Chapter 1

**Introduction and Review of Literature**

**1.1 Introduction**

Total Hip Arthroplasty (THA) or hip replacement is a standard surgical reconstruction

procedure that offers relief from pain and restoration of hip joint functions for patients

suffering from osteoarthritis (arthrosis), rheumatoid arthritis, congenital deformities or

post-traumatic disorders. The working principle of hip joint is similar to that of a

typical ball-and-socket joint, wherein the head of the femur rotates with respect to the

acetabulum. In a standard hip replacement procedure, the proximal part of the femur

is replaced by an implant, consisting of a femoral stem and a modular head, whereas

on the acetabular side, a hemi-spherical cup is attached to the socket of the pelvic

bone. Based on the fixation technique, THA can be broadly classified as cemented

and cementless arthroplasties. In cemented fixation, the implant is made to adhere to

the bone using bone-cement, whereas the implant-bone fixation in cementless

prosthesis is attained through bone ingrowth into the porous-coated or fibre-meshed

surface on the implant. Although both the techniques have their own advantages and

disadvantages, the cementless THA is being increasingly preferred by surgeons owing

to its more natural (biologic) fixation with bone (Yamada *et al.*, 2009).

The past few decades have seen an exceptional growth of hip procedures

globally. Each year, over 800,000 THA operations are performed all over the world

(Fraldi *et al.*, 2009). From 1967 to 2013, the total number of primary total hip

replacements (THRs) in Sweden has skyrocketed from a humble 6 operations to a

whopping 16,330 incidences (Swedish Hip Arthroplasty Register, Annual Report

2013). More than 285,000 THAs are performed each year in the United States

(Source: Agency for Healthcare Research and Quality, U.S.A.) and the number of

annual hip fractures in the country has been projected to surpass 500,000 annually by

the year 2040 (Cummings *et al.*, 1990). The number of hip procedures in Australia

has increased by 46.50% since 2003, and it is further anticipated that the rate of

increase will continue in future (National Joint Replacement Registry, Annual Report

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2014). Between the years 2003 and 2013, a total of 620,400 primary hip replacements

were reported in the 11th Annual Report of National Joint Registry for England and

Wales (2014), while osteoarthritis accounted for the majority (93%) of the cases. The

registry also reported an increase in the use of cementless implants from 16.8% to

42.5% over the same period, and corresponding decrease in the use of cemented

counterparts from 60.5% to 33.2%. In India, the annual incidence rate of the surgery

is approximately 470,000 (Source: The American national Institute of Arthritis and

Musculoskeletal and Skin Diseases). However, in a country of over 1.2 billion people,

the yearly rate of incidences is postulated to rise (Pachore *et al.*, 2013). Furthermore,

according to the report, 65% of the THAs in India were performed using cementless

prostheses. In the United States, 60% to 90% of the THAs performed yearly involve

both cementless cup and cementless stem (Dunbar, 2009; Lombardi *et al.*, 2009).

The immense success of THA notwithstanding, the failure rate is estimated to be

10% globally (Mancuso *et al.*, 1997; Kurtz *et al.*, 2007), and with the recent rise in

incidences, there has been a significant increase in the absolute number of failed joints

(Taylor and Prendergast, 2015). The principal measure of outcome of a THA is time

to first revision surgery. Ahnfelt *et al.* (1990) reported that the failed 10% hip

replacements need revision surgery after a mean duration of 10 years in use,

depending on the patient’s conditions, disorder and the type of implants used.

Although these failures have been due to multifactorial reasons, the majority may be

attributed to the biomechanical causes. Implant-induced adverse bone remodelling

and excessive implant-bone interface stresses, leading to progressive interface

debonding, are two major biomechanical failure mechanisms that may compromise

the durability of cementless hip prostheses. Amongst the short-term failure

mechanisms, lack of primary stability due to excessive interfacial micromotion

strongly influences the success of cementless arthroplasties by compromising the

biologic attachment between the implant and femur. Cumulative or individual effect

of all of these mechanisms may lead to gross aseptic loosening of the implant or in

extreme cases, femur fracture. Besides key aspects, such as surgical procedure and

patient conditions, the design (or geometry) of the femoral implant is also known to

affect these mechanisms (Huiskes and Boeklagen, 1988; Viceconti *et al.*, 2001).

Although a vast variety of cementless femoral implants are commercially available in

the market (Fig. 1.1), for many of them the design outcomes remain unexplored

primarily due to lack of clinical data. The mechanical designs of hip implant,

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therefore, may be assessed preclinically and search for optimal geometry may be

conducted in order to minimize the effects of all these failure mechanisms.

The design solutions of a prosthesis may be either structural or functional, or

both. However, investigations have centered mostly around the structural aspects of a

prosthesis. Among various structural aspects of hip prosthesis, the geometry of the

femoral implant plays a critical role in determining the design outcome. Although the

gross appearance of a femoral stem has hardly changed much since it was first

mentioned (Gluck, 1891), the overall non-primitive shape offers a lot of scope for

intricate study by altering the profile of stem transverse sections along the stem-length

using the state-of-the-art solid modelling and finite element (FE) analysis software.

Moreover, with the advent of modern day high-performance computers, a large

number of stem shapes may be assessed in a relatively small amount of time and the

most suitable one may be chosen based on its predicted design outcomes. Therefore, a

suitable design optimization strategy in combination with a solid modelling and FE

analysis may lead to a more improved prosthesis design.

Shape (or geometry) optimization is a particular stage of structural optimization,

which deals with the search of the optimal configuration of a design domain

(Fraternali *et al.*, 2011). In shape optimization, design variables are introduced to

control the geometry of the structure and the methodology typically requires an FE

model that changes during the course of the optimization. The growing interest in

shape optimization reflects a realization of the effectiveness of shape changes for

improving structural performance. By employing shape optimization as a design tool,

stem geometries can be evaluated based on biomechanical cost functions, framed on

the basis of the failure principles. Therefore, the formulation of suitable cost

functions, representing the global effects of these failure mechanisms is necessary in

order to search for optimal designs of the cementless femoral implant that would

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**Fig. 1.1**: Variations in design of cementless femoral implants

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enhance prosthesis durability. However, for *a priori* and practical understanding of

the failure scenarios associated with THA, a study on the biomechanics of hip joint is

required.

**1.2 Anatomy and biomechanics of hip joint**

**1.2.1 Anatomical planes and directions**

Biomechanics of the hip joint constitutes a basic understanding of the human

anatomy. Typical orientations of different anatomical planes of the human body are

presented in the Fig. 1.2a. The transverse (axial or horizontal) plane, which is parallel

to the ground, separates the superior (top) from the inferior (bottom) part of the

human body. The coronal (frontal) plane, perpendicular to the ground, separates the

anterior (front) from the posterior (back). The sagittal (median) plane is perpendicular

to both the transverse and coronal plane, and it separates the left from the right part of

the body. The direction towards and away from the midline of the body are termed as

the ‘medial’ and ‘lateral’ direction, respectively (Fig. 1.2b). The ‘anterior’ and

‘posterior’ directions are direction towards the front and the back side of the body,

respectively. The term ‘proximal’ is used to describe the direction towards the limbs

origin, while the part away from the origin of the limbs is termed as the ‘distal’. This

clinical definition is done based on their proximity with respect to the head. The

‘superior’ and ‘inferior’ directions indicate the top and the bottom parts of the body,

respectively.

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Superior

Abduction Adduction

Internal Rotation

External Rotation

**Transverse Transverse**

Medial Lateral

Inferior Midline of the body

(a)

(b)

**Fig. 1.2:** Sketch showing (a) the anatomical planes of reference and (b) anatomical directions and movements of the hip joint (Martini and Bartholomew, 2000).

Flexion Extension

Anterior Posterior

Proximal

Distal

**1.2.2 Hip anatomy**

The primary connection between the bones of the lower and upper limbs of the human

skeletal system is formed by the hip joint, scientifically referred to as the

*acetabulofemoral joint*. The hip-joint supports the body weight and transfers load

from upper limb to the lower limb. The main parts that constitute this joint are a ball

(femoral head) and a hemi-spherical socket (acetabulum) (Fig. 1.3). The femoral head

is situated at the top of the

thighbone (femur) and it fits into

the acetabulum in the pelvis by

means of bands of tissue called

ligaments (hip capsule). The

ligaments provide stability to the

joint. A smooth durable cover of

articular cartilage (a protein

substance) cushions the ends of

the bones between the two bones’

surfaces (femoral head and

**Fig. 1.3:** Natural hip-joint *(http://www.ouh.nhs.uk/hipandknee/information/hip/*)

acetabulum), and enables them to move easily. All remaining surfaces of the hip joint

are covered by a thin, smooth tissue called the synovial membrane. In a healthy hip,

this membrane generates a small amount of fluid that lubricates and alleviates

frictional resistance in the hip joint. All of these parts of the hip-joint work in

harmony, allowing easy, painless movement.

**1.2.3 Structure of the femur**

The femur is the longest and strongest bone in the human skeletal system. It consists,

primarily, of a central shaft or diaphysis and two wider and rounded bulges known as

the epiphyses (Fig. 1.4). Each epiphysis is connected to the diaphysis via conical

regions called the metaphysis. The diaphysis is mainly composed of hard cortical

bone with a small spongy core, while the epiphysis and metaphysis contain mostly

cancellous or spongy bone within a thin shell of cortical bone. The proximal part of

the femur has a head, a neck, a greater trochanter and a lesser trochanter (Fig. 1.4).

The head forms two-thirds of a sphere and is directed upward, medialward, and a little

forward. The surface of the head is smooth and coated with cartilage tissue in the

fresh state, except over an ovoid depression, clinically known as the *fovea capitis*

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*femoris*. The neck is a flattened pyramidal part of the bone, connecting the head with

the femoral shaft and forming with the latter a wide angle opening medial-ward

(Gray, 1918). This angle of inclination of neck to the shaft in the frontal plane is

known as neck-shaft angle. In addition to projecting upward and towards the medial

side of the femur body, the neck also

projects a little forward. This angle of

inclination of the neck to the shaft in

transverse plane is known as the angle

of anteversion. The neck of the femur

bone has an irregular cross-section. It is

almost circular at the upper end and

roughly elliptical with major and minor

axes in the ratio of about 1.6 at the

lower end close to the femoral shaft.

With aging, the femoral neck gradually

undergoes degenerative changes. The

greater trochanter is a large, irregular,

quadrilateral eminence, situated at the

junction of the neck with the upper part

**Fig. 1.4:** Anatomy of human femur bone

of the shaft, which provides attachment sites for a number of muscles and thus, forms

the most palpable part of the femur. It is directed a little lateral ward and backward,

and about 10 mm lower than the head in the adult (Gray, 1918). The lesser trochanter,

on the other hand, is a conical eminence on the medial side of the femur.

