Biomechanics of skeletal fracture fixation and spine structure

Krishna Kotlanka Rama

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**BIOMECHANICS OF SKELETAL FRACTURE
FIXATION AND SPINE STRUCTURE**

KOTLANKA RAMA KRISHNA

SCHOOL OF MECHANICAL AND AEROSPACE ENGINEERING

2006

Biomechanics of Skeletal Fracture Fixation and Spine Structure

Kotlanka Rama Krishna

School of Mechanical and Aerospace Engineering

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Abstract

This dissertation is on ‘biomechanical optimization analysis of bone-fracture fixation and spinal unit’s structures of the vertebral body and intervertebral disc’.

Biomechanical optimal analysis of bone-fracture fixation involves (i) determination of optimal plate geometry (ii) demonstration of stiffness-graded plates causing less stress-shielding and (iii) use of helical plates for transverse fracture and for improved plate-bone holding capacity.

Biomechanical optimal analysis of the spinal vertebral body (VB) and intervertebral disc (IVD) demonstrates (i) how the VB transmits all types of loading as axial forces through its cortex, to demonstrate its inherent design as a high-strength light-weight structure, (ii) how the IVD effectively contains deformation with increasing level of applied forces, because of the role of the nucleus pulposus in stressing the annulus and raising its elastic modulus, so that nucleotomy (wherein the nucleus pulposus is removed) is a contra-indication for the ruptured disc.

The objective of treating the fractured bone is to achieve proper (anatomical congruent) healing at the fracture as early as possible. To achieve this, one standard method that can be adopted is internal fixation by a stainless steel (SS) plate. Recently, there is considerable interest in the usage of compliant plates to enhance bone healing with reduced stress shielding. In this dissertation, firstly an analytical solution is developed to determine the screw forces in the plate assembly that stabilizes the fractured bone under bending load.

Based on the analytical calculations, an optimal plate selection criterion for necessary and sufficient stress shielding is proposed.

Secondly, the effectiveness of employing a non-homogeneous stiffness graded (SG) plate (rather than a homogeneous SS plate) for reduced stress shielding is investigated using, finite-element analysis. It is found that stress shielding on bone by SG plate is less compared to SS plate.

Fixation of fractured bones poses problems of screw loosening and backing out. In view of the above factors, the plate fixation should be such that its holding power to the bone is improved. For this purpose, contouring a straight plate into a hemi-helical form (also called hemi-helical plate) for fracture fixation is proposed. The efficacy of hemi-helical plates is elucidated through screw pull-out experiments and finite-element analysis, for axial compression, bending and torsional loadings.

Spinal biomechanical efficacy lies in its being able to sustain heavy loads (in spite of its light weight), while retaining its flexibility. This property is to a large extent based on the optimal intrinsic designs of its component structures, namely the spinal vertebral body (VB) and the intervertebral disc (IVD) for load bearing. The VB is shaped like a hyperboloid shell, whose generators are criss-crossed straight lines. This makes it possible for all the loadings sustained by the VB to be transmitted through its cortex walls as axial forces (in the hyperboloid shell generators). The VB stress-analysis is carried out to understand how effectively the cortical VB can bear uniaxial compression, bending and torsional loads, by transmitting those loads as axial forces in its walls. In this process, the

relationship between the dimensions of the VB (based on physiological loading conditions) that makes it to be a functionally optimal (light-weight and high-strength) structure is developed. The calculated geometrical parameters are in agreement with the Magnetic Resonance Imaging (MRI) scans of VB.

The IVD acts as a shock absorbing unit, and effectively contains its lateral and axial deformations while providing the necessary flexibility to the spine. The above stated functions are due to the stress-stiffening material (elastic modulus) property of its annulus. One of the biomechanical roles of the nucleus pulposus (NP) in the IVD is to stress the annulus, while the IVD is loaded. Elasticity solutions of the IVD, with NP and without NP (i.e. nucleotomized IVD), subjected to the compressive load are developed. Based on the analyses, it is observed that the deformations of the intact IVD do not increase in proportion to the load. However, it is shown that the nucleotomized IVD deforms more than the healthy IVD, because the annulus stiffening effect caused by the pressurization of the NP is absent, thus for the same level of loading, the nucleotomized IVD deform more than the intact IVD. This result is a contra-indication for nucleotomy.

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2. K.Ramakrishna, S.Sivashanker, I.Sridhar, K.S.Khong and D.N.Ghista 'Stiffness-Graded Bone Plate for Fracture-Fixation: An Inside View' in "Advances in Medical Diagnostic Techniques and Procedures" eds Meghna Singh and S.Radhakrishnan, Anshan Ltd., UK, pp181-186, 2005.

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Contents

Abstract.....	ii
Acknowledgement.....	v
Contents	vii
List of figures.....	x
List of tables	xviii
Abbreviations	xix
Notations	xx
Glossary of terms	xxi
Chapter 1	1
Introduction.....	1
1.1 Theme of the dissertation.....	3
1.2 Need and the objectives of research	5
1.3 Scope and layout of dissertation	7
Chapter 2	10
Literature review	10
2.1 Bone role, properties and fracture patterns.....	11
2.2 Bone healing (under fixation).....	16
2.3 Bone fracture fixation	27
2.4 Structural optimization in anatomy	44
2.5 The spinal vertebral body as an optimal structure	49
2.6 The spinal intervertebral disc.....	72
Chapter 3	82
Structural analyses and finite element modelling of bone-plate assembly, for optimal bone fracture fixation	82
3.1 Analysis of forces in the screws of an internally-fixed bone under axial load.....	83

3.2 Structural analysis of plate-reinforced bone under bending, to determine the forces applied by the screws.....	86
3.3 Finite-element analysis of bone fracture fixation	98
Chapter 4	131
New modality of fracture fixation using a hemi-helical plate: Optimality considerations.....	131
4.1 Four-point bending test on fracture fixed bone, by means of a dynamic compression plate.....	134
4.2 Hemi-helical versus straight-plate bone fracture fixation: Pull out experiments observations	141
4.3 Hemi-helical verses straight-plate bone fracture fixation: Finite element analysis	149
4.4 Clinical application of hemi-helical plate.....	165
4.5 Remarks on hemi-helical plate	166
Chapter 5	170
Intrinsic features of the spine vertebral body and intervertebral disc as optimal structural design	170
5.1 Optimal design of the vertebral body	171
5.2 Conceptual idea of biomimic anterior fixator.....	175
5.3 Intervertebral disc stress deformation characteristics.....	177
5.4 Analysis: Disc stresses, displacements and deformed geometry	178
5.5 Stress analysis of the healthy disc under compression	183
5.6 Mechanism and computation of disc deformation.....	185
5.7 Disc herniation, back pain and nucleotomy.....	190
5.8 The nucleotomised disc: stresses analysis	190
5.9 Mechanism of disc deformation in nucleotomised disc	192
5.10 The intervertebral disc as an optimal structure.....	194

Chapter 6	197
Conclusions and scope for future work	197
6.1 Summary	198
6.2 Conclusions.....	201
6.3 The key contributions of this work.....	204
6.4 Limitations of this work.....	207
6.5 Future work.....	207
 References.....	 209

List of figures

Figure 2-1: Photoelastic stress contours on the femur model with and without iliotibial tract.....	13
Figure 2-2: Typical long bone fractures morphology corresponding to the type of external load applied to the long bone.	15
Figure 2-3: Relative bending rigidity provided by callus formation and plate.....	20
Figure 2-4: Canine tibia fracture callus in relation to implants	21
Figure 2-5: Effect of flexible plating in producing exuberant medulary as well as extracortical callus on the opposite surface which will protect the implant from failure, in spite of the minimal use of screw.....	21
Figure 2-6: Principle of leaving large fracture gaps which rapidly fill with solid callus where gap strain is small.	24
Figure 2-7: Tissue differentiation concept relating mechanical loading history to skeletal tissue regeneration (of pluripotential mesenchymal tissue of callus).....	26
Figure 2-8: Helical Plate	37
Figure 2-9: Factors affecting the bone-plate fixation	38
Figure 2-10: Screw mechanical characteristics.	39
Figure 2-11: (a) Bending open (all screws) (b) Bending open (no inner screws)	41
Figure 2-12: (a) Compression development between the plate and bone by tightening of the screws (b) Locked compression of plate with locking screws.	42
Figure 2-13: Finite element model for bone fracture fixation	43
Figure 2-14: Femur models.....	46
Figure 2-15: (a) Optimal ratio of r_i/r_e for minimal weight and maximal strength of a long bone (b) Magnetic resonance image of the femur cross section at diaphysis.	47

Figure 2-16: The cortical vertebral body is shaped as a hyperboloid (HP) shell formed of two sets of generators, which are anatomically tied, so as to reduce their effective lengths.....	49
Figure 2-17: The cortical vertebral body is shaped as a hyperboloid (HP) shell formed of two sets of generators.	51
Figure 2-18: The geometry of the VB hyperboloid (HP) shells	52
Figure 2-19: Geometry of hyperboloid generators	53
Figure 2-20: Stresses acting on an element of the HP Shell.....	54
Figure 2-21: Stress components at waist section of HP Shell	55
Figure 2-22: Equivalent straight bars (aligned with the generators) placed at equal spacing to take up the stresses.	56
Figure 2-23: Equilibrium of forces on a shell segment	56
Figure 2-24: Equivalent diagonal forces in the intersecting-bars to take up the stresses around a shell element.....	57
Figure 2-25: (a) Bending moment on the VB (b) plan view at the section BB (i.e. at waist circle).....	59
Figure 2-26: (a) Bending stress at the waist section of the VB hyperboloid shell (b) Stresses resultants at the waist-circle on a shell element of the HP shell, under the action of the bending moment M.....	61
Figure 2-27: Equivalent diagonal forces in the intersecting-bars to take up the stresses on a shell element on the compression side of the HP shell.....	61
Figure 2-28: Stress resultants in the HP shell element ($N_\phi=N_\theta=0$ and $N_{\phi\theta} = \tau t$) due to torsion T acting on the VB.....	62
Figure 2-29: Equilibrium of a shell segment under torsion (T) and shear stresses (τ) (or shear stress-resultant $N_{\phi\theta}$).....	63
Figure 2-30: Equivalent diagonal forces in the intersecting generators to take up the stresses acting in the shell element	63
Figure 2-31: An axial burst fracture	65
Figure 2-32: Posterior fixation technique as per AO ASIF recommendation	66

Figure 2-33: Forces exerted on a lumbar spinal cross-section due to the anteriorly acting weight load.....	67
Figure 2-34: Anterior placement of the dynamic compression plate according to AO ASIF	68
Figure 2-35: Rezaian spinal fixator is placed along the loading axis of the spine	69
Figure 2-36: Rezaian spinal fixator biomechanics	70
Figure 2-37: Radiograph of the combined anterior and lateral fixators	71
Figure 2-38: (a) The location of intervertebral disc within the spinal column (b) Schematic of the disc structure. The NP is surrounded by annulus fibrosus. This outer layer is made up of concentric heically-oriented laminar bands.....	73
Figure 2-39: Stress-strain curve in compression of wet lumbar intervertebral disc of persons 40 to 59 years of age.....	74
Figure 2-40: Nutrition mechanism of the disc (a) during loading, the NP enters the cancellous vertebral body and (b) during unloading, the NP draws the nutrition into the disc.....	75
Figure 2-41: Finite element model of the intervertebral disc	76
Figure 2-42: Axial compressive force Vs axial displacement of the intervertebral disc.....	77
Figure 2-43: Deformed horizontal cross sectional shape of the disc under compression loading.....	78
Figure 2-44: (a) Herniated disc. NP compressing the nerve is schematically depicted in the insert (b) Progression of the herniated disc.....	79
Figure 2-45: (a) NP evacuation time vs. NP volume for different suction pressures (=14,0,-14 psi in a,b,c) (b) NP evacuation time vs. pressure drop around the probe for 50%, 70% and 90% of evacuation for different probe length/diameter ratios	81
Figure 3-1: Free body diagram of bone and plate fixation	83
Figure 3-2: Free body diagram with detailed representation of forces.....	84

Figure 3-3: Influence of $\bar{E}$ and $\bar{A}$ on the shear force on the screw in axial loading condition.	85
Figure 3-4: (a) Fracture fixation by plate under bending moment (b) Normal stress distribution for bone-plate assembly under bending moment (c) the stresses in figure 4b are a combination of the stresses due to axial forces and bending moment (d) representation of the axial and bending moment acting on the fracture fixation.....	89
Figure 3-5: Free body diagram of bone and plate as clamped boundary condition.....	91
Figure 3-6: Bending moment diagram on the bone	93
Figure 3-7: Free body diagram of bone and plate as a beam with six screws	96
Figure 3-8: Schematic of bending stress distribution in bone without and with plate.....	100
Figure 3-9: (a) Schematic representation of dimensions (mm) and loading conditions used for FEA (b) uniform stiffness plate (c) stiffness graded plate in length (d) stiffness graded plate in thickness.....	101
Figure 3-10: Normal stress distribution at the callus (crack interface) and neutral axis location for different callus and plate properties, as healing progresses.	102
Figure 3-11: Comparison of the stresses along length of bone-plate interface for SS, SGL and SGT.....	104
Figure 3-12: Different screw locations for which FEA is carried out	106
Figure 3-13: Normal stresses at the top face of bone in contact with the plate for S6	109
Figure 3-14: Normal stresses at the top face of bone in contact with the plate for S4-1 (a) at initial stages of healing (b) final stages of healing	110
Figure 3-15: Normal stresses at the top face of bone in contact with the plate for S4-2.....	111
Figure 3-16: Normal stresses at the top face of bone in contact with the plate for S4-3.....	112
Figure 3-17: Normal stresses at the top face of bone in contact with the plate for S2N.....	113

