate the potentially damaging effects of bleeding at the cement-bone interface.

These effects in conjunction with an extensive laboratory simulation study formed the basis for the femoral cementing technique that has been in use in Exeter since 1984. This concentrates on the retrograde insertion of reduced viscosity cement dough into a thoroughly clean and distally plugged medullary canal, followed by prolonged pressurisation of the cavity using a gun and proximal seal, the delayed insertion of a pre-warmed stem and the subsequent pressurisation of the proximal end of the canal using a seal around the stem that is retained until polymerisation.

MIGRATION OF FEMORAL STEM:

Migration of femoral stem occurs either at the interface of cement and bone or prosthesis and cement or it may be result of creep in the cement. It is a combination of rotation and translation. Migration occurring at the cement and bone are more prone for failure. In 1975 Weber and Charnley noted prosthesis when subsides take a new position in the tapered cavity wherein load is uniformly transferred in the cement mantle and attains a

stable position.(11) The migration of the stem is dependent of design i.e tapered stem should subside where as a non-tapered stem are not designed to subside. So if a non-tapered collared stem subsides, it means that the implant is failing. Further the rate of migration is also one of the deciding factors to determine failure.With satisfactory implantation,the initial migration is rapid but then it slows down where as in those of non-satisfying implantation, rapid migration continues after the initial phase. It is therefore generally believed that design of implant and high rate of migration are prone to give unsatisfactory long term outcomes.(12,13).

Kobayashi et al noted that if prosthesis subsides more than 0.4mm at two years,it is likely to fail. This observation is mainly for the implant that is not designed to migrate. Exeter stems are made to susbside and if it does so, it will attain a stable position. Rapid migration of stem i.e more than 2mm within 2 years have higher probability of failure.(14)

Femoral stems like Charnley Elite do not subside within the cement mantle whereas Exeter stemssubside. Charnley's Elite is a small collared, flange that helps to compress the cement and prevents stem migraton. The modification which helps to resist torsional loads is the 'vaquasheen' finish of the surface, which is matt.The smooth polished, collarless tapered stem of the Exeter, allows itself to subide within the cement.

The Exeter was found to have rapid early distal migration which is associated with slight collapse in valgus and slow posterior migration of the head,while the Charnley Elite was found to have rapid early posterior migration of the head with mild distal migrationbut during the follow up it was found that migration of both implants slows down while pattern of migration remains the same.(12)

Alfaro Adrien et al (12) showed that the change of pattern or direction of migration changes with time and the change in pattern is greater than change in rate. The bony layer resorption caused due to surgical trauma or the heat of polymerisation of PMMA cement

may be the cause for rapid early migration. The migration occurs at the cement-bone interface which depends on the extent of bone damage. The posterior aspect migration is due to the posterior component of the joint contact force, which is large during stair-climbing, straight-leg raising and rising from a chair. The medial migration is mainly due to distal or distal and lateral joint force reaction this can be explained by our findings that the tip is the point with least migration. Therefore it implies that tip of the implant is securely fixed and it will tend to rotate about it. Medial migration of the implant is mainly due to vertical component that cause the implant to tilt in varus.

Many authors have stated that collarless, polished tapered Exeter stem during the first year slowly migrate distally without substantial bone loss and probably results from combination of creep in the cement allowing the implant to sink within the cement mantle.

This slow gradual creep occurs during the entire life span and aids in gradual remodelling of the bone and fibrous tissues around the cement. Hence Exeter stems give long term good clinical outcomes.

RADIO STEREOMETRIC ANALYSIS:

Radiostereometric analysis is the standard method to measure the migration of an implant relative to bone in 3 dimensions with accuracy of a few tenths of millimetre. RSA has been used to establish a relationship between early migration and late loosening in THA. Distal migration does not correlate with failure. Instead, posterior head migration probably is the best predictor of loosening. Implants with very high posterior head migration, defined as > 2 SD from the mean, are particularly likely to fail.(12)

Most authors have shown that thin cement mantles and defects are associated with increased failure rates. Complete non-uniform cement mantles with a minimum thickness of about 3 mm are associated with good biomechanical and clinical results.(16) Some, however, show that canal-filling stems with thin and often incomplete cement mantles have good long-term results as well.(17) Peak stresses increase once the thickness of the cement is below 1 mm, which will then cause fragmentation of the mantle, leading to failure.

RADIOGRAPHIC ASSESSMENT OF EXETER STEM

ASSESSMENT OF CEMENTING TECHNIQUE:

Based onBarrack, Mulroy and Harris et al in 1992 described a system to grade the radiographic appearance of the cementing on the immediate postoperative radiograph in all the 14 zones of Gruen. (18)

The four grades are

Grade A is defined as complete filling of the medullary cavity by cement, so-called "white-out" at the cement-bone interface.

Grade B as the presence of slight radiolucency at the interface between the bone and cement.

Grade C as radiolucency involving 50 to 99% of the cement-bone interface, or a defective or incomplete cement mantle of any size, with metal against bone.

Grade D as radiolucency involving 100% of the cement-bone interface in any projection, or a failure to fill the canal with cement such that the distal tip of the prosthesis is not covered.

Postoperative and follow-up radiographs were reviewed for "loosening" and they assessed the relation of the cementing technique to implant loosening.

'Definite' loosening was defined as migration, or a change in position of the stem or the cement. This included fracture or bending of the stem, fracture of the cement, the appearance of a radiolucent line at the cement-stem interface not present on the immediate postoperative radiograph, and a shift in the position of the cement mantle relative to the femur.

Radiographs that showed a continuous (100%) radiolucent line at the cement-bone interface without evidence of migration were graded as'probably' loose.

If a radiolucent zone was present that was not complete, but involved between 50%and 99% of the interface, the component was classified as ‘possibly’ loose.

They had no hips with Grade C or Grade D cementing. The reduced loosening rates in their study were attributed to the introduction of improved cementing techniques and better stem designs.

ASSESSMENT OF CEMENTMANTLE THICKNESS:

This was done on basis of Ebramzadeh (19)1994 in an analysis of cement mantle in total hip replacements, they have assessed the various factors in immediate and followup post op radiographs. The thickness of the proximal medial part of the cement mantle on anteroposterior view of hip joint by measuring the distance from endosteal edge of the proximal femoral cut to the medial border of the implant. These are categorised into 4 groups:

1. < 2mm cement mantle thickness.
2. 2 to 5mm cement mantle thickness.
3. 5 to 10mm cement mantle thickness.
4. > 10mm cement mantle thickness.

Stems with 5 to 10 mm thickness were at lower risk for cortical hypertrophy than those with less than 2mm or 2 to 5mm thickness.

Total hip replacements with a proximal medial cement mantle thicker than ten millimetres were at a greater risk for progressive loosening of the femoral component, fracture of the cement, and radiolucent lines about the femoral stem-cement or bone-cement interface than those with a cement mantle that was two to five millimeters or five to ten millimetres thick. Similarly, total hip replacements with a cement mantle that was five to ten

millimeters thick were at a greater risk for radiolucent lines at the femoral bone-cement interface than those that had a two to five millimeter-thick mantle.

The filling of the distal part of the canal by the femoral stem was recorded as the ratio of the width of the stem to the width of the canal, measured seven centimeters distal to the collar of the stem. The hips were divided into two groups on the basis of the canal fill ratio more than 50 percent , 50 percent or less than 50percent.

Stems that filled more than half of the canal were at a significantly lower risk for progressive loosening, fracture of the cement, and the development of radiolucent lines at the stem-cement interface and bone-cement interface. However, the femoral components that filled more than half of the canal were at a significantly higher risk for calcarresorption and cortical hypertrophy.

Relationship of cementing technique and cement thickness with aseptic loosening:

1. Inadequate removal of cancellous bone on medial surface of femoral neck means that a column of cement may not rest on bone.
2. Inadequate quantity of cement.
3. Inadequate cement mantle thickness around the stem particularly the tip should be supported as it is subjected to axial loading.
4. Failure to pressurize may lead to inadequate interdigitation of cement within the cortex.
5. Presence of void in the cement mantle as a result of improper mixing .
6. Poor filling of the medullary canal by improper injection technique.
7. Failure to prevent motion while cement is hardening

STEM BROACH MISMATCH:

Various clinical and biomechanical (20)analysis have recommended ideal thickness of cement mantle should be 2 to 5mm. These cement mantle are subjected to high stress when subjected to load. Cement mantle thickness of 5 to 10mm causes more micromovement which leads to cement mantle fractures. Finite element analysis demonstrated that rate of propagation of cracks was independent of thickness. On loading the stem with less than 2mm thickness cracks progressed, so together with cement cracks and defects in the cement mantle is the cause for subsequent loosening.

Metal debris from the implant pass from the stem cement interface through the cracks and reach the bone cement interface and finally leads to particle induced osteolysis. In order to create a thick flawless cement mantle some systems use undersize stem when compared to broach.

Some manufacturers use stem size equal to broach. Linglais et al (21) noted excellent clinical results on using polished tapered stem with rectangular cement filling with using largest broach. The aim was to direct load transfer to the cortex preventing subsidence acting like a shape closed stem.

By using smaller implant with larger broach leaving behind some cancellous bone in the proximal part of the femur helps in pressurization of the cement and interdigitation within the cancellous bone. This gives line to line contact with the bone and direct transfer of load. Thus line to line contact stems are more user friendly in the hands less experienced surgeons.

Orientation of stem:

The orientation of the stem was recorded as the angle between the axis of the distal portion of the stem and the axis of the femoral shaft. The hips were divided into five groups according to the orientation of the stem:

neutral (a stem-shaft angle between 0 and 3 degrees), slight valgus or varus angulation (a stem-shaft angle of 3 to 5 degrees), and valgus or varus angulation (a stem-shaft angle of more than 5degrees).

Stems that were oriented in neutral, in slight varus (5 degrees or less), or in slight valgus had similar radiographic behaviour. Stems that had been implanted in more than 5 degrees of varus were at a significantly higher risk for progressive loosening, fracture of the cement, and the development of radiolucent lines at the stem-cement and bone-cement interfaces than those implanted in neutral or valgus (more than 5 degrees). Varus stems performed poorly independently of the thickness of the cement mantle, possibly because of the increased loading of the cement or of the bone in the critical proximal medial and distal lateral regions.

Brian Jewett (22) has stated that stem geometry has less effect on the success of cemented THA than does stem surface finish. They compared four polished cemented stem designs and found no substantial difference between them. The surface finish of cemented femoral stems has undergone intense scrutiny over the past two decades.

Ong et al suggested four types of roughened stem failures:

bone-cement loosening, stem-cement debonding, progressive focal osteolysis, and stem fracture. All patients with rough stem failures in his study had extensive femoral bone damage. Polished stem failures showed minimal bone damage compared with rough stem

failures. Also, patients with polished stem failures seemed to function well for a long period of time with their loose stems.

ECTOPIC BONE FORMATION

Ectopic bone formation following Total Hip Replacement is a recognized complication. Charnley stated that a notable degree of ectopic ossification is seen in 5 per cent of hips not previously operated on. Harris noted myositis ossificans in 14 per cent of his patients but stated that only 3 per cent had significant interference with motion.

Brooker(23)devised a classification system for ectopic ossification following THR based on his study at the Johns Hopkins Hospital on supine AP roentgenograms of the hip taken with a fixed tube-to-plate distance of 101.6 centimeters.

Class I: Islands of bone within the soft tissues about the hip.

Class II: Bone spurs from the pelvis or proximal end of the femur, leaving at least one centimeter between opposing bone surfaces.

Class III: Bone spursfrom the pelvis or proximal end of the femur, reducing the space between opposing bone surfaces to less than one centimetre.

Class IV: Apparent bony ankylosis of the hip.

He stated that patients with previous procedures have a much higher incidence of ectopic ossification and that though patients have ectopic ossification after THR, they do not necessarily have poor functional results.

ASEPTIC LOOSENING OF POLISHED CEMENTED STEMS:

As an aid to classify the loosening of cemented femoral stems a retrospective sequential radiographic evaluation was done by Gruen (24)in 1979. Loosening is defined as radiographic interpretation of change in mechanical integrity of the load cemented femoral component specifically seen as fractured cement mantle and an interface gap such as radiolucent zone at the stem-cement or at the bone interface.

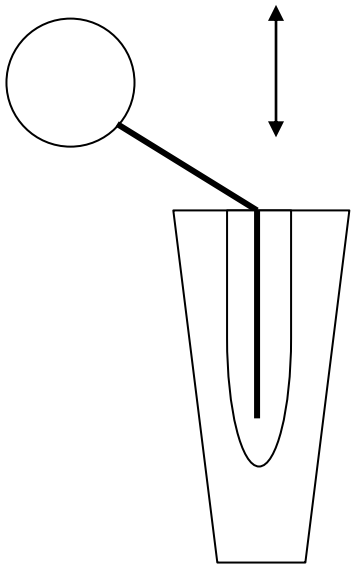
Proximal femur was divided into 7 zones in anteroposterior radiograph of cemented femoral stem. These radiographs were evaluated to assess loosening as manifested by progressive changes in width or length of radiolucent zones, appearance of sclerotic changes in bone, fracture of cement mantle,fragmentation of cement, gross migration of the stem or stem fracture.

Loosening was described by one of 4 modes of failure as follows:

a. Mode I – Pistoning behaviour
    i. I A – Stem within the cement.
    ii. I B – stem within bone.
b. Mode II – Medial midstem Pivot.
c. Mode III – calcar Pivot.
d. Mode IV – Bending cantilever fatigue.

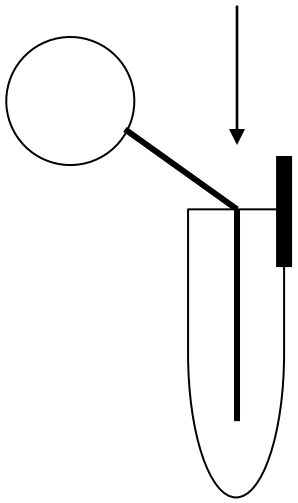
The radiolucent zone at the cement bone interface was predominant evidence of loosening. Radiolucent lines at immediate post-op is indicative of inadequate cement penetration into cancellous bone, late insertion of implant or inadequate removal of residual fibrous membrane.

Mode I A:Pistoning behaviour:



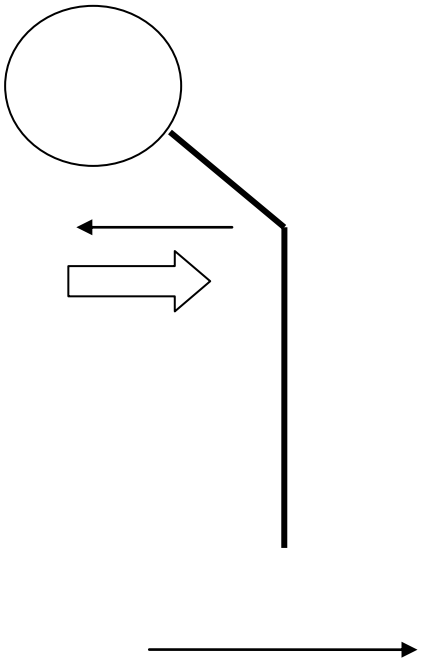
It occurs as a result incomplete cementing around the stem or loss of proximal medial acrylic support while axial loading the stem is displaced distally. This results in appearance of radiolucent line in zone I and punchout fracture of cement mantle in distal tip of stem.

Mode I B :



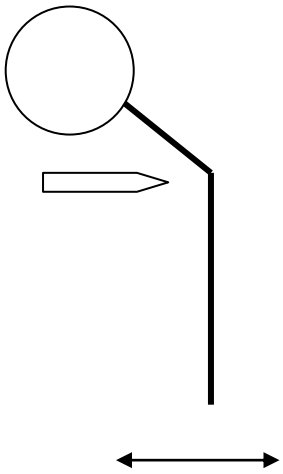
This is as a result of inadequate interdigitation of cement within the cancellous bone, and so when stress is applied debonding of cement bone interface with slip occurs. This is the familiar type to recognize as there is most of it or all around the cement bone interface. There can be sclerotic or halo reaction seen.

Mode II : midstem pivot:



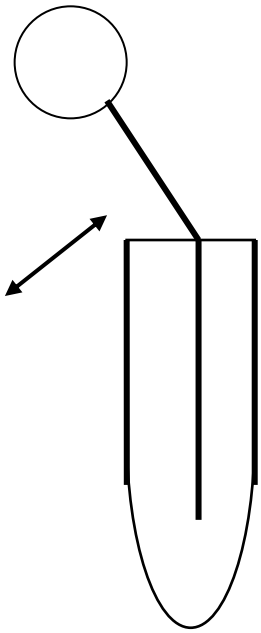
This type of failure occurs following I A type when the distal cement mantle punchout occurs the proximal stem migrates medially and distal tip migrates laterally (coupled migration).

Mode III : calcar Pivot



This is windshield type of failure where in proximal support is good while distal cement support is lacking. Here the stem will be hanging with medial cortical support where it pivots.

Mode IV : Bending cantilever fatigues



It is characterised by loss of proximal medial support while the distal part is rigidly fixed. The stress passed is transferred directly to distal part of stem, radiolucent lines are seen in the lateral convex portion of the implant.