**1.2.4 Human gait cycle**

The human gait is the way locomotion is achieved by forward propulsion of the body,

while maintaining synergy with the help of human limbs. Though the nature of gait

varies from individual to individual, it typically follows a common pattern. Human

gait is bipedal and biphasic. The two distinct but interconnected phases that constitute

the gait cycle are the stance phase and the swing phase. These phases can be further

subdivided into eight different phases, as described in terms of percentage of each gait

cycle. In the stance phase, which is approximately 60% of the normal walking cycle,

the foot remains in contact with the ground. The cycle begins with the heel contact at

the start of the right foot stance phase. The right foot then comes in flat contact with

the ground before the heel rises. Lifting the toe off the ground marks the end of the

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stance phase. The remaining 40% of the gait cycle is known as the swing phase, when

the foot moves in the air. During the right swing phase, the left leg solely supports the

body. The swing phase ends with heel contact and the cycle repeats itself. The same

cycle applies to the left leg with a phase difference. The duration, when both feet

remain in contact with the ground, is known as the double support. A typical gait

cycle is presented in Fig. 1.5.

**1.2.5 Musculoskeletal loading of hip joint**

The movements of the hip joint are facilitated by a total of twenty one muscle forces.

However, not all of them play a major role in load transmission (Nordin and Frankel,

2001). The muscles are grouped primarily as flexors, extensors, abductors and

adductors, based on the movements they produce. The lines of action of the muscles

are assumed to extend from the centre of the area of origin to the centre of the area of

their insertion or to any bony surfaces over which they pass (Brand *et al.*, 1982; Duda

*et al.*, 1996). The origin and insertion of the hip joint muscles are presented in Table

1.1. Musculoskeletal loading is known to play a significant role in the biological

process of fracture healing, bone remodelling and primary stability of an implant

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**Fig. 1.5:** A typical human gait cycle (Inman *et al.*, 1981)

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(Bitsakos *et al.*, 2005; Duda *et al.*, 1998; Weinans *et al.*, 2000). Apart from these

muscle forces, the hip joint reaction force has a significant influence in transferring

load between the two extremities of human body (Dalstra and Huiskes, 1995).

Several investigators have measured hip joint reaction (or hip contact) force

either using force platforms and kinematic data combined with electromyography

(EMG) for the normal hip joint (Crowninshield *et al.*, 1978; Paul, 1967; Röhrle *et al.*,

1984; van den Bogert *et al.*, 1999) or using instrumented hip prostheses for the

implanted hip joint (Bergmann *et al.*, 1993; 1995; 2001; 2004; Davy *et al.*, 1988;

Kotzar *et al.*, 1991; Taylor *et al.*, 1997). A large amount of inter-patient variability

was considered in these studies for the measurement of hip contact force. A summary

of the range of peak hip contact forces and torsional moments during routine activities

is presented in the Table 1.2. In a cohort study using four patients, Bergmann *et al.*

(2001) measured the hip contact forces during most-frequent daily activities, such as

normal walking and stair climbing, and also calculated the average joint forces. The

average value of the peak hip contact force, reported in the study, was roughly 238%

of body weight (BW) during walking (at a speed of 4 km/h). However, during stair

climbing and going downstairs, the average measured hip contact forces were

reported to be higher, 251% and 260% BW, respectively. The variation of the hip

contact forces over the entire duration of a gait cycle is shown in Fig. 1.6. It may be

noted that the hip joint force reaches its peak value right after the heel strike, which

occurs approximately at 18% of the gait cycle.

Although accurate measurements of hip contact force on the femoral head were

possible using instrumented prostheses, ethical complication associated with invasive

**) WB%(e crofn oitcaert nioJ**8 300

250

200

**Measured**

**Calculated**

0 50 100 150 200

**Measurement frame (Time through one gait cycle)**

(a) (b)

**Fig. 1.6:** Hip joint reaction: (a) joint reaction force diagram for the hip joint for normal gait; (b) comparison between calculated and measured joint reaction force (Bergmann *et al.,* 2001; Heller *et al.,* 2001).

150

100

50

0

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**Table 1.1:** Principal actions of dominant hip muscles (adapted from Dowson *et al.*, 1981). The abbreviation m. stands for muscle.

**Movement Muscle Origin Insertion**

m.gracilis m.pectineus m.iliopsoas Flexion

m.sartorius m.rectus femoris

9 Pubic bone Pubic bone Iliac fossa, anterior lumber spine Anterior superior iliac spine Anterior superior iliac spine

Anterior medial tibial condyle Pectineal line Lesser trochanter

Anterior medial tibial condyle Tibial tuber via patellar tendon

Extension

m.gluteus maximus

m.biceps femoris

m.semitendinosus

m.semimembranosus

Posterior ilium, sacrum

Ischial tuberosity, linea aspera Ischial tuberosity

Ischial tuberosity

Iliotibial band and gluteal tuberosity Fibular head

Anterior - medial tibial condyle Medial tibial condyle

Abduction

m.tensor fascia latae

m.gluteus medius m.gluteus minimus

Lateral to Anterior superior iliac spine Gluteal lines on posterior ilium Gluteal lines on posterior ilium

Inserts into iliotibial band

Greater trochanter

Greater trochanter

Adduction

m.adductor magnus

m.adductor longus m.adductor brevis

Inferior pubis and ischium

Pubic bone Pubic bone

Adductor tuberosity, linea aspera Linea aspera Upper linea aspera

methods served as a deterrent for quantitative *in vivo* assessment of muscle forces.

This led to the wide use of mathematical optimisation algorithms for estimation of the

complex distribution of *in vivo* muscle forces (Brand *et al.*, 1982; 1986; 1994;

Crowninshield and Brand, 1981; Duda *et al.*, 1996; 1997; 1998; Glitsch and

Baumann, 1997; Heller *et al.*, 2001; Pedersen *et al.*, 1997). The data obtained from

the optimization method was found to be in good agreement with the measured EMG

data of the muscle forces during normal gait (Crowninshield and Brand, 1981; Glitsch

and Baumann, 1997). In a comprehensive optimization study, Heller et al. (2001)

calculated the magnitude of muscle forces and the hip contact force for daily

activities, e.g., walking and stairs climbing, for four patients.

The optimisation procedure incorporated the criterion of minimising the sum of

all muscle forces (Crowninshield, 1978), coupled with the inequality constraints

imposed on the maximum muscle forces (Challis, 1997). Since maximum muscle

activation during the mentioned activities was unlikely to occur, muscle forces were

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**Table 1.2:** Range of peak hip contact force and torsional moments in routine activities from selected studies (adapted from Pal, 2009).

Activity Hip contact

force (% BW)

10 Twisting moment (% BW.m)

Instrument References

Walking

260 – 280 -

Instrumented telemetric hip prosthesis

Davy *et al.*, 1988 270 - Kotzar *et al.*, 1991 277 - Taylor *et al.*, 1997 280 – 480## 1.30 – 4.40## Bergmann *et al.*, 1993 211 – 285 1.20 – 190 Bergmann *et al.*, 2001 220 – 280 -

EMG/force plate

van den Bogert *et al.*, 1999 490 – 700 - Paul, 1967 450 – 750 - Crowninshield *et al.*, 1978

Stair climbing

260 -

Instrumented telemetric hip prosthesis

Davy *et al.*, 1988 320 - Taylor *et al.*, 1997 350 – 550# 3.70 – 5.70# Bergmann *et al.*, 1995 227 – 314 1.80 – 3.00 Bergmann *et al.*, 2001 Jogging 550 5.30 Bergmann *et al.*, 1993 Stumbling 870 5.40 Bergmann *et al.*, 1993 Bergmann *et al.*, 2004 Single leg stance

210 – 280 - Kotzar *et al.*, 1991

Standing up 181 – 220 0.80 – 1.21 Sitting down 149 – 176 0.40 – 0.91 Bergmann *et al.*, 2001 Knee bend 117 – 177 0.58 – 0.83 **Notes:** ## Upper value for walking at 5 km∙h-1

# Upper value measured in one patient only and considered abnormally high

**Table 1.3:** Forces applied by major muscles and ligament on the femur in terms of body weight (BW) at approximately 20% of the gait cycle. The abbreviation m. stands for muscle.

Muscle Name Force (%BW)

Normal walking Stairs climbing

m. abductor 104.2 113.8

Iliotibial tract, proximal 0.0 16.8

Iliotibial tract, distal 0.0 16.8

m.tensor fascia lata, proximal part 19.0 6.5

m. tensor fascia lata, distal part 19.0 6.5

m. vastus lateralis 94.8 137.0

m. vastus medialis 0.0 270.1

**Source:** Heller *et al.*, (2001).

restricted to below 85% of physiological muscle forces (Heller *et al.*, 2001). The

forces were calculated as the product of each muscle’s physiological cross-section

area (PCSA) (Brand *et al.*, 1986; Duda *et al.*, 1996) and a muscle stress of 1 MPa (An

*et al.*, 1989). Figure 1.6b shows a graphical representation of the measured and

calculated values of hip contact force during normal walking. Although the

optimization method yielded hip contact force values (Heller *et al.*, 2001), reasonably

similar to measured values (Bergmann *et al.*, 2001), deviations in measured and

calculated values were observed throughout the entire gait cycle. The major muscle

forces calculated by Heller *et al.* (2001), corresponding to the peak hip contact force,

are summarised in Table 1.3. These forces were based on the data from hip joint

implanted with telemetric prostheses (Bergmann *et al.*, 2001; Heller *et al.*, 2001).

For biomechanical analyses of long bones, Duda *et al.* (1996) stressed on the

importance of accurate quantification of the locations and size of muscle attachment.

Different methods were adopted to quantify the muscles attachment size and locations

in lower limbs (Brand *et al.*, 1982; Chao *et al.*, 1993; 1994; Crowninshiled *et al.*,

1978; Dostal and Andrews, 1981; Duda *et al.*, 1996; Lengsfeld *et al.*, 1994). Duda *et*

*al.* (1996) employed a digitising method to determine reproducibly the muscle

attachment area, centroidal location of the area and the muscle volume corresponding

to six femoral specimens. Considerable amount of inter-specimen variability was

reported in the measured muscle volume and computed area of muscle attachments

**Fig. 1.7:** Major group of muscles and their attachment points: P1, P2 and P3 are the attachment sites of the muscles (Bergmann *et al.*, 2001; Heller *et al.*, 2001).

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(Brand *et al.*, 1982; Duda *et al.*, 1996). Typical attachment points for major muscles

of the hip joint are presented in Fig. 1.7 (Bergmann *et al.*, 2001; Heller *et al.*, 2001).

According to the location data provided by Brand *et al.* (1982) and Duda *et al.* (1996),

muscles were represented as straight lines spanning from the centre of origin to the

centre of insertion.

Both computational and *in vitro* studies indicated that the hip contact force and

abductor muscle forces have the greatest influence on the strain distribution within the

proximal femur during walking and stair climbing. The other significant contributors

are the vastus (medialis and lateralis), tensor fasciae latae and iliotibial tract.