Figure 3-18: Normal stresses at the top face of bone in contact with the plate for S2E.....	114
Figure 3-19: Models developed in Pro/E.....	116
Figure 3-20: Assembly of plate, screw and bone in ABAQUS.....	117
Figure 3-21: Bone plate assembly depicting the contact surfaces.....	120
Figure 3-22: Boundary conditions and loading conditions for 3D model.....	122
Figure 3-23: (a) Mesh for fracture fixed bone by plate and screw. (b) The variation of bending moment with the number of elements used in the analyses.	123
Figure 3-24: Analysis of fixation with Stainless-steel plate (a) Von-mises stresses (MPa) in the plate (b) Stresses (S_{22}) in screws (MPa) along the axis of the screws (c) Stress (S_{22}) (MPa) developed in the screws while loading (in 2-3 plane)	126
Figure 3-25: Analysis of fixation with Stainless-steel plate (a) Von-mises stresses (MPa) in the bone (b) Normal stress distribution (MPa) in bone at various cross-sections.....	127
Figure 3-26: Analysis of fixation with Stiffness-graded plate (a) Von-mises stresses (MPa) in the plate (b) Stresses (S_{22}) in screws (MPa) along the axis of the screws (c) Stress (S_{22}) (MPa) developed in the screws while loading (in 2-3 plane)	128
Figure 3-27: Analysis of fixation with Stiffness-graded plate (a) Von-mises stresses (MPa) in the bone (b) Normal stress distribution (MPa) in bone at various cross-sections.....	129
Figure 4-1: (a) perpendicular screw (b) convergent (c) divergent (d) alternating. All the inclinations are 15° normal to the axis of the bone.....	133
Figure 4-2: Experiment setup of the fracture fixed bone before loading.....	136
Figure 4-3: Position of strain gauges on synbone and plate. 1 st and 2 nd are bolt gauges, 3 rd is strain gauge for stainless steel; 4 th and 5 th are strain gauge for plastics.....	136
Figure 4-4: Load displacement graph for PSO, CSO, DSO, ASO specimen configuration. The slope of the load-displacement curve represents the	

stiffness of the assemblies and the area of the load-displacement curve represents energy to re-fracture.	138
Figure 4-5: Force in each screw vs moment applied for PSO,DSO, CSO, ASO configurations	140
Figure 4-6. Terms of a helical plate. Insert is the side view of the helical plate depicting the $\frac{1}{2}$ pitch of the plate.	141
Figure 4-7: Inclined screw orientations	143
Figure 4-8: Set up of the pull-out test with newly designed grippers holding the assembly: Bone-180 ⁰ helical plate held by four cortical screws.....	144
Figure 4-9: Load Vs Extension curves for all the configurations of fixations shown in figure 4-7	145
Figure 4-10: (a) Sequential pull-out of straight plate PSO, CSO, DSO, ASO configurations (b) The holding power of HHP is high, such that sequential screw pull-out is not observed (c) However, the bone failed indicating that the fixation is stiff enough so that screw loosening does not occur.	146
Figure 4-11: FE models in ABAQUS (a) straight plate model (b) 90 ⁰ helical plate model (c) 180 ⁰ helical plate model (d) oblique fracture fixed by a helical plate. The bone axis (depicted in the figure) is along coordinate 3.	151
Figure 4-12: Boundary and loading conditions applied on the 180 ⁰ helical plate fixation on the simulated fractured bone: (a) compressive load (b) torsional load and (c) bending load. Similar loading conditions are applied on the straight plate and the 90 ⁰ helical plate fixations.	152
Figure 4-13: Mesh sensitivity analyses on a straight plate fixation.....	154
Figure 4-14. Comparison of stiffness of assembly	156
Figure 4-15: Different locations considered in the finite element analysis for computing fracture gap movement.	157
Figure 4-16.Relative movement along axis 3 at A,B,C and D location on the fracture gap	158

Figure 4-17: Relative movement along axis 2 at A,B,C and D location on the fracture gap (a) for compressive load (b) for bending moment (c) for torsional load. Along axis 2, the movements in helical plate	159
Figure 4-18. Relative movement along axis 1 at A,B,C and D location on the fracture gap	160
Figure 4-19. Location of the neutral axis (NA) on the bone cross-section at different places along the length of the bone for straight plate 90^0 helical plate and 180^0 helical plate fixations.	164
Figure 4-20: Clinical application of hemi-helical plate.	166
Figure 4-21: Schematic of a fracture-fixed bone by a 180^0 helical plate under torsion.	168
Figure 5-1: A couple of man-made hyperboloid structures	172
Figure 5-2: MRI of lumbar vertebrae. $H/R = 0.7$ (average of L2 to L5) and a/R is 0.91 (average of L2 to L5).....	174
Figure 5-3: Biomimic anterior fixator.	176
Figure 5-4: (a) Geometry and deformation variables of the spinal disc, loaded in compressive force F. (b) Comparison of the effects of including linear and non-linear material (M) and geometry (G) solution options on compressive behaviour of the disc.....	179
Figure 5-5: Normal stresses σ_r and σ_z under the applied force compressive F.	183
Figure 5-6: (a) Disc vertical deformation vs. compressive force on the annulus (b) radial bulge at $r=a$ compressive force on the annulus (c) Disc radial bulge at $r=b$ vs. compressive force (d) Disc $(u_{b,nu}-u_{a,nu})$ vs. F.	188
Figure 5-7: Graphical representation of disc deformation from the unloaded state until the compressive load of 2000N is reached.....	189
Figure 5-8: Normal stress $\sigma_{z,nu}$ equilibrating the applied force F in a nucleotomized disc.....	191
Figure 5-9: (a) Disc vertical deformation Vs compressive force on the annulus with and with out NP (b) Disc $u_{a,nu}$ vs. F with and with out NP (c) Disc $u_{b,nu}$	

vs. F with and with out NP (d) Disc ($u_{b,nu}-u_{a,nu}$) vs. F with and without NP.	193
Figure 5-10: Graphical representation of nucleotomized disc deformation from the unloaded state till the compressive load of 2000N.....	194
Figure 5-11: (a) Prosthetic disc nucleus (b) balloon intervertebral nucleus developed by Disc dynamics, Inc. Minnetonka.....	195

List of tables

Table 3-1. Design parameters of plate and calculated stress values in the bone callus at sites 1 and in the bone at site 2.	94
Table 3-2. Design parameters of the plate and calculated stress values in the bone callus at site 1 and in the bone at site 2.	97
Table 3-3. Forces in the screws for six screw fixation.	97
Table 3-4. Central deflection, shear stresses at the screw (at bone-plate interface), and the maximum compressive normal stress at the fracture site for two, four and six screw fixation illustrated in figure 3-12. SS: stainless steel, SGL: Stiffness graded along length, SGT: Stiffness graded along thickness.	108
Table 3-5. Effectiveness of stiffness graded plate compared with stainless steel plate	125
Table 4-1. Stiffness and energy to re-fracture for perpendicular screw orientation (PSO), convergent screw orientation (CSO), divergent screw orientation (DSO) and alternating screw orientation (ASO) configurations	137
Table 4-2. Stiffness, energy to initiate pull-out and peak pull-out for PSO, CSO, DSO ASO and hemi-helix configurations.	147
Table 4-3. Location of the neutral axis at different sites along the length of the bone	165

Abbreviations

<i>CBM</i>	Cell Biology based Model
<i>CET</i>	Cowin's adaptive Elastic Theory
<i>CFRP</i>	Carbon Fiber Reinforced Plastic
<i>FEA</i>	Finite Element Analysis
<i>FEM</i>	Finite Element Methods
<i>FGM</i>	Functionally Graded Materials
<i>FNT</i>	Frost's Flexural Neutralization Theory
<i>HHP</i>	Hemi Helical plate
<i>HP</i>	Hyperboloid
<i>IVD</i>	Intervertebral body
<i>LC-DCP</i>	Limited Contact- Dynamic Compression Plate
<i>NA</i>	Neutral Axis
<i>NP</i>	Nucleus Pulposus
<i>PST</i>	Pauwels' Stress magnitude Theory
<i>S2E</i>	Two Screw Extreme Fixation
<i>S2N</i>	Two Screw Near Fixation
<i>S4-1</i>	Four Screw mode 1 Fixation
<i>S4-2</i>	Four Screw mode 2 Fixation
<i>S4-3</i>	Four Screw mode 3 Fixation
<i>S6</i>	Six Screw Fixation
<i>SGL</i>	Stiffness Graded along Length
<i>SGT</i>	Stiffness Graded along Thickness
<i>SS</i>	Stainless Steel
<i>VB</i>	Vertebral Body

Notations

C	Distance between neutral axis and plate top surface
d_b	Diameter of bone
d_l	Distance between centers of plate and bone
D	Elastic matrix
E	Young's modulus
G	Shear modulus
I_p	Moment of inertia of plate
I_b	Moment of inertia of bone
M	Total bending moment applied
M_p	Bending moment on plate
M_b	Bending moment on bone
y_l	Distance between NA and center of plate
y_2	Distance between NA and center of bone
U	Strain energy density
ν	Poisson's ratio
σ_Y	Yield stress
σ	Normal stress
τ	Shear stress
ε	Strain

Glossary of terms

Anisotropic	not isotropic; having mechanical and/or physical properties, which vary with direction at a point in the material
Anterior	of or towards the front of the body
Asymptotes	straight lines that have the property of becoming and staying arbitrarily close to the curve as the distance from the origin increases to infinity. For example, the x-axis is the only asymptote to the graph of $\sin(x)/x$.
Biocompatible material	a characteristic of some materials that when they are inserted into the body does not produce a significant rejection or immune response
Biodegradation	the breakdown of organic materials into simple chemicals commonly found in the body
Bone marrow	the tissue contained within the internal cavities of the bones. A major function of this tissue is to produce red blood cells
Bone plate	usually a relatively thin metal device which is affixed to bone via screws. Bone plates are used to immobilize the fractured bone such that healing can occur
Bone screw	a threaded metal device which is inserted into bone. The functions of bone screws are to immobilize bone fragments or to affix other medical devices, such as metal bone plates, to bones
Bone	the hard tissue that provides structural support to the body. It is primarily composed of hydroxyapatite crystals and collagen. Individual bones may be classed as long, short, or flat
Brittle material	material deformation with negligible plastic deformation before fracture
Burst fracture	it is a descriptive term for an injury to the spine in which the vertebral body is severely compressed. They typically occur

	from severe trauma, such as a motor vehicle accident or a fall from a height. With a great deal of force vertically onto the spine, a vertebra may be crushed
Calcification	the deposition of hydroxyapatite onto osteoid to form new bone tissue
Callus	the mass of woven bone that forms during initial stages of fracture healing
Cancellous bone	bone tissue that characteristically has many grossly visible pores and openings, typically found in the ends of long bones
Cannaliculi	a microscopic tunnel in bone tissue, which houses a dendritic projection used by osteocytes to communicate with each other and with blood stream
Cartilage	The hard, thin layer of white glossy tissue that covers the end of bone at a joint. This tissue allows motion to take place with a minimum amount of friction
Collagen	the primary component of organic matrix of bone, occurring as fibers
Compact bone	also known as cortical bone, Bone tissue that is relatively dense, having spaces or canals, typically found in the shafts of long bones
Compression	a force that tends to move the atoms or molecules of a substance closer to each other
Cortical bone	see compact bone
De-mineralized bone	bone tissue which has been depleted of its minerals; e.g., calcium and phosphorous
Diaphysis	the shaft of a long bone
Distal	in the limbs, away from the trunk or towards the terminal part of the limb

Endosteum	a membrane that lines the medullar or marrow cavity of bones
Energy	the capacity for doing work, as in moving load over a given distance, measured in joules
Epiphysis	a secondary center of ossification of a bone, found especially at the ends of long bones
Extension	the action that increases, or straightens, the angle at joint
Fixation	the immobilization or prevention of further movement of fragments following a fracture, often by medical intervention
Fracture	one type of trauma, involving breakage of bone
Haversian canal	the bony tube surrounding a blood vessel and oriented longitudinally within a bone, which nourishes bone tissue as part of the Haversian system
Hematoma	a blood clot
Homogenous	material properties are independent of the position in the structure
Hydroxyapatite	a crystalline compound of calcium and phosphorus that is the inorganic component of bone
Hyperboloid	it is a surface of revolution obtained by rotating a hyperbola about the perpendicular bisector to the line between the foci
Immobilization	limitation of motion or fixation of a body part usually to promote healing
In Vitro	describing biological phenomena that are made to occur outside the living body
In Vivo	within a living body. In vivo is Latin for in life
Inferior	of or toward the bottom or lower part of body
Intervertebral disc	they are found between each vertebra, which makes the spine flexible and act as a shock absorber.
Isotropic	Having the same properties irrespective of direction

Lamellar bone	mature bone tissue organized into concentric rings or lamellae of bone, with 15-20 lamellae surrounding a haversian canal through which blood vessels runs, produced by remodelling some type of immature bone tissue
Lateral	away from the body's midline
Medial	towards the body's midline
Medullar cavity	the marrow cavity inside long bones
Metaphysic	the region at either end of an immature long bone
MRI	it is a method used to visualize the inside of living organisms as well as to detect their structural compositions
Orthotropic	having three mutually perpendicular planes of elastic symmetry.
Ossification	the formation of new bones by the replacement of pre-existing tissues
Osteoblast	the cell responsible for secreting osteoid, the organic component of bone, and forming new bone tissue
Osteoclast	the large, multinucleate cell responsible for resorbing bone tissue and initiating remodelling of bone tissue
Osteocyte	a transformed osteoblast cell trapped in calcifying osteoid, which communicates with other bone cells
Osteoporosis	a progressive disease in which the bones gradually become weaker and weaker, causing changes in posture and making the individual extremely susceptible to bone fractures
Periosteum	a tough, highly vascularized membrane that covers the outer surfaces of bone
Piezoelectric	producing electrical current when deformed, characteristic of both whole bones and collagen
Posterior	of or towards the back of the body
Proximal	towards the trunk or superior part of the limb

Resorption	the removal of bone tissue by normal physiological process or as part of a pathological process such as an infection
Tension	a force that tends to separate the atoms or molecules of a substance
Torsion	a twisting force
Trabeculae	see cancellous bone
Transverse	a horizontal plane or section that divides the body into superior and inferior portions
Trauma	any wound or injury
Vertebral body	it is a thin ring of dense cortical bone and shaped like an hourglass, thinner in the center with thicker ends

Chapter 1

Introduction

This chapter provides an introduction for the dissertation and contains the theme, objectives and the scope of the dissertation.