With increasing incidence of stem fracture and femoral prosthesis loosening Gruen et al emphasised that mechanical failure was due to loss of proximal femoral acrylic cement support which lead to debonding at stem cement interface or bone cement interface. Various factors contribute to looseness but main emphasis is on cement mantle fracture which was 19.5% of cases with radiographic looseness. Most of the acrylic cement matle fracture was on

lateral side when compared to medial side this mainly due to weak tensile and brittle nature of cement. Cement mantle fracture in distal end of stem was also noted in other studies done by Salvati et al and Charnley et al characteristic of mode Ia failure.

Gruen et al noted that even with no radiolucent line in x-ray and functionally normal hip of 5 hips on post-mortem there was thin layer of fibrous tissue between stem and cement.

Immediate post op evidence of radiolucent lines is indicative of inadequate penetration of cement into cancellous bone , inadequate removal of residual fibrous tissue and late insertion of prosthesis. Fibrous membraneare mostly seen in revision total hip arthroplasty. Various studies have proved failure of prosthesis occurred in one of the mode as explained earlier or progression of one mode to the other.

In some cases mode of failure progress to gross failure with patient being asymptomatic. Arrested loosening is other phenomenon where controlateral hip or other joint is involved leading to decreased daily activities.

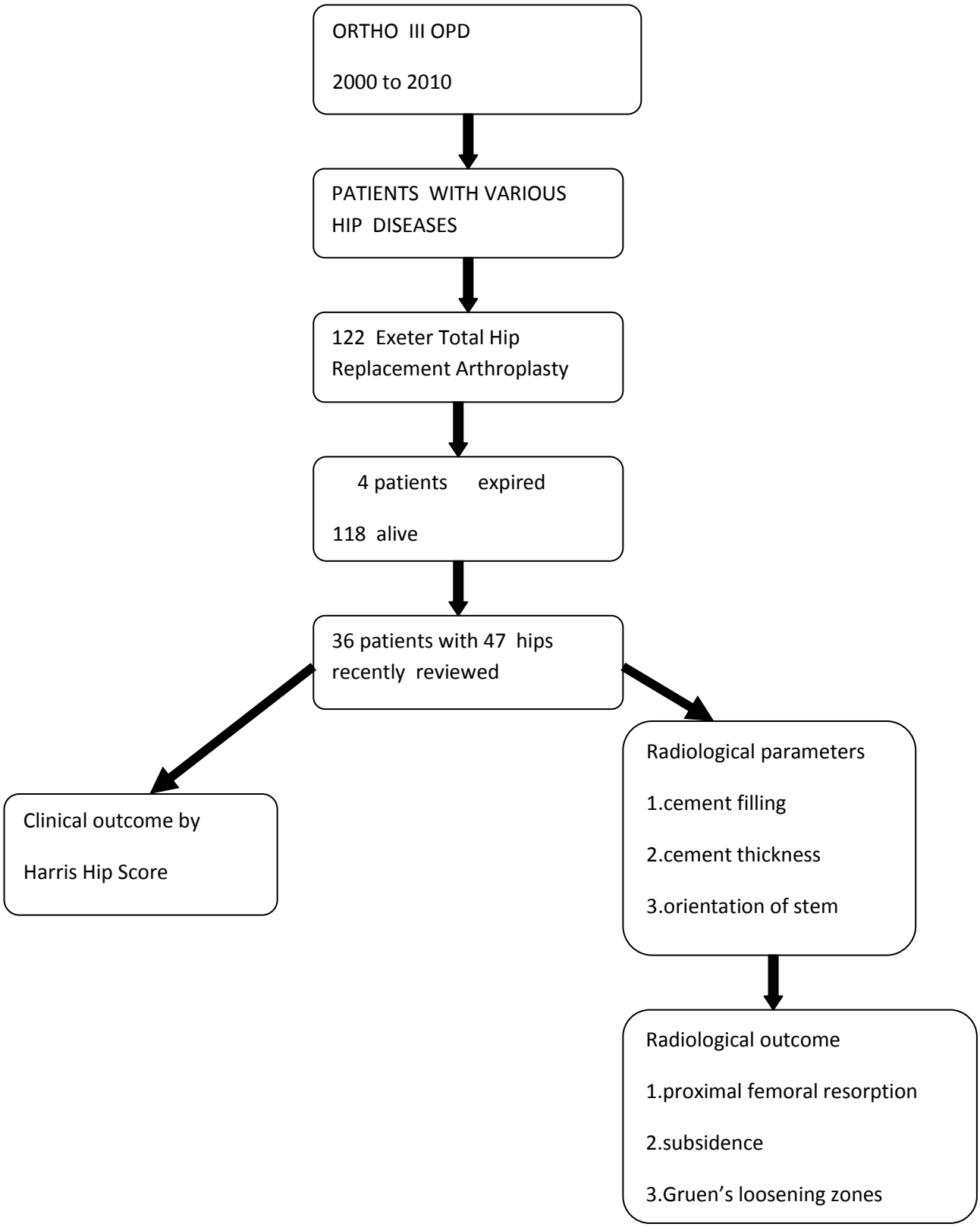
Theoretical studies have demonstrated that well fixed stems the stresses are relatively in safer level but still loosening is a possibility. This loosening can be attributed by various factors like age, weight of patient,activity levels, loading configuration, weakness of acrylic cement and bone strength. Once proximal loosening occurs there is no cortical support proximally with strong bonding of stem distally stress levels are two to three times higher in the stem. Thus proximal loosening in most sinister with respect to stem performance and durability.

Thus recent concern is to use larger stems to fit in the medullary canal with less amount of acrylic cement between the stem and inner cortex of the canal. There by reducing mode II mid stem pivot and Mode III calcar pivot.

BASIC DESIGN OF CEMENTED FEMORAL PROSTHESIS AND FACTORS CONTRIBUTING FOR ITS SURVIVORSHIP:

1. It should be highly polished. Matt finish stems, though it gives rotational stability, if debonding occurs, it generates more debris and finally leads to osteolysis and aseptic loosening.
2. There should not be any sharp edges as it may cause stress risers which eventually cause cement mantle fracture.
3. Most designers favour cobalt chrome alloy as it has higher modulus of elasticity that may reduce the stress in the proximal cement mantle.
4. Cross section of the stem should be broad medial border and lateral border to uniformly load the proximal cement mantle.
5. Tapered stems are preferred as it subsides to a stable position.
6. Variety of sizes should be available to occupy atleast 80% of cross section of medullary canal.
7. Cement mantle thickness of 4mm proximally and 2 mm distally gives good outcome.
8. Placement of stem in neutral lessens the chances of thin cement mantle around the prosthesis.
9. Use of centalizer helps in placement of stem in centre thereby uniform cement mantle around the prosthesis is achieved.
10. Use of longer stems in case of need (eg: weak cortex caused by screw holes, perforation of anterior cortex by implant or any revision procedures).

SCHEMATIC REPRESENTATION 0F THE STUDY



MATERIALS AND METHODS

This is retrospective study of clinical and radiological outcome cemented Exeter total hip arthroplasty done by single surgeon in our institute Department of Orthopaedics Unit III from 2000 to 2010. Patients were invited for a followup through telephone and letter. Patients who responded and came for followup within this year were taken up for study.

Inclusion criteria:

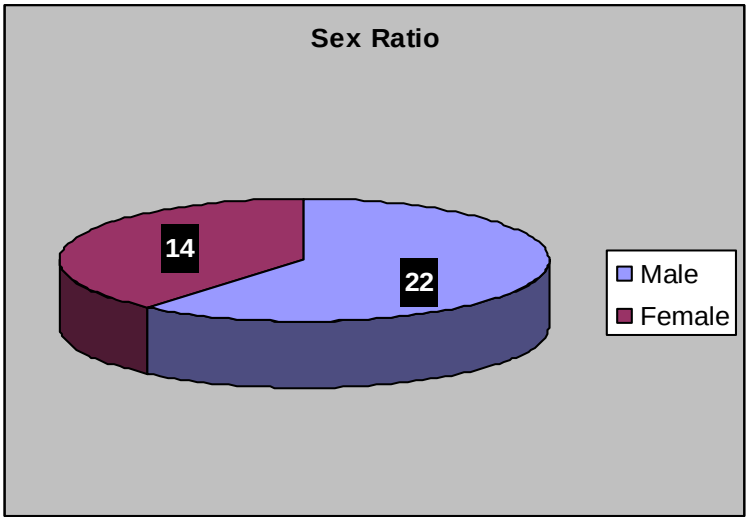
Primary and revision cemented total hip arthroplasty done with Exeter system.

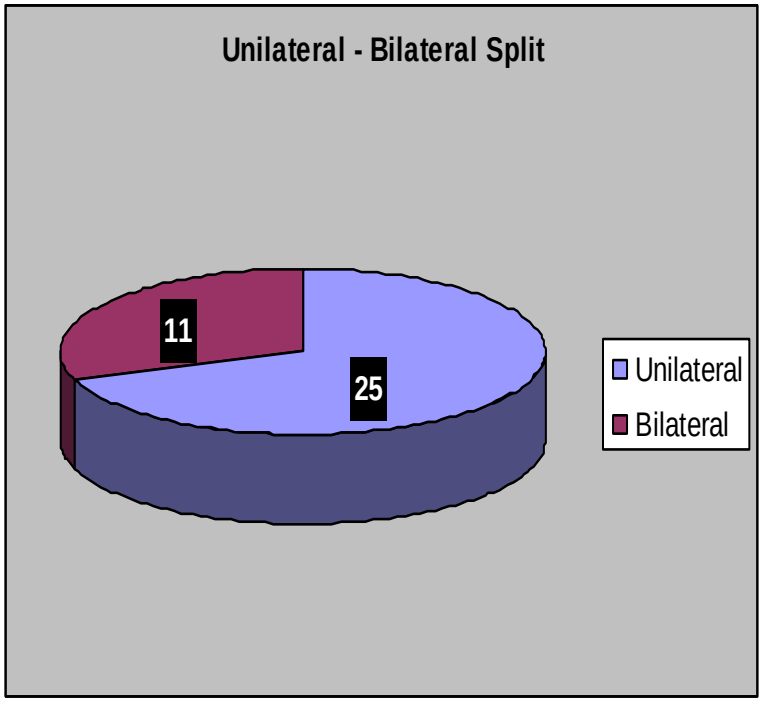
Exclusion criteria:

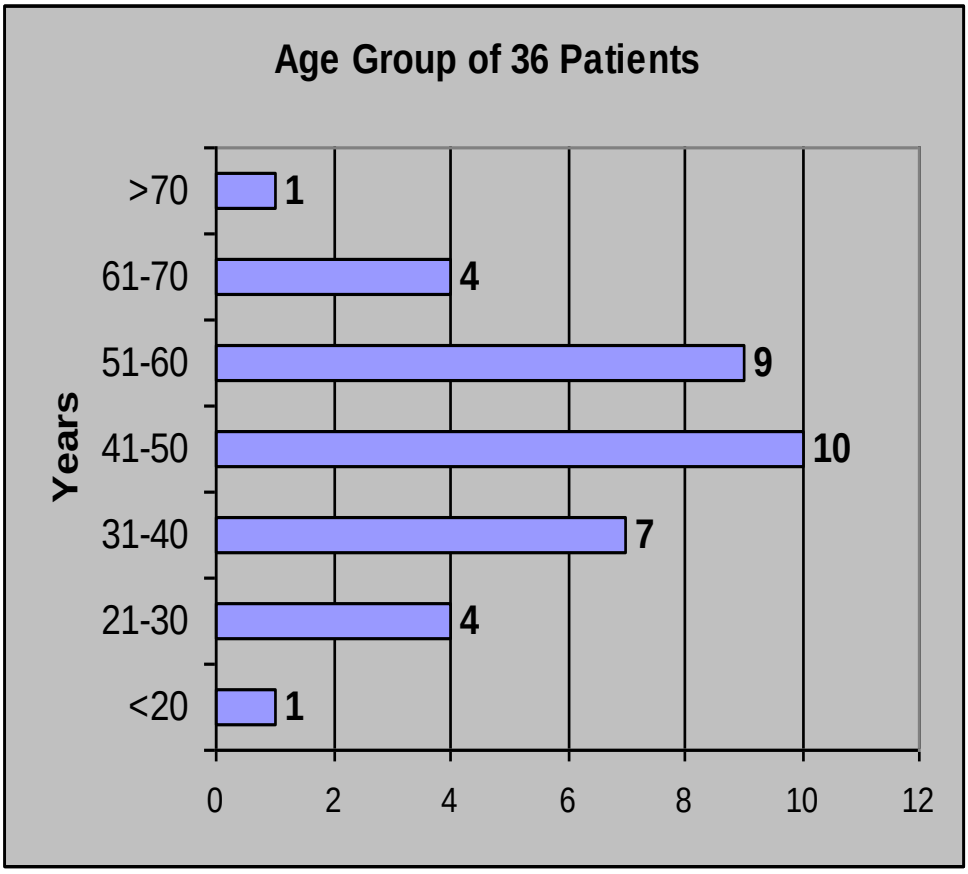
Hybrid total hip arthroplasty with Exeter stem and revision long stem prosthesis.

PATIENT DEMOGRAPHICS:

Total number of patients who underwent Exeter total hip arthroplasty from 2000 to 2010 was 124. 4 patients are not alive. 121 patients were called for followup. 36 patients were followed up recently. Mean age was 46.82 and there was 22 men and 14 female. 17 were right side 19 was left side and 11 were bilateral. Mean follow up in months 84.44.


Sex Ratio
14
22
Male
Female

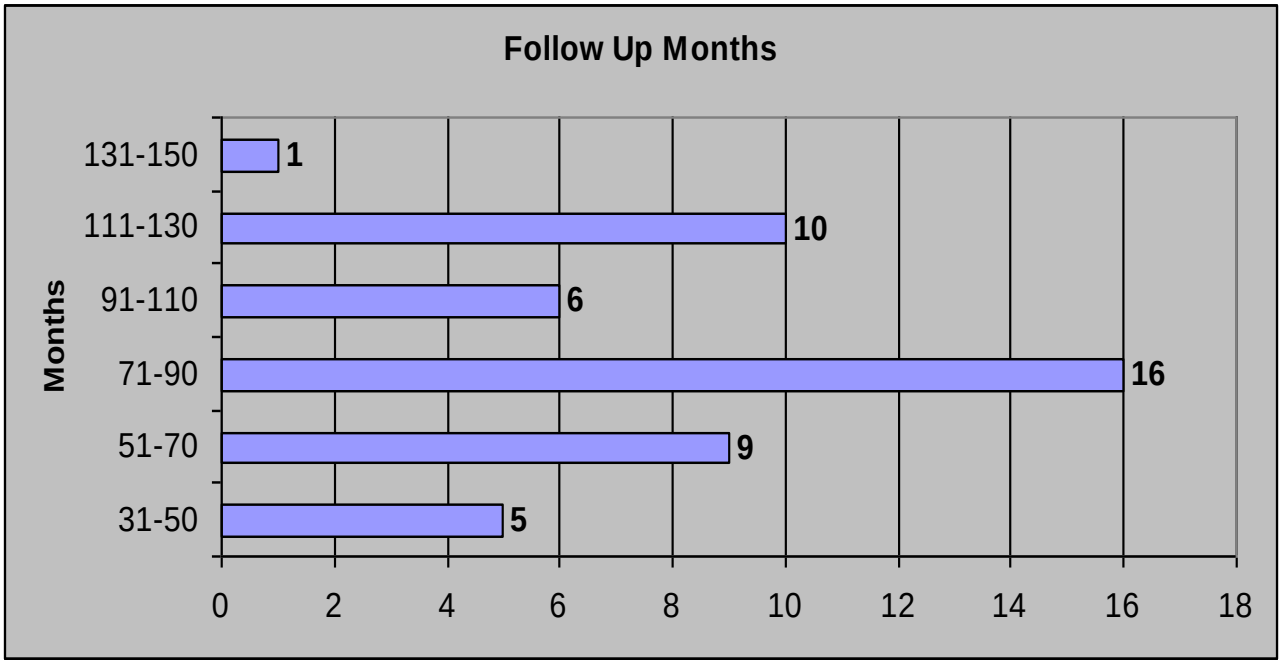

Unilateral - Bilateral Split
11
25
Unilateral
Bilateral



AGE DISTRIBUTION

Mean age is 46.82.

There are more of numbers in 40 to 60 range.



	N	Minimum	Maximum	Mean	Std. Deviation
FOLLOW UP	**47**	**36.00**	**135.00**	**84.4468**	**26.52547**
	47				

FS – Follow up in months.

Minimum follow up is 36 and maximum follow up is 135.

Mean follow up is 84.44 months.

VARIOUS INDICATIONS;

	Frequency	Percent	Valid Percent	Cumulative Percent
Arthritis	**9**	**25.0**	**25.0**	**25.0**
Fracture	**5**	**13.9**	**13.9**	**38.9**
AVN	**9**	**25.0**	**25.0**	**63.9**
Pathological conditions	**2**	**5.6**	**5.6**	**69.4**
Others	**1**	**2.8**	**2.8**	**72.2**
Ank.spon	**7**	**19.4**	**19.4**	**91.7**
RA	**3**	**8.3**	**8.3**	**100.0**
TOTAL	**36**	**100.0**	**100.0**	

AVN- Avascular necrosis, ANK.SPON- Ankylosing spondylitis, RA- Rheumatoid arthritis,

Others include – Failed DHS, Neglected DDH, etc.