Musculoskeletal hip loading data of Bergmann *et al.* (2001) and Heller *et al.* (2001)

have been extensively used in most of the recent investigations on the proximal

femur. The hip contact force acts at a distributed area on the surface of the femur head

and makes an angle of 17° with the vertical in the frontal plane. Abductor muscle

force also acts parallel to the hip contact force, albeit along an opposite direction and

at a different location of attachment (P1) in the greater trochanter region. Surrounding

the area around the point P1 attached are the iliotibial tract (proximal and distal) and

the muscle tensor fascia latae (proximal and distal). The respective attachment sites

for vastus lateralis and vastus medialis are P2 and P3. Musculoskeletal loading

conditions for normal walking comprise of the hip contact force and the muscle forces

of abductor, tensor fascia latae (proximal and distal) and vastus lateralis (Bergmann *et*

*al.*, 2001; Heller *et al.*, 2001). The loading conditions for stairs climbing include the

additional effects of iliotibial tract (proximal and distal) and vastus medialis, along

with the hip contact force and the muscle forces applied during normal walking.

**1.3 Bone structure and properties**

Bone is a solid structural element of the human body that constitutes part of the

vertebral skeleton. A connective tissue with unique structural and mechanical

properties, bone protects the soft tissues and organs of the body, and transmits weight

and muscle forces from one part of the body to another during daily activities, while

maintaining shape of the body. The primary function of bone, however, is to bear

load. From engineering perspective, bone is an anisotropic, non-homogeneous and

viscoelastic material. Like most biological tissues, it is able to adapt its structure

according to change in mechanical environment. Moreover, it exhibits wide variations

in morphology depending on the porosity of the structure.

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Macroscopically, bone exists in two basic forms depending on their relative

densities or volume fractions of solids: cortical and cancellous (Gibson, 1985). The

dense outer shell surrounding the core spongy cancellous part is known as the cortical

or compact bone. Cortical bone has a volume fraction of solids greater than 70%,

whereas the cancellous (or trabecular or spongy) bone is porous with a volume

fraction of solids less than 70%. The distribution of cortical and cancellous bone

varies considerably from bone to bone, and also from patient to patient. The

mechanical properties of bone tissues are governed by the mineral and organic

composition. The hydroxyapatite (HA) (scientifically referred to as *hydrated calcium*

*phosphate*, Ca10(PO4)6(OH)2) contributes significantly to the stiffness of the cortical bone, while the collagen content determines the ductility (Guo, 2008). Cancellous

bone has a distinctive lattice structured network of interconnecting rods and plates.

This lattice of rods and plates is called trabeculae; hence the name trabecular bone.

However, cortical bone constitutes a solid mass with only microscopic channels.

From the molecular perspective, bone mimics a true composite material (Currey,

1984). It consists of 65% mineral (HA), 35% organic matrix (mostly collagen fibers),

water, cells and vessels. The mineral content is largely impure HA in the form of

small crystals with the shape of needles, plates and rods located within and between

the organic matrix. The organic matrix is comprised of 90% collagen and 10% of

various noncollagenous proteins (Jee, 2008). Depending on the differences of the

architecture and arrangement of collagen fibres, bone can be categorised mainly into

two types; woven and lamellar bone. Woven bone is premature temporary phase of

bone. It grows rapidly and typically found in foetus, at younger ages and during

fracture healing of bones. The collagen fibres in woven bone are comparatively

loosely packed and randomly oriented, as compared to lamellar bone. Lamellar bone

is more regularly arranged and the growth rate is not as fast as in woven bone. The

fibres of collagen and associated calcium phosphate are oriented in forms of sheets,

known as lamellae. The mineral content in this type of bone is usually lower than the

woven bone (Currey, 1984). Lamellar bone can be further categorised into primary

and secondary lamellar bone. Small cavities (lacunae) connected by their tubular

canals (canaliculi) are found throughout the woven and lamellar bone. Entrapped bone

cells (osteocytes) and their long cytoplasmic processes occupy the lacunae and

canaliculi, respectively (Jee, 2008).

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**1.3.1 Mechanical properties of cortical bone**

Cortical bone represents nearly 80% of the body’s bone mass in an adult human

skeleton, but accounts for only 20% of the bone volume. It is a solid compact tissue

constituting the diaphysis of the long bones and outer shell of the epiphyses and

metaphyses. Cortical bone exhibits anisotropic material behaviour, with a larger

ultimate strength and elastic modulus in the longitudinal direction than in the

transverse directions. Moreover, it is stronger in compression than in tension. Ashman

*et al.* (1984) measured the elastic moduli of cortical bone using a continuous wave

ultrasound technique. They estimated the elastic moduli to be about 20 – 22 GPa

along the axis of the long bone and 12 – 14 GPa transversely. This indicates that the

cortical bone is transversely isotropic; about 1.5 – 2 times stiffer and stronger in the

longitudinal direction than in either the radial or circumferential directions. In spite of

its inherent anisotropy, an orthotropic or transversely isotropic constitutive

relationship describes the cortical bone elastic properties fairly well (Guo, 2008).

Elastic moduli of cortical bone, measured using mechanical testing, were reported to

be in the range of 17.5 ± 1.9 GPa (Carter *et al.*, 1981). However, the reported values

of Elastic moduli and strengths are only indicative as they may vary depending on

ethnicity, age and sex of the patient.

The stress-strain behaviour of human femoral cortical bone was reported by

Özkaya and Nordin (1999), who observed three distinct regions in the stress-strain

curve. An Elastic modulus in the range of 17 GPa was found in the initial linearly

elastic region. In the intermediate region, the bone exhibits nonlinear elastoplastic

behaviour. This region is characterised by bone yielding with yield strength value

reported to be around 110 MPa. The final region exhibits linear plastic behaviour with

a strain hardening modulus of 0.9 GPa. The bone was found to have fractured when

the tensile stress was 128 MPa and the corresponding tensile strain was 0.026

(Özkaya and Nordin, 1999). The study also reported that the elastic moduli and

strength values of a bone specimen depends on the strain rate, which is indicative of

the viscoelastic property of the bone (Özkaya and Nordin, 1999). Further

investigations based on mechanical testing also suggested that the stress-strain

behaviour of the bone is dependent on the orientation of the bone with respect to the

direction of loading. Investigations were also carried out to provide data on the

material properties of human femur under dynamic loading (Funk *et al.*, 2004;

Asgharpour *et al.*, 2014).

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**1.3.2 Mechanical properties of cancellous bone**

The mechanical behaviour of cancellous or trabecular bone varies extensively

depending on the mode of loading. The stress-strain curve of cancellous bone under

compressive load contains an initial linearly elastic region, followed by a plateau

region of almost constant stress and finally, an increasingly steep region culminating

into fracture (Gibson, 1985; Özkaya and Nordin, 1999). The material yielding tends to

occur as the trabeculae begin to fracture. It should, however, be noted that the

mechanical yield property of cancellous bone varies significantly with anatomical

location (Morgan and Keaveny, 2001; Morgan *et al.*, 2003). As opposed to the

cortical bone, cancellous bone fractures abruptly under tensile forces, exhibiting

brittle material behaviour. The energy absorption capacity of cancellous bone is

higher under compressive load than under tensile load (Kaneko *et al.*, 2004).

The material properties and the stress-strain characteristics of cancellous bone

depend not only on the mode of loading but also on its apparent density. It is reported

to exhibit mechanical behaviours similar to other solid cellular structures, e.g.,

polymeric foam (Gibson, 1985; Gibson and Ashby, 1988; Pugh *et al.*, 1973; Rajan,

1985). The apparent or relative density is equivalent to the volume fraction of solids

in the cancellous bone, which is calculated from the cancellous bone density and

volume of the trabeculae (or solid cell wall). At low relative densities, it has rods

connecting to form open cells. At higher relative densities, more material is

accumulated in the cell walls and the structure transforms into a more closed network

of plates. The analysis by Gibson (1985) showed that the Young’s modulus varies

with the square of the density for an open cell structure, and with the cube of density

for a closed cell structure. This prediction was further corroborated by Carter and

Hayes (1977) who suggested a transition from rod-like to plate-like elements at a

relative density of 0.20.

A series of experimental studies were carried out to find empirical power law

relationships between apparent bone density and elastic modulus (Carter *et al.*, 1987;

1989; Morgan and Keaveny, 2001; Morgan *et al.*, 2003). Different equations were deduced, all based on the same basic relationship:*E* = C*ρ*D . The values for constant C

were found to vary in the range 3,000 − 30,000, whereas values for constant D ranged

between 1.14 and 3.2, depending on the location of the bone (Morgan *et al.*, 2003).

Evidently, a single elastic modulus-density relationship is not applicable across all the

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**Table 1.4:** Range of constant C and D used in the power-law regression between the elastic modulus (*E* in MPa) and apparent density (*ρ* in g.cm-3).

Anatomic site Apparent density

(Range)

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*E* = C*ρ*D

C (95% CI) D (95% CI)

Vertebra (T10 – L5)

(0.11 – 0.35) 4730

(3050 – 7320)

1.56

Proximal Tibia (0.09 – 0.41) 15520

(10830 – 22230)

1.93

Greater Trochanter (0.14 – 0.28) 15010

(7590 – 29690)

2.18

Femoral Neck (0.26 – 0.75) 6850

(5440 – 8630)

1.49

Pooled (0.09 – 0.75) 8920

(7540 – 10550)

1.83

**Source:** Morgan *et al.* (2003), Helgason *et al.* (2008). CI denotes Confidence Interval

**Table 1.5:** Trabecular bone mechanical properties (mean ± standard deviation) by anatomic site and loading mode.

Anatomic site- Loading mode

Apparent density

(g∙cm-3) Modulus (MPa) Yield strain (%) Yield stress (MPa)

Vertebra Compression 0.18 ± 0.05 344 ± 148 0.77 ± 0.06 2.02 ± 0.92

Tension 0.19 ± 0.04 349 ± 133 0.70 ± 0.05 1.72 ± 0.64

p-value NS NS <0.001 NS

Proximal tibia Compression 0.23 ± 0.06 1091 ± 634 0.73 ± 0.06 5.83 ± 3.42

Tension 0.23 ± 0.10 1068 ± 840 0.65 ± 0.05 4.50 ± 3.14

p-value NS NS <0.001 NS

Greater trochanter Compression 0.22 ± 0.05 622 ± 302 0.70 ± 0.05 3.21 ± 1.83

Tension 0.22 ± 0.04 597 ± 330 0.61 ± 0.05 2.44 ± 1.26

p-value NS NS <0.001 NS

Femoral neck Compression 0.58 ± 0.11 3230 ± 936 0.85 ± 0.10 17.45 ± 6.15

Tension 0.54 ± 0.12 2700 ± 772 0.61 ± 0.03 10.93 ± 3.08

p-value NS NS <0.001 0.003 **Source:** Morgan and Keaveny (2001).

NS indicate no significant differences (p>0.05)

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anatomic sites (Table 1.4). A similar principle was adopted by Kaplan *et al.* (1985)

and Stone *et al.* (1983), who determined the static strength of trabecular bone by

relating it to the local bone density through power law relationship.

It is evident from the yield strength data for various anatomical locations and

loading conditions that bone is a non-homogeneous anisotropic material (Table 1.5).