Biomechanics is a sub-field of biomedical engineering that involves the application of engineering mechanics dealing with the mechanical behavior of tissues and design of medical devices and implants. In orthopedics, biomechanics establishes the knowledge base for skeletal and spinal injury causation and prevention, reviews the methodologies used for the recovery of lost function for the quality of life improvement, and for the design of associated prosthetic devices. This dissertation deals with biomechanics of internal skeletal fracture fixation and spinal structures, from the viewpoint of optimization: how to optimize skeletal fracture fixation and what is the underlining biomechanics behind the intrinsically optimal design of spinal structures.

The major functions of the bones are to: (1) provide movement in conjunction with muscle action, (2) protect the internal body organs, (3) produce red blood cells from the bone marrow and (4) act as a store house for minerals (e.g. calcium). Fractures cause trauma to the bones, and the bone in response to the trauma tries to restore its integrity and adapt to closely resemble its pretrauma condition through the phases of bone healing.

Long bone fractures often heal functionally, but the muscles may pull apart the distal fragments, resulting in a permanent shortening or a union with a deformity. In the case of the fractures of the vertebral body, the spinal system kyphosis changes and damages the spinal cord. Surgical restoration and prosthetic devices (either through non-invasive or invasive surgical technique) is necessary to provide the fertile conditions for the healing and restore the lost function.

The principles of fracture treatment (either of long bones or vertebral fracture) are: (1) anatomical rectification, (2) stable fixation (through implants usage) designed to fulfill the biomechanical demands at the fracture, (3) preservation of the blood supply to the bone

fragments and the soft tissues and (4) early pain-free mobilization of the patient. Skeletal fracture fixation optimization concerns optimal design of plates and screws to stabilize the fractured bone.

Spinal structures (namely the vertebral body and the intervertebral disc) impart rigidity and flexibility, high strength and light weight to the spinal column to enable it to support the torso and upper limbs, enable the body to be erect and bend, and lift loads without causing trauma to the embedded spinal cord. Implicit in the natural design of these spinal structures is the biomechanics of (1) how vertebral body constitutes a high strength light weight structure, and (2) how spinal disc can take on heavy loads without proportionally large deformations to cause herniation of the spinal cord structures, resulting in back pain.

1.1 Theme of the dissertation

The unifying theme of the dissertation is optimization. This dissertation delineates (1) how to develop optimal fixation of fractured bones by means of plates and screws, and (2) what makes the spinal vertebral body (VB) and intervertebral body (IVD) to be intrinsically optimal structures.

Skeletal fracture fixation considers the bone and plate as structures connected by screws to restore the stiffness of the fractured bone, to destress the callus during healing, to reduce the fracture gap, and to prevent bone stress-shielding away from the fracture gap. The optimization aspect to satisfy the above criteria considers (1) the stiffness of the plate, (2) stiffness variation of the plate (both longitudinally and transversely), and (3) the

number and location of the screws with respect to the fracture site. This optimization is carried out both analytically and by finite element analysis (FEA) in chapter 3.

Then another aspect of bone fixation is considered for a transverse fracture in chapter 4. Here, the helical plating concept is introduced, which is deemed to be one of the optimal modes for fixing of transverse fractures. Herein, the analysis deals with both experimentation and FEA on the fracture fixed bones. In FEA, both 90^0 and 180^0 contoured plate fixations are analyzed and compared with straight plate fixation, from the viewpoint of fracture gap reduction and stress-shielding. Through experimentation, screw-holding capacities of the straight plate fixation and helical plate fixation are compared.

Next, structural optimization of spinal structures is discussed in chapter 5. In the case of spine, the analysis comprise (1) how the hyperboloid-shaped vertebral body (VB) shell takes on and transmits all types of loads as axial forces through its cortex, thereby making it an intrinsically optimal structure, and (2) how the intervertebral disc (IVD) compression of the annulus and nucleus pulposus (NP) enables the disc to bear increasing amounts of axial loading without proportional increase in disc deformations. It is recognized that a lot of work has been carried out on the spinal VB and IVD, particularly in finite element analysis of the VB incorporating posterior structures and the non-circular shape of the disc. However in this dissertation, spinal structural analysis primarily emphasizes the optimal aspects of the intrinsic designs of the VB and IVD.

In the case of the VB, the hyperboloid shape comes about by means of inclined generators connecting the top and bottom end-plate rings. It is shown in this dissertation that these generators transmit loadings from the top to bottom end-plate as axial forces,

without involving the VB cortex in bending stresses. This is what makes the VB to be a high-strength and light-weight intrinsically-optimal structure.

As regards the IVD under compression, the annulus gets stressed and also pressurizes the NP. The annulus elastic modulus is stress dependent, and its modulus increases with increase in stress. When the disc is subjected to increasing loads, the NP gets increasingly pressurized and the annulus gets increasingly stressed, but its elastic modulus increases at diminishing rate. This is what makes the disc deformation to not increase in proportion to the load increase.

However when the annulus gets ruptured, this protective property of the disc is disrupted and the disc herniates, bulges out between vertebrae and impinges on the spinal nerves and spinal cord. Nucleotomy is one of the methods of treatment for herniated disc. Here again, it is shown how the nucleotomised disc deforms in proportion to the load, and hence cannot retain its underlining optimal principle.

1.2 Need and the objectives of research

Fracture-fixation of long bones using a plate is increasingly gaining importance with advances in the surgical techniques. Despite the advances in surgical techniques, stress-shielding (cortex thinning) and sequential screw failure (essentially loosening of screws and later pullout) are often seen during and after bone healing. Stress-shielding is often attributed to the flexural rigidity of the plate and to compressive forces between the bone and plate during fixing. The plate fixation should provide sufficient flexural rigidity to the fractured bone. Similarly, using more number of screws in the fracture-fixation will

weaken the bone. Thus, there needs to be optimality between the plate flexural rigidity and the number of screws in order to obtain effective healing. Thus the objectives are

1. To develop the biomechanics for the internal fracture fixation by plate and screws.
The remodelling of the bone due to biological changes is not considered in this study.
2. To identify the role of the plate modulus and positioning of screws for optimal fracture fixation (on long bone) through analytical solutions and finite element analysis (FEA).
3. To compare the stresses induced in the long bone (in bending loading conditions) by plate made up of stainless steel and stiffness-graded material (both longitudinally and transversely) using FEA.
4. To delineate the efficacy of helical plate in internal fracture fixation using FEA and experimentation to address stress-shielding, fracture gap movement and screw holding capacity.

Julius Wolff's Law states "*the form of a bone being given, the bone elements place or displace themselves in the direction of the functional pressure and increase or decrease their mass to reflect the amount of pressure*". As per the above stated law, it is apparent that in a bone structure few bone cells die and get replaced by new cells in a bid to sustain the form of the bone, and hence enable it to bear the loading prevalent on it (be it long bone or vertebral body). It is illustrated (as an exemplification of Wolff's law) that the trabecular structure within the proximal femur of the human bone (being a load bearing structure) follows the principal stress trajectories. Similarly in the case of human spine, Wolff's law

exemplified the hyperboloid shape of the vertebral body (VB). Herein, analysis of the hyperboloid VB shell is to demonstrate how its shape makes it a structure capable of bearing the loads sustained by it. Hence, the hyperboloid shaped VB shell is analyzed in compression, bending and torsional loads.

The human spine is made up of alternating vertebral body and intervertebral disc (IVD). IVD forms a strong joint and permits various movements of the vertebral column. An IVD is composed of an annulus fibrosus and a nucleus pulposus (NP). The annulus is a stress-stiffening solid, such that its elastic modulus increases with the increase in stress. The NP has another very important role, namely to contain the disc axial and radial deformations. Here, the objective is to develop the mechanism of how the annulus and the NP contain the deformations of the IVD.

1.3 Scope and layout of dissertation

This dissertation consists of the following topics

1. a. Literature review on the fracture fixation methods of the long bone and the mechanics behind such fixation.
- b. Summary of various designs (both geometry and materials) in internal fracture fixation by plates (especially on the long bones) which include the detailed discussion on the developments in plates.
- c. Literature review on the role of the spinal unit system as a flexible weight-bearing structure.

The above mentioned aspects are detailed in the literature review chapter (i.e. chapter 2).

2. Study on the transfer of load by screws between the plate and bone according to number and location of the screws through analytical solution. This solution is delineated in chapter 3.
3.
 - a. Two dimensional finite element models for fracture-fixed bone by rigid stainless steel plate and stiffness graded plate (both longitudinal and transverse), for different screw placement during different stages of healing are compared under bending loading condition.
 - b. Three dimensional finite element models for transverse fracture-fixed bone by rigid stainless steel plate and stiffness graded plate (only longitudinal) are compared, for bending moment. These models also provide insight on the stresses on screws.

The finite element analysis is described in chapter 3.

4.
 - a. Experimentation on the fracture-fixed bone by the plate and the screws under bending moment to determine the forces in the screws, for different angulations in the screws.
 - b. Experimentation to compare the holding capacities of the straight plate and the hemi-helical plate fixations.
 - c. FEA of the helical plating, to analyze for fracture gap movement as well as stresses on the plate, bone and screws, subjected to compression, bending moment and torsion.

The above mentioned experiments and finite element analyses are detailed in chapter 4.

5. The hyperboloid vertebral body is analyzed for compression, bending and torsion loading. It is shown that for all those loadings, the vertebral body cortex sustain and transmit only axial forces and no bending stresses through it (in chapter 2). Based on the analysis, a biomimic anterior fixator is proposed. The analytical solution of hyperboloid vertebral body is provided in chapter 5.
6. The intervertebral disc effectively bears heavy loads, and at the same time contains its deformation. The role of the nucleus pulposus (NP) in containing the deformation is studied by an elasticity analysis, that compares the deformations in the healthy disc (with NP) and nucleotomised disc (without NP). Based on the deformations, it is noted that nucleotomy is a contra-indication for ruptured discs. The analysis of intervertebral disc in compression is provided in chapter 5.

The *conclusion and future work* chapter is followed after the chapter five.

Chapter 2

Literature review

The aim of this chapter is to provide information on works deals with biomechanics for optimal fracture fixation and biomechanics of intrinsically optimal spinal structures' design analysis. This chapter is subdivided into four parts.

Part one deals with the biomechanical role of bone, its mechanical properties, and fracture patterns. Part two deals with the phases of bone healing, role of fracture fixation techniques in healing, and mechanisms (and theories) of fracture fixation.

Part three deals with works on the first part of the dissertation, namely on internal fracture fixation of bone. It discusses the types of fracture fixations (with an emphasis on plate fixation), in an attempt to relate to the objective of the dissertation on optimal fracture fixation.

Part four provide information related to second primary part of the dissertation, namely to design analyses of spinal vertebral body and intervertebral disc. The emphasis in the dissertation is on what makes them intrinsically optimal structures. Even though there is a paucity of work oriented to this objective, works somewhat related to this objective will be discussed. Sections 2.5.1 , 2.5.2 and 2.5.3 are a part of the course materials learnt from the course Biomechanics-II (M6529) offered at Nanyang Technological University in 2003.

2.1 Bone role, properties and fracture patterns

The skeletal system is made up of individual bones and the connective tissues that join them, and serves the body both mechanically and metabolically. Bone is the main constituent of the system, and differs from the connective tissues in rigidity and strength. The rigidity and strength of bone enable the skeletal system to maintain the shape of the body, to protect the internal organs, to supply the framework for the bone marrow, and to transmit forces of the muscular contraction from one part of the body to another during movement [1-8].

Bone is considered as a mineral-reinforced composite material, consisting of fibrous protein, collagen (abundant and structural protein) and the mineral of the bone (crystalline analogue of hydroxyapatite $[\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2]$). The mineral content of bone serves as a reservoir for ions, particularly calcium, and also contributes to the regulation of extra-cellular fluid composition, particularly ionized calcium concentration [9-15].

Bone is an anisotropic, heterogeneous, viscoelastic, piezoelectric material. In addition, bone is a self-repair structural material, able to adapt its mass, shape and properties to change in mechanical requirements [16-29].

Bone aging is accompanied by a continual decrease in water content, leading to the loss in strength and toughness but increase in elastic modulus. Thus, growing bone has different mechanical properties from mature bone [30]. Immature bone, especially in the earliest phases of growth, can undergo large deformations without gross fracture, whereas mature bone undergoes small deformation before fracture. Typical mechanical properties of cortical bone are given in the Table 2-1.

Table 2-1: Mechanical properties of bone* [17]

Property	human	bovine
Elastic modulus, GPa		
Longitudinal	17.4	20.4
Transverse	9.6	11.7
Bending	14.8	19.9
Shear modulus, GPa	3.51	4.14
Poisson's ratio	0.39	0.36
Tensile yield stress, MPa		
Longitudinal	115	141
Transverse	—	—
Compressive yield stress, MPa		
Longitudinal	182	196
Transverse	121	150
Shear Yield stress, MPa	54	57
Tensile ultimate stress, MPa		
Longitudinal	133	156
Transverse	51	50
Compressive ultimate stress, MPa		
Longitudinal	195	237
Transverse	133	178
Shear ultimate stress, MPa	69	73
Bending ultimate stress, MPa	208.6	223.8
Tensile ultimate strain		
Longitudinal	0.0293	0.72%
Transverse	0.0324	0.67%
Compressive ultimate strain		
Longitudinal	0.0220	2.53%
Transverse	0.0464	5.17%
Shear ultimate strain	0.33	39.0%
Bending ultimate strain	—	1.78%

A long bone (e.g. femur) acts as a column to support compressive load, as a shaft to resist torsion, and as a beam to resist the bending moments. The internal forces acting within the intact femur with the muscles attached to the femur was described by Pauwel

* Martin, R.B. and Burr, D.B. 1998. Skeletal tissue mechanics. pp.137. *Springer, New York.*

[4]. His observation through a photoelastic experiment was that the bending moment and compressive forces on the mid shaft of the femur model with iliotibial tract are minimal compared to the femur model without iliotibial tract (figure 2-1). Without iliotibial tract, femur model is strongly stressed in bending moment and compressive forces as shown in figure 2-1a. With iliotibial tract which progressively tightens with the loading (body weight), the bending moment and compressive forces are largely reduced as shown in figure 2-1b. However, due to the lack of precise muscle force values no exact quantification of compressive and bending moments was provided.