Of 36 patients with 47 hips had been for operated various diagnoses. 25% Avascular necrosis, 25% arthritis , anylosing spondylitis 19%, fracture neck of femur 13.9%.

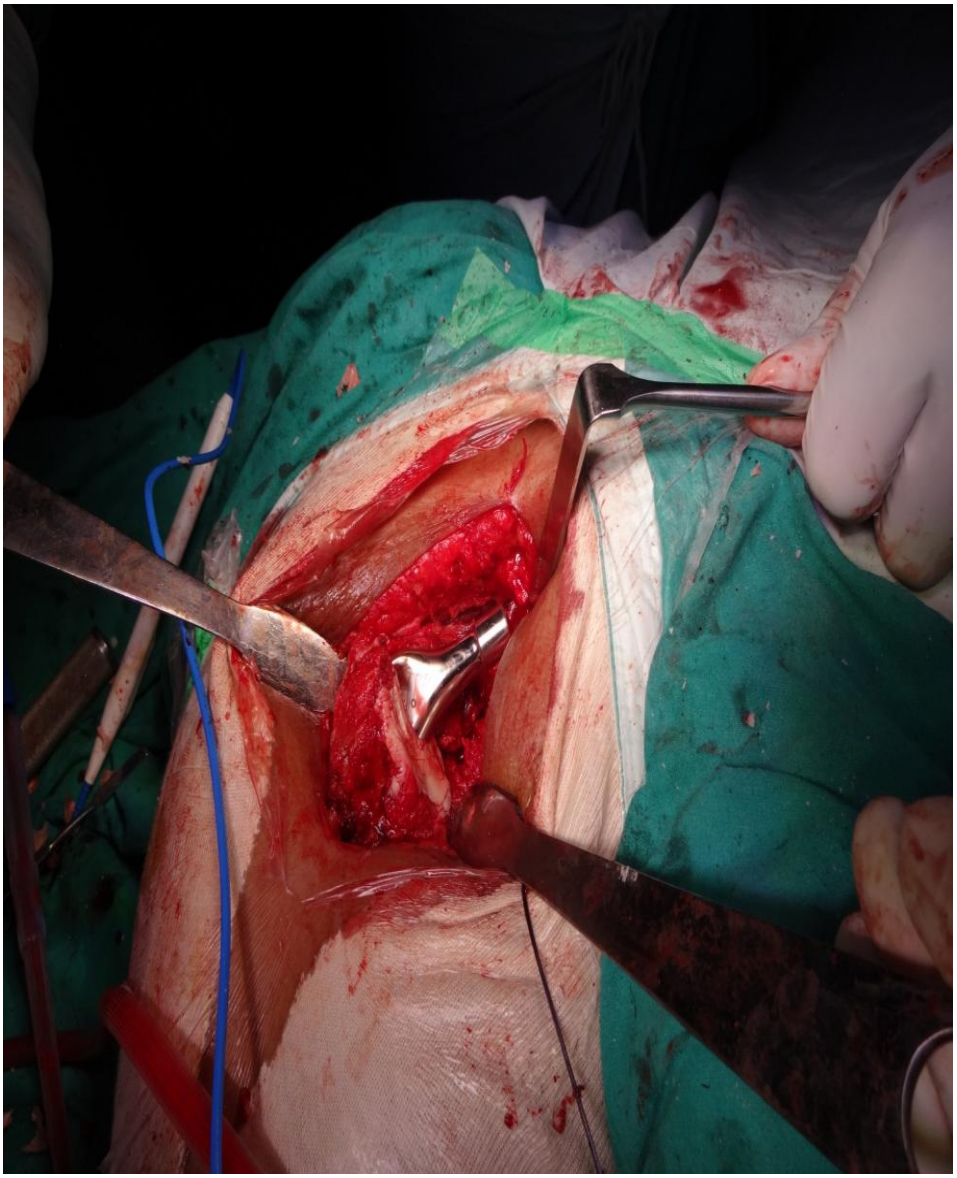
OPERATIVE PROCEDURE:

All patients were admitted on the day before surgery and evaluated in detail with history and clinical findings with range of motion were documented. All these surgeries are done by single surgeon for various indications. Patients were operated in lateral position using ‘omega approach of Learmonth. The approaches used were

1. Posterior Moore approach in lateral position.
2. Lateral Omega approach of Learmonth in lateral position.
3. Modified Hardinge lateral approach in supine/lateral position.
4. Lateral approach with trochanteric osteotomy in lateral position.

All patients were administered pre-operative intravenous antibiotic and continued for 48 hours till drain removal.

Second generation cementing technique was used. Wound was routinely closed with suction drain. An abduction pillow was placed in between legs in operating room before transfer. On the first post-op the patients were taught static quadriceps, hamstring exercises and ankle pump exercises. TED stockings were applied to prevent DVT. Physical therapy regimen was started from day one. Drains were removed after 48 hours and xray of pelvis with both hips AP was taken. Full weight bearing walking with walker was used initially and gradually progressed to crutches.



INTRAOP PICTURE

ASSESSMENT OF CLINICAL OUTCOME:

The clinical outcome of patients was assessed using Harris hip score.

The components of Harris hip score is summarised as follows:

1. Pain score ranges from 0 to 44. (0 totally disabled to 44 ignores pain).
2. Limp (severe limp score 0 to no limp scoring 11).
3. Support (unable to walk 0 to walks normally without support scoring 11).
4. Distance walked (bed and chair bound score 0 to unlimited walking distance 11).
5. Sitting (unable to sit in chair 0 – able to sit more than 1 hour score 5).
6. Enter public transportation (Yes- 1/No-0).
7. Climbing Stairs (unable score 0 to climb normal without using railing score 5).
8. Put on shoes (unable – 0 to with ease score 5).
9. Absence of deformity score 4.
10. Scoresfor specific range of movement.

    Total score was categorised as < 70 poor,71 to 79 fair, 80 to 89 good and >90 excellent.

RADIOLOGICAL ASSESSMENT

All patients underwent anteroposterior and lateral radiographs after 48 hours drain removal. Patient were positioned supine with both feet internally rotated 15 degrees so that great toe touch each other and xray tube was positioned at 100 centimetres from the bulky. The xray tube was centred over the pubic symphysis covering upto cement restrictor. The radiographs were retrieved for study from PACS using GE centricity software version 3.0. The availability of radiographs for the study was 100%.

Radiological assessment includes:

1. Assessment at immediate post-op x-rays for
    a. Cement filling based on Barracks grading system.
    b. Cement mantle thickness.
    c. Orientation of femoral stem.

2. Assessment of follow up x-rays .
    a. Proximal femoral resorption.
    b. Assessment of radiolucent lines in Gruen's zones.
    c. Analysing cement mantle fractures.
    d. Ectopic bone formation.
    e. Any periprosthetic fracture.

Cementing technique:

Based on Barrack's grading system cement filling was categorised as

1. Grade A- complete filling (white out)
2. Grade B- slight radiolucency in cement bone interface.
3. Grade C- 50 to 90% radiolucency.
4. Grade D incomplete filling – uncovering of stem tip.

Cement mantle thickness:

This was measured on Anteroposterior view by measuring the distance between the inner medullary cortex of proximal femur to medial aspect of stem. This was categorised as thickness < 2mm, 2 to 5mm, 5 to 10mm and > 10mm.

ORIENTATION OF THE FEMORAL STEM

The orientation of the femoral stem was recorded as the angle between the axis of the distal portion of the stem and the axis of the femoral shaft in the anteroposterior radiograph.

The hips were divided into three groups according to the orientation of the stem:

1. neutral (a stem-shaft angle between 0 and 5 degrees),
2. valgus angulation (a stem-shaft angle of more than 5 degrees valgus), and
3. varus angulation (a stem-shaft angle of more than 5degrees varus).

ASSESSMENT OF FOLLOW UP RADIOGRAPHS

PROXIMAL FEMORAL RESORPTION:

Proximal femoral resorption or stress shielding was defined in the follow-anteroposterior radiographs using the criteria described by Engh et al.(25,26).

First degree - slight rounding of the proximal-medial edge of the cut femoral neck

Second degree - rounding of the proximal-medial aspect combined with loss of the medial cortical density to the level of the lesser trochanter

Third degree - extensive resorption of cortical bone with involvement of the anterior cortex at the level of the lesser trochanter and the medial cortex below the lesser trochanter

Fourth degree - resorption extends into the diaphysis.

ASSESSMENT OF SUBSIDENCE OF FEMORAL STEM:

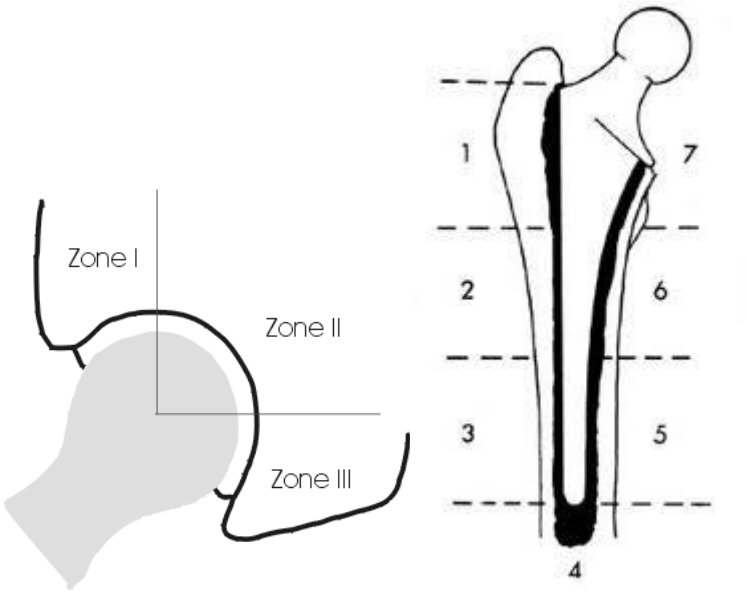
Subsidence of the femoral stem within the cement mantle can be measured by various methods as described by Sutherland et al, Ianotti et al and Malchau et al(27) by measuring the distance between two landmarks in successive radiographs. In the Sutherland method, the bone landmark was the tip of the greater trochanter and the prosthetic landmark was the femoral head center(28). Ianotti used the most inferior part of the lesser trochanter and the prosthetic stem shoulder as the bone and prosthetic landmarks. In the Malchau method, the landmarks were the medial tip of the lesser trochanter and the femoral head center. Fowler et al (29) measured the distance between the stem shoulder and cement.Malpositioning during successive radiographs can cause errors in measurement with these methods.

The subsidence of the femoral stem in our study was calculated by comparing the change in distance between the distal tip of the stem and the inferior pole of the cement restrictor in successive, comparable anteroposterior radiographs. All radiographs were digitalized and adjustment for magnification was calculated on the basis of the known diameter of the prosthetic head (28 mm). This was done by a computer-assisted method using the GE Centricity software version 3.0. Many studies have assessed periodic migration of stem but in our study we have taken subsidence at the latest followup.

Assessment of Gruens loosening zones:

Based on Gruen et al, the femoral segment is divided into 7 zones and the radiolucent lines seen between the cement bone interface or cement stem interface are assessed.

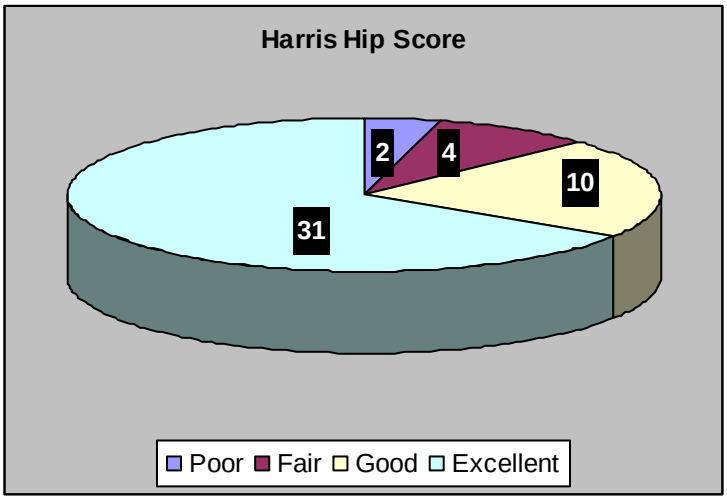
Presence of endosteallysis, cement mantle fracture and distal cortical hypertrophy is also analysed.



RESULTS

Patient who underwent Exeter cemented total hip arthroplasty for various indications from 2000 to 2010 were called for follow up.Out of 122 patients 4 expired. 118 patients were alive and most ofthe patients were form West Bengal, Bihar and Bangladesh. All these patients were requested to come for followupthrough letter and telephone. 36 patients came for follow up within this study period weretakenup for analysis.

The clinical outcome is analysed by Harris hip score:



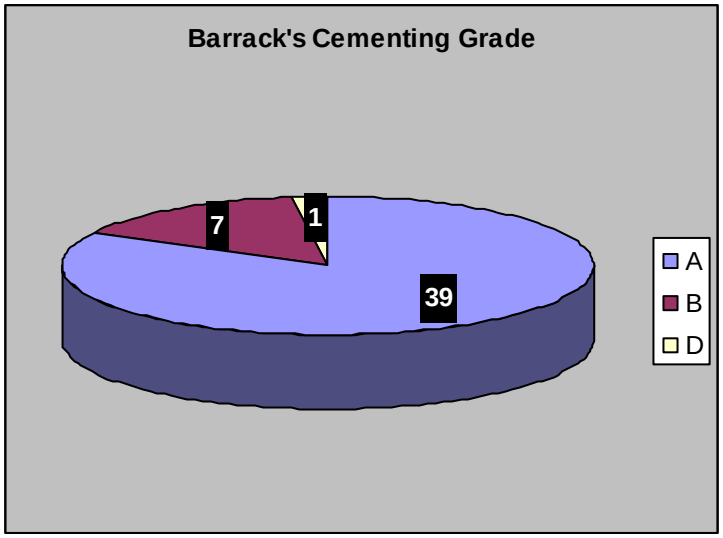
Harris hip score	Frequency	Percent	Cum.Percent
0 (Poor)	2	4.26	4.26
1 (Fair)	4	8.51	12.77
2 (Good)	10	21.28	34.04
3 (Excellent)	31	65.96	100.00
Total	47	100.00	

Harris hip score was categorised as 0= score less than 70 as poor, 1 = score of 70 to 79 as fair, 2= score of 80 to 89 as good and3 = >90 as excellent.

Of 47 hips poor results were 4.26%, Fair 8.51%,Good 21.28% and excellent 65.96%.

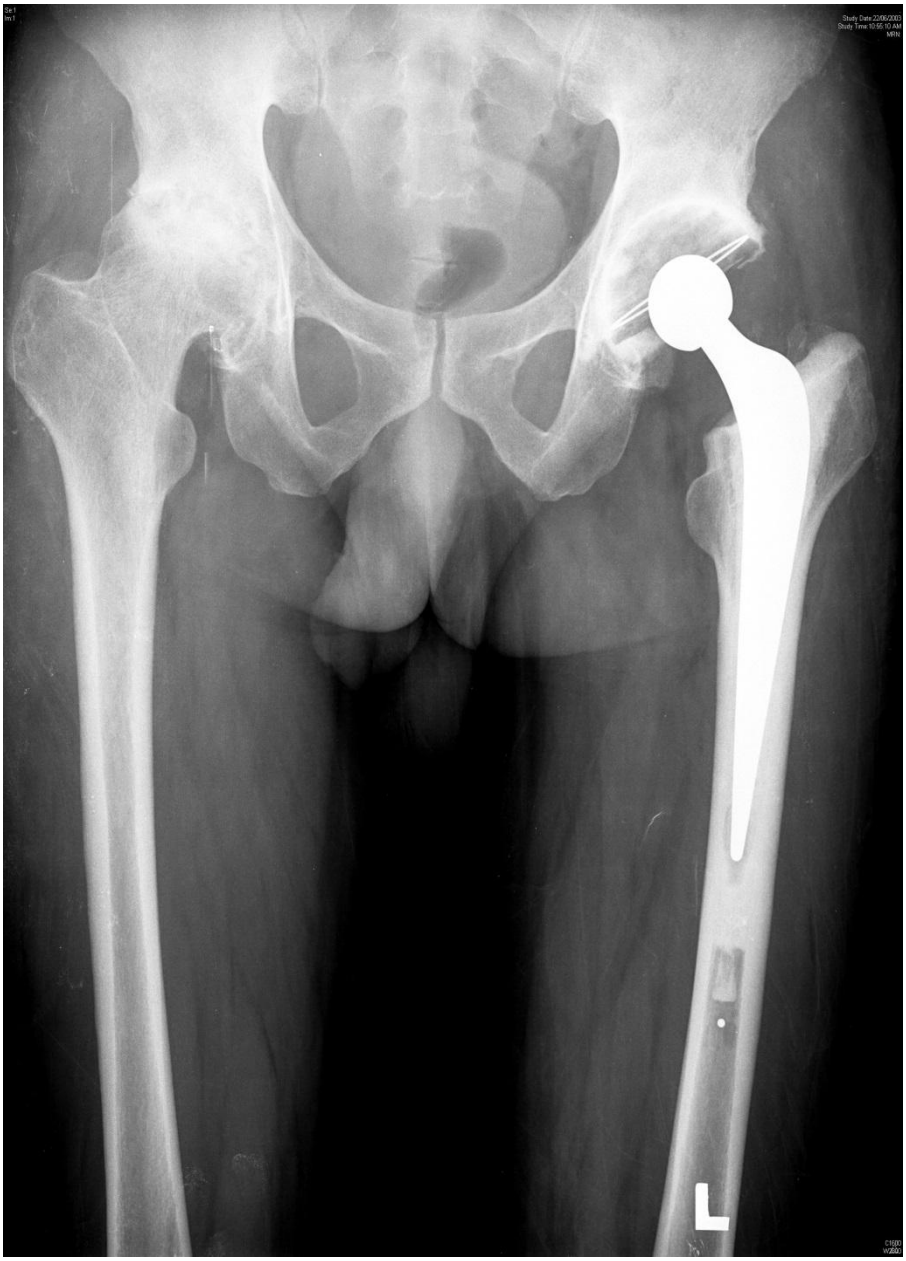
ANALYSIS OF INITIAL RADIOGRAPHS:

CEMENTING TECHNIQUE:



Barracks grade	Frequency	Percent	Cum.Percent
A	39	82.92	82.92
B	7	14.89	97.87
C	0	0	0
D	1	2.13	100
Total	47	100	

Cementing technique is graded based on Barracks grading system. Of the 47 hips the cement mantle is graded as A in 82.92, B in 14.89,C in 0 and D in 2.13.