However, the site-specific differences between the yield strain results were found to

be small. Turner (1989) observed that the correlations between yield strain and the

trabecular orientation, structural density and bone density vary little for differing

definitions of yield. This suggests that yield strain in cancellous bone is independent

of the structural anisotropy. A further investigation suggested that the apparent

density in bovine cancellous bone adapts in a manner such that the continuum-level

strains are uniform (Turner *et al.*, 1996). The uniform strain criterion was found to

reproduce realistic density distributions in the proximal femur and was also applicable

to human bone. In a recent experimental study by Morgan and Keaveny (2001), it is

suggested that strain-based criteria for human trabecular bone may be more

mathematically simple and statistically powerful. They tested cylindrical specimens of

human trabecular bone taken from different anatomic site under both uniaxial tensile

and compressive loads and subsequently, confirmed that the yield strains of this bone

depend on anatomic site. Moreover, due to the weak dependence on the apparent

density, the yield strains can be considered uniform within a single site despite

substantial variation in elastic modulus and yield stress.

**1.4 Review of literature: hip arthroplasty**

Hip replacement surgery has over 100 years of operative history. However, the

procedure has undergone a series of revolutionary changes and modifications over the

years. The earliest recorded attempts at hip replacement happened in Germany back in

1891 by Themistocles Gluck, with results presented at the 10th International Medical

Conference. Later in the late 19th and early 20th century, surgeons experimented with

interpositional arthroplasty, which involved placing various tissues (fascia lata, skin,

pig bladders submucosa) between articulating hip surfaces of the arthritic hip

(Learmonth *et al.*, 2007). Surgeon Marius Smith-Petersen may be credited for the

development of the first glass-made ‘mold arthroplasty’ in 1925. The prosthesis

consisted of a hollow hemisphere which could fit over the femoral head to provide a

new smooth articulating surface. However, the surface failed to withstand the hip joint

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forces and ruptured. Marius Smith-Petersen and Philip Wiles later independently

tested cobalt-chrome (Co-Cr) implant, a dramatic improvement in the field of

arthroplasty, in the first THR that was fitted to bone with bolts and screws (Smith-

Petersen, 1948; Wiles, 1957). While this new metal proved to be a success, the actual

resurfacing technique was found to be inadequate. In order to address the problem of

the femur fracture and arthritic femoral head, Frederick R. Thompson and Austin T.

Moore separately developed replacements for the entire femoral head (hemi-

arthroplasty). In spite of being hugely popular in the 1950s, unpredictability in

outcome and damage of the acetabular cavity persisted. Moreover, no effective

method of securing the component to the bone was found as yet.

English surgeon George McKee was the first to use a metal-on-metal prosthesis

on a regular basis. In 1953, he started to use modified Thompson stem with a new

one-piece Co-Cr socket as the new acetabulum. McKee, together with Watson-Farrar,

further developed on this design. This prosthesis was reported to have good survival

rate, with one study recently showing survival rate of 74% in a 28-year follow-up

(Brown *et al.*, 2002). Nevertheless, the popularity of the method waned by the mid-

1970’s, owing to high frictional resistance producing wear particle debris (McKellop

*et al.*, 1996). As early as in 1938, Judet brother, working in Paris, attempted to use an

acrylic material to replace arthritic hip surfaces. Although a smooth surface was

achieved using this technique, the occasional loosening remained an issue. Hence, the

search for alternative prosthesis design continued.

Surgeon Sir John Charnley is considered the father of the modern THA. In 1962,

while working at the Manchester Royal Infirmary, he developed the Charnley THR, a

gold standard of primary hip replacement. Following unsatisfactory experience with

Teflon cups (1959-62), Charnley introduced his first low friction arthroplasty (LFA)

(Charnley, 1970), which was identical, in principle, to the prostheses used today. It

consisted of three parts: a metal femoral stem, a high density polyethylene acetabular

component and acrylic bone cement. This work of his resulted in a design that

completely replaced the other designs by the 1960s. It was called ‘low friction

arthroplasty’ as Charnley advocated the use of a small femoral head leading to

considerable reduction in wear due to smaller surface area. Long-term results of the

Charnley LFA, including 35-year follow-up, reflected a 78% femoral implant

survival.2, although the design suffered from poor joint stability. Despite this, the

Charnley LFA design was the most accepted artificial hip over two decades.

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However, the original Charnley prosthesis has undergone further modifications, since

1969, with regard to stem shape, surface texture and femoral head material to further

reduce failure of the THA.

**1.4.1 Hip replacement: cemented vis-à-vis cementless fixation**

Until about late 1970s and early 1980s, cemented fixation was the predominant

technique used for THA. Although the Charnley LFA presented a successful

cemented design and technique, the outcomes of the other cemented THA procedures

were distinctly poor with high and early loosening rate (Yamada *et al.*, 2009). These

failures were found to be associated with localised areas of bone destruction and

resorption (osteolysis). The root cause of these failures was initially believed to be

infection (Charnley, 1979). However, subsequent revelations attributed the cause to a

local inflammatory response initiated by cement particles. Histological examination of

tissue taken from these localised areas of osteolysis showed the presence of

‘polymethyl methacrylate debris’ (Harris *et al.*, 1976), which led to the conclusion

that the premature loosening of cemented components was related to so-called

‘cement disease’ (Jasty *et al.*, 1986; Jones and Hungerford, 1987; Maloney *et al.*,

1990). This prompted researchers to find alternative method of fixation in THA.

Later investigations further pointed out that cementing the prostheses has certain

disadvantages; prominent among them are necrosis and bone thermal injury (Mont *et*

*al.*, 2006; Beaulé *et al.*, 2007). Moreover, cement is strong in compression, but weak

in tension. The implant-cement interface has often been reported as the weakest link

in the implanted bone, leading to interface debonding. Cement particles abraded from

the cement mantle may lead to particulate reactions by macrophages, osteolysis, soft

tissue interposition and eventual loosening of the implant. These issues, although not

very well understood earlier, might have led to the development of cementless, press-

fitted implant designs. The principles of cementless fixation have evolved since the

first outcomes were reported in 1979 (Lord *et al.*, 1979). The design aim was to obtain

stability through biologic fixation occurring naturally at the implant-bone interface.

The anatomic medullary locking (AML) stem was the first cementless femoral

implant approved for use in the United States. The design featured a straight,

extensively porous coated Co-Cr stem that employed diaphyseal fixation. The stem

has an exceptional track-record, including up to 98% survivorship at 20 years

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(Belmont *et al.*, 2008). However, disadvantages include proximal stress shielding and

occasional thigh pain due to distal cortical hypertrophy (Belmont *et al.*, 2008).

The success of AML notwithstanding, the clinical outcomes of majority of early

cementless designs were equally poor compared to their cemented counterparts. This

is partly because of the implant designs having smooth surface, which failed to adhere

strongly to the bone. As a result of these smooth-surfaced cementless THAs, aseptic

loosening was reported to occur several years after surgery, and in many cases

required revision surgery (Kawamoto *et al.*, 1998). The development of material

engineering during the 1980s, however, revolutionised cementless implants with the

advent of materials that allow biologic fixation. This biologic fixation can be achieved

through bone ingrowth or ongrowth, or a combination of both. Porous-coated

implants facilitate the host bone to grow inside the pores of the implant surface and a

stable biologic fixation through osseointegration occurs naturally. This process is

clinically termed as bone ingrowth. For grit blasted implants, the bone grows onto the

microdivots of the textured implant surface and the biologic fixation is attained

through bone ongrowth, and finally osseoincorporation. Nevertheless, porous-coated

ingrowth type implants are more common in hip replacement procedures. Different

type of surface processing, such as titanium (Ti) fibre mesh, Co-Cr beads, Ti plasma

spray, are presently in use for the development of bone-ingrowth type implants. Fig.

(a) (b)

**Fig. 1.8:** Cementless total hip arthroplasty: (a) the surgical procedure and (b) the typical hip replacement components (Source: *http://www.oakazoo.com/allHips/hip\_replacement.htm*).

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1.8 illustrates the modern THA procedure (cementless) and the corresponding hip

replacement components including a proximally porous-coated femoral stem.

The relative superiority between cementless and cemented technique, however,

remained a matter of debate in the field of THA. Nevertheless, the long-term survival

rate of cemented implants was reported to have surpassed that for any cementless

implant system (Malchau *et al.*, 1996). The reason behind the relatively inferior

results for cementless technique may, in part, be ascribed to the apparent paucity of

understanding of the fixation method and hence, further investigations − clinical as

well as preclinical − are warranted. Nevertheless, the enormous computing abilities of

the modern-day computers have enabled researchers to dig deeper into the

understanding of the performance of cementless implants. The recent advancement of

image processing techniques and 3-D printing is further ushering a new age of

cementless implant design.

**1.4.2 Reasons for hip replacement**

The primary symptom of a diseased hip joint is pain, which, in extreme cases, calls

for hip replacement. The pain can be mild to debilitating; however the ability to

perform normal activities becomes restricted nonetheless. Subsequent to hip

replacement, the patient gets a new lease of life with improved mobility and

considerable reduction in pain. The most common ailments that lead to hip surgery

are described as follows:

*Osteoarthritis* (OA) is the most common reason for hip replacement surgery,

accounting for over 75% of the THAs performed globally. Primarily associated with

aging, the disease degenerates cartilage exposing the bone surfaces to come into direct

contact of each other, causing pain and restricted mobility. Gait abnormalities and

limitation of motion can also cause muscle atrophy and weakness over time. Although

post-traumatic arthritis is caused by trauma or injury, the diagnosis and symptoms are

similar to that of OA. The trauma may be induced in the form of a fracture or

dislocation, altering the mechanics of the hip joint.

*Rheumatoid Arthritis* (RA) is a chronic and progressive joint disease that causes

inflammation in the cartilage of the joints, eventually leading to swelling, pain and

immobility to the patient. Tipped as an autoimmune disorder, the root cause of RA is

not properly known yet. Multiple joints, both weight-bearing and non weight-bearing,

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are affected by the disease. RA is known to inflame the synovial membrane which, as

a result, starts to release enzymes. These enzymes digest bone and cartilage, leading

to eventual deformation of the joint and inflammation of the joint lining, and thereby

causing damage to the joint surface.

*Osteonecrosis* (ON), sometimes called as aseptic or avascular necrosis, is a condition

in which the part of the femoral head loses its blood supply resulting in bone cells

dying due to the lack of oxygen and nutrients. Patients having fractured or dislocated

hip and having been on steroids or having a history of heavy alcohol use are at higher

risk of developing this condition. Evidences suggest that early stages bear little or no

X-ray findings, while at advanced stages, joint damage identical to OA can be

observed. Though the major symptom of ON is pain in groin, often the patient carries

the disease for a considerable period of time without any noticeable symptom. Initial

treatments typically include the use of walking aids to reduce the load on the joint.

However, no preventive medicines or treatments for ON have been established as yet.

Consequently, surgical intervention, such as joint replacement, osteotomy of the bone

and bone grafting, becomes the major course for ON treatment. Other reasons for hip

surgery include femoral neck fracture and inter-trochanteric fracture owing to trauma

or low bone quality, or a combination of both.