Figure 2-1: Photoelastic stress contours on the femur model with and without iliotibial tract. (a) without iliotibial tract, femur shaft is strongly stressed in bending and compression (b) with iliotibial tract, the bending moment and compression is reduced significantly. This depicts the tension band effect on the femur due to the iliotibial tract [4].

The exact forces in the fracture-fixed bone (femur) by plates and screws (during various stages of healing) are not reported in the literature. This is due to (i) a wide variety of fracture treatment techniques that varies with the severity of the fracture, and (ii) immobilization of the fracture fixed bone along with the treatment of the soft tissues (which includes muscles). Nevertheless, bending is a major loading condition that contributes to bone stress shielding and screw failure either by pull out or loosening from the fixation. Thus, bending load is predominantly considered in this dissertation.

It is to be noted that the four-point bending moment is not a physiological loading condition, but is a practical way of applying pure bending moment in the region of interest. Hence, four-point loading was performed to understand the behavior of the fracture-fixed bone-plate assembly in bending.

Prior to the discussion on bone healing and fracture fixation, its failure mechanisms and fracture patterns of bone are summarized in this section. The loading conditions on bone are broadly categorized as impact, axial (compression and tension), bending, torsion and fatigue [31-37]. When the applied load exceeds the sustainable limit, bone will fail in the form of a fracture. Every fracture leads to a complex tissue injury involving bone and the surrounding soft tissue creating local circulatory disturbances, pain and reflex immobilization.

Figure 2-2 Typical long bone fractures morphology corresponding to the type of external load applied to the long bone [35,38,39]. (a) transverse fracture (b) oblique fracture (c) transverse fracture (d) butterfly fracture and (e) spiral fracture

Fracture patterns of long bones follow basic rules. In axial tensile loading conditions, maximum tensile stresses are generated in a plane perpendicular to the load applied leading to transverse fracture pattern (figure 2-2a). Compressive load leads to oblique fracture due to shear failure (figure 2-2b). Under pure bending, the convex side and concave side are subjected to tension and compression respectively. The deformation of an element inscribed in bone that undergoes bending is illustrated in the figure 2-2c, with elongating surface in tension and shortening surface in compression. Because bone is more susceptible to failure in tension than in compression, the tension side fractures first. The fracture on tension surface progresses across the bone, creating a transverse fracture without comminution (figure 2-2c).

Long bones are slightly curved (especially the femur) and are subjected to a combination of axial compression and bending. Under combined loading (bending and axial compression), the bone under compression breaks as a result of shear stress before

the tension failure progresses all the way across the bone, resulting in multiple fragments (commonly called butterfly fracture) as shown in figure 2-2d [35,38].

Pure torsion results in a spiral fracture, with the fracture line oriented about 45^0 to the axis about which torque is applied (figure 2-2e). In torsion, an element on the surface of the bone that was initially square will distort into a parallelogram (insert in figure 2-2e), with the longer diagonal in tension, and the crack generated perpendicular to the diagonal in tension [40,41].

2.2 Bone healing (under fixation)

2.2.1 Phases of bone fracture healing

Although this section does not have bearing on our work on bone fracture-fixation, it is provided here by way of information. The healing of a fracture is remarkable repair process, at attempting reconstitution of the injured bone close to its original form [8,10,17,38]. Changes associated with the healing of fracture can broadly classified as inflammatory, repair and remodeling [42-44].

In the *inflammatory phase*, chemotactic factors and cytokines will induce host defense cells as well as *highly vascularised repair granulation tissue* to form around the damaged and necrotic bone ends. With high local tissue oxygen, fibrogenic tissue will proliferate to provide an initial scaffold between the fracture ends. This phase lasts from the first 24-48 hours of injury into the first week. Granulation tissue can tolerate 100%⁺

⁺ <http://www.wheelessonline.com/ortho/strain> viewed on 19 June 2006

strain, and hence surgical fracture fixation should take this into account, and prevent devascularization of this repair tissue [10].

Under conditions of low oxygen as the inflammatory phase progresses, *hyaline and fibrocartilage differentiation* will occur. This process begins within 48 hours after injury and may peak at 9-14 days, depending on the tissue milieu. It also follows the peak fracture blood vascularization at 2 weeks [4,7,45]. Osteogenic factors then cause further differentiation of chondroid tissue into bone, much in the way as ossification occurs during normal growth. Intramembraneous ossification occurs as “hard” fracture callus further from the fracture site, whilst endochondral ossification occurs as “soft” callus around the fracture ends.

In the case of fractured bone, mechanical stability (induced by appropriate fracture fixation) allows replacement of cartilage with bone. If excessive motion is applied to the bone ends, there will be increased vascularity and fibrogenic tissue abounds - resulting in non-union. Goodship and Kenwright [46] however demonstrated bony enhancement with interfragmentary motion in the order of 500 μ (microns), and applied micromovement during the first month of treatment resulting in significantly shorter healing time. A slightly flexible fixation promotes micromotion which produces exuberant callus clearly visible on x-rays, whilst very rigid fixation diminishes this. Herein, lies the relevance of mechanobiology to osteosynthesis.

The consolidation phase follows the inflammatory and endochondral ossification phase. When the tissue strain is below 2%, all calcified cartilage will turn into bone provided there are adequate osteogenic factors [39]. This process is easily monitored by radiographs in which the fracture gap will slowly disappear with more mineralization.

There is also a reduction in osteopenia, concomitant with the reduction of hypervascularity at 12 weeks. Consolidation begins as early as 6 weeks and may last up to 6 months. Strain of between 5-20% will result in limited ossification, resulting in persistence of fibrous tissue and fibrous non-union. This phase is called the repair phase [39,42-44].

The repair phase is followed by the bone remodeling phase. Herein, progressive maturation of bone results in the realignment of the 3-dimensional bone structure, according to the lines of stress applied to the bone according to Wolff's Law. This final process of fracture healing begins at about 3 months, and may take up to a year or more to complete. It lasts until the bone has completely returned to its original morphology, including restoration of the medullary canal and all the woven bone is replaced by lamellar bone. Cancellous bone consolidates and remodels only to the trabecular phase, which takes about half the time of cortical bone, which must remodel into a complex Haversian structure through a slower process.

In fracture-fixation, callus plays a prominent role. Fracture callus of mineralized cartilage occurs between bone ends (*gap callus*), along the medullary cavity (*medullary callus*) and on the outer cortex (*periosteal callus*) (figure 2-3). The importance of callus is in providing the tissue mass that is required to provide initial stiffness between the fracture ends so that osteogenesis can occur. The stiffness generated must resist bending and torsional forces. This stiffness is minimal in the early phase of healing, and hence fracture immobilization or internal fixation is required. If absolute stability is provided by implants, then there is no stimulation for the callus process, and healing is by "primary" intention, ie. by gap callus healing. In this case, the consolidation process is essentially bypassed into the

remodelling phase. The bone callus response and formation in fractured bone (with and without implants) is illustrated in figure 2-3.

In “secondary” fracture healing, the weakest callus is gap callus generated between well-reduced fracture ends. In figure 2-3, medullary callus (b) provides some resistance to bending forces, but it is periosteal or extracortical callus (c) that is most effective in providing the bending and torsional resistance. Mechanically-speaking, a collar of fracture callus is good, and not considered as a sign of unstable osteosynthesis. With intramedullary devices, one is able to see large extracortical callus, while medullary callus is minimal, as shown in figure 2-4. With plate osteosynthesis, there is abundant medullary callus [47,48]. Periosteal callus also forms on the side opposite to the plate, especially on the compression (-ve strain) side of the bone (figure 2-5).

Fracture without implant **Fracture with implant**

Figure 2-3: Relative bending rigidity provided by callus formation and plate. Relative Bending Rigidity (RBR) is the ratio of bending rigidity of fractured bone (including callus/plate) and bending rigidity of intact bone. Bending rigidity is the product of the moment of inertia and the modulus of fixators.

Moment of inertia (used in bending) is given by $\frac{\pi}{4}(r_e^4 - r_i^4)$ where r_e is outer radius of bone and r_i is internal radius of bone. From these formulations, we can see that the RBR for fractured bone is zero as in fig (a). RBR for fig (b) is 1/100 as callus is only in the endosteum portion of bone. RBR for fig (c) increases with the increase in the outer radius (keeping the inner radius constant) due to the callus mass on the periosteum. This means that the callus formed around the periosteum provides more rigidity (as rigidity increases with the increase in callus away from the center of bone). With callus at both periosteum and endosteum, RBR increases as shown in fig (d). RBR for a fracture fixed bone with Intramedullary nail or plate is high as in fig (e) and (f). All dimensions are in mm [10].

Figure 2-4 Canine tibia fracture callus in relation to implants. Note the absence of medullary callus in nailed bone. The total volume of callus is formed by more extracortical callus than in fractures which are plated [48].

Figure 2-5 Effect of flexible plating in producing exuberant medullary as well as extracortical callus on the opposite surface which will protect the implant from failure, in spite of the minimal use of screw. X-Ray by courtesy of Dr.Khong Kok Sun

2.2.2 Fracture healing following plate fixation

Plates for bridging two (or more) portions of broken bone are formed to provide axial, bending and torsional stiffness suitable to the fractured bone. In the last three decades, the major efforts in the development of plate fixation have been towards a stable fixation, whereby a plate of a stiff material (such as stainless steel or titanium, etc) is securely attached to the bone to hold the fractured ends together. The overriding emphasis has been the development of high stiffness plate, which has the advantage that the bone can be brought under normal load very quickly, thus aiding the healing process [49-52].

However, this approach has clearly not achieved optimal results, as the long term physiological response of bone to plate has been largely ignored [53-55]. The plates have an undesirable consequence in providing stiffness that accompanies the protection of the underlying bone from stresses after the fracture has been healed [4,11,55-74]. Since the healing process is normally accelerated by moderate flexure of the bone about the fracture site, with rigid fixation methods primary union in humans is slow (taking about 12 to 24 months). During such a prolonged period of healing and after the fracture has been united, the bone shielded from stresses and strains by the plates may undergo osteopenia, i.e. bone porosity may increase and cortical thickness may decrease, which may result in the bone being prone to re-fracture following removal of the plate [75-79].

2.2.3 Role of piezoelectricity in fracture healing

Bone is electrically polarized when it is mechanically deformed (as bone is a piezoelectric material) [80-82]. This piezoelectric property of bone plays an important (but not so well-defined role in the healing and remodeling of bone. The magnitude of the polarization depends on the electrical field developed in the bone. In bending of bone,

tensile and compressive stresses are generated on convex and concave side of the deformed bone, respectively. Compressive stress induces negative electrical potentials, and tensile stresses induce positive potentials on the bone. Negative potentials signal for the apposition of bone, whereas positive potentials signal for the resorption of the bone. Thus, bone is laid on the concave side of the bone and resorption occurs on the convex side of the bone. It is therefore desirable that plates act as a tension band on the *convex* surface, to allow compressive forces to load the opposite *concave* cortex [82].

2.2.4 Role of stability in fracture healing

Absolute stability, taken to mean minimal or no gap strain, results in non-appearance of fracture callus, especially when the fracture ends are highly compressed without macro-gaps. Should there be failure or delay in union by gap callus, cyclical fatigue of the implant may occur from functional loading of the limb. Fatigue failure may occur at points of weakness within the plate such as a screw hole. It is thus imperative that during the healing stage the period of high stress in an implant be kept just adequate to permit callus formation and its conversion into bone, especially in slowly healing cortical bone. In cancellous bone, healing occurs at twice the rate of cortical bone, so that the implant does not fail from fatigue but may fail from loosening, especially in osteoporotic bone [83-86].

Relative stability is preferred as it encourages the formation of fracture callus. There needs to be a symbiotic “partnership” between an artificial implant and callus. The increasing stiffness and strength of fracture callus gradually unloads stress from the implant, and prevents the stress-shielding of the bone. Plate is most prone to fail at the

beginning of the healing. Hence callus stiffness cannot protect the plate. In the clinical setting, this is best desired in the diaphysis [39].

In the application of Wolff's Law to fracture mechanobiology, it may even be more beneficial to have somewhat flexible plating, so as to simulate callus response in the extracortical tissue (figure 2-6). *One needs to move from the concept of plates being "stress-protecting" to them being "stress-sharing" implants.* Future implants may need to have in-built variable stiffness [87-94].

Figure 2-6 Principle of leaving large fracture gaps which rapidly fill with solid callus where gap strain is small. No bone grafting was performed in this case and the callus is indistinguishable from that produced by intramedullary nailing. X-Ray by courtesy of Dr.Khong Kok Sun

2.2.5 The gap strain theory

Interfragmentary screw reduction of these fragments reduce fracture gaps, thus increasing gap strain unfavourably *without* making significant difference to overall fixation stability. The stresses in the plate, screws and bone are dependent on the fracture gap. Stresses in the plate and screws at the fracture site will be high when the fracture gap is more (say 6mm) in comparison with the stresses in plate and screws for small fracture gap (1mm) [95]. However, in providing appropriate fracture fixation to stimulate bone healing, one needs to take cognizance of the gap-strain theory [39,83].

The surfaces of fractured bone fragments are irregular and exact apposition between bone fragments as well as stability may be difficult to achieve. Due to this reason, different forms of tissues are formed at the fracture site as a biological requirement (i.e. bridging the fracture gap). The explanation for different types of tissues formed based on the strain at the fracture gap is delineated by interfragmentary strain theory - also called gap-strain theory by Perren [83]. Essentially, it states that if the fracture gap is very small, then for an applied load at the fracture site, the strain (elongation/gap width) is large. Thus granulation tissue, which can accommodate 100% strain, is formed at a small fracture gap. For similar loading, a larger fracture gap permits cartilage formation, as the strain is smaller. The tissue formed contributes to a reduction in strain at fracture site. This further diminishes interfragmentary strain, and will allow bony formation. *This theory implies that a somewhat larger gap may be more conducive to bone formation than a smaller gap.* However, further quantification of this mechanism is needed. While end-to-end bony apposition is advocated, side-to-side gaps need not be closed, allowing micromotion to establish callus between “butterfly” and the main shaft fragments (Figure 2-6).