BARRACK’SGRADE –A CEMENT FILLING.

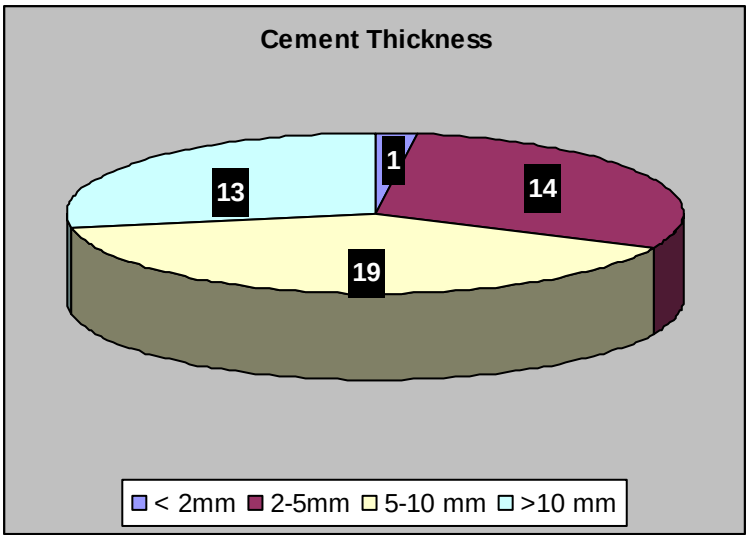
COMPLETE WHITE OUT.

BARRACK'S GRADE B – CEMENT FILLING.

BARRACK'S GRADE C - CEMENT FILLING

50 to 90% cement filling defect.

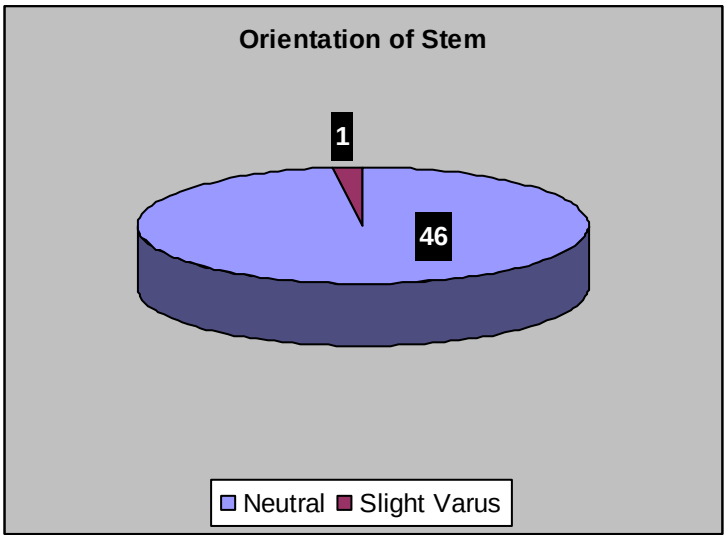
CEMENT THICKNESS:



Cement thickness	Frequency	Percent	Cum.percent
< 2 mm	1	2.13	2.13
2 to 5 mm	14	29.79	31.91
5 to 10mm	19	40.43	72.34
>10 mm	13	27.66	100
Total	47	100	

Cement thickness in medial calcar region is categorises as < 2mm, 2 to 5mm, 5 to 10mm and more than 10mm. Of the 47 hips there 2.13% for < 2mm, 2 to 5 mm 29.79%, 5 to 10mm 40.43% and more than 10mm is 27.66%.

ORIENTATION OF STEM:

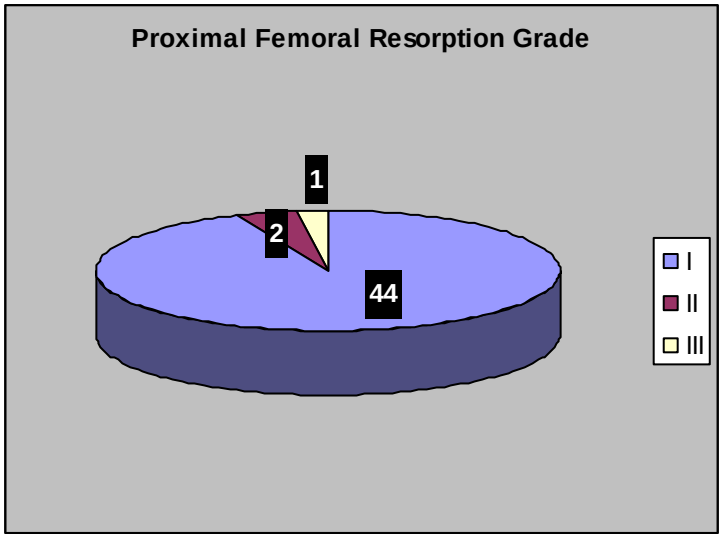


Orientation	Frequency	Percent	Cum.percent
Neutral	467	97.87	97.87
Slight varus	1	2.13	100
Total	47	100	

Orientation of stem is analysed as Neutral when angle is 0 to 3 degrees, 3 to 5 degrees as slight valgus, more than 5 degrees as valgus, 3 to 5 degrees as slight varus and more than 5 degrees as valgus. Of 47 hips 97.87% is in neutral and slight varus is 1 i.e 2.13%.

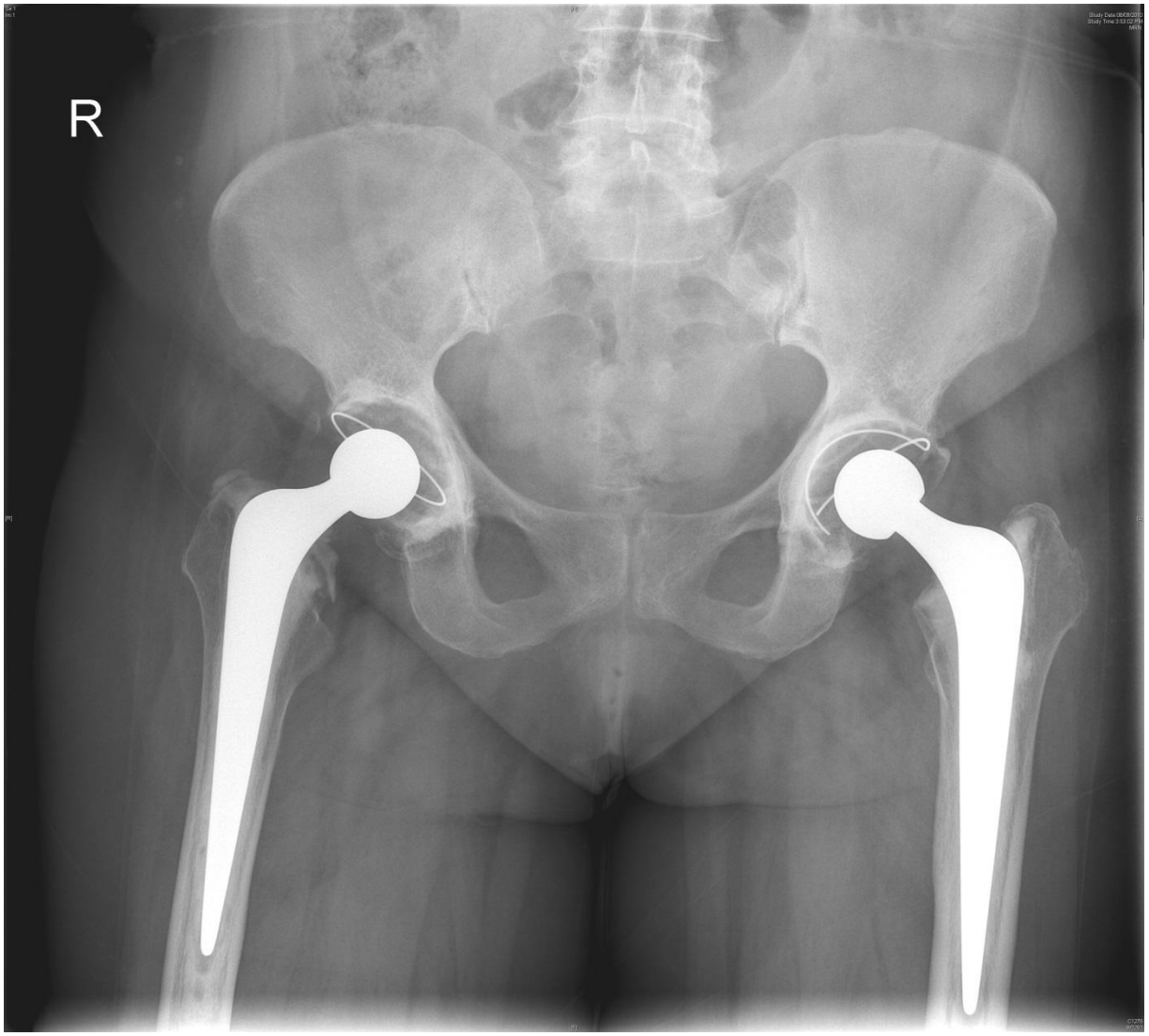
ANALYSIS OF FOLLOW UP RADIOGRAPHS:

PROXIMAL FEMORAL RESORPTION:



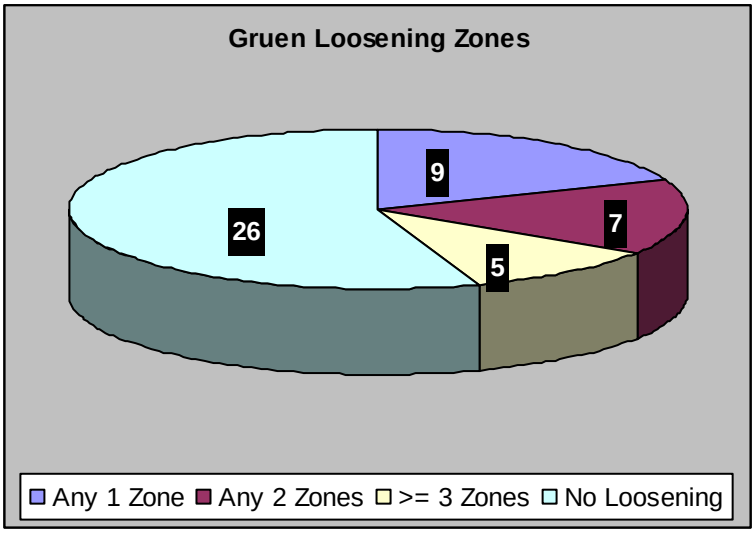
PFR- Grade	Frequency	Percent	Cum.percent
I	44	93.62	93.62
II	2	4.26	97.87
III	1	2.13	100
	47	100	

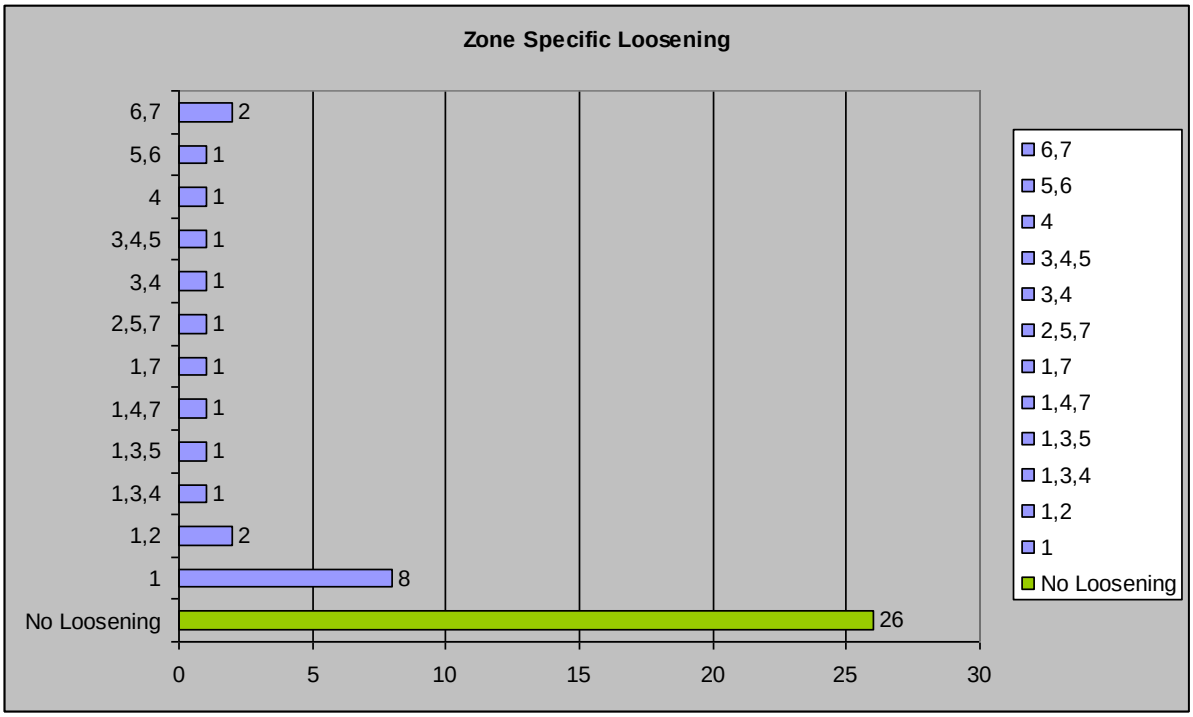
Proximal femoral resorption is grade as I slight rounding in proximal medial femur, grade II rounding with loss of cortical to the level of lesser trochanter, grade III extensive resorption of cortical bone at the level of lesser trochanter and medial cortex below the level of lessertrochanter and grade IV resorptionupto diaphysis. Of the 47 hips 93.62 % is grade I, 4.26 % is grade II and 2.13 % is grade III.There is no grade IV in our analysis.