**1.4.3 Hip replacement: failure scenarios**

Although failure of a hip prosthesis may be due to multifactorial reasons, the initiation

of the failure process can be attributed to mechanical events. Three dominant failure

scenarios, as suggested by Huiskes (1993) for reconstructed hip joints, are presented

as follows:

*Accumulated damage failure scenarios*: The likelihood of mechanical failure depends

on the stresses induced within an implant material or at various material interfaces

within the implant-bone structure, as compared to the strength of the material or the

respective material interface. These implant materials or interfaces are too weak to

sustain the effect of long-term, dynamic loads due to normal physiological activities.

As a result, mechanical damage, typically micro-cracks, is gradually accumulated

within the implanted bone structure, eventually causing failure.

*Particulate-reaction failure scenarios:* There are three possible sources of generation

of wear particle debris in joint replacement: (1) wear of articulating surfaces, (2)

abrasion of cement/prosthesis/bone interfaces, and (3) fretting between metal parts in

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modular prostheses. As a result of the generation and migration of these wear particle

debris, the cement-bone interface gradually disintegrates, causing interfacial

micromotion and eventual loosening.

Among other aseptic failure mechanisms of the implanted hip joint, dislocation,

migration, and effect of stress shielding and bone remodelling need special mention:

*Dislocation:* Surgical intervention disturbs the stable structure of the normal hip joint,

enhancing the risk of dislocation. The small bearing size at the articulating surface

may also be responsible for dislocation. Impaction allografting, a technique to treat

cavitary defects, is also reported to cause dislocation (Dattani, 2007).

*Migration:* All cemented and cementless implants are subject to some extent of initial

migration relative to the bone. However, cementless implants are more prone to

migration due to lack of initial adhesive aids, e.g., bone cement. A portion of the

implant support may be lost due to microcracking of the trabeculae in the bone,

allowing it to subside (Burr *et al.*, 1985). This is observed in the regions of high

stress, particularly around the tip of the femoral implant. Rapid early migration is

associated with premature loosening of the implant (Glyn-Jones *et al.*, 2004).

*Stress shielding and bone remodelling:* In the implanted femur, the implant carries

bulk of the load, which was formerly transferred by the bone itself. This shields the

bone from the mechanical load and brings forth abrupt changes in the mechanical

environment within the bone, eventually causing bone resorption and osteolysis. This

phenomenon, known as adaptive bone remodelling, is related to long-term failure of

THA. In brief, the multi-axial stresses (tensile, compression and shear) generated at the

material interfaces should not be high enough to initiate interface failure. Moreover,

implant-induced adverse changes in stress distribution should be reduced, such that a

more biologic load transfer, as prevailing in the natural bone, may be attained.

Furthermore, the initial migration and implant-bone relative displacements, especially

for cementless implants, should also be minimal.

**1.4.4 Bone remodelling**

Bone is capable to adapt its structure, both externally and internally, in response to

change in mechanical loading by bone apposition (formation) and bone resorption

(loss) through the activities of cells called osteoblasts and osteoclasts, respectively.

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This process is known as bone remodelling. Internal bone remodelling refers to

changes in internal morphology, whereas external remodelling is described as

occurring relative to periosteal geometry. Internal remodelling, thus, is expressed as a

change of density or porosity of the cancellous bone (Carter *et al.*, 1989; Huiskes *et*

*al.*, 1987), whereas the geometric (or shape) changes of the cortical bone are referred

to as external remodelling (Hart *et al.*, 1984; Hart and Davy, 1989). For an adult, the

cancellous bone usually has a higher rate of metabolic activity and hence, appears to

respond more rapidly to changes in mechanical loads than the cortical bone (García *et*

*al.*, 2002). Therefore, the geometry changes are considerably less in comparison to

internal adaptation or internal remodelling of the bone. The combined effect of

internal and external remodelling models has been investigated by several researchers

(Beaupré *et al.*, 1990a; Fridez *et al.*, 1998; García *et al.*, 2001; Huiskes *et al.*, 1987;

Weinans *et al.*, 1993).

No net changes in bone morphology may be observed in the natural bone, since

the rate of bone resorption and that of bone apposition remain in equilibrium (Frost,

1964; Parfitt, 1984; Weinans, 1991). However, any mechanical intervention disturbs

the normal state of equilibrium between apposition and resorption processes, and

subsequently, the bone tries to reach a new state of equilibrium. Surgical

reconstruction of bone with prosthesis alters the mechanical environment within the

bone by changing the load transfer mechanism. As a result, the prosthesis starts to

share the joint load in the implanted situation, which was otherwise carried

exclusively by the bone in the pre-operative stage.

Bone remodelling process is known to be regulated by external loading condition

(Duncan and Turner, 1995; Huiskes *et al.*, 1989; Mullender *et al.*, 2004; Nomura and Takano-Yamamoto, 2000; Turner and Pavalko, 1998). Way back in the 17th century,

the famous Italian physicist, Galileo Galilei first observed a certain relationship

between mechanical forces (body weight) and bone morphology (as cited by

Treherne, 1981; Carter, 1984). Considerable scientific interest developed thereafter to

describe the relation between the bone structure and its function. A notable

contribution came from Wolff (1892), who further developed the theory of functional

adaptation originally conceived by Roux (Roesler, 1981; Roux, 1881). These studies

concluded that the combination of bone apposition and resorption is a biological

control process that depends on the local state of stress (Roux, 1881). According to

Wolff’s hypothesis, every change in the form and the function of a bone is followed

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by certain definite changes in their internal architecture and equally definite

secondary alterations in their external geometry, based on certain mathematical laws

(Wolff, 1892). This ‘law of bone transformation’ by Wolff was later referred to as

‘Wolff’s Law’. A series of investigations followed to describe this law in terms of

mathematical formulation and to further quantify the process of bone remodelling

(Beaupré *et al.*, 1990a; Cowin and Hegedus, 1976; Doblaré and García, 2002; Fyhrie

and Carter, 1986; Hart *et al.*, 1984; Hart and Davy, 1989; García *et al.*, 2001; Huiskes

*et al.*, 1987; Jacobs *et al.*, 1997).

The mathematical formulations were based on the common assumption that bone

has certain sensing capability to measure the change in internal mechanical conditions

(stimulus) within it and respond to that change (combined with other biological

factors) by the action of osteoblasts and osteoclasts. Although most of these models

considered apparent density (*ρ*) as variable to represent the remodelling state, the

choice of mechanical stimulus varied depending on the model. Several diverse

mechanical stimuli have been defined as a function of strain, stress, strain energy

density (SED), elastic strain energy per unit bone mass to predict bone adaptations

(Carter *et al.*, 1989; Cowin and Hegedus, 1976; Fyhrie and Carter, 1986; Huiskes *et*

*al.*, 1987; Weinans *et al.*, 1992). Cowin and Hegedus (1976) proposed a ‘site-specific’

remodelling objective, described as a normalisation of the active local strain values to

the strain values occurring under normal physiological conditions at the same

locations. According to this model, the amount of local bone resorption or apposition

depends on the local differences in strains between an actual and the corresponding

normal situation. In a ‘non-site specific’ theory, Fyhrie and Carter (1986) proposed

that the tissue strives to optimize its state of stresses and strain to a uniform stimulus

level over its entire volume. They also suggested that the SED normalised to the

apparent density can be used as the mechanical stimulus for bone adaptation. Huiskes

*et al.* (1987) predicted bone adaptation phenomenon around intramedullary implants

using the local SED as the remodelling signal.

Bone, however, does not respond to small deviations in the mechanical stimulus

(Frost, 1964). A bare minimum threshold value of the inhibitory signal, the difference

between the mechanical stimuli for altered and natural situations, is required for the

bone remodelling process to initiate (Huiskes *et al.*, 1987). The range of values of

mechanical stimuli, where bone does not respond, is known as the ‘dead zone’ or

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‘lazy zone’. Huiskes *et al.* (1987) accounted for an inclusion of the ‘dead zone’ in

their mathematical formulation for bone remodelling. Iterative computer-simulation

procedures, in combination with the FE analysis, were described to predict adaptive

bone remodelling around prostheses (Huiskes *et al.* 1987; van Rietbergen *et al.* 1993).

Nevertheless, these theories were based on an assumption that bone is an isotropic

material.

Trabecular bone orientation is heterogeneous, and hence, can be described by

anisotropic continuum material properties. Using anisotropic strain data reported by

Carter (1978), Beaupré *et al.* (1990a; 1990b) defined a daily tissue level stress

stimulus as the equilibrium state for a time dependent remodelling theory. An

anisotropic model was developed by Jacobs *et al.* (1995a; 1995b; 1997) based on

density adaptation and anisotropy reorientation, considering the principal stresses as

the mechanical stimulus. Damage-based theoretical models have also proved to be

capable of successfully predicting some aspects of bone remodelling (Prendergast and

Taylor, 1994; Prendergast and Huiskes, 1995). Doblaré and García (2002) proposed

an anisotropic bone remodelling theory based on damage repair theory, where

microdamage in the bone surface was considered to be the remodelling stimulus.

Moreover, combined strain and microdamage has also been proposed as remodelling

stimulus (McNamara and Prendergast, 2007). Several studies have investigated

structural topology optimization for bone remodelling simulation (Hollister *et al.*,

1994; Fernandes *et al.*, 1999; Bagge, 2000; Jang and Kim, 2008; Jang *et al.*, 2009).

More recently, a 3-D orthotropic adaptation algorithm was proposed and implemented

on an FE model of femur, wherein bone was modelled as optimised strain-driven

continuum with local orthotropic symmetry (Geraldes and Phillips, 2014).

**1.4.4.1 Adaptive bone remodelling: numerical simulations**

The mathematical formulation of bone remodelling is based on ‘Wolff’s law’ (Wolff,

1892). The well-known theory of adaptive bone remodelling assumed the ‘elastic

strain energy per unit mass of bone’ as the corresponding mechanical stimulus (Cowin

and Hegedus, 1976; Carter *et al.*, 1989; Huiskes *et al.*, 1987). A detailed description

of the numerical simulation based on FE models of intact and implanted bone is

provided in the following paragraphs.

The reference stimulus *S ref* of each bone element is obtained from the intact

model, which is subsequently compared with the remodelling stimulus *S* of the

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corresponding bone element of the implanted model. The amount of bone remodelling

depends on the difference between *S* and *S ref* , and the dead zone *s.* At successive

iterations, a new model having updated bone material properties is obtained, which,

on subsequent analysis, gives rise to a new stimulus *S*. The iterative procedure is

allowed to continue until an equilibrium state in terms of density is reached. It should

be noted that the elements having mechanical stimulus within the dead zone and limiting density values of 0.01 g.cm-3 (no-bone condition) and 1.73 g.cm-3 (cortical

bone) are not allowed to take part in the remodelling process.

According to the theory, the reference stimulus (*Sref*) and the remodelling stimulus (*S*) are the local (per element) elastic strain energy (*U*) per unit of bone mass

averaged over a loading history (*n*), for an intact and an implanted bone, respectively.