Like ‘gap strain theory’ developed by Perren [83], Carter *et al.* [84] developed a hypothesis that correlates the tissue differentiation with local stress/strain history in callus. The phase diagram of the tissue differentiation concept of callus is depicted in figure 2-7. They hypothesized that: 1) hydrostatic pressure on callus directs the formation of bone, cartilage, fibrous cartilage, or fibrous tissue; 2) significant tensile strain leads to fibrogenesis; 3) significant tensile strain with a superimposed hydrostatic compressive stress causes fibrocartilage formation; 4) given adequate vascularity, minimal levels of hydrostatic stress and tensile strain allow direct bone formation; and 5) in a low strain environment, bone formation can be accelerated by slight hydrostatic tension.

Figure 2-7: Tissue differentiation concept relating mechanical loading history to skeletal tissue regeneration (of pluripotential mesenchymal tissue of callus) [27].

2.3 Bone fracture fixation

This section is relevant to works on bone fracture fixation, particularly by plate fixation of bone fractures.

2.3.1 Types of fracture fixation

Injury to bone can occur by a multitude of causes. In addition to the physical injury (trauma), infection, tumor, and genetic disorders can produce changes in bone that could be considered injurious [4,10,39]. Depending on the nature of injury, suitable method of treatment will be proposed for achieving the normal functioning of the injured bone. Bone fractures are broadly classified as “closed” or “open”.

Stress fractures and other mild bone breakages, where there is no skin lesion, are known as closed fractures. Open fractures describe those fractures wherein the skin is open, and the fracture is exposed to the external environment. In healthy individuals, fractures are often caused by excessive cyclical stress loading which exceeds the healing rate of the bone tissue. Such minor breaks, if not continuously aggravated, are generally treated by providing rest for a short to intermediate period (1-2 weeks) with the formation of micro callus [39,96-100]. In some cases, it is necessary to apply external immobilization to the bone or adjacent joints, by using either a brace or a cast.

For simple fractures, measures must be taken to correct the damage, and permit callus to form around the bone to allow union of the fracture [49]. In many cases, it is sufficient to align the bone by initially placing the surfaces of the bone segments which need to be held in contact with one another, and applying external immobilization. Loadings of a light to moderate level are conducive to bone growth. However, if the strains during healing are excessive, the fracture may not heal, and will alternatively go on to form

a non-union [39,56]. Plaster casts (which are contraindicated for use with open fractures) are utilized to provide stabilization of the bone, as well as to eliminate excessive stress loading during the healing process. With the use of plaster casts, the fractured bone reunites with a large amount of callus being formed at the fracture site. However, with the use of plaster casts, there is difficulty in obtaining adequate reduction of fracture. Also, there is a tendency for the joints on the either side of the fracture to stiffen and for the muscle surrounded by the cast to atrophy.

In comminuted fractures, the segments of the broken bone make the reduction of the fracture difficult, and invasive surgical procedures must be carried out in order to openly reduce the fractured bone segments together and fix them by the application of internal or external fixators. The principle objective of surgical procedures (fracture fixation) is to provide immobilization in the early stages of fracture healing, but make it flexible enough to avoid bone deterioration following the initial healing stage. Of course, all fixation devices should meet the general requirement of biomaterials i.e. biocompatibility, sufficient strength within dimensional constraints, and corrosion resistance [50].

Fixation methods can be broadly divided in to external and internal fixation [23]. External fixation is a technique where the pins are driven into the bone on both sides of fracture, and are secured by clamps or rods (external frame) located outside the body. External fixator (eg Ilizarov frame) is one type of popular fixation used for the fractures in tibia; however external fixator is not the likely choice of fixation if the fracture is on femur, humerus etc. External fixators are likely to develop infection at the places where the wires protrude out from flesh, if hygienic conditions are not maintained well.

Internal fixation is the method where plates, screws, intramedullary rods, wires, are the common devices fixed inside the body for providing immobilization at fracture site. Most fixation devices basically act as mechanical fasteners. The purpose of fixation is to transfer the combination of loads (compression, bending and torsion) from one end of a broken bone to another. A concise summary of advantages and complications of the external fixation, bone plates and intramedullary rods is listed in Table 2-2.

Table 2-2: Summary of issues related to external and internal fracture fixations

Fixator	Capabilities	Complications
External Fixator [101-106]	<ul style="list-style-type: none"> • Skeletal stabilization at a distance from the site of injury, disease or deformity • Free access to an injury site for surgical procedures • Adjustability of alignment, strength, and mechanical properties after the device has been applied • Ability to use other internal fixation devices after/before the device has been applied • Can be applied along with the internal fixators • Minimal interference with adjacent joints <p>Mobilization of limb and patient, including full weight bearing.</p>	<ul style="list-style-type: none"> • Faulty pin placement causing vascular injuries and joint stiffness (impalement of tendons, ligaments) • Component failure caused by misuse • Complex device for fixation and complex instruction • Pin problems (loosening, infection) • Delayed bony consolidation • Implant is bulky
Plates [47, 50-53, 57-73, 77-79, 107-114]	<ul style="list-style-type: none"> • Stable fixation (rigid immobilization at fracture site) or flexible fixation is possible • Reduces the fracture gap • Allow primary bone-healing or heal without visible callus or heal by endosteal callus • Early union was generally observed (compared to external fixators and intramedullary rod) 	<ul style="list-style-type: none"> • Loosening of screws • Local effect on vascularity of the cortex beneath the plate (blocking the normal blood flow) • Excessive shielding of stresses from bone (leading to osteoporosis)

	Can be applied to most of the fractures (simple and compound), including the fractures.	
Intramedullary nailing [48,49,115-121]	<ul style="list-style-type: none"> • Simpler and quicker in application • Soft tissue trauma is minimized • Unlike plate fixation, distraction of the ends does not occur • Operative time is reduced by the simplicity of the technique. 	<ul style="list-style-type: none"> • Less stability in fixation is achieved • Delayed healing • Intramedullary nails (with or without reaming) interfere with the re-establishment of blood circulation at fracture site • Cortex thinning (due to remodelling of bone) • Can be applied only on long bone fractures • Intramedullary nails will always be rotationally unstable • Current nails not designed to handle proximal and distal third diaphyseal fractures well • Nails do not address concomitant articular fractures • Nailing not possible with another implant/prosthesis • Difficult to bone graft nailed fracture gap • Medullary reaming may cause systemic problems

The clinical goal of effective treatment is rapid healing without significant deformity, aimed at restoring the patient bone close to its pre-fracture level of function. In this dissertation, only internal fracture fixation by means of plates is dealt with.

2.3.2 Osteosynthesis with plate fixation

Irrespective of the type of fracture fixation, the main purpose of using a fracture implant is to:

- transfer the loads (tension, bending and torsion) from one end of a broken bone to another
- provide initial stable fixation, with a compressive strain of the order of 2% at the fractured site to promote bone healing
- allow as much of the surrounding bone to be stressed under normal loading during the healing process, so as to prevent “disuse” osteoporosis of the bone.

The factors governing the success of fracture healing are:

- the degree of contact of the broken bone fragments
- alignment of the broken bone fragments
- controlled micro-movement at fracture site
- other parameters such as age, health, and nutritional status of the patient
- non-occurrence of implant failure.

2.3.3 Materials used in plate

The biocompatible materials used for bone plates are: stainless steel (SS), cobalt base alloys, bioceramics, titanium alloys, pure titanium, carbon fiber reinforced plastic composite materials, and polymers (non-resorbable and bioresorbable). Each of the above materials can broadly be categorized as (i) bioinert (ii) porous, (iii) bioactive, and (iv) bioresorbable [122-125]. In general, bioinert material is selected for bone-plates, because bioactive material gets bonded with the bone (along with the soft tissues) and causes problems if plate removal or corrective surgery is required [39].

The bioceramic materials (which are bioinert) possess Young's modulus (E) in the range of 400 ± 20 GPa. While the properties of ceramics (such as high hardness, chemical

inertness, oxidation resistance, high strength, high melting points and low fracture toughness) are suited to the requirement for the bone-plate, its brittleness and high 'E' result in excessive stress-shielding of the bone, thus limiting its use for bone-plates [126].

Cobalt-base alloys (e.g CoCrW, CoCrMo) have a modulus of 250 ± 10 GPa along with good wear, corrosion and heat resistances. However, their poor formability and high cost [127] limit their usage for bone plates. Stainless steel (e.g 316L) is one of the most preferred biomaterials for bone-plates, because of its mechanical properties ('E = 200 ± 20 GPa', ductility etc), corrosion resistance, bioinert and cost-effectiveness in comparison with other biocompatible metals [128]. In this dissertation, stainless steel material properties are employed in finite element analysis.

Titanium alloys (e.g Ti-6Al-7Nb, Ti-6Al-4V), with E of 110 ± 10 GPa, are especially preferred because of their increased corrosion resistance. However, although titanium alloys offer improved strength (with less ductility) compared to pure titanium, they are difficult to contour (as required for pelvic and mandibular plates). Titanium alloys are also preferred for intramedullary rods, spinal clamps, self-drilling bone screws and other implants, because of their high strength and low 'E' [129].

Pure titanium is also one of the most widely chosen materials for the bone-plates, because of its excellent biocompatibility and corrosion resistance. The ductility of titanium is less compared to SS, because of its hexagonal close packed crystal structure. This makes contouring of titanium plates difficult, compared to stainless steel plates. Titanium plates also offer less stress-shielding to bone (for the same geometries) after healing, because its 'E' is 68 GPa compared to 200 GPa of SS [130].

Composite materials (e.g. Carbon Fiber Reinforced Plastic, CFRP) consist of a polymer matrix and fibre, which are combined to achieve the requisite high strength and adequate 'E' value. The polymer matrix materials can be broadly classified as resorbable (e.g. polysorb, biosyn) and nonresorbable (such as polyetheretherketone or PEEK, ultrahigh molecular weight polyethylene or UHMWPE). Polymers per se do not have the strength and stiffness required for bone-plates; hence polymers reinforced by fibers are employed for the bone-plate application or used as scaffolds in the preparation of bone grafts [131]. Composite materials used for bone-plates mainly consist of a thermoplastic polymer matrix (such as PEEK, polymethylmethacrylate or PMMA etc.) and fibres such as glass or carbon. The disadvantage of using a composite material is that in the case of implant failure (when revision surgery is warranted) there is the risk of fibre breakage and subsequent penetration of small fibre particles into the bone tissue, causing irritation and inflammation [26,57,58,61,132-135].

The increased use of bioresorbable polymers (i.e. polymers which degrade in-vivo to non-harmful by-products) in the recent year's poses the problem of their strength loss while bone-healing is in progress [74,136,137]. It is to be noted that resorbable bone-plate fracture-fixation should sustain loads for at least 1.5 to 2 years [53], which is yet to be achieved with resorbable materials. Hence, a new class of resorbable materials needs to be developed, having adequate mechanical properties and resorption time increased by 1 to 2 years.

In view of the above discussion, polymers and calcium phosphates are osteoinductive and resorbable; they cannot behave as load-sharing members and fail in in-vivo loading conditions [138]. For a reinforced fractured bone, it is important to initially

have a plate with sufficient stiffness so as to prevent tensile stresses at the fracture interface, while allowing the bone away from the fracture site to be stressed under loading conditions (so as to prevent loss of bone strength). An optimal plate needs to be designed such that it caters to the above mentioned objectives.

To make the healing process faster, fixation techniques are employed to provide immobilization between the fractured bones. The requirements of the material stiffness during healing to meet the mechanical demands of loading are given below in Table 2-3.

Table 2-3: Stages of fracture healing [93]

1. Tissue destruction and haematoma formation	}	<ul style="list-style-type: none"> • Duration: 24-48 Hrs • Whole system to be immobile
<ul style="list-style-type: none"> • Bone at the fracture surface deprived of blood supply dies. 		
2. Cellular proliferation	}	High stiffness material is required
<ul style="list-style-type: none"> • The fragment ends are surrounded by cellular tissues which bridge the fractured site 		
3. Callus formation	}	<ul style="list-style-type: none"> • Duration: 8-12 Weeks • Mechanical stimulus needed
<ul style="list-style-type: none"> • Under the right circumstance the cell population changes to osteoblast and osteoclasts. Dead bone is mopped up and woven bone appears in the fractured callus 		
4. Consolidation	}	Stiffness of material should gradually reduced to zero
<ul style="list-style-type: none"> • Woven bone is replaced by lamellar bone and fracture is solidly united 		
5. Remodelling	}	
<ul style="list-style-type: none"> • New bone is remodelled to resemble the normal structure 		

Based on these considerations, the use of stiffness-graded materials (SGMs) for bone-plates is recommended. SGMs are characterized by a smooth and continuous change of the mechanical properties from one characteristic surface to the other. Stiffness-graded material is a relatively new concept in bone-plates in order to decrease stress shielding (this concept is well documented for dental implants) [87-91,139]. Controlled segregation, controlled blending, vapor deposition, plasma spraying, electrophoretic deposition, controlled powder mixing, slipcasting, sedimentation forming, centrifugal forming, laser cladding, metal infiltration, controlled volatilization, and self propagating high-temperature

synthesis are few manufacturing techniques that are involved in fabrication of SGMs. However, current production of SGMs is hampered by the current manufacturing process technology [94]. A preliminary comparison of the stiffness graded plates with stainless steel plates is provided, with respect to bone healing stages and stress-shielding by means of finite element analysis in chapter 3.

2.3.4 Design parameters in plate design

Internal fixation by plate is considered as a significant development in fracture fixation methods. However, the adverse effects of rigidity of the plate (stress-shielding, loosening of screws, failures of the fixation) have led researchers to vary the design of plate. It is generally believed that the earliest technique of internal fixation was the use of wire suture around 1770s. The use of plate and screw probably started in 1840⁺. The prime design parameters that have been considered in plates are as follows:

- Stiffness or rigidity of plate: In order to avoid the loss of bone mineral content due to the usage of high stiffness plate and to enhance the healing, compliant plates with high fatigue strength have been developed [59-73].
- Minimum contact between the bone and the plate: To allow normal/proper tissue growth underneath the plate (i.e. bone–plate interface), plates with different geometries were developed to avoid contact with the bone [39,73,95,114,141, 144].
- Interfragmentary compression: To achieve compression at fracture site, screw holes in plate which accommodate lag screw for an inclination of up to 22⁰ were developed [39,95,142-144].