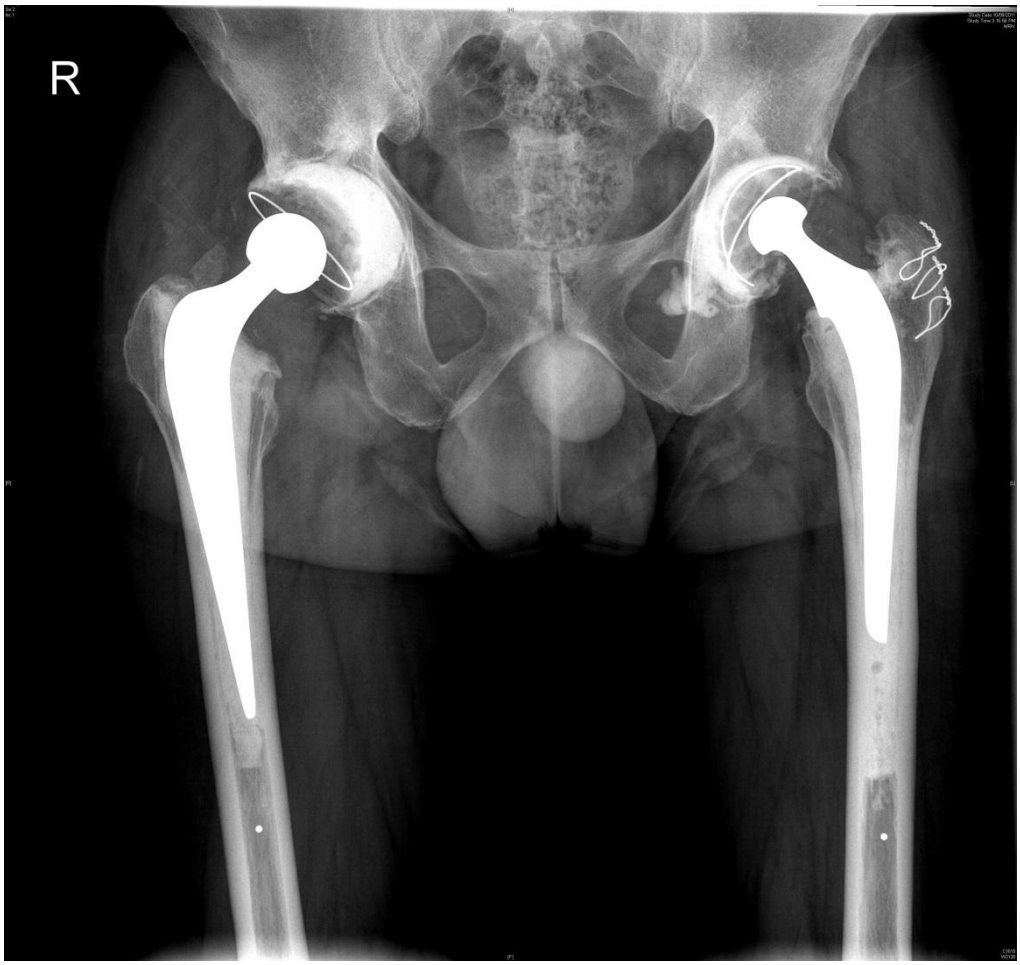


PROXIMAL FEMORAL RESORPTION – GRADE II

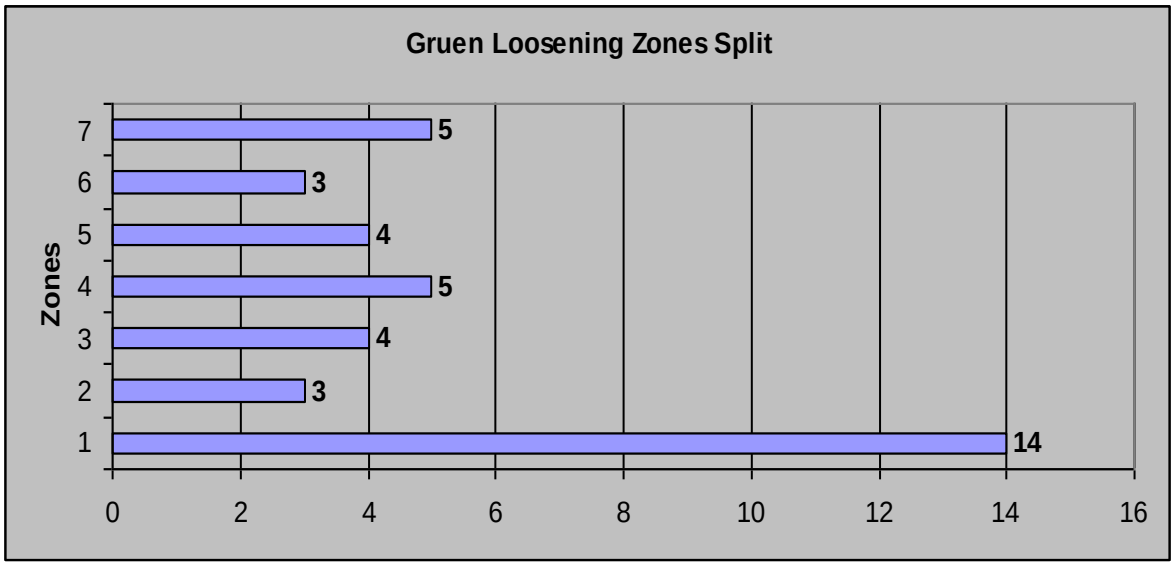
GRUENS LOOSENING ZONES:







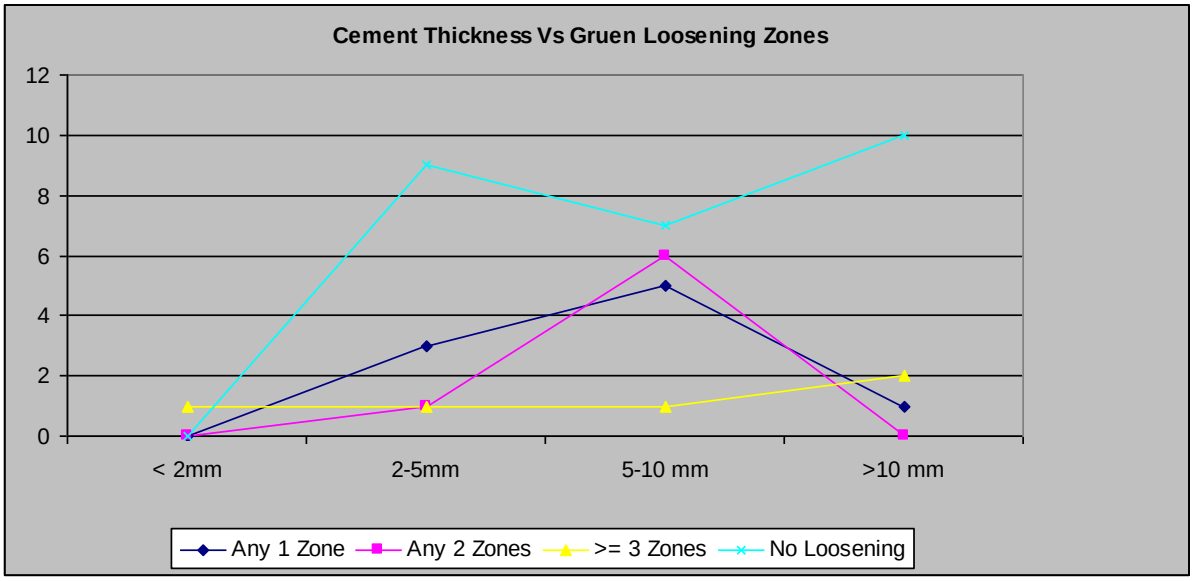
GRUENS ZONES OF LOOSENING = ZONES 1,5 AND 7



Zone	Frequency	Percent	Cum.percent
Any 1 zone	9	19.15	19.15
Any 2 zones	7	14.89	34.04
=>3 zones	5	10.64	44.68
No Loosening	26	55.32	100.00
Total	47	100.00	

Gruens loosening zones is categorised as Zone I = one zone loosening, 2 = two zones loosening, 3 = equal to three or more than 3 zones loosening, 4 = all zones loosening, 5 = cement mantle fracture and 6 = No loosening. Of 47 hips, 9 hips i.e 19.15% has loosening in 1 zone, 7 hips i.e 14.89% has loosening in two zones, 5 hips 10.64% has loosening in 3 zones and 26 hips 55.32% has no loosening.

Correlation of cement thickness with Gruens loosening:



Gruens loosening zones

S.NO	Cement Thickness	No loosening	1 zone	2 zones	3 or >3 zones	Total
1	<2mm	0 0.00	0 0.00	0 0.00	1 20.00	1 2.13
2	2 - 5mm	9 34.62	3 33.33	1 14.29	1 20.00	14 29.79
3	5 - 10mm	7 26.92	5 55.56	6 85.71	1 20.00	19 40.43
4	>10mm	10 38.46	1 11.11	0 0.00	2 40.00	13 27.66
	Total	26 100.00	9 100.00	7 100.00	5 100.00	47 100.00

In this study, with a cement mantle thickness of less than 2 mm there was 1 patient (2.13%) with 3 or more loosening in Gruens zones.

In patients with 2 to 5mm cement mantle; 9 cases (19.14%) had no loosening; 3 patients (6.38%) had loosening in one region; 1 patient (2.13%) had loosening in 2 zones and 1 patient (2.13%) had loosening in 3 or more than 3 zones.

In patients with 5 to 10mm cement mantle thickness 7 cases (14.28%) had no loosening; 5 cases (10.63%) had loosening in one zone; 6 cases (12.76%) had loosening in 2 zones and 1 patient (2.13%) had loosening in 3 or more than 3 zones.

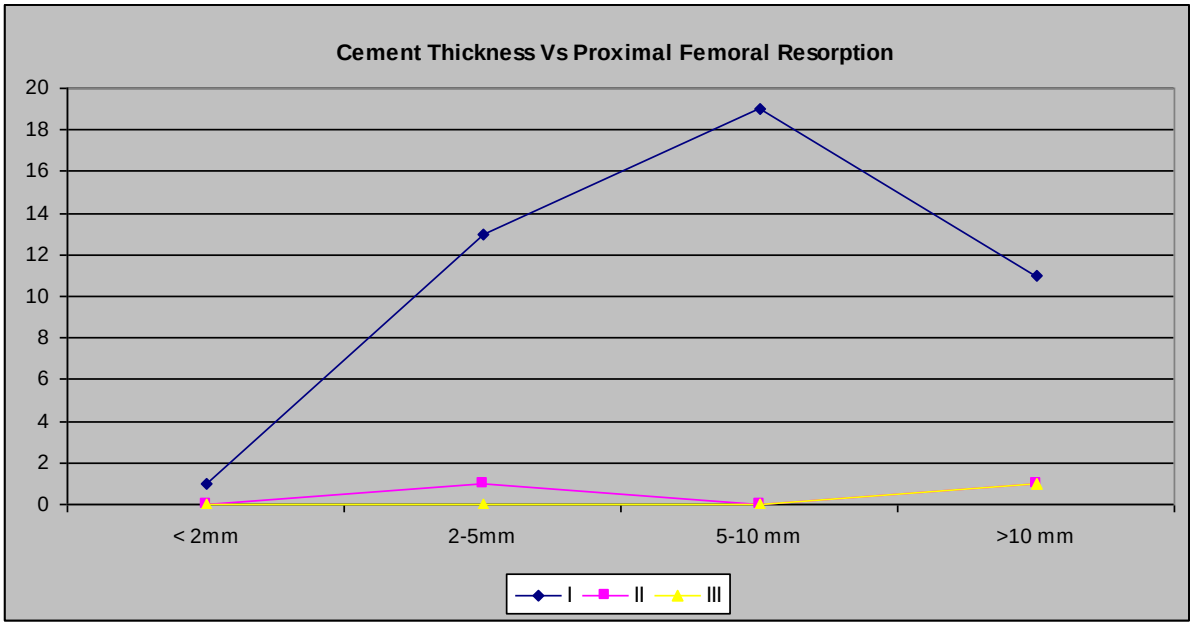
In patients with more than 10mm cement mantle thickness 10 patients (21.27%) had no loosening; 1 patient (2.13%) had loosening in 1 zone and 2 patients (4.26%) had loosening in 3 or more than 3 zones.

Altogether 5 patients (10.63%) had loosening in 3 or more zones but none (0%) were symptomatic or required revision.

There were no cases of loosening in all zones or cement mantle fracture.

On conducting the test of significance the thickness of cement mantle showed a positive correlation with Gruens loosening zones.

Correlation of cement thickness with proximal femoral resorption:



Proximal femoral resorption

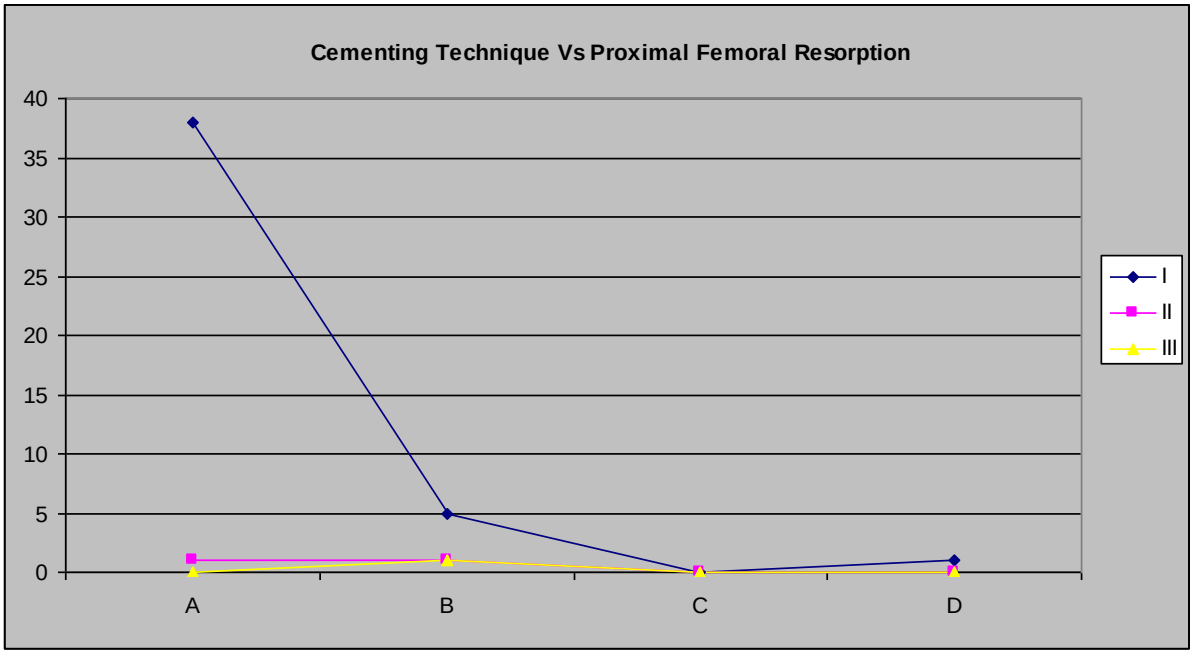
Cement thickness	1	2	3	Total
<2mm	1 2.27	0 0.00	0 0.00	1 2.13
2 to 5mm	13 29.55	1 50.00	0 0.00	14 29.79
5 to 10mm	19 43.18	0 0.00	0 0.00	19 40.43
>10mm	11 25.00	1 50.00	1 100.00	13 27.66
Total	44 100.00	2 100.00	1 100.00	47 100.00

Pearson chi square (6) = 4.3021 Pr = 0.636

Fischer's Exact = 0.262.

Of 47 hips, 44 had grade I proximal femoral resorption of which 19 hips had cement thickness of 5 to 10mm, 13 hips of 5 to 10mm thickness. On correlating with pearson chi square test and Fischers exact test, P value = 0.6 no significance**.**

Correlation of cementing filling technique with proximal femoral resorption:



Proximal femoral resorption

Cement Filling	Grade I	Grade II	Grade III	Total
1	38 86.36	1 50.00	0 0.00	39 82.98
2	5 11.36	1 50.00	1 100.00	7 14.89
4	1 2.27	0 0.00	0 0.00	1 2.13
Total	44 100.00	2 100.00	1 100.00	47 100.00

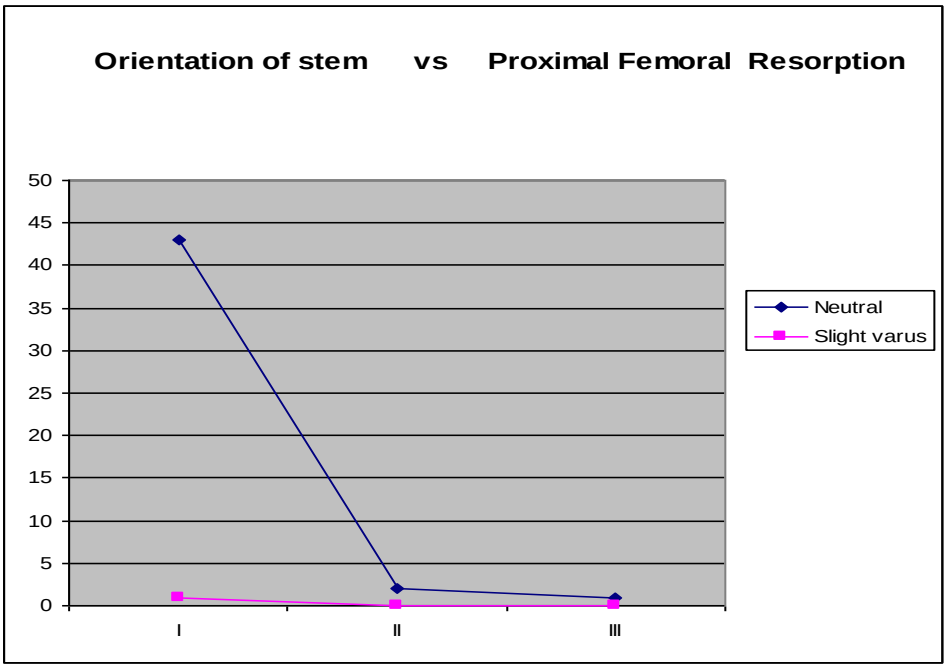
Pearson chi square (4) = 8.1072

pr = 0.088

Fischer's exact = 0.116

Of 47 hips, 39 hips had grade A cementing technique of which 38 hips had grade I proximal femoral resorption and 1 had grade II proximal femoral resorption. of 7 Grade B cementing technique had 5 grade I proximal femoral resorption, 1 had grade II proximal femoral resorption and 1 in grade III proximal femoral resorption. Of 1 grade D cementing technique had grade I proximal femoral resorption. On using pearson chi square test and Fischer's exact test the P value is 0.088 with denotes there is no significance. Though in our study statistically insignificant the above graph shows better cementing technique has better preservation of proximal femur.