The mechanical stimulus for each bone element is estimated from the output of FE

models. The strain energy density, *U*, varies in each location over time during a gait

cycle, owing to variations in the hip-joint force and muscle loads. In order to take

some of these variations into account, an average strain energy density, *Ua*, for a number of loading cases was used to calculate the remodelling stimuli (Carter *et al.,*

1989; van Rietbergen *et al.,* 1993), expressed as follows:

*S* = 1 *n* ∑*ni* =1

*UU*

*i* ρ

= *a*

ρ ... (1.1)

As discussed previously, bone is unresponsive in the region known as ‘lazy zone’

or ‘dead zone’ (Beaupré *et al.*, 1990b; Huiskes *et al.*, 1987; van Rietbergen *et al.*, 1993). The region between ( −1 *Ss* ) *ref* and ( +1 *Ss* ) *ref* represents the dead zone, as

**Apposition Apposition (gain) (gain)**

**dead dead zone zone**

**2*s* 2*s SSref ref***

***SSref ref***

**Stimulus Stimulus**

**(1-*s*) (1-*s*) *SSref ref***

**(1+*s*) (1+*s*) *SSref ref***

**Resorption Resorption (loss) (loss)**

**Fig. 1.9:** The relationship between remodelling stimulus and rates bone resorption and apposition used in the adaptive bone remodelling simulation.

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shown in Fig. 1.9. The dead zone (*s*) is usually taken as ±0.75 of *Sref* for human (Engh *et al.*, 1992; Huiskes *et al.*, 1992). A certain threshold stimulus value is required to

overcome this zone and initiate remodelling. Furthermore, for remodelling prediction, estimation of free surface area in terms of apparent density values, i.e., ( *AA* = ( )ρ ) is

required. The internal free surface area per unit volume of the whole bone, *a* ( ρ ) = *VA* ( ρ ) / , is calculated using Martin’s assumptions (Martin, 1972). It is

assumed that *a* ( ρ ) = 0.0 for ρ = ρ max = 73.1 g.cm-3. Therefore, no remodelling occurs

in the cortical bone with an apparent density of 1.73 g.cm-3.

The adaptive quasi-static process in the operative bone is expressed in terms of

the rate of change of bone mass as follows:

*dM dt*

= τ *SA* ( ρ ) [ − ( 1 − *Ss* ) *ref* ] , if *S* ≤ ( 1 − *Ss* ) *ref* ... (1.2a)

*dM dt*

= 0 , if ( 1 − *sSs* ) *ref* < < ( 1 + *Ss* ) *ref* ... (1.2b)

*dM dt*

= τ *SA* ( ρ ) [ − ( 1 + *Ss* ) *ref* ] , if *S* ≥ ( 1 + *Ss* ) *ref* ... (1.2c)

01.0 ≤ ρ ≤ 73.1 g.cm-3

The parameter τ is a time constant given in gm/(mm2(J/gm) per month), *A* ( )ρ is the

free surface at the internal bone structure, *S* represents the bone remodelling stimulus.

The time *t* is given in units of one month. The rate of change of bone mass *dM dt*

can

be expressed as a rate of change in the internal bone mass due to porosity change, and

represented in mathematical terms as follows:

*dM dt*

= *V d dt*ρ ... (1.3)

where *V* is the volume in which the change in bone mass change takes place (the

volume of the element) and *d*ρ *dt*is the rate of change in apparent density. Thus, by

rearranging Eq. 1.2, the mathematical description of adaptive bone density change

(non-zero) can be expressed as:

∆ ρ = *Sa* ( ρ ) [ − ( 1 ± *tSs* ) *ref* ] τ ∆ , if *S* ≤ ( 1 − *Ss* ) *ref* or *S* ≥ ( 1 + *Ss* ) *ref* ... (1.4)

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Using Euler’s integration, Eq. 1.4 can be solved iteratively to yield a new value of

apparent density. Thus, a chosen time step Δ*t* and apparent density in each element

can be determined using the following equations for the above two conditions:

∆ ρ *i* = τ *Sa* })1(){( ρ − ± *Ss ref* ... (1.5a)

ρ *i* + 1 = ρ *i* + ∆ ρ *i* ... (1.5b)

The integration was carried out in steps of ‘simulation time scale’ τΔ*t* (Weinans

*et al.*, 1993). The time step (Δ*t*) was variable and was determined in each iteration

using the following equation, where the maximum bone density change in the most

highly stimulated element was assumed to be equal to the half of maximum bone

density ( 1

2ρ max = 865.0 g.cm-3) (Weinans *et al.*, 1993): τ ∆ *t* = })1()(({

*Sa* ρ 865.0

− ± *Ss ref* max ... (1.6)

The adaptation rate (*τ*) was assumed to be equal to 129.6 g.mm-2 (J/g) per month for

calculating Δ*t* (Weinans et al., 1993). Bone is modelled as continuous material at all

times, the porous structure of bone is accounted by the apparent density variable, which is related to the Young’s modulus (*E*) according to *E* = C*ρ*D (Table 1.4), where C and D are constants; *E* is expressed in MPa and the ρ in g.cm-3.

**Fig. 1.10:** Computational scheme for iterative bone remodelling simulation.

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It was observed that the size of time-step had minor influence on the predicted

final configuration, as long as it is sufficiently small to guarantee convergence of the

process (Weinans, 1993). However, the relationship between iterative time-step for

bone density predictions and actual time is not properly known yet. Comparison of

these simulation results with dual energy X-ray absorptiometry (DEXA) scans

involving same human femoral specimen may lead to more precise validation,

allowing iterative time-step to be related to physical time. A schematic description of

iterative bone remodelling combined with FE analysis is presented in Fig. 1.10.

**1.4.5 Fixation of cementless implant: primary and secondary stability**

The biologic fixation is an important criterion associated with the long-term survival

of cementless THA. The absence of biologic fixation has often been reported as one

of the major causes of aseptic loosening of cementess hip implant (Maloney et al.,

1989; Sugiyama *et al.*, 1989; Philips *et al.*, 1990; Pal and Gupta, 2011). A

combination of both primary as well as secondary stability is necessary for long-term

success of the THA. During early post-operative period, when the bone ingrowth is

yet to commence, the primary stability or the mechanical stability is typically

governed by the amount of bone-implant relative micromotion, induced by the

physiological loading (Viceconti *et al.*, 2006). Secondary stability indicates the

implant-bone relative micromotion occurring under physiological loading conditions,

after mechanical interlocking through bone ingrowth is completed. This biologic

interlocking is clinically known as ‘osseointegration’. On the basis of human retrieval

studies, Albrektsson *et al.* (1981) described ‘osseointegration’ as the attachment of

lamellar bone to implants without intervening fibrous tissue. Further animal studies

and human retrieval analyses of implants have led to a better understanding of this

process (Galante *et al.*, 1971; Zweymüller *et al.*, 1988).

Subsequent to implantation, the implant-bone interface undergoes an adaptive

process of bone ingrowth upto a point, when the two parts become osseointegrated

(Kienapfel *et al.*, 1999; Lintner *et al.*, 1986). The long-term mechanical stability (or

secondary stability) of the prosthesis is determined by this amount of

osseointegration. However, the initial post-operative micromotion (i.e., lack of

primary stability) has predominant influence on the bone ingrowth, and subsequent

osseointegration (Manley *et al.*, 1995; Spears *et al.*, 2000; Callaghan *et al.*, 1992).

Lack of primary stability of cementless implants inhibits bone ingrowth, but promotes

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fibrous tissue formation (Pilliar *et al.*, 1986; Engh *et al.*, 1992; Bragdon *et al.*, 1996;

Jasty *et al.*, 1997). On exceeding certain threshold value, micromotion may lead to the

formation of fibrous layer at the interface (Engh *et al.,* 1992; Jasty *et al.*, 1997). This

may impair the implant-bone interface stiffness, resulting in poor secondary stability

of the prosthesis. A threshold micromotion value of 40 μm was reported by Engh *et*

*al.* (1992), whereas Jasty *et al.* (1997) suggested a more conservative value of 20 μm.

In essence, a desired level of primary stability should prevail postoperatively in order

to promote secondary (i.e., long-term) fixation through osseointegration (Burke *et al.*,

1991; SØballe *et al.*, 1993).

**1.4.6 Cementless femoral implant designs: clinical findings**

A large variety of cementless femoral implants are available in the market. Barring a

few, majority of these fall into three broad design categories: cylindrical, tapered and

anatomic (Fig. 1.11). Early designs of femoral implants were cylindrical, with

extensive coating at the distal leg of the implant. Consequently, a considerable

amount of diaphyseal bone ingrowth could be attained with these implants. However,

many of these designs were associated with a high rate of cortical atrophy, proximal

stress shielding and bone resorption. Additionally, patients sometimes complained of

thigh pain, presumably owing to elastic mismatch between the stiff stem and the

biologically flexible femur (Bourne *et al.*, 1994; Lavernia *et al.*, 2004).

In order to provide an enhanced physiological proximal loading of the femur to

counter stress shielding, a porous ingrowth surface was provided metaphyseally,

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(a) (b) (c)

**Fig. 1.11:** Different designs of cementless femoral implant: (a) fully-coated cylindrical, (b) tapered round and (c) anatomic (adapted from Khanuja *et al.*, 2011)*.*

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while keeping the distal shape still cylindrical (Keaveny and Bartel, 1995). The

porous coatings in these early stems were not applied circumferentially, but rather in

patches throughout the proximal region. These designs, however, recorded significant

distal osteolysis. The cause of this osteolysis was believed to be polyethylene

particles; gaining access to the distal femur through channels between the areas of

porous coating (Schmalzried *et al.*, 1992). This led to the development of femoral

implants with circumferential proximal porous coating to eliminate access channels

for particulate debris.

Distal fixation in femoral stems not only imparts immediate stabilisation, but also

allows for a greater lever arm to resist torsional forces as compared to proximally

coated stems. In order to achieve distal

fixation in cylindrical stems, cortical

support was a requirement. Consequently,

the prosthesis needed to be canal-filling,

with implants having large diameter. Stem

stiffness depends on the Elastic modulus of

the material and is proportional to the

fourth power of the diameter. Therefore,

an increase in the stem diameter resulted in

greater stem stiffness − a factor that has

been linked to distal thigh pain and

proximal stress-shielding (Vresilovic *et al.*,

1996). A 2-year radiograph, shown in Fig.

1.12, demonstrates pronounced proximal

**Fig. 1.12:** Radiographs demonstrating bone-remodelling: (*left*) the immediate bone remodelling due to stress shielding in

post-operative image, (*right*) the 2-year radiograph (Bugbee *et al.*, 1997). a femur of a 66-year old woman, fitted

with distal fixation type cylindrical stem (Bugbee *et al.*, 1997). The frequency of thigh

pain has been reported between 1.9% and 40% in some studies, wherein the cause of

pain is attributed to large stem-size, distal porous coating, and material composition

(Bourne *et al.*, 1994; Lavernia *et al.*, 2004).