⁺ From http://www.depuyace.com/history_of_trauma/history_of_trauma_intfixm.htm on September 23, 2003

- Gradual biodegradation: To avoid surgery for removal of the implants after bone healing, biodegradable materials have been developed [145].

2.3.5 A distinctive plate design - Helical Plate

The clinical use of a plate extruded over helical paths (i.e. helical plate as shown in figure 2-8a) for bone fixation is presented by Fernandez [146]. The possible configurations of helical plate are shown in figure 2-8b. One of the clinical advantages of a helical plate is that it permits more degrees of freedom when choosing an entry point for minimally invasive surgery. Also, it is possible to position the plate on different aspects of bone (for instance, laterally in the proximal part of the bone or anteriorly in the distal part of the bone as shown in figure 2-8c). These advantages of helical plate have proven particularly useful when attempting to avoid damage to the vascular system of the femoral head and humeral shaft. A helical implant fixator (shown in figure 2-8d) is designed and manufactured for humerus. According to him, helical implants have opened up a new and still unexplored field in bone fixation. Chapter 4 in this dissertation delineates the biomechanical advantages of the helical plate.

Figure 2-8: Helical plate (a) Helical plate is obtained by extrusion of a rectangle over a helical path (b) Helical plate on the bone based on the degree of twisting (c) Helical plating in comminuted humerus fracture, it behaves as a lateral plate up and anterior plate down (d) Manufactured helical plate for humerus [146].

2.3.6 Application of plate mechanobiology in fracture fixation

Important aspects of the plate

The role of plate and screws is to hold the fragments of the bone in position until the bone heals. The major factors affecting the bone-plate fixation are (figure 2-9):

- geometry and material of plate,
- placement of plate relative to loading vector,
- bone-screw interface,
- induction of compressive stress between bone fragments,
- quality of bone,

- surface area of bone-plate interface,
- number and location of screws.

By taking into account the above factors, a surgeon can decide whether to achieve rigid fixation or flexible fixation.

Figure 2-9: Factors affecting the bone-plate fixation [35]

Although the nature of *in-vivo* loading is complex, it can be broadly categorized as axial (compression and tension), bending, torsion and fatigue. Bending alone is considered in most studies on fracture fixation, because bending will induce both tension and compression stresses in the bone and tend to open the fracture gap, leading to instability of the fracture-fixation. Bending moment is caused by muscle action during movement at the joints and by off-set forces on long curved bones (eg. femur, humerus) especially after fracture-fixation. The role of the bone-plate is to absorb the tension component of the fractured bone, while compressive stress is generated to the surface opposite to the surface under tension. In transverse fractures, torsional forces are added to bending forces. A weak

portion of the plate (eg. an unfilled screw hole) should thus not be placed exactly over the fracture gap so as to avoid fatigue plate failure.

Important aspects of screws

The bone screw is a critical implant-bone interface, and its design has been studied extensively. What surgeons have now are essentially two types of screws, cortical and cancellous, to accommodate the type of bone and “holding power” required. The theory of “thread shape factor” (as shown in figure 2-10) has been outlined by Chapman [107]. It is clear that screw integrity varies with many factors, such as bone quality, screw quality, insertion technique, and even thermal necrosis and resorption of bone associated with drilling [49,147]. The use of sharp drill bits and fluid irrigation reduce thermal effects on drill holes. Attention needs to be paid on the locations and number of screws for optimal fracture fixation. This constitutes one of the works of this dissertation.

Figure 2-10: Screw mechanical Characteristics. Shear failure force (F_s) of a screw is given by $F_s = S * A_s = \{S * L * \pi * D_{major}\} * TSF$

where ‘S’ material ultimate shear stress, A_s is the thread shear area, L is the length of thread engagement in material, D_{major} is the major diameter (mm), TSF is $(0.5 + 0.57735d/p)$, d is $(D_{major} - D_{minor})/2$, P is thread pitch. Adapted from Chapman [107].

Number of screws in a plate

In a tension band plate, the screw farthest to the fracture site is loaded more than the screws near to the fracture site in bending. By keeping the length of the plate constant, with the increase in number of screws, there is a decrease in the magnitude of force in each screw. This means that with more number of screws, the fixation is more rigid and there is less tendency of failure due to screw pull-out. However, more screws weaken the bone. Hence the appropriate number of screws should be selected by balancing fracture rigidity and screw pull-out failures. Stoffel [95], based on the experimental and finite element analysis on the fractured composite bone cylinder (with a diaphysial fractures) fixed using locking compression plates, found that there is no significant improvement in fracture fixation (in terms of gaining axial and torsional rigidity) beyond 3 screws on either side of a fracture of the lower limb, and 4 screws per side in the upper limb. His conclusion on the limited number of screws on either side of the fracture is valid for simple fractures. It is however difficult to generalize the number of screw usage in fracture fixation, because of its dependency on the type and severity of the fracture.

Influence of screw placement relative to the fracture site

The screws enable the plate to conform to the bone surface. Minimizing the distance between the nearest screws on either side of the bone fragments (also called working length) increases stiffness at the fracture (i.e. reducing gap motion) (figure 2-11). The stresses within this short working plate length are also higher. When the inner-most screws are further away from the fracture site, the working length of the plate is greater, allowing bone deformation and gap opening (figure 2-11b) [35].

Figure 2-11: (a) Bending open (all screws) (b) Bending open (no inner screws) [35]

Bone plate interface

High frictional compressive forces will be developed between plate and bone from tightening of the screws (figure 2-12a). This friction force prevents the sliding motion between plate and bone during loading, and helps to reduce shear forces on screws at the bone plate interface. However, compressive forces will damage the blood supply in bone underneath the plate. Thus, the bone underneath the plate will remodel, and lead to cortex thinning or temporary porosity due to internal remodeling. The coefficient of friction between plate and bone is 0.37, and the factors affecting the coefficient of friction are the surface roughness of the plate and compressive force applied during tightening of the screws [35,67].

Recent developments in fracture fixation implants are locked compression plates (LCP) (figure 2-12b). LCP avoids damage to periosteum as the plate stands off from bone. Force transfer is purely through screws and not by contact between plate and bone. The periosteum can be preserved and cortex thinning is reduced. However, shear forces at the bone-plate interfaces are high. In titanium implants, cold-welding may occur between

screw head and the hole. Removal of the implant may then be very difficult or even impossible [43].

Figure 2-12: (a) Compression developed between the plate and bone by tightening of the screws (b) Locked compression plate with locking screws

2.3.7 Finite element analysis on the fracture fixation by plates

Much of the work on the internal fracture fixation by plate is conducted through clinical trails, experiments (both in-vivo and in-vitro). With the advent of high speed, greater data storage capacity computers and the rapid developments in computational modelling methods, numerical simulations (precisely, the finite element analysis) have become more popular in analysing fracture fixation. Also, developments in the imaging techniques, like computer tomography (CT), facilitate the extraction of exact bone and implant geometry for finite element analysis. Hence, now a days, researches are using finite element analysis to reduce the reliance on animal experimentation and to complement clinical trails [84-86,148-164].

In most of the finite element models of fracture-fixed bone by plate (quarter symmetric model is depicted in figure 2-13), the long bone is assumed as a hollow beam with circular cross-section. The bone is taken to be transversely isotropic with

homogeneous properties, and analyzed within the linear elastic limit. These assumptions were imposed, in order to reduce the computational time and save the memory utilized for the analysis. The finite element models (fracture fixed bones by plate) simulate healing of the fracture in the form of a composite beam sharing the load between the plate and bone. These models are used to calculate the stresses in the implant and fracture fixed bone under the experimental loading conditions [92-94,164]. In all loading conditions (i.e. axial, bending and torsion), plate and bone are assumed to be held firmly together by screws preventing shear.

Figure 2-13: Finite element model for bone fracture fixation [150]

The finite element results [150] suggest that the majority of the load is transferred from bone to plate through the inner-most screw from fracture site under axial and torsional loading. Under bending, the outer-most screws from the fracture site are stressed more than the inner screws. The presence of screw holes in the bone gives rise to stress concentrations of approximately 3.5 times the normal stress. With the screws in the holes, the stress concentration is slightly reduced, as the screws protect the surround bone of the hole [150]. Under combined loading (bending and axial), the stresses within the bone are much higher

than for the individual (axial, bend and torsion) loading. It is reported that plate carries 80% of the applied loads, thus shielding the bone from axial, bending, and torsional stresses [148-155].

The behavior of both bone and the screw due to screw pull-out have been analyzed using FEA, and the results are that: (1) cancellous bone screw pull-out causes failure due to bone shearing with little or no damage on screw, (2) the shear stress along the threaded length is nearly uniform, (3) the size of the bone has little effect on the pull-out strength, and (4) the effect of the major diameter on screw pull-out strength is more significant than that of the minor diameter and pitch. These results are in good agreement with experimental results [150].

2.4 Structural optimization in anatomy

As per the concept of optimal design in nature [165-167], anatomical structures are customized to be functionally optimal. If it is a load-bearing structure, then it is adroitly designed to be a light-weight and high-strength structure. For example, a long bone is modeled such that it can sustain maximum loading with least material or mass. As an example, consider the case of the femur, its shape and material density correspond to its stress trajectories under its functional loading and its shape is often compared to a crane (as shown in figure 2-14a) [167-172]. In other words, the stress trajectories on the bone correspond to the loading conditions sustained by it (figure 2-14b,c). Further, there needs to be less density of bone where the stress trajectories are apart (such as in trabecular bone) and more density of bone where the stress trajectories are closer (as in cortical bone). The shape of the femur can help appreciate the fact that the femur shape has evolved such that

bone material is adroitly organized to be necessarily and sufficient to bear the loading. It is also interesting to compare the femur shape (figure 2-14c) with structures such as crane, the lamp bracket and proximal femoral nail (figure 2-14 d, e). However, the design of a hip implant might need to be modified in light of this application of Wolff's law governing the optimal shapes of skeletal structures.

At diaphysial (i.e. cortical) segment of a femur, Ghista *et al.* [173] have provided the biomechanical explanation for its hollowness, using the Euler-Bernoulli flexural equation. According to them, the bending moment capacity (at failure) of the diaphysial segment of a femur is given by

$$M \equiv \frac{\pi \sigma_b (= \sigma_f) (r_e^4 - r_i^4)}{4 r_e} = \frac{\pi \sigma_f r_e^3}{4} \left[1 - \left(\frac{r_i}{r_e} \right)^4 \right] \quad (1)$$

so that its normalized bending strength (*BS*) can be defined as

$$BS \equiv \frac{4M}{\pi \sigma_f r_e^3} = 1 - \left(\frac{r_i}{r_e} \right)^4 \quad (2)$$

where '*M*' is the moment on the femur diaphysial segment, ' σ_b ' is the maximum stress on the bone induced due to '*M*', ' σ_f ' is the failure stress (at which the bone will crack), ' r_e ' is the external radius of the bone and ' r_i ' is the internal radius of the bone (considering diaphysial segment to be a hollow cylinder). *BS* is also equal to the bending moment capacity of the cortical diaphysial hollow bone segment normalised with respect to the bending moment capacity of a hypothetical bone of solid cross section with the same outer diameter (r_e) as the hollow bone. Also, normalized Weight Factor (*WF*, i.e. normalized weight per unit length) of a long bone can be represented as

$$WF \equiv \frac{\pi(r_e^2 - r_i^2)}{\pi r_e^2} = 1 - \left(\frac{r_i}{r_e}\right)^2 \quad (3)$$

Figure 2-14: Femur models (a) Dixon's comparison of femur with a crane (b) Cullman's crane analogy of femur (c) Wolff's drawing of trabecular orientation in the proximal part of the femur and the cross section of the femur. It is noted that the bone material distribution corresponds to the orientation of the stress trajectories (d) Ward's comparison of femur with a lamp bracket (e) Ward's lamp bracket comparison might possibly led to the proximal femoral nail [172].

Now, adopting the concept that the femur is customized (by an evolutionary process) to be a high-strength and light weight- structure, the optimal value of (r_i/r_e) for which the BS is maximal and its weight is minimal can be determined (figure 2-15a). Accordingly, the function $(BS-WF)$ with respect to the (r_i/r_e) variable was maximized. The optimal (r_i/r_e) is found to be $1/\sqrt{2}$ ($=0.707$), at which a long bone has minimum weight and maximum bending strength. Comparison with femoral cross-section (figure 2-15b) confirms the

application of this optimal-design model. In a way, the intramedullary nail somewhat mimics the long bone intrinsic feature.

Figure 2-15: (a) Optimal ratio of r_i/r_e for minimal weight and maximal strength of a long bone (b) Magnetic resonance image of the femur cross section at diaphysis.

Therefore, theoretical understanding of anatomical structures is important for developing biomimic implant designs. In this regard, the spine is one of the most important parts of the body, which we have studied from this optimal design aspect. The analyses of the intrinsic features of the spinal components (i.e. vertebral body and intervertebral disc) will provide an understanding on the basis of their performances under physiological loading conditions. This will then also provide some insights into the implants to replace the fracture vertebral body and ruptured intervertebral disc.

2.4.1 The human spine

Spine gives the body structure, support and allows the body to bend with flexibility. It is also designed to protect the spinal cord. The spine is made up of 24 small bones (vertebrae) that are stacked on top of each other to create the spinal column. Between each vertebra, there is an intervertebral disc that helps to cushion and transmit the load between the vertebrae and keeps the vertebrae from rubbing against each other [175]. The flexibility of the spine is primarily due to the intervertebral discs [176]. Each vertebra is held to the others by groups of ligaments. There are also tendons that fasten muscles to the vertebrae⁺. The normal spine has an "S"-like curve when looking at it from the lateral side. The "S" curve must have evolved to help a healthy spine to perform its role in providing stability, strength and flexibility [177,178].