Correlation of orientation of stem with proximal femoral resorption:



Proximal femoral resorption

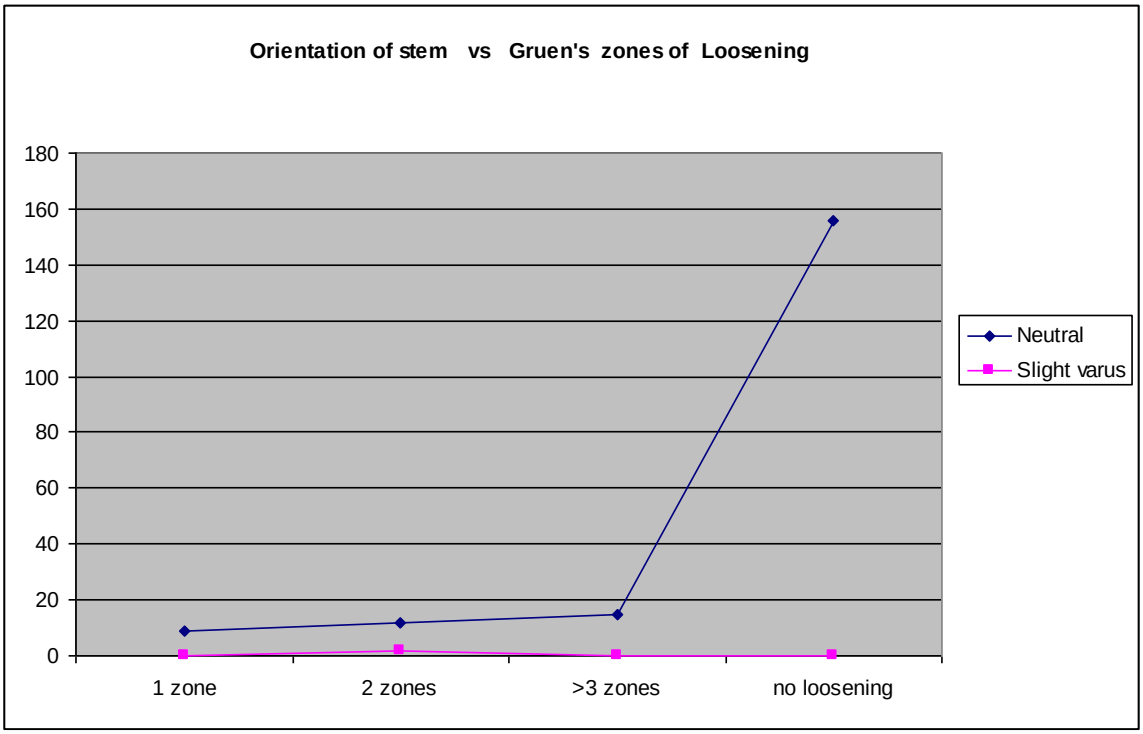
Orientation Of stem	Grade I	Grade II	Grade III	Total
Neutral	43 97.73	2 100.00	1 100.00	46 97.87
Slight varus	1 2.27	0 0.00	0 0.0	1 2.13
Total	44 100.00	2 100.00	1 100.00	47 100.00

Pearson chi square(2) = 0.0697 Pr = 0.966

Fischers exact = 1.000

In our study of 47 hips, 43 hips of neutral alignment had grade I proximal femoral resorption, 2 hips of neutral alignment had grade II proximal femoral resorption and 1 in slight varus had grade I proximal femoral resorption. On correlation with pearson chi square test and fischer's exact test p value was 0.966 which was not significant. The above graph depicts that better position of stem preserves the proximal femur which evident by more number of neutral stem had grade I proximal femoral resorption.

Correlation of orientation of stem with Gruens zones:



Orientation of stem	Any 1 Zone	Any 2 zones	= > 3 zones	No loosening	Total
Neutral	9 100.00	6 85.71	5 100.00	26 100.00	46 97.87
Slight varus	0 0.00	1 14.29	0 0.00	0 0.00	1 2.13
Total	9 100.00	7 100.00	5 100.00	26 100.00	47 100.00

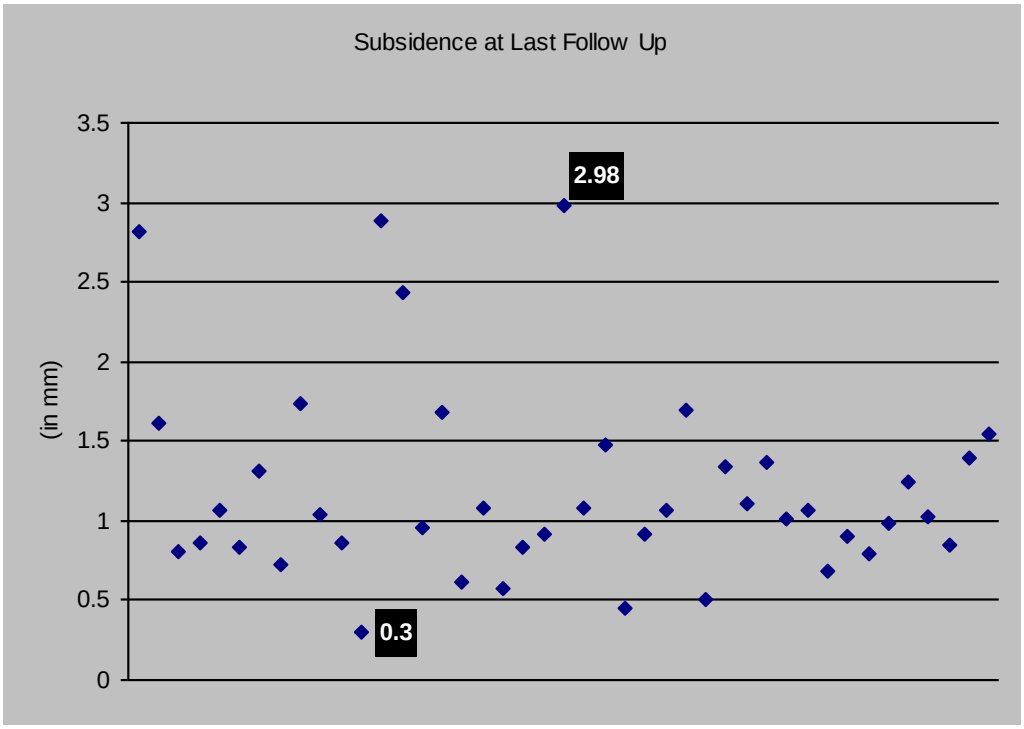
Pearsons chisqaure (3) = 5.8385 Pr = 0.120

Fischers exact test = 0.255

Of 47 hips, 46 were in neutral position. Among the 46 neutral stems 26 had no radiolucent lines either in cement bone interface of stem cement interface. 9 stems of neutral category showed loosening in zone I which may be a indicative of subsidence but not loosening. 6 stems had loosening in 2 zones and 5 stems had loosening n 3 zones. But none of these stems had osteolysis or subsidence of more than 3 mm. On correlating with pearson chi square test and Fischer exact test P value was 0.120 which is of no significance. Though our study is not statistically significant number of no loosening stems is higher in neutrally oriented stem.

Among 47 hips only one hip was slight varus with available samples it implies that our stems are oriented well within the cement mantle.

SUBSIDENCE:



The mean subsidence in our study was 1.19 mm.

Minimum subsidence was 0.30mm.

Maximum subsidence was 2.98mm.

Subsidence in our study was measured based on Fowler method.

It was measured in two ways :

1. Measuring radiolucent zone I i.e the distance between the stem shoulder and cement mantle.

2. For those with no radiolucent line in zone I , the distance between the stem tip and the cement restrictor was taken. Magnification error was corrected by calculating with known head size.

COMPLICATIONS:

COMPLICATIONS	FREQUENCY	PERCENTAGE
Dislocation	**1**	**2.1%**
Acetabular cup loosening	**1**	**2.1%**
Total	**47**	**100**

DISLOCATION:

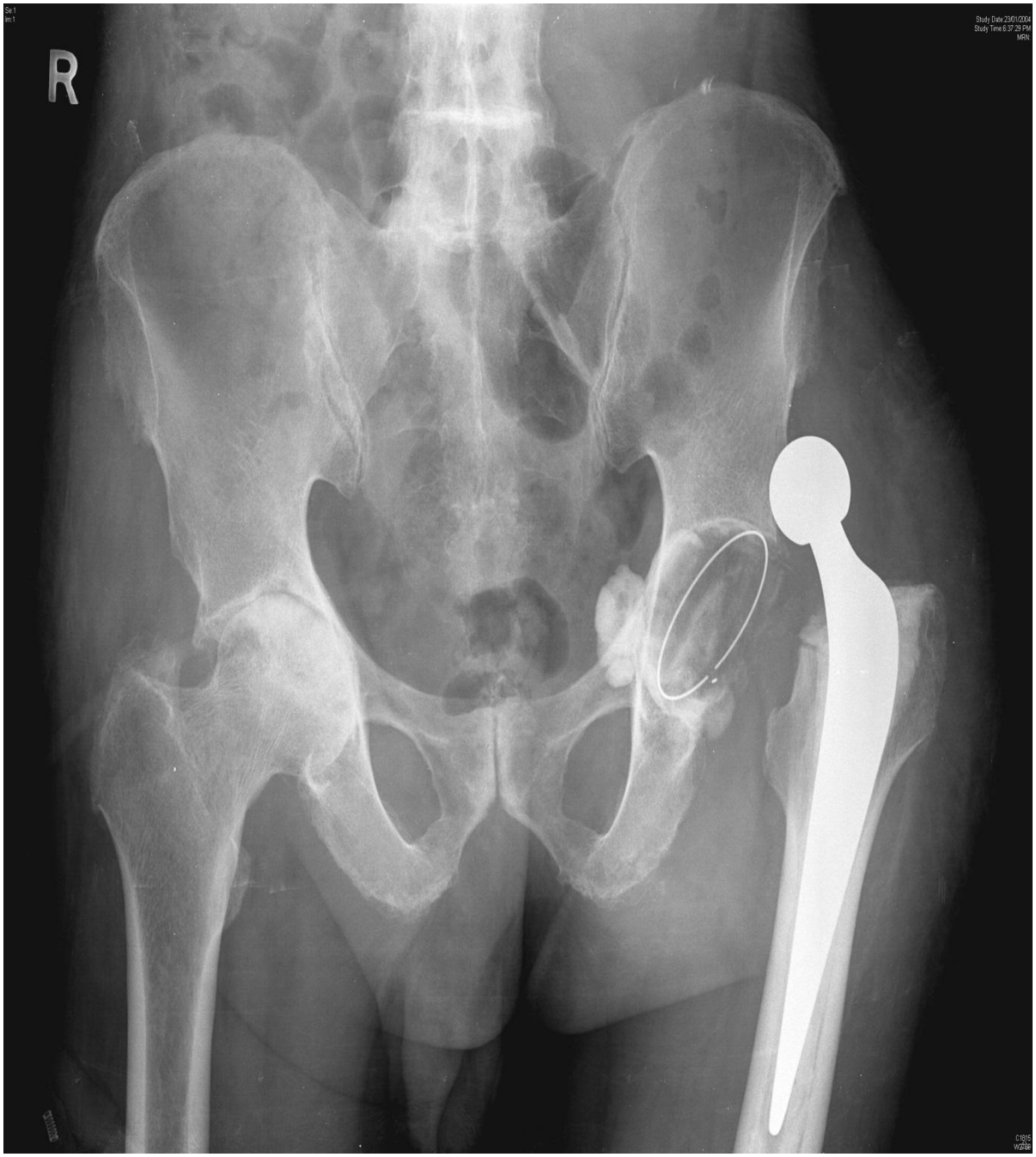
In our study there was one post op dislocation on day 12. After the patient was discharged, while riding in autorickshaw patient adducted unknowingly. Closed reduction was done under general anaesthesia and hip was found to be stable. At present patient reviewed after 7 years for follow up with no history of recurrant dislocation and her Harris hip score was 86. Radiologically no signs of aseptic loosening is seen.

ACETABULUM LOOSENING:

The other complication in our study was a patient on 8 year follow up who came with complaints of groin pain. Clinically his activities of living were not affected much. His Harris hip score was 84. Radiologically he was diagnosed to have radiolucent lines in all 3 zones of acetabulum and change in cup position. He underwent acetabular cup revision recently. On the femoral side there was no sign of aseptic loosening.

ECTOPIC BONE FORMATION:

Of the 47 hips with recent review there was no ectopic bone formation.



DISLOCATION

ACETABULUM CUP LOOSENING

DISCUSSION

Exeter total hip replacement is one of the safest and most successful operation in orthopaedic surgery, providing excellent results in restoration of hip function and patient satisfaction. This is evidenced by the ongoing success of the Exeter Universal femoral stem since its introduction in the 1970s. Recent long-term follow-up studies of the Exeter Universal stem have shown excellent clinical performance of the prosthesis, with low rates of mechanical failure and complications such as excessive subsidence, endosteolysis and radiolucencies.(30,31)

A.CLINICAL RESULTS:

HARRIS HIP SCORE:

In all 36 patients with 47 hips were followed up for detailed clinical and radiological evaluation. In these patients a harris hip score of 90 -100 (excellent) was achieved in 31 hips (65.96%); a score of 80 – 89 (good) in 10 patients (21.28%); a score of 70 – 79 (fair) in 4 cases (8.51%) and less than 70 (poor) in 2 patients (4.26%).

Overall excellent and good results were obtained in 41 of 47 hips (87.24%).

These results are better than some of studies published by Robert . L Barrack et al (18) in a study with improved cementing technique and femoral component loosening in young patients with hip arthroplasty had of 39 hips with 12 years follow up had 24 hips excellent, 6 good, 6 fair and 3 poor Harris hip score results.

One patient had a poor outcome with a post-operative Harris hip score of 47.This patient had multiple comorbidities like community acquired pneumonia, Crohn’s disease and seronegativespondyloarthropathy. A recent follow up shows that range of movements in hips were normal.

Our results are comparable with various other studies Chiu KH and Shen (32) showed clinical outcome Exeter total hip arthroplasty in small femur was 82.3.

In other study by Justin Sherfy (33) showed gross improvement of pre-op Harris hip score was 40 improved to 84 which was comparable to our results.

B.RADIOLOGICAL RESULTS:

1.CEMENTING TECHNIQUE:

Of 47 hips 82.92% were graded a A, 14.89% was grade B and 2.13% grade D. This indicates overall our cementing techniques is good. On comparing with other study byS.Hook (34) in 2006, 74 patients with 88 hips cementing technique was graded based on Barrack's grading system 72% were grade A, No patients with grade B, 24% patients with grade C and 4% in grade D our results more are less equal .

In original article by Robert.L Barrack et al(18) 50 hips cementing technique was graded as grade A 32, grade B 18 , Grade C and D nil. With improved cementing technique there was no femoral component revised at the end of 12 years. The use of cement gun and intramedullary plug helps in uniform filling of cement within the canal and there no void distal to the stem tip this is clearly proven by no stems were in grade C and D.

In other study by Simon C et al (35) number of grade A was 40, grade B 51, grade C 27 and grade D was 2 . In our study grade A was 39, grade B 7, grade C 0 and grade D was 1. On comparison with our study grade A and D cementing technique was equal.

The Exeter universal cemented component study by H.D Williams (41) cement grading was done based on Barrack grading system Grade A 34, B-107,C-51 and no Grade D. taking revision as endpoint for femoral component at 8 to 12 yrs the survivorship for femoral stem was 100%.

Eugene Ek (36) in his comparative study of Exeter and C-stem showed that the cement mantle was graded as A in 36.5%, B in 56.6%, and C in 6.9% of his Exeter hips. Clinical results showed no stem needed revision for loosening and extent of proximal femoral resorption was comparable.

Our study showed a much better cementing technique, with 82.92% of hips graded as Barrack A. There was also a statistically significant difference in the cementing technique, with the Exeter group showing more grade A hips . This may be due to the fact that the surgeon who uses the Exeter implant tends to oversize the femoral stem in most cases, leading to better cement penetration of cancellous bone and “white out”.

The number of grade C hips in our Exeter stem is nil than most other studies which shows that adequate mantles can routinely be achieved even with larger stems as long as care is taken to remove enough cancellous bone and to align the stem properly.

Chiu et al (37)from their experience with the Exeter stem in Chinese patients with small femora, showed that there was early loosening in a population in which oversizing of the stem was common, with a resultant incomplete cement mantle and high rates of failure. These incomplete mantles can be avoided by downsizing the implant from the last broach used as long as there are adequate smaller sizes available to allow this. Scheerlinck et al(38) confirmed that cement mantles were less likely to be deficient when the stems were downsized from the broach, although they felt that support for the larger stems was good because of excellent penetration of the cancellous bone and the more secure support afforded by the cortical bone.

Downsizing actually reduces subsidence of the stem with polished tapers. This can probably explain lower subsidence of the stem in the C-stem group compared to the Exeter group, where we routinely oversize femoral stems. Also, the slightly higher subsidence in the Exeter group is still very much within the permissible limits and gives very good clinical and radiological results.

2.CEMENT THICKNESS:

In our study < 2mm cement mantle thickness group had 1 (2.13%), 2-5mm thickness group had 14 cases (29.79%), 5-10mm thickness 19 cases (40.43%) and more than 10mm thickness had 27.66%.

In an analysis by Ebramzadeh demonstrated that stems with cement mantle thickness on 2 to 5mm had better results than the thicker and thinner ones. In our analysis cement mantle thickness was intermediate with more groups in 5 to 10mm and 2 to 5 mm. There is only one case with cement mantle thickness of less than 2 mm. None of our stems requires revision for aseptic loosening.