In order to minimize stem stiffness, some implants were designed with coronal

slots within the distal third of the stem and longitudinal grooves that can enhance stem

strength without increasing the diameter. Another attempt was to use proximal

cancellous bony ingrowth along with three-point stem fixation to obtain immediate

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stability. This led to the development of tapered stems. Clinical results of straight

tapered stems with at least 10-year follow-up have been fairly good, with stem

survivorship reported between 92% and 100% (Bourne *et al.*, 2001; Reitman *et al.*,

2003; Parvizi *et al.*, 2004). Moreover, the incidences of thigh pain were considerably

reduced when compared with cylindrical stems.

Anatomic stems, as the name suggests, were designed to mimic the natural

biomechanics of hip joint by facilitating biological load transfer. They incorporate an

anteroposterior curve to match the natural bow of the patient’s femur. It was hoped

that the anatomic design would allow for enhanced physiological loading of the

femur, thereby reducing stress-shielding and distal thigh pain. However, the results

were found to be a tag discouraging, with studies indicating a higher frequency of

thigh pain compared with other traditional designs, e.g., tapered or cylindrical

(Campbell *et al.*, 1992; McAuley *et al.*, 1998). Nevertheless, some recent follow-up

studies reported stable fixation and better durability for anatomic femoral stems

(Butler *et al.*, 2005; Ferrel *et al.*, 2009; Nakamura *et al.*, 2012).

With increasing number of younger, healthier and more active patients

undergoing hip replacement surgery, the method of bone preservation has become

essential now-a-days (Mai *et al.*, 2010). Proximal fixation with less subsequent stress

shielding has become the design focus. These implant designs typically include

double-taper metaphyseal filling stems and single M-L (medial-lateral) taper stems.

Each of these implants relies on metaphyseal fixation and bone ingrowth in the

proximal, diaphyseal and subtrochanteric regions. A double taper design allows for

‘fit-and-fill’ of the metaphysis, theoretically allowing more rotational support (Howie

*et al.*, 2007). Both these stem designs have an exceptional track record with minimal

thigh pain and survivorship greater than 95% at 20 years (Lombardi *et al.*, 2009;

Khanuja *et al.*, 2011). Apart from these, a lot of cementless stem designs have been

reported to possess excellent long-term clinical and radiographic outcomes (Bojescul

*et al.*, 2003; Capello *et al.*, 2003; 2006; Gul *et al.*, 2008; Guo *et al.*, 2009; Kim, 2005).

Short metaphyseal stems with minimal or no distal leg are also available. The

design rationale behind these implants was to improve load transmission and to

preserve femoral bone stock with no reaming and minimal broaching. These implants

further address the problem of metaphyseal-diaphyseal diameter mismatch, a problem

associated with some patients. However, there is a dearth in long-term follow-up

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investigations on this design. In a 2-year follow-up study using short metaphyseal

stem, Schmidutz *et al.* (2012) observed that the outcome was comparable to that of

clinically proven conventional hip implants. They further suggested that the design

might be an alternative for young patients, provided the results are confirmed by a

more rigorous and longer term study.

Modern THAs are performed using femoral stems made of stainless steel, cobalt-

chrome alloy (Co-Cr), Ti-alloy, e.g., Ti-6Al-4V and, on a limited basis, composites

having low modulus of elasticity. There is ample clinical evidence to support Ti-6Al-

4V as the material of choice for cementless femoral stems (Bobyn *et al.*, 1992;

Qureshi *et al.*, 2002; Kim, 2004; 2005). The primary advantages of Ti-6Al-4V over

Co-Cr are relatively lower modulus of elasticity (*E* = 110 GPa) and greater

biocompatibility. These factors result in decreased stress shielding and favourable

bone ingrowth, respectively. Moreover, Ti-alloy is clinically found to be relatively

inert in the physiologic environment. Currently, Ti-6Al-4V is extensively used as the

cementless implant material in conjunction with hydroxyapatite coating (HAC).

**1.4.7 Investigations on shape optimization of femoral implants**

The shape (or geometry) of a femoral stem is known to influence the clinical outcome

of a hip prosthesis (Huiskes and Boeklagen, 1988; Viceconti *et al.*, 2001). This

prompted researchers to carry out shape optimization studies on hip implants. The

earliest ever study of shape optimization of femoral implants was conducted by Yoon

*et al.* (1989), who minimized the stress concentration in the cement mantle. In their

seminal work, Huiskes and Boeklagen (1989) optimized the shape of a cemented stem

with the objective of minimizing the stresses in the cement layer. In this 2-D study, a

numerical shape optimization (NSO) procedure was introduced to minimize strain

energy density (SED) of the cement mantle at the bone-cement interface for various

loading conditions. The geometric parameters were varied manually during the

iterative process, using the values of the objective function. The optimal stem shape,

thus obtained, was found to be narrower at the proximal side and distally tapered, with

a relatively pronounced mid-stem area. The study culminated into commercialization of a novel design of cemented hip stem, called Biomet®. However simplistic be the

model, it was the first step towards optimally designed stem providing valuable

insights into future scope of study.

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The study by Katoozian and Davy (2000) implemented a numerical procedure for

the 3-D shape optimization of the femoral component in THA for both cemented and

cementless prostheses. A parametric scheme was developed for characterizing the

component geometry in terms of longitudinal and cross-sectional shape variables. The

3-D design model was integrated with a 3-D FE analysis and a numerical optimization

procedure. An idealized femoral geometry and perfectly bonded interfaces were used

in the study. The design objective was to uniformly distribute stresses along the bone-

stem interface. The effects of two different musculoskeletal loading conditions and

several different objective functions were examined. The general trend in all

optimization outcomes was to produce a somewhat bulky implant with a rectangular

cross-section. The outcome was, however, found to be more strongly affected by

loading condition, rather than the choice of objective function. The study, conducted

by Chang *et al.* (2001), was based on minimizing the difference between strain energy

density of the intact and the implanted femur bone using a reduced mid-stem implant

design. A sensitivity analysis was performed in the study to determine influential

design and environmental factors. The reduced mid-stem geometry with a short

stabilizing distal tip was found to minimize the bone remodelling signal while

maintaining satisfactory stability. Hip joint force orientation was found to be more

influential than the effect of the controllable design variables on bone remodelling,

whereas the cancellous bone Elastic modulus was found to have predominant

influence on the relative implant-bone displacement.

The post-operative short-term failure scenarios associated with cementless hip

stem were addressed in the study proposed by Kowalczyk (2001). The failure type

considered in the study was the post-operative factors leading to improper bone

ingrowth into the porous-coated implant surface, which results in formation of a

permanent gap filled with fibrous tissue. The reason for this is believed to be either

initial improper fitting of the implant into the medullary canal or excessive

micromotions occurring at the bone-implant interface. Such micromotions can prevent

osseointegration and a permanent layer of fibrous tissue is formed instead of a desired

level of implant-bone bonding. Such an interfacial layer, even if mechanically stable,

may lead to inflammatory reactions and bone resorption in the long run (Kowalczyk,

2001). Hence, the initial stability was taken as the objective function for the study.

The study assumed that the implant fitted the medullary canal perfectly. Thus, the

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investigation was carried out towards minimizing the micromotions between the bone

internal surface and the porous-coated part of the implant surface. Furthermore,

perfect bonding condition was assumed in the porous-coated part of implant surface.

A gradient-based optimization scheme was employed for the study. The optimum

shape appeared to be relatively long and proximally porous-coated on about half of

the stem length.

Thus far, all the shape optimization models were single-objective in nature.

However, it was evident that the assessment of femoral implant design needs to

account for more than one failure objective. Therefore, a multi-criteria optimization

model appeared to be a better design approach. Fernandes *et al.* (2006), in the first

ever multi-objective study of hip prosthesis, proposed a 2-D FE model for shape

optimization of cementless hip stems by minimizing relative displacement and stress

on bone-stem interface. In order to incorporate several daily life activities, multiple

loads were considered in the study. Geometric parameters at some selected cross

sections were identified as design variables. The parameters were subjected to

geometric constraints to ensure a clinically admissible shape. The implant-bone

construct was considered a structure in equilibrium and contact condition at the

interface was assumed. Different lengths of porous coating were analysed. The

optimization problem was solved numerically using a steepest descent algorithm.

In a more sophisticated study on shape optimization of cementless stem, Ruben *et*

*al.* (2012) developed a 3-D shape optimization procedure to design prostheses with a

better initial stability and less proximal bone loss. The proposed model used a multi-

criteria formulation that allowed the simultaneous minimization of three important

criteria for uncemented implants: relative tangential displacement, contact stress and

proximal bone loss. The optimization method considered bone and interface

conditions immediately after the surgery. However, a concurrent model for bone

remodelling and osseointegration was also used to study the long-term behaviour of

the optimized stem shapes. Stem shapes, thus obtained, were found to be

contradictory. The minimization of displacement criterion led to stems with wedge-

design and rectangular sections to improve axial and rotational stability, respectively

(Min *et al*., 2008). The minimization of contact stress criterion led to small stem tips

to avoid direct contact with the cortical bone (Romagnoli, 2002). With the

minimization of remodelling criterion ‘minimally invasive stems’ were obtained

(Niinimaki *et al.*, 2001). The non-dominated solutions had a combination of

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geometric characteristics depending on the weight coefficients imposed on the

objectives. The trade-off designs were found to predict better performance compared

to the initial prosthesis geometry. The long-term analysis was in agreement with some

clinical observations; totally coated stems were found to have more stability, whilst

the partially coated designs yielded less bone loss (Sluimer *et al.*, 2006).

The genetic algorithm (GA) was first used by Ishida *et al.* (2011) to solve shape

optimization problem for a cemented prosthesis. The multi-objective analysis

considered the largest maximum principal stress of the cement mantle, proximal and

distal, as two separate objective functions to be minimized. Two boundary conditions,

walking and stairs climbing were considered separately. Hence, a total of four

objective functions were evaluated. A total of 10 design parameters were used for the

parametric 3-D model of the hip implant. The parameters were subjected to geometric

constraints. A cement mantle of uniform thickness (2 mm) was added around the

stem. The neighbourhood cultivation genetic algorithm (NCGA) was introduced to

solve the multi-objective optimization problem. The objective functions were found to

be mutually contradictory, for both walking and stairs climbing conditions. Five

dominant stem shapes were chosen as the Pareto-optimal solutions. The optimization

method was proposed for minimization of the chances of cement mantle fracture.

**1.5 Evolutionary computing and genetic algorithms**

Earlier computer scientists were as much interested in developing computers as in

understanding the biological processes of evolution. In their quest for finding means

to imbue computer programs with artificial intelligence, several scientists

independently studied evolutionary systems with a vision that evolution could be used

as an effective optimization tool for engineering problems. The primary objective of

all these systems was to evolve a population of candidate solutions to a given problem

using genetically inspired operators. Rechenberg (1965; 1973) introduced a method

called ‘evolution strategies’ to optimize real-valued parameters for devices such as

airfoils. This idea was further developed by Schwefel (1977). Fogel *et al.* (1966)

implemented a technique called ‘evolutionary programming’, in which candidate

solutions were represented as finite-state machines, which were evolved through

random mutation and natural selection. In the 1950s and the 1960s, several other

investigators developed algorithms inspired by natural evolution for optimization and

machine learning (Box, 1957; Friedman, 1959; Bledsoe, 1961; Bremermann, 1962;

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Reed *et al.*, 1967). In addition, a significant number of studies involved use of

computers to simulate evolution for the purpose of controlled experiments (Fraser,

1957a; 1957b; Martin and Cockerham, 1960; Baricelli, 1962).