On the same concept of an optimal design in nature (in section 2.4), spinal biomechanical efficacy is to a large extent based on the optimal intrinsic designs of the spinal vertebral body and the disc for load bearing. The vertebral body (VB) is shaped like a hyperboloid shell, whose generators are criss-crossed straight lines. This makes it possible for all the loadings sustained by it to be transmitted through its walls as axial forces [173]. The shock-absorbing intervertebral disc needs to have the flexibility to enable the spine to bend and twist. At the same time under loading, its lateral and axial deformations have to be contained, so that it does not herniate and impinge on the spinal-chord. The disc is composed of a fluid-like nucleus pulposus (NP) contained within an annulus. Hence when the disc is loaded, the NP gets pressurized and stresses the surrounding annulus. Now because its elastic modulus is stress-dependent, the annulus

⁺ http://www.umm.edu/spinecenter/education/anatomy_and_function_of_the_spine.html viewed on 10 October 2005

stiffens under loading. In this way, the flexible disc is able to sustain its loading with minimal deformation [177-181].

2.5 The spinal vertebral body as an optimal structure

The vertebral body (VB) is characterized by its unique hyperboloid shape [173,174]. This makes it possible for all types of loadings (axial compression, bending moment and torsion) to be effectively sustained by the VB, as axial forces in the hyperboloid generators. The generators of the VB are anatomically tied at their intersection point (as shown in figure 2-16), so that their effective length is minimized. This intrinsic design of the VB makes it a high-strength structure, whose material is minimized because the cortical wall (containing the hyperboloid generators) only needs to bear axial forces. This makes the VB an intrinsically high-strength light-weight structure.

Figure 2-16: The cortical vertebral body is shaped as a hyperboloid (HP) shell formed of two sets of generators, which are anatomically tied, so as to reduce their effective lengths.

The loading conditions and the geometrical parameters of the VB were reported through in-vivo experiments and the anatomical measurements respectively [182-184]. Goel *et al.* [185] provided an explanation for the variation of the elastic modulus within the vertebral body using remodeling theory. The relationship between the hyperboloid shape of

VB (based on physiological loading conditions) that makes it to be a functionally optimal (light-weight and high-strength) structure needs to be developed. This detailed analysis is provided in chapter 5.

The relationship between the geometrical parameters of the VB that makes it an intrinsically optimal structure can lead to the development of anterior fixator design that is closer to the VB in its natural form. The conceptual idea of the biomimic anterior fixator based on this analysis is provided in chapter 5. Before presenting the conceptual idea, it is important to understand the current treatment along with the implants used in treating burst fractures. Also, an overview of the fixators (posterior and anterior) used in treating the burst fractures is presented. Numerous clinical, experimental and finite element models describing the design, manufacturing and performance of spinal implants are available. However, only the relevant information outlining the posterior fixators and anterior fixators is provided in this chapter.

2.5.1 The vertebral body shape and membrane stresses

Hyperboloid geometry of the vertebral body

The hyperboloid (HP) geometry of the cortical vertebral body (VB) is formed by two families of generators, as shown in figure 2-17. Shell membrane theory is used to show, how this hyperboloid VB geometry enables the VB to efficiently sustain: (1) compressive loading ' C ' on the vertebral body, to cause axial compression in both sets of generators, (2) bending-moment ' M ', to result in compressive forces in one set of generators (i.e. on the compression side of the neutral axis) and tensile forces in other set of generators, and (3) torsional loading ' T ', to result in compressive forces (per unit length) in

one family of generators and tensile forces in the other family of generators oriented in the other direction.

Figure 2-17: The cortical vertebral body is shaped as a hyperboloid (HP) shell formed of two sets of generators.

Figure 2-18 illustrates the hyperboloid geometry of the spinal vertebral body. If the HP shell surface is intersected by a vertical plane parallel to the yz plane but at $x=0$, then the intersecting curves will be

$$\frac{a^2 + y^2}{a^2} - \frac{z^2}{b^2} = 1, \quad \text{or} \quad z = \pm \left(\frac{b}{a} \right) y \quad (4)$$

which have the same slope as the asymptotes. Based on the hyperboloid geometry [215], the HP surface can be generated by a pair of intersecting lines inclined at an angle $\beta = \tan^{-1}(a/b)$ in the vertical plane tangent to the waist circle ($r_0=a$).

Figure 2-18: The geometry of the VB hyperboloid (HP) shells [8,9].

The construction of the cortical VB hyperboloid by a set of generators [216], is illustrated by figure 2-19, wherein the end plate radius NA is R , radius of the waist circle is ' a ', and the height of the VB is $2H$. Based on this geometry,

$$\tan \beta = \frac{\sqrt{(R^2 - a^2)}}{H} = \frac{a}{b} \quad (5)$$

The primary dimensional parameters of the VB hyperboloid are hence R , a and H ; equation (5), for $\tan \beta$, provides a relationship among them.

Figure 2-19: Geometry of hyperboloid generators: The generators AD and BC form the basis of the construction of the hyperboloid. By altering the angle β , the geometry of the VB hyperboloid can be altered.

Membrane stresses in the vertebral-body cortex

According to the membrane theory of shells, the membrane stresses (meridional stress σ_θ) and (hoop stress σ_ϕ) sustain the normal pressure p_r , as depicted in figure 2-20 [217]. The equilibrium of forces in the radial (r) direction gives

$$-2\sigma_\phi t(r_2 d\theta) \sin\left(\frac{d\phi}{2}\right) + 2\sigma_\theta t(r_1 d\phi) \sin\left(\frac{d\theta}{2}\right) + p_r \left[2r_1 \sin\left(\frac{d\phi}{2}\right) \cdot 2r_2 \sin\left(\frac{d\theta}{2}\right) \right] = 0 \quad (6)$$

wherein, in the case of a hyperboloid, r_2 is considered to be positive and r_1 is considered to be negative, and their magnitudes in terms of a , b and ϕ are

$$r_1 = \frac{a^2 b^2}{(a^2 \sin^2 \phi - b^2 \cos^2 \phi)^{3/2}} \quad (7)$$

$$r_2 = \frac{a^2}{(a^2 \sin^2 \phi - b^2 \cos^2 \phi)^{1/2}} \quad (8)$$

Figure 2-20: Stresses acting on an element of the HP Shell

For small angle θ , $\sin\theta \approx \theta$, which leads to

$$-\sigma_{\phi} t r_2 (d\theta)(d\phi) + \sigma_{\theta} t r_1 (d\phi)(d\theta) = -p_r [r_1 (d\phi) r_2 (d\theta)]$$

$$\text{or, } \frac{\sigma_{\phi} t}{r_1} - \frac{\sigma_{\theta} t}{r_2} = p_r \quad (9)$$

with t being the VB wall thickness

Denoting $N_{\phi} (= \sigma_{\phi} t)$ and $N_{\theta} (= \sigma_{\theta} t)$ as stress-resultants

$$\frac{N_{\phi}}{r_1} - \frac{N_{\theta}}{r_2} = p_r \quad (10)$$

which is the “**membrane equation**” for the HP-VB shell. This is because for a hyperboloid shell, r_1 is negative and r_2 is positive. Now if $p_r = 0$ and from equation (10)

$$N_{\phi} = \left(\frac{r_1}{r_2} \right) N_{\theta} \quad (11)$$

Substituting $r_1 = (b^2/a^4)r_2^3$, from figure 2-18, into equation (11),

$$N_{\phi} = \left(\frac{b^2}{a^4} r_2^2 \right) N_{\theta} \quad (12)$$

2.5.2 Analysis for forces in the VB generators under compression

Now the HP shell is analyzed for the stresses due to an uniaxial compressive force, as shown in figure 2-21. Assume that there are two sets of 'n' number of straight bars (placed at equal spacing of $2\pi a/n$ measured at the waist circle), to constitute the HP surface, as shown in figure 2-22. Due to the axi-symmetric nature of the vertical load, no shear stresses are incurred in the shell, i.e. $\sigma_{\phi\theta}=0$. A segment of the HP shell is now delineated to consider its force equilibrium (as illustrated in figure 2-23). At any horizontal section, by force equilibrium

$$(2\pi r_o) N_{\phi} (\sin \phi) = C \quad (13)$$

Figure 2-21: Stress components at waist section of HP Shell

Figure 2-22: Equivalent straight bars (aligned with the generators) placed at equal spacing to take up the stresses.

Figure 2-23: Equilibrium of forces on a shell segment.

Now, consider the segment above the waist circle, where $\phi=90^\circ$ and $r_2=r_0=a$ (throat radius)

$$(2\pi a)N_{\phi(\phi=90^\circ)} = C, \text{ or } N_{\phi(\phi=90^\circ)} = \frac{C}{2\pi a}, \text{ compressive} \quad (14)$$

At the waist circle where $r_2=a$, equation (12) yields

$$N_{\theta(\phi=90^\circ)} = \left(\frac{a^4}{b^2} \frac{1}{r_2^2} \right) N_{\phi(\phi=90^\circ)} = \left(\frac{a^2}{b^2} \right) N_{\phi(\phi=90^\circ)}$$

which, combining with equation (14), leads to

$$N_{\theta(\phi=90^\circ)} = \left(\frac{a^2}{b^2}\right) \frac{C}{2\pi a} = \frac{C}{2\pi a} (\tan \beta)^2 \quad (15)$$

which is also compressive. Thus both N_ϕ and N_θ are compressive.

In figure 2-24, consider the equilibrium of a shell element under the action of N_ϕ and N_θ , to obtain the resulting forces (F_c) in the hyperboloid VB cortical shell generators. The equivalent resultant compressive force ' F_c ' (in the generator of the HP surface) is given by

$$F_c^2 = \left[N_\phi \left(\frac{\pi a}{n} \right) \right]^2 + \left[N_\theta \left(\frac{\pi b}{n} \right) \right]^2 \quad (16)$$

Substituting equations (14 and 15) into equations 16,

$$F_c = \frac{C}{2n \cos \beta} = \frac{C \sqrt{H^2 + R^2 - a^2}}{2nH} \quad (17)$$

Thus the total axial loading is transmitted into the HP-shell's straight generators as compressive forces.

Figure 2-24: Equivalent diagonal forces in the intersecting-bars to take up the stresses around a shell element

2.5.3 VB stress analysis under bending moment

When the VB subjected to a bending moment (M), normal stresses (σ_y) are developed at the waist circle ($r_0=a$) cross-section, as shown in figure 2-25. The bending moment sustained at the waist circle is given by

$$M = 2 \int_0^a \sigma_y \left[2 \frac{t}{\cos \alpha} dy \right] y \quad (18)$$

where σ_y is the compressive stress normal to the cross-section (due to the bending moment M) acting on the two rectangular elements of length $2(t/\cos \alpha)$ and width dy .

Also

$$\sigma_y = \frac{y}{a} (\sigma_a) \quad (19)$$

where σ_a is the stress at $y=a$.

Upon combining equations (18) and (19)

$$\begin{aligned} M &= 4 \int_0^a \frac{y^2}{a} (\sigma_a) \frac{t}{\cos \alpha} dy \\ &= 4t(\sigma_a) \int_0^a \frac{y^2}{a \cos \alpha} dy \end{aligned} \quad (20)$$

Substituting for $y = a \sin \alpha$ and $dy = a \cos \alpha d\alpha$, equation (20) can be rewritten as

$$M = 4t(\sigma_a) \int_0^{\pi/2} \frac{a^2 \sin^2 \alpha}{a \cos \alpha} a \cos \alpha d\alpha \quad (21)$$

Figure 2-25: (a) Bending moment on the VB (b) plan view at the section BB (i.e. at waist circle)

Integrating equation (21), gives

$$M = \pi a^2 t (\sigma_a) \quad (22)$$

The normal stress (σ_a) at the waist circle in terms of the bending moment (M) can hence be written as

$$(\sigma_a) = \frac{M}{\pi a^2 t} \quad (23)$$

These bending stresses are depicted in figure 2-26a. Then, the corresponding stress-resultant N_ϕ , on the waist-circle element at 'a' distance from the neutral axis, is given by

$$(N_\phi)_a = (\sigma_a) t$$

Thus from equation (23),

$$(N_\phi)_a = \frac{M}{\pi a^2} \quad (24)$$

From equations (24 and 12), the stress-resultants (N_θ) are given by

$$(N_\theta)_a = \frac{M}{\pi b^2} \quad (25)$$

Now, consider the shell element (depicted in figure 2-27) between successive generators and analyse its equilibrium under the action of $(N_\theta)_a$ and $(N_\theta)_a$ to obtain the resulting F_m force in the generators (due to N_θ and N_θ):

$$F_m^2 = \left[\left(\frac{\pi a}{n} (N_\phi)_a \right)^2 + \left(\frac{\pi b}{n} (N_\theta)_a \right)^2 \right] \quad (26)$$

Substituting for N_θ value from equation (12),

$$F_m^2 = \left[\left(\frac{\pi a}{n} (N_\phi)_a \right)^2 + \left(\frac{\pi b}{n} \left(\frac{a^2}{b^2} (N_\phi)_a \right) \right)^2 \right] \quad (26)$$

Since $\tan \beta = a/b$, equation (27) reduces to

$$F_m^2 = \left(\frac{M}{\pi a^2} \right)^2 \left(\frac{\pi a}{n} \right)^2 [1 + \tan^2 \beta]$$

$$\text{or, } F_m = \frac{M}{na \cos \beta} \quad (28)$$

where ' F_m ' can either be compressive or tensile force, depending on the location of the generators relative to the neutral axis plane (through NA in figure 2-26b) about which the bending moment is applied.

Figure 2-26: (a) Bending stress at the waist section of the VB hyperboloid shell (b) Stresses resultants at the waist-circle on a shell element of the HP shell, under the action of the bending moment M .

Figure 2-27: Equivalent diagonal forces in the intersecting-bars to take up the stresses on a shell element on the compression side of the HP shell.

2.5.4 Stress analysis under torsional loading

Next, the compressive and tensile forces in the HP shell generators when the VB is subjected to pure torsion (T) are analysed. In this case (refer to figure 2-28), the normal stress resultants (N_θ and N_ϕ) are zero, and there is only shear stress-resultants ($N_{\phi\theta}$)

$$N_\phi = N_\theta = 0 \quad \text{and} \quad N_{\phi\theta} = \tau t \quad (29)$$

The equilibrium of a shell element at the waist circle (as shown in figure 2-29) gives,

$$[(2\pi r_0) N_{\phi\theta}] r_0 = T, \text{ or } (2\pi r_0^2) N_{\phi\theta} = T \quad (30)$$

Figure 2-28: Stress resultants in the HP shell element ($N_\phi = N_\theta = 0$ and $N_{\phi\theta} = \tau t$) due to torsion T acting on the VB.