In a study by I.R chambers et al (43) out of 1081 Charnleys replacements 499 were reviewed for clinical and radiological analysis. 44% of stems were taken for analysis. They graded A and B as adequate and C and D as inadequate. 69% of stems were graded as inadequate. 69% of stems had failures of 15 hips whereas 32% of adequate cementing had 7%. Mostofthe stem with cement mantle lesser than 2 mm were in failure whereas more than 2mm were in safer level. Cement mantle thickness < 2mm in all areas of gruens zones were 95 hips of which 25 stems failed.

3.FEMORAL STEM ORIENTATION:

Ebramzadeh et al (19) in his study illustrates that stem lying in more than 5 degrees of varus were prone to develop cement mantle fractures,progressive loosening which will be demonstrated by appearance of radiolucent lines in stem cement interface or bone cement interface where less chance of loosening with stems in neutral and valgus position.

Russotti et al (39) noted that varus or valgus positioning of the femoral stem and less than two centimetres of cement extending past the tip of the femoral stem were significantly associated with new or progressive radiolucent lines about the femoral stem, which shows the significance of alignment.

In our study 97.87% were neutral and 2.13% were slight varus. None of the stems needing revision for aseptic loosening.

4.PROXIMAL FEMORAL RESORPTION:

Proximal femoral resorption was categorised into 4 category based on Engh et al. In a comparative study Eugene Ek(36) the tapered design of the stem acts as wedge and settles itself in a stable position I degree rounding was 16.5%, II degree was noted in 1.2% with no III and IV degrees. No hip was considered with risk of aseptic loosening.

Fowler J.L et al (29) demonstrated in a study of Experience with the Exeter total hip replacement in 1970 thatresorption of proximal medial femoral calcar was relatedto the thickness of cement mantle with no loss in 63.25% , < 1mm in 27.5%, 1-3 mm in 5.79%, 4-6 mm 0.48% and 10 or more than 10mm in 0.96% .

In our study slight rounding of proximal medial calcar was seen in 93.62%, mild lysis at the level of lesser trochanter was in 4.26% and lysis below the level of lesser trochanter was seen in 2.13%. Our results shows our cementing technique are good and so there is uniform loading in the proximal femur providing hoop stress there by preventing lysis at calcar.

Wilson J.N et al (42) in analysis of loosening of total hip replacements with cement fixation described that when load is transmitted to distal bone i.e region of bone distal to

femoral neck it causes disuse atrophy of proximal femoral neck. The same finding was reported by Blacker 69.2% of calcarresorption ranging 4 to 27mm in 7 to 13 yrs in 169 total hip replacements.

Piers et al (45) 44.7% had 0 to grade I resorption, 51.3% had second degree resorption, 3.9% had III degree resorption and none in IV degree resorption. Our results are similar to this study.

DISTAL CORTICAL HYPERTROPHY:

In our study of 47 hips there was no distal cortical hypertrophy. This shows that modern cementing technique obliterates the distal cortical hypertrophy.

J.L Fowler et al in a study demonstrated distal cortical hypertrophy and distal movement of the stem within the cement mantle at 5 to 10 years review. He noted that with modern cementing technique distal cortical hypertrophy is completely obliterated. In this study nil distal cortical hypertrophy in relation to subsidence at 11 to 16 years 22.0%, uncertain 25.0%, < 1mm 36.36%, 1-2 mm in 52.2%, 3-4mm in 70.0%, 5-7mm 71.4%, 8-10mm in 25.0% and more than 10mm is 100%.

Piers et al (45) had reported 5 hips with cortical hypertrophy 3 in zone 5, 1 in zone 6 and 1 in zone 2. They also emphasised that distal cortical hypertrophy was present in only in hips with cement mantle defects but no cement mantle fractures were noted.

SUBSIDENCE OF FEMORAL STEM:

The mean subsidence in our study is 1.19mm with maximum of 2.98mm and minimum of 0.30mm.

The Exeter universal femoral component study byH.D.Williams(41) the subsidence was measured by Fowlers method in zone I region or distance between the stem tip and the centraliser in 196 hips. The mean subsidence was 1.38mm, taking revision as endpoint for survivorship , the survivorship of femoral stem was 100%.

Exeter stems are designed such a way that on axial loading over time should produce a compressive force which is transmitted equally from proximal to distal thereby producing a distal movement in the cement without disrupting the cement bone interface. Stem acts like a wedge due to viscoelastic nature of cement and settles in a tight fit relationship within the cement mantle. With cyclic loading the cement is stronger in compression and weaker in relaxation thereby subsidence reaches a plateau and prosthesis becomes more stable.

In a comparative study by Eugene Ek(36) between Exeter and C stem subsidence was noted. Early subsidence in Exeter group was 0.40mm per year. This was a radiosterometric analysis which shows migration occurs early and continues to migrate to attain a stable position. The average subsidence in this study was 0.92mm (range 0.5mm to 1.4mm). No stem was at the risk of aseptic loosening needing revision.

Subsidence of stem is based stem design. Collarless tapered stems are desiged to subside whereas collared shape closed stems are bound to fix rigid with cement. Subsidence varies with design from design to design, the mean subsidence for loaded taper was 0.9mm to 1.4mm and retroversion was 0.4mm to 0.5mm whereas for composite beam stem initial migration 0.1mm to 0.5mm and some tend to migrate retroversion 0.28mm to 0.8mm.

Various studies shows that early subsidence rates have been used to predict stem failure. However, in such studies, stem migration is measured as the overall movement of the stem in relation to bone. Therefore, a distinction must be made between early subsidence within the cement mantle, which is advantageous in a tapered prosthesis, and movement between the cement and bone, which is associated with implant failure.

Radiostereometric analysis (RSA) is the gold standard for measuring implant migration. This technique involves the implantation of tantalum marker beads into the bone around the prosthesis. Migration is measured using 2 radiographs of the hip taken simultaneously at different angles, with the subject placed in front of a specialized calibration cage. The relative positions of the implant, bone, and cage markers are analysed using sophisticated software to give a 3-dimensional migration measurement. Although RSA is accurate and precise, it requires specialized equipment, is time consuming, and can be used only prospectively in subjects with marker beads.

Several simple methods have been described for measuring migration directly from plain radiographs without specialized equipment. These measurements can be applied retrospectively but give a 2-dimensional representation of migration and can be subject to large errors. Inaccuracy and poor precision of direct plain radiographic measurements may arise because of pre-analytical or analytical errors. Pre-analytical errors include variations in patient positioning and rotation, film centering, and focus-to-film distance between radiographs, resulting in factitious migration measurements. Analytical errors include interobserver variation and experience. Inaccurate pencil marking and the limited resolution of a hand-held ruler also may be sources of analytical variability.

Many sophisticated computerized techniques have been developed for measuring migration from routine radiographs with the aim of improving precision and accuracy. Use of digitized radiographs and specialized analysis software also improve precision.

The EBRA(24) study for migration suggests that measures taken to optimize radiographic standardization in the clinical setting, where time taken, cost, repeated radiographic exposure, and the frequent change of radiographic staff are important issues, may be limited. As such, the direction for improving the utility of migration measurements made from plain radiographs may be directed more effectively toward improvement in the analysis of routine radiographs using digital technology, appropriate measurement landmarks and by excluding non-comparable radiographs.

RADIOLUCENCIES:

The definition of radiolucency is explained as Kobayashi et al(15),as the radiolucency adjacent to sclerotic line. More over,the radiolucent line seen in cement bone interface is more important than radiolucency seen in stem cement interface.

In a study by H.D.Williams(41) the Exeter universal cemented femoral component a study of first 325 hips the survivorship analysis of femoral component with revision for aseptic loosening was 100%, for acetabulum with revision as endpoint 96.86% and reoperation for various reasons was 91.74%.

In a study by Ek Et et al radiolucency was noted in cement stem interface in zone I. Zone I radiolucency mainly explains the subsidence of the stem rather than loosening. Most of stems had loosening in zone 1 and zone 7 region but none were in the risk of loosening needing revision.

Correlation between cement mantle and Gruen's loosening zone :

In a study by M.A Ritter et al radiological factors influencing femoral and acetabulum failures, 185 hips were analysed with mean follow up of 11.5 years. All the hips were analysed periodically to see the changes in zones. 15 femoral stems were loose of which 10 was revised and the mean time for revision was 11.3 years. On step wise logistic correlation analysis for single variable or a combination variable i.e with orientation of stem and cement mantle none were related.

In our study on correlating cement thickness and Gruen's loosening zones there was significance when the cement mantle was lesser than 2mm. Our correlation might not be statistically significance as our sample size is less .

CONCLUSION

1. In our study of 47 hips we had excellent - 65.96% ; Good- 21.28% ; Fair – 8.51% and poor- 4.26% results.

2. There were no cases of femoral stem loosening (0%) and 1 case (2.1%) ofacetabular cup loosening.

3. There was significant correlation between cement thickness and Gruen's loosening zones.

4. There was no significant correlation between cement thickness and proximal femoral resorption.

5. There was no significant correlation between cementing technique and proximal femoral resorption.

6. There was no significant correlation between cementing technique and Gruen's loosening zones.

7. There was no significant correlation between orientation of stem with proximal femoral resorption.

8. There was no significant correlation between orientation of stem with Gruens loosening zones.

9. Second generation of cementing technique produced 82.92% grade A; 14.89% grade B; 0% in grade C and 2.13% grade D which also did not have a correlation with stem revision.

LIMITATIONS OF STUDY

1. Most of our patients are from North India. Hence a periodic follow up was not possible.
2. Study was done in a small set of patients who responded to our call letter. Hence the functional outcome may not be a representative of entire group of patients.
3. Analysis of changes in the cement bone interface and stem cement interface with serial x-rays in regular periodic interval is necessary to predict the future of implant.
4. Our method of measuring the subsidence may not be as accurate as radio-stereo metric analysis which is gold standard.

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ANNEXURE

INFORMED CONSENT

Christian Medical College, Vellore
Department of Orthopedics

A retrospective analysis of clinical and radiological outcome in Exeter total hip arthroplasty

Information sheet

You are being requested to participate in a study to evaluate the clinical and radiological outcome in Exeter cemented total hip arthroplasty. The implant is supposed to provide a good functional outcome by achieving subsidence within the cement mantle. However there are concerns about aseptic loosening leading to implant failure, which leads us to analyse the factors leading to loosening and analyse the safe level of subsidence.

What does a cemented Exeter total hip arthroplasty provide?

Exeter is a double tapered polished stem which is fixed to the femur with bone cement. It provides early mobilization and longterm stability. Here bone cement used does not act like a glue to anchor the implant instead it acts like a grout where implant is seated in stable position.

Do Exeter total hip arthroplasty have any problems?

Many surgeons all over the world have done Exeter total hip arthroplasty and it has become a standard implant for cemented total hip arthroplasty. The problems are similar as of any cemented total hip arthroplasty is aseptic looseing.

If you take part what will you have to do?

If you agree to participate in this study, you will have to come over to Vellore and undergo clinical examination and xrays. You will be given few questionnaires, relating to the present health and activity, which you should answer. An x-ray of the pelvis with both the hips and the lateral view of the operated hip +/- frog leg view will be done free of cost.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you.

you have to pay for the investigations?

As this visit forms part of your follow-up check-ups, you have to pay on your own for OPD registration, the cost of x-rays will be free.

What happens after the study is over?

You may or may not benefit from the study that is done. Once the study is over, if any intervention is required for you, all efforts would be made towards it .You may be informed the results of the study.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, people associated with the study, without your additional permission, should you decide to participate in this study, may review your medical notes and data and xrays obtained may be used for further studies.

If you have any further questions, please ask Dr.A.Arun shankar, (tel: 0416-2282091: Cell 9842098033) or email: drarunshankar11@gmail.com

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: *Retrospective analysis of clinical and radiological outcomes in Exeter cemented total hip arthroplasty from 2000 to 2010.*

Study Number:
Participant's name:
Date of Birth / Age (in years):

I_____
_____, son /daughter of _____

declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]
I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights. [ ]
I also understand that during the period of the study, the investigations done should be paid by me except the special tests mentioned in the information sheet. [ ]
I understand that I will receive free treatment for any study related injury or adverse event, if any [rare], but I will not receive any other financial compensation. [ ]
I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access.
I understand that my identity will not be revealed in any information released to third parties or published. [ ]
I also understand that the study data and material obtained from me may be used in future studies. [ ]
I voluntarily agree to take part in this study. [ ]

_____

Signature of study participant/thumb impression:

Name of study participant:_____
Date:_____

Signature of impartial witness:

Name of impartial witness: :_____
Date:

Signature of principal investigator:

Name of principal investigator: Dr.A.Arun Shankar.
Date:

கிறிஸ்டியன் மருத்துவக் கல்லூரி - வேலூர்

சிமெண்ட் உபயோகிகப்பட்ட எக்சிடர் மூட்டு மாற்று அறுவை சிகிச்சைக்கான ஆய்வு 2000 – 2010

தகவலறிக்கை

அன்புடையீர்,

தாங்கள் சிமெண்ட் உபயோகிக்கப்பட்ட Exeter இருப்புமூட்டு மாற்று அறுவைசிகிச்சை செய்து கொண்டதால் தங்களை அதற்கான ஆய்வில் கலந்து கொள்ள அழைக்கிறோம். இந்த ஆய்வில் மேற்குறிப்பிட்ட அறுவைச் சிகிச்சையின் பலன்கள், மற்றும் பிரச்சனைகள் பற்றி ஆய்வு செய்யப்படுகிறது. இந்த அறுவைசிகிச்சையின் நோக்கமானது விரைவாகவும், எளிதாகவும் நடப்பதற்கும், நீண்டநாள் பயன்படுத்தவதற்கே ஆகும். ஆனால் இது மற்ற மூட்டு மாற்று அறுவைசிகிச்சைபோல் தானாகவே இலகும் தன்மை அடையக்கூடிய வாய்ப்பு உள்ளது. இந்த ஆய்வின் நோக்கமானது அறுவைச்சிகிச்சை முடிந்து நிண்ட நாள் கழித்து இடுப்பு மூட்டிலும் சிமெண்ட் மற்றும் Exeter மூட்டு மாற்றுக்கருவிகளில் ஏற்படும் மாற்றங்களைக் கண்டறிவதே ஆகும்.

சிமெண்ட் உபயோகிக்கப்பட்ட Exeter இடுப்பு மூட்டு மாற்று அறுவைச் சிகிச்சையின் பயன்கள் என்ன?

Exeter கருவி இருபுறம் சன்னமாகவும், பளபளப்பாகவும் இருக்கும். இது எலும்பு மஜ்ஜைக்குள் பொருத்துவதற்கு எலும்பு சிமெண்ட் உபயோகிக்கப்படுகிறது. எலும்பு சிமெண்ட் ஆனது Exeter கருவியை எலும்புடன் இணைப்பதற்குப் பசைபோல் விளங்காமல் ஒரு அச்சாக விளங்குகிறது. ஆகவே நோயாளி நடக்கும்போது Exeter கருவி எலும்பு சிமெண்டிற்கு நகர்ந்து தன்னிலை அடைந்து வலிமை மிக்கதாகவும் நீண்ட நாள் பயன்படும்படி அமைகிறது.

சிமெண்ட் உபயோகிக்கப்பட்ட Exeter இடுப்பு மூட்டு மாற்று அறுவைச் சிகிச்சையின் பின் விளைவுகள் என்ன?

இது மற்ற மூட்டு மாற்று அறுவைச் சிகிச்சைபோல் தானாகவே இலகும் தன்மை உள்ளது.

ஆய்வில் பங்குபெற தாங்கள் செய்ய வேண்டியவை என்ன?

தாங்கள் இந்த ஆய்வில் கலந்துகொள்ள விருப்பப்பட்டால் தாங்கள் நேரில் சி.எம்.சி மருத்துவமனைக்கு வந்து மருத்துவ மற்றும் "எக்ஸ்ரே" ஆய்விற்குத் தங்களை ஆட்படுத்திக் கொள்ள வேண்டும். அந்த சமயத்தில் தங்களிடம் வழங்கப்படும் படிவத்திலுள்ள தங்களின் உடல்நிலை மற்றும் செயல்திறன் குறித்து கேட்கப்பட்டுள்ள கேள்விகளுக்குப் பதில் எழுதித்தர வேண்டும். ஆய்வின்போது எடுக்கப்படும் "எக்ஸ்ரேக்கள்" இலவசமாக எடுத்துத்தரப்படும்.

ஆய்வு தொடங்கிய பிறகு அதிலிருந்து தாங்கள் விலகிக்ககொள்ள முடியுமா?

ஆய்வு என்பது முற்றிலும் சேவை மனப்பான்மையில் உதவும் நோக்கத்தில் மேற்கொள்ள உள்ளதால் தாங்கள் எப்போது வேண்டுமானாலும் விலகிக் கொள்ளலாம். அவ்வாறு விலகிக்கொள்வதால் தங்களுக்கு இந்த மருத்துவமனையில் வழங்கிக் கொண்டிருக்கும் வேறுவித சிகிச்சைகள் எவ்விதத்திலும் பாதிக்கப்படாது.

ஆய்வின் போது ஏதாவது பாதிப்ப ஏற்பட்டால் என்ன உதவி கிடைக்கும்?