Genetic algorithms (GAs) were invented by John Holland in the 1960s, and later

further developments were carried out by his group at the University of Michigan.

GAs are heuristic search techniques developed on the basis of natural selection and

are routinely used as an optimization tool for a variety of engineering problems, as

well as problems in other fields. In a GA-based optimization, a population of

candidate solutions (or individuals) is evolved towards better solutions while passing

through a series of operations. The evolution starts from a population of randomly

generated individuals, with the population in each iteration called a ‘generation’. The

fitness of every individual in the population is evaluated in each generation, while the

fitness is usually the value of the objective function in the optimization problem to be

solved. The fitter individuals are preferred from the current population based on

suitable selection scheme, and each individual’s genome is modified using genetic

operators, cross-over and mutation, to form a new generation. The new generation of

candidate solutions is then used in the next iteration (or generation). The algorithm is

set to terminate when either a maximum number of generations has been attained, or a

satisfactory fitness level has been reached for the population. The solutions are

typically encoded in binary as strings of 0s and 1s; however, other types of encoding

are also used.

Whilst a combination of evolution strategies, evolutionary programming and

genetic algorithms form the backbone of the field of evolutionary computation,

genetic algorithms, in particular, garnered extensive popularity over the years owing

to its vast applicability. Many modern-day engineering problems demand searching

through a large number of possibilities for optimum solutions. Moreover, there is

further requirement for an algorithm to be adaptive for consistent performance under

changing environment. Biological evolution has been an appealing source of

inspiration for addressing these problems. In this natural process, fittest individuals or

organisms, that are able to survive and reproduce in their environment, are chosen as

desired ‘solutions’ from an enormous set of genetic sequences. Seen in this light, the

evolution can also be conceived as a method for designing innovative solutions to

complex problems by searching through a constantly changing set of possibilities. GA

presents a robust theoretical framework which is patterned after such evolutionary

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search mechanisms. The inherently adaptive nature of GA, thus, makes it perform

more consistently compared to the traditional optimization tools.

**1.6 Motivation of the study: unsolved problems**

Although several shape optimization models were studied and new femoral stem

designs were proposed, there were several limitations in those studies (Huiskes and

Boeklagen, 1989; Kowalczyk, 2001; Fernandes *et al.*, 2006; Ruben *et al.*, 2012). Most

of these studies were based on idealised femoral bone model, consisting of one

distinct layer for cortex and one homogeneous core of cancellous bone (Fernandes *et*

*al.*, 2006; Ruben *et al.*, 2012; Ishida *et al.*, 2011). Such an idealised bone model does

not represent the cancellous bone heterogeneity, since it has been observed that the

bone material property varies considerably across the proximal part of the bone.

The biomechanical causes of failure may sometimes be mutually conflicting in

nature (Kuiper and Huiskes, 1997). Consequently, solution of one problem has been

reported to trigger another (Khanoki and Passini, 2012). Therefore, it is necessary to

implement multi-objective shape optimization as a pre-clinical tool to tackle the

design conflict, and subsequently attain trade-off implant designs by judiciously

compromising on the design objectives. Nonetheless, most of the existing shape

optimization studies on femoral implants were single-objective in nature (Yoon *et al.*,

1989; Katoozian and Davy, 2000; Kowalczyk, 2001).

The existing parameterization schemes for defining 3-D implant geometry

(Katoozian and Davy, 2000; Ruben *et al.*, 2012; Ishida *et al.*, 2011) too have certain

limitations with regard to exploring vast varieties of implant shapes. The search for an

optimal geometry calls for extensive exploration of all possible and admissible

shapes. In order to explore such vast possibilities, more number of design parameters

need to be introduced, which would further enhance the design complexities. Such

complexities may not be suitably handled by traditional optimization tools and

requires more robust search technique to be implemented.

Shape optimization problems were further reported to be typically non-convex

and characterized by multiple local optima (Fraternali *et al.*, 2011). Compared to a

traditional optimization method, such as the steepest-descent method, a robust

heuristic method, such as the GA, has the advantage of complex multi-variable

analysis and its search for optimum values does not require a gradient function.

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Therefore, the chance of a GA-solution being trapped into a local minimum is

diminished. The single solution approach of Fernandes *et al.* (2006), while searching

for optimization direction, was also criticized in a recent study by Ishida *et al.* (2011).

The GA, on the other hand, presents a multi-solution approach to the optimization

problem without requiring knowledge of the search environment. Thus, the GA seems

to be a more appropriate optimization tool for solving such a multi-variable space

optimization problem. The multi-criteria optimization study by Ruben *et al.* (2012)

considered imposing weight coefficients for setting relative priorities on the objective

functions. However, such approaches may fail to attain Pareto-optimality due lack of

selection pressure on the solutions (Deb *et al.*, 2002). Multi-objective GAs, such as

non-dominated sorting genetic algorithms-II (NSGA-II), have proven capabilities to

address such issues.

The importance of primary stability of the implant-bone interface with regard to

the hip stem design has already been discussed. Extensive preclinical investigations

on various hip implant designs, considering primary stability as design objective, have

scarcely been carried out. The design evaluation of thousands of new implant models

involves remeshing on each implanted model; a task which is manually intensive in

nature (Harrysson *et al.*, 2007; Bah *et al.*, 2011; Abdul-Kadir, 2014). Moreover,

solving the non-linear finite element (FE) model to assess the corresponding implant-

bone relative micromotion is computationally expensive and time consuming.

Therefore, the development of a predictive mathematical model, with no recourse to

FE analyses, may be endeavoured in order to identify the relationship between the

design parameters and post-operative micromotion of hip implant. Finally, a hybrid

intelligent framework, comprising of both GA and neural network (NN), may be

employed to build a multi-objective optimization scheme in order to gain further

insights into the optimal design of hip stem. However, there is a scarcity of such

investigations in the field of shape optimization of cementless THA.

**1.7 Objectives and scope of the thesis**

The primary goal of the study is to find optimally designed cementless femoral stems

for better performance and durability, using a 3-D multi-objective shape optimization

scheme, aided by a hybrid intelligent framework comprising of the GA and NN. The

generic biomechanical failures related to cementless THA were addressed in an

attempt to evolve improved design of femoral implant. The study was based on static

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analysis considering multiple musculoskeletal load cases, representing normal

walking and stairs climbing. Final design outcomes were reassessed using an

evolutionary interfacial condition by simulating the combined effect of bone

remodelling and implant-bone interface adaptation due to bone ingrowth. The present

investigation consists of the following objectives, which collectively contribute

towards achieving the goal of the study.

• Development and experimental validation of FE models of intact and

implanted femur using digital image correlation (DIC).

• Multi-objective shape optimization of cementless femoral implant based on

minimization of stress shielding and interface stresses.

• A combined neural network and genetic algorithm based approach for

optimally designed femoral implant having improved primary stability.

• Effects of interfacial conditions on shape optimization of cementless femoral

implant: a study based on hybrid intelligent framework.

• Assessment of optimally designed femoral implant based on evolutionary

interfacial conditions.

**1.8 Structure of the thesis**

This study presents a novel custom-based multi-objective shape optimization scheme

for cementless femoral implant that employs genetic algorithms (GA) as the

optimization tool. Mechanically induced post-implantation adverse complications,

such as excessive implant-bone interface stresses, bone resorption due to stress

shielding and initial micromotion, were minimized in the optimally designed implants

and important conclusions on the favourable geometric features of the implants were

discussed. A general introduction, including literature review, motivation, and

objectives of the study is presented in Chapter 1. The scope of other chapters of the

thesis, which collectively contributes towards achieving the primary goal of this

study, is presented in the following order.

In Chapter 2, FE predictions of surface strains in intact and implanted composite

femurs were verified using DIC. Relationships were sought between post implantation

strain states and clinically observed longer-term bone density changes. An elaborate

description on the development of the 3-D FE models of the femurs (implanted and

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intact) is presented, with necessary details of geometry, meshing, material properties,

interface conditions, and loading and boundary condition data. Once validated, the FE

model generation technique was adopted for further numerical investigations in the

subsequent chapters of the thesis.

Chapter 3 presents a customised approach to develop a fully automated 3-D

multi-objective shape optimization scheme for cementless femoral implant design by

integrating FE analysis and the GA. The FE model of the femur bone was developed

and subsequently, heterogeneous bone material properties were assigned element-

wise based on a subject-specific CT-scan dataset. Two biomechanical failure criteria

associated with cementless THA, stress shielding induced proximal bone resorption

and excessive interface stresses, were minimized simultaneously and optimal femoral

stems were assessed, subsequently, based on adaptive bone remodelling algorithm.

Chapter 4 presents a predictive mathematical model based on back-propagation

neural network (BPNN) to relate femoral stem design parameters to the post-operative

implant-bone micromotion. The sample data set used for training the BPNN was

obtained from multiple FE analyses of bone-implant constructs for a range of implant

designs. Unlike bonded implant-bone interfacial condition used in Chapter 2,

frictional contact was assumed for obtaining sliding micromotion data at the

interfacial nodes. Once the BPNN was trained and validated, a single-objective

mixed-integer GA-search was carried out to seek for the optimal stem geometry that

would minimize micromotion.

The conflicting design outcomes arising from the previous two chapters were

reconciled in a multi-objective shape optimization in Chapter 5, by introducing a

novel hybrid intelligent system, comprising of the GA, NN and FE analysis. In this

chapter, bonded interfacial condition was used to analyse the long-term failure

objectives, stress shielding and interface stresses, whereas the BPNN developed in

Chapter 3 was used to predict micromotion, based on the implant geometry. From the

cluster of Pareto-optimal solutions, two dominant trade-off stem geometries were

chosen for further analysis.

In Chapter 6, a trade-off implant model was assessed based on an evolutionary

interfacial condition and the results were compared with a generic design of femoral

implant. The entire simulation accounted for the combined effect of adaptive changes

in bone density (bone remodelling) and bone ingrowth, which eventually influenced

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the evolutionary interfacial characteristics. Several rule-based criteria were adopted to

predict bone ingrowth onto the cementless implant, assuming a fully-coated implant

surface. The internal bone remodelling simulation was carried out based on the

adaptive bone remodelling theory.

Finally, in Chapter 7, the significance and conclusions of the study, as a whole,

are presented. Based on the results of each chapter, conclusions pertaining to

favourable design outcomes of cementless femoral implants have been discussed in

detail. Furthermore, a retrospective review and recommendations for future research

on the shape optimization of cementless femoral implants have been presented.

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