Figure 2-29: Equilibrium of a shell segment under torsion (T) and shear stresses (τ) (or shear stress-resultant $N_{\phi\theta}$).

Figure 2-30: Equivalent diagonal forces in the intersecting generators to take up the stresses acting in the shell element

At the waist circle, $r_2 = r_0 = a$ (throat radius):

$$[(\tau \cdot t)(2\pi a)]a = T, \text{ i.e., } N_{\phi\theta} = \frac{T}{2\pi a^2} \quad (31)$$

Now, consider a shell element between the successive generators at the waist circle, as shown in figure 2-30. The equivalent compressive force (F_{cT}) and tensile force (F_{iT}), in the two shell generators (due to $N_{\phi\theta}$), are given by

$$F_{cT}^2 = F_{iT}^2 = \left(N_{\phi\theta} \frac{\pi a}{n} \right)^2 + \left(N_{\phi\theta} \frac{\pi b}{n} \right)^2$$

$$\text{or, } |F_{cT}| = |F_{iT}| = \frac{T}{2na \sin \beta} \quad (32)$$

Thus, a torsional loading on the HP-shell VB is taken up by one set of generators being in compression and the other set of generators being in tension.

2.5.5 Overview of vertebral body fixators and impact of our intrinsic design analysis on a conceptually better anterior fixation

Spinal vertebral body (VB) fails if the load exceeds the sustainable limits. This generally happens during car crash or fall from a height (essentially impact loading conditions). Failure of the VB is very painful to the person, as the fractured VB impinges on the nerve roots and the spinal cord and disrupts the stability^{*} of the spine. VB injury can either cause burst fractures or dislocation of the VB. Burst fractures are more frequent to T12, L1, L2 and L3 of spine VB, and cover up to 66.16% of all the spinal injuries [186].

^{*} A stable spine should be one that can withstand axial forces posteriorly and rotational forces, thus being able to function to hold the body erect with out progressive kyphosis and to protect the spinal cord contents from further injury.

Burst fractures cause loss of sensory and neural stimulation below the level of the injury, often resulting in paraplegia.

The characteristics of burst fracture (figure 2-31) are that the VB is partially or completely commuted, with the fragments of the posterior wall retropulsed into the spinal canal causing neural injury. However the posterior ligamentous complex will still be intact. These fractures are unstable in flexion-compression. As a result, the VB height reduces, and the spinal canal is often extremely narrowed by the protruding posterior wall fragments [186-189].

Figure 2-31: An axial burst fracture [186].

The goals of surgical treatment in burst fracture is to (i) achieve pain free and stable spine, (ii) enable neurological recovery, (iii) restore the capacity of the spine to withstand physiological loads, (iv) cause minimal resection of injured fragments, (v) and employ small implants. The methods available are posterior technique (with posterior fixators), anterior technique (with anterior fixator), or a combination of posterior and

anterior techniques. A comparison of the biomechanical efficacies of fixation techniques has been reported by Ghista and Rezaian [187,188], and clinically by Verlaan *et al.* [189].

Posterior fixators (illustrated in figure 2-32) stabilize the spine by reinforcing the spine posteriorly and in tension due to bending under torso weight thereby they increase the fractured-spine stiffness, and protect the fractured (VB) from being over stressed. Distraction applied by the posterior systems generates an anteriorly directed force on the retropulsed fragments (by the posterior ligament complex) to retract the fragments and decompress the spinal cord.

Figure 2-32: Posterior fixation technique as per AO ASIF recommendation: (a) the pedicles are entered and Kirschner wires are inserted in each hole (b) the plates are fitted in position over the Kirschner wires (c) later bone graft is used between the vertebrae [186].

According to Ghista *et al.* [187], as the body weight acts anterior to the spinal column, the spine is subjected to a flexion moment such that the fractured VB is subjected

to a compressive force. In the absence of the posterior fixator, the tensile force is not adequately resisted by the posterior spinal column. Hence the burst VB is subjected to high compressive stresses causing posterior displacement of the fractured fragment, and impingement of the neural structures. The role of the posterior fixator is to bear this tensile force, by putting compression on the posterior column. This is because the posterior fixator and fractured VB act as a composite structure (when subjected to flexion bending) with the neutral axis located posteriorly in the spinal column (figure 2-33).

Figure 2-33: Forces exerted on a lumbar spinal cross-section due to the anteriorly acting weight load. Note that under the flexion bending moment acting on the spinal column the anterior portion of the spinal column is in the compression, so that the fractured VB will be in compression. However, the tensile force in the posterior portion of the spinal column will be reduced by the compression force applied to it by the posterior devices. This will in turn reduce the compressive force and stresses on the fractured VB [187].

Even then, the fractured VB is subjected to some compressive stresses and can undergo kyphosis or the VB may not be able to sustain such compressive force. Also, as the posterior system is offset from the spine column, the amount of tensile stress and strain on this posterior fixator can cause it fail [190,191]. Thus a brace may need to be worn in conjunction with posterior fixator. Also, the disadvantage of using posterior fixator (generally spans 5-6 VB segments) is the reduction in the flexibility of the spinal system. These factors make a supporting case for anterior fixation technique!

Anterior fixation technique is used to support the anterior column when instability persists, particularly with the loss of height of VB. A Dynamic compression plate (DCP) plate (figure 2-34) can be placed anteriorly. However, because such a plate will be subjected to bending, loosening of the screws due to poor fixation in the cancellous bone and backing out of screws can be a problem that can cause erosion of aorta and vena cava.

Figure 2-34: Anterior placement of the dynamic compression plate according to AO ASIF [186]

Thus the anterior fixator placed along the loading axis of the spine seems to be an appropriate treatment option for burst fractures, like the Rezaian fixator illustrated in figure 2-35. This technique requires the removal of some of the fractured VB, and two discs upper and lower portions of the fractured VB. The Rezaian fixator is embedded into the endplates of the VB and allows adjustment of the height by the turnbuckle technique [192].

Figure 2-35: Rezaian spinal fixator is placed along the loading axis of the spine [188]

Figure 2-36 demonstrates the manner in which the Rezaian fixator is simple and at the same time an efficient anterior fixator, which bears and transmits compression, bending moment and torsional loadings on the spinal column. As illustrated in these figures (2-34 and 2-36), the novelty of this fixator is that all the forces and stresses are transmitted

directly through the body of the fixator [187-188], and there is no bending sustained by the fixator.

Figure 2-36: Rezaian spinal fixator biomechanics [187,188].

The Rezaian fixator is fixed to the top and below of the VBs by means of four spikes (which form part of the fixator). This makes the VBs rest on the fixator and hence directly transmit the forces through the fixator. This is the reason for the high success rate of this fixator, enabling the paraplegic patient to become ambulatory after a few days of hospitalization. The disadvantages are that the spikes may be not sufficient to hold the

fixator within the spinal column due to the distraction and rotational forces. There will be some movement at the bone fixator interface, which can progress to a dislocation of the fixator. This problem needs attention.

Figure 2-37: Radiograph of the combined anterior and lateral fixators [193]

One of the recent developments in the treating burst fractures is the combination of lateral and anterior fixator, wherein anterior fixator constitutes a titanium cage as shown in figure 2-23, and the lateral fixator is a short rod bridging only two VBs [193]. The titanium cage is aligned along the axis of the VB, and due to its hollowness it gives more room for grafting. However, the fixation needs to be secured by additional lateral fixators, as the cage alone is unstable in torsion.

A totally new design insight for an anterior fixator is proposed in chapter 5, based on the optimal design analysis of the VB as a hyperboloid shell structure. What is conceptually proposed is that a fixator be designed to simulate the cortical VB. It would be made up of two end-plate rings with spikes to fix them into adjacent discs. The rings could then be connected by criss-crossed generators. The fractured VB pieces could be enclosed within this fixator, and even solidified by introducing hydroxyapatite slurry.

2.6 The spinal intervertebral disc

As earlier described, the human spine is made up of alternating vertebral body and intervertebral disc. In section 2.5 it is explained, how the vertebral body is designed as an optimal light-weight structure because of its hyperboloid shape. An additional feature of the spine as a structure is its ‘S’ shape configuration (as described in section 2.5). In this function of the spine to act as a flexible shock-absorbing and protective structure, the intervertebral disc has an important role.

The intervertebral disc (IVD), as the principal component of the intervertebral joint (shown in figure 2-38a), sustains and transmits compressional, bending and torsional loadings. It constitutes 20-33% of the entire height of the vertebral column. It is comprised of three distinct parts: the annulus fibrosus, the nucleus pulposus (NP), and the cartilaginous end-plates [194,195].

The annulus fibrosus forms the outer boundary of the disc. This structure is composed of fibrous tissue in concentric laminated bands (figure 2-38b). The annulus fibers are oriented helically, at almost 30° - 50° [194]. Under torsion, the torsional shear stresses on a disc element will result in diagonally-oriented tensile and compressive

stresses. It is revealing that these tensile stresses due to torsion of the disc can thus be directly absorbed by these angled fibers of the annulus. Thus, the IVD is ideally designed for compression and bending as well as for torsion [196-205]. The annulus fibers are attached to the cartilaginous end plates. The cartilaginous endplate is composed of hyaline cartilage that separates the disc from the vertebral body.

Figure 2-38: (a) The location of intervertebral disc within the spinal column (b) Schematic of the disc structure. The NP is surrounded by annulus fibrosus. This outer layer is made up of concentric heically-oriented laminar bands [194].

The Nucleus pulposus (NP) is centrally located in the IVD and surrounded by the annulus. It is composed of a very loose and translucent mucoprotein gel. The water content ranges from 70-90% [194]. From a biomechanical viewpoint, the NP has a very important role, namely to contain the disc axial and radial deformations. The causative mechanism is that when the disc is loaded in axial compression (or bending or torsion), the NP fluid gets

pressurized (due to its fluid like behaviour) and stresses the surrounding annulus. The annulus is a stress-stiffening solid (as shown in figure 2-39), such that its elastic modulus (E) increases with the increase in stress [206,207]. Hence under increased loadings, its elastic modulus value also increases, so that the deformations are thereby contained.

Figure 2-39: Stress-strain curve in compression of wet lumbar intervertebral disc of persons 40 to 59 years of age [206].

However, substantial changes occur in the composition and microstructure of the disc with ageing. Most importantly, the nucleus dehydrates with aging and instead of behaving in a fluid-like manner, it acts more like a highly viscous gel, which is unable to generate the necessary pressure and stress the annulus. This reduced ability of nucleus to generate necessary pressure when loaded alters the overall mechanics of the disc, which leads to implications such as back pain in aged people [177,208].

The IVD functions as the shock-absorbing component of the spinal unit, comprising of two adjacent vertebral bodies on either side of the IVD. Additionally, the central portion

of the cartilaginous endplate functions as a diaphragm, through which (under compressive loading) NP fluid moves out of the disc into the VB, thereby helping to draw nutrition (as shown in figure 2-40) into the disc upon removal of the loading. However under rapidly applied loading, the VB end-plate offers resistance to the intrusion of fluid into the VB blood compartment, thereby lending a shock-absorbing property to the disc. Indeed, the IVD can be regarded as an effective viscoelastic shock-absorbing structure [209,210].

Figure 2-40: Nutrition mechanism of the disc (a) during loading, the NP enters the cancellous vertebral body and (b) during unloading, the NP draws the nutrition into the disc [209].

2.6.1 Structural design analysis of the intervertebral disc

Shirazi-Adl *et al.* [210] have developed a comprehensive biomechanics model of the intervertebral disc (as shown in figure 2-41) using finite element method. This model simulates the disc, the facet joints and the ligaments. The vertebrae are modeled with appropriate stiffness values for cortical and cancellous bones. The facets are modeled as

two sliding surfaces mimicking real facet joints. The ligaments are modeled as nonlinear springs. Also, the disc is modeled by three components; incompressible fluid representing nucleus, fibers representing collagenous fibers of the annulus, and a ground substance surrounding the fibers and simulating the adhesion between the fibers. This model's result compares with some measured parameters like disc bulge, load-deformation curve [210].

Figure 2-41: Finite element model of the disc and vertebral body (a) Sagittal cross-section of the intervertebral disc, (b) section through the middle of the disc, and (c) section through the endplate (d) 3D view of the annulus [210].

Uniform compressive load of 3000N is applied to the IVD. At the start of the loading, the intra-discal pressure has been assumed to be equal to 0.1MPa. This is about the value of intra-discal pressure in the lying down position. Upon loading, the pressure in the nucleus increases and this in turn stresses the disc annulus layers. Also, with the increase in intra-discal pressure, the reduction in disc height is decreased (as shown in figure 2-42). From a biomechanical viewpoint, it can be said that intra-discal pressure causes fibers to be stretched and become stiffer. In turn, the disc becomes stiffer. Because the load carrying capacity of stiffened fibres is greater, the height reduction, (for a certain level of compressional loading) decreases. This aspect is emphasized in our elastic analysis of the intervertebral disc chapter (i.e. chapter 5). The intra-discal pressure will reduce as the disc progressively denucleates. Hence, for a clinical interpretation, it is indicated that with the increased denucleation, greater reduction in disc height is expected. This aspect is also brought out in our elasticity analysis of the denucleated intervertebral disc.

Figure 2-42: Axial compression force V s axial displacement of intervertebral disc. The intra-discal pressure (P_i) in unloaded state is 0.1MPa [210].

The disc bulge response to compression loading is shown in figure 2-43. It is to be noted, the healthy disc bulges outward both anteriorly and posteriorly when loaded. This will induce circumferential tensile strains in the annulus. However, as can be gauged from the figure, the annulus thickness decreases a bit; in other words, the radial strains are compressive.

Figure 2-43: Deformed horizontal cross sectional shape of the disc under compression loading. The disc with the nucleus simulated as incompressible fluid, under a compressive force of 3000N. P_r is intra-discal pressure [210].

2.6.2 Disc herniation, back pain and nucleotomy

If the load becomes very big (eg. impact load), the stresses in the annulus can exceed the sustainable value and cause the annulus to develop radial cracks. Then the NP breaks through the annulus (depicted in figure 2-44). A herniated disc occurs most often in the lumbar region of the spine especially at