இந்த ஆய்வில் எவ்வித பக்கவிளைகளோ, பாதிப்புகளோ ஏற்பட வாய்ப்பில்லை.

ஆய்விற்கு ஏதாவது தொகை செலுத்த வேண்டுமா?

தாங்கள் மேற்கொண்ட அறுவை சிகிச்சைக்கு வருடம் ஒருமுறை பரிசோதனை செய்துகொள்ள வேண்டியிருப்பதால் மருத்தவமனை பதிவுத் தொகை மட்டுமே செலுத்தினால் போதும் இந்த ஆய்விற்கென்று தனியாக தொகை செலுத்த வேண்டிய தேவையில்லை.

ஆய்வின் முடிவில் என்ன நடக்கும்?

ஆய்வு முடிவு தங்களுக்கு நேர்முகமாகவும் மறைமுகமாகவும் பயன்படலாம் அல்லது பயன்படாமலும் இருக்கலாம். ஆனால் முடிவில் தங்களுக்கு ஏதேனும் பிரச்சனைகள் இருப்பதை கண்டறிந்தால் சரி செய்ய வேண்டிய நிலை இருப்பின், அதற்கான சிகிச்சை மூலம் சரிசெய்ய அனைத்து முயற்சிகளும் மேற்கொள்ளப்படும். ஆய்வு முடிவுகள் தங்களுக்கு உரியமுறையில் தெரிவிக்கப்படும்.

ஆய்வின் முடிவுகள் ரகசியமாக வைக்கப்படுமா?

மருத்தவம் குறித்து நடைபெறுகிற மாநாடுகள், கூட்டங்கள் மற்றும் மருத்துவம் குறித்து நடைபெறும் பதிப்புகள் போன்றவற்றில் தங்களின் பெயரோ, தங்கள் குறித்த வேறு அடையாளங்களோ தெரியா வண்ணம் ஆய்வு அறிக்கை மட்டும் வெளியிடப்படும். மேலும் தொடர்ந்து இந்த ஆய்வு மெற்கொள்ளப்படுமாயின் அந்த சமயங்களில் தங்களின் அனுமதியின்றி தங்களிடம் சேகரிக்கப்பட்ட மருத்துவ ஆய்வு அறிக்கைகள் மற்றும் "எக்ஸ்ரே" போன்ற ஆவணங்கள் பயன்படுத்திக் கொள்ளப்படும்.

இந்த ஆய்வு குறித்து மேலும் விவரங்கள் பெற டாக்டர் அ.அருண்சங்கர் (தொலைபேசி 0416 – 2286091) (கைபேசி 9842098033) அவர்களை தொடர்பு கொள்ளவும்.

கிறிஸ்டியன் மருத்துவக் கல்லூரி - வேலூர்
சிமெண்ட் உபயோகிக்கப்பட்ட எக்சிடர் மூட்டு மாற்று அறுவை சிகிச்சைக்கான ஆய்வு 2000 – 2010

ஆய்விற்கான ஒப்புதல் வாக்குமூலம்

பெயர் :

பிறந்த தேதி :

வயது :

நான் _____ த/பெ _____

மேற்குறிப்பிட்ட தகவலறிக்கை படித்து என்னுடைய சந்தேகங்களை கேட்டு அறிந்து கொண்டேன்.

இந்த ஆய்வில் என்னை முழு மனதுடன் ஈடுபடுத்திக் கொள்ள விரும்புகிறேன். அதேபோல் எந்த நேரத்திலும் இந்த ஆய்விலிருந்து விலக்கிக் கொள்ள உரிமை உள்ளது என்பதையும் நான் அறிந்து கொண்டேன். அதனால் எனக்கு தேவைப்படும் சிகிச்சைகள் பாதிக்கப்படாது என்பதையும் அறிந்து கொண்டேன்.

இந்த ஆய்வில் எக்ஸ்ரே தவிர மீதமுள்ள அனைத்து பரிசோதனைகளும் சொந்த செல்வில் செய்து கொள்ள வேண்டும் என்பதை அறிந்து கொண்டேன்.

இந்த ஆய்வினால் ஏற்படும் பின் விளைவுகளுக்கு இலவசமாக சிகிச்சை அளிக்கப்படும் ஆனால் அதற்கு ஈடாக பணமாக பெற முடியாது என்பதை அறிந்து கொண்டேன்.

மேலும் இந்த அய்விலிருந்து நான் விலகிக்க கொண்டாலும் அய்வு செய்பவர்களும், கல்லூரியின் Ethics Committeeயும் என்னுடைய ஆய்வின் அறிக்கைகளை என்னுடைய அனுமதியின்றி பயன்படுத்திக் கொள்ளலாம் என்று அறிகிறேன்.

என்னுடைய பெயரோ மற்ற அடையளாங்களோ வெளிடப்படாது என்பதையும் அறிந்து கொண்டேன்.

இந்த அய்வின் தகவல்கள் மற்றும் முடிவுகள் பிற்காலத்திலும் என்னுடைய அனுமதியின்றி பயன்படுத்திக் கொள்ளப்படும் என்பதை அறிகிறேன்.

இந்த ஆய்வில் என்னை முழு மனதாக ஈடுபடுத்திக் கொள்ள விரும்புகிறேன்.

ஆய்வில் கலந்து கொள்பவரின் கையொப்பம் / கைவிரல் ரேகை

ஆய்வில் கலந்து கொள்பவரின் பெயர்

சாட்சி கையொப்பம்

ஆய்வு செய்பவரின் கையொப்பம்

ஆய்வு செய்பவர் பெயர் : டாக்டர். அருணசங்கர்

தேதி :

सूचित सहमति पत्र

क्रिश्चियन मेडिकल कॉलेज, वेल्लोर

हड्डी रोग विभाग

एक विश्लेषण क्लीनिकल और रेडियोलॉजिकल परिणाम एक्सेटर हिप आरथ्रोप्लास्टि का

सूचना पत्र

आपको पूछा जा रहा है कि एक्सेटर हिप आरथ्रोप्लास्टि के परिणाम का मूल्यांकन करने के लिए इस अध्ययन में कहा जा रहा है। इस इम्प्लान्ट से आपको लाभ करने के लिए और अच्छा परिणाम प्रदान कर सकता है, परन्तु क्या यह ढीला होगा जिसके कारण इम्प्लान्ट विफल हो सकता है, अगर ढीला होता है तो उसका कारण क्या है, इस बारे में यह खोज कर रहे हैं,

यह एक्सेटर हिप आरथ्रोप्लास्टि क्या प्रदान करता है

एक्सेटर एक पतला, ऊबल, पॉलिश स्टेम है जो कि फीमर हड्डी में हड्डी सीमेंट

के साथ जुड़ा हुआ है, यह आपको जल्दी उठने बैठने में और ज्यादा समय स्थिरता देगा। यहाँ इस्तमाल किया जाता हड्डी सीमेंट गोंद की तरह नहीं परन्तु "ग्राउट" की तरह काम करता है जो कि इम्पलान्ट को स्थिरता प्रदान करता है।

एक्सेटर हिप आरथरोप्लास्टि करने में कोई समस्या है क्या?

दुनिया भर में बहुत सर्जनों ने एक्सेटर हिप आरथरोप्लास्टि किया है और यह सब जगह एक ही तरह उपयोग में लाया जा रहा है, किसी भी प्रकार के हिप आरथरोप्लास्टि में एक समस्या है इम्पलान्ट ढीला होना जो यहाँ भी हो सकता है।

अगर आप अध्ययन में भाग लेने की सहमति देते हैं तो क्या करना होगा?

आपको वेल्लोर आना होगा, आपका जाँच और 'एक्सरे' किया जायेगा। आपके वर्तमान

स्वास्थ्य और गतिविधि से संबंधित कुछ प्रश्नों का जवाब देना होगा। आपके हिप का एक एक्सरे लेनी जाएगा बिना पैसे, फ्री, में किया जाएगा।

क्या आप अध्ययन शुरू होने के बाद पीछे हट सकते हैं क्या?

इस अध्ययन में आपकी भागीदारी पूरी तरह स्वैच्छिक है और आप किसी भी समय भाग न लेने का भी फैसला कर सकते हैं, यदि आप ऐसा करते हैं तो भी आपका उपचार इस अस्पताल में किसी भी तरह प्रभावित नहीं होगा।

अगर आपको अध्ययन के समय कुछ चोट पहुँची तो क्या होगा?

हमें पूरा विश्वास है कि आपको कोई चोट नहीं पहुँचेगी परन्तु अगर कोई साइड इफेक्ट या चोट होती है तो आपका इलाज यहाँ बिना पैसे के किया जाएगा।

क्या आपको जाँच कराने के लिए रुपया देना होगा

आपके ओपीडी रजिस्ट्रेशन के लिए आपको साधारण रूप से जो फीस है उसे देना होगा। एक्स-रे के लिए कुछ नहीं देना होगा,

अध्ययन समाप्त होने के बाद क्या होगा?

इस अध्ययन से आपको लाभ हो और नहीं भी सकता है, अध्ययन के बाद भी आपको ब्लड चाहिए तो यहीं पर किया जाएगा साधारण रूप में, इस अध्ययन के परिणाम के बारे में भी बताया जाएगा,

आपकी व्यक्तिगत जानकारी गोपनीय रखी जाएगी।

इस अध्ययन के परिणाम एक मेडिकल जर्नल में प्रकाशित किया जाएगा, पर आपका नाम या पहचान कहीं पर नहीं दिया जाएगा, इस अध्ययन में आगे से अध्ययन संबंधित लोग शायद आपके अस्पताल चिकित्सा नोट्स या रिकॉर्ड देख सकते हैं, एक्स-रे भी भविष्य में कोई अध्ययन के लिए,

आपको किसी प्रकार का प्रश्न हो तो पूछ सकते हैं, ईमेल- drarunshankar 11@gmail.com, या Dr. A. Arun Shankar टेलिफोन नंबर (0416-2282091, 9842098033)

सहमति पत्र

अध्ययन का नाम : एक विश्लेषण क्लीनिकल और रेडियोलॉजिकल परिणाम एम्सेट्र डिम आरथ्रोप्लास्टि में, वर्ष 2000 से 2010 तक

अध्ययन नम्बर :

भागीदार नाम :

जन्म तिथि / उम्र

मैं _____, जो कि _____

_____ के बेटा / बेटी हूँ

घोषणा करता हूँ कि मैंने सूचना पत्र में और मैंने आपसे संदेह स्पष्ट किया है। [ ]

आप समझते हैं कि भागीदारी पूरी तरह स्वैच्छिक है आप किसी भी समय भागीदारी न लेने का निर्णय ले सकते हैं, भाग लेने या न लेने से आपका इस संस्थान में इलाज या कानूनी अधिकार में कोई प्रभाव नहीं होगा। [ ]

इस अध्ययन के दौरान साधारण जांच के लिए आपको पैरामेन्ट करना है सिर्फ सूचना पत्र में बताये गये जाँच का पेरामन्ट नहीं करना है। [ ]

मैं समझता हूँ कि अध्ययन संबंधित कोई चोट पहुँचे
के या प्रतिकूल घटना होने पर निःशुल्क इलाज
प्राप्त होगा, परन्तु किसी भी प्रकार का पैसा
नहीं दिया जाएगा। [ ]

मैं समझता हूँ कि परिक्षण के स्टाफ और संस्थान
के अभीष्ट सदस्य मेरा अस्पताल रिकॉर्ड या
नोट्स देख सकते हैं, इसके लिए मेरे अनुमति
की जरूरत नहीं है, मेरी पहचान या मेरा नाम
किसी को नहीं बताया जाएगा। [ ]

मैं समझता हूँ कि अध्ययन संबंधित रिकॉर्ड
भविष्य अध्ययन में भी प्रयोग किया जाएगा। [ ]

मैं इस अध्ययन में भाग लेने का फैसला
कर रहा हूँ जो कि स्वैच्छिक है। [ ]

भागीदार हस्ताक्षर :

भागीदार का नाम : _____

दिनांक :

निष्पक्षगवाह का हस्ताक्षर :

निष्पक्षगवाह का नाम : _____

दिनांक

प्रमुख अन्वेषकर्ता का नाम एवं हस्ताक्षर :

प्रमुख अन्वेषकर्ता नाम :

दिनांक .

uidno	age	sex	ds	fs	sd	ds1	hs	cf	ct	pfr	os	sb6	sb1	sb2	sbl	gz	sgz	cp	
1	36	1	23/10/2007	76	1	2	3	2	4	3	1					2.81	3 1,4,7		
2	54	1	02/11/2006	85	2	2	3	1	3	1	1	1.52		1.56		1.61	2 6,7		
3	58	2	24/01/2006	96	2	1	3	1	3	1	1		0.78			0.81	2 6,7		
4	30	1	14/12/2006	90	1	4	3	1	3	1	1		0.98			1.07	2 1,7		
5	53	2	29/03/2005	111	2	7	2	1	3	1	1		0.54			0.84	6		
6	62	2	30/08/2007	80	2	6	0	4	1	1	1	0.48	0.69			0.72	3 3,4,5		
7	51	1	18/03/2008	72	2	3	2	1	3	1	1	0.29	0.68			1.04	6		
8	37	1	17/03/2005	111	2	1	3	1	3	1	1		0.59	0.59		0.86	1 1		
9	37	1	14/09/2010	43	1	3	3	1	4	1	1					0.3	3 1,3,4		
10	49	1	18/09/2004	82	1	3	2	1	3	1	1		1.66	2.65		2.89	1 1		
11	61	1	26/01/2005	115	2	1	3	1	3	1	1	2.18	2.24			2.44	6		
12	26	2	02/11/2010	45	1	7	3	1	4	1	1					0.96			
13	55	1	06/04/2006	96	2	3	3	1	4	1	1		1.24	1.28		1.68	6		
14	29	2	31/07/2007	94	2	4	3	1	2	1	1	0.43	0.6	0.62		0.62	6		
15	49	2	13/05/2008	57	1	1	3	1	3	1	1		0.87	0.89		1.08	6		
16	50	1	26/10/2006	94	2	3	2	1	3	1	1					0.58	1 1		5
17	37	1	13/09/2007	72	1	5	3	1	4	1	1	0.96		1.52			6		
18	43	2	02/02/2006	87	2	1	3	1	2	1	1		0.62			0.84	6		
19	56	1	15/07/2003	121	1	6	1	2	4	1	1								
20	46	1	01/07/2003	135	2	7	2	1	4	1	1		0.36	0.84		0.92	6		
21	70	1	01/04/2005	123	1	2	2	1	3	1	1	0.9		0.94		1.08	2 5,6		
22	42	1	29/02/2004	126	1	6	3	1	4	1	1	0.94	0.94			1.48	6		
23	51	1	17/04/2007	89	2	2	3	1	4	1	1	0.73	0.84			0.92	6		
24	35	2	11/04/2006	72	2	3	3	1	2	1	1	0.79				1.07	6		
25	60	2	25/10/2005	62	1	1	1	1	2	1	1		0.5			0.5	6		
26	31	1	21/02/2006	63	2	6	2	2	2	1	1	0.74		1.32		1.34	6		
27	54	2	26/10/2010	36	2	3	3	1	3	1	1			0.73		1.11	6		
28	24	1	12/10/2010	45	2	6	3	1	3	1	1		0.81	0.93		1.01	1 1		
29	49	1	08/01/2008	67	2	1	3	2	3	1	1	0.84	0.86			1.06	2 1,2		
30	41	1	05/05/2008	75	1	6	1	2	4	1	1	0.58	0.6			0.68	1 1		
31	36	2	04/03/2008	77	1	1	3	1	2	1	1					0.9	1 1		
32	76	2	08/11/2007	80	1	2	3	1	2	1	1	0.46		0.53		0.79	1 4		1
33	46	1	03/06/2008	66	1	6	3	1	3	1	1	0.75				0.98	2 1,2		
34	63	2	01/06/2003	128	1	3	3	1	4	2	1	1				1.02			
35	18	1	01/03/2007	52	1	3	3	1	2	1	1	0.56				1.39	6		
36	42	2	18/12/2004	108	1	1	2	1	2	1	1		0.58	1.32		1.54	1 1		

s2	ds2	fs1	ds3	hs1	cf1	ct1	pfr1	os1	sb	sb7	sb3	sb4	sbl1	gz1	sgz1	cp1
1	13/02/2007	84	1	3	1	2	1	4			0.84			0.86	2 3,4	
1	11/10/2005	105	7	2	1	3	1	1			1.21			1.31	3 2,5,7	
1	04/01/2009	63	6	0	2	2	2	1			1.62			1.74	3 1,3,5	
1	08/01/2008	64	4	3	1	3	1	1	0.45	0.64			0.78			
2	15/07/2003	121	6	1	2	4	1	1								
1	01/03/2004	125	7	2	1	4	1	1	1.18	2.08	2.24			2.98	6	
2	13/02/2008	79	6	3	1	2	1	1		0.12				0.45	6	
1	11/04/2006	72	3	3	1	2	1	1		1.28				1.7	6	
1	26/01/2010	36	3	3	1	2	1	1					0.86	1.37	6	
2	03/06/2008	66	6	3	1	3	1	1	1.03					1.25	1 1	
2	20/11/2003	123	3	3	1	3	1	1		0.7				0.85	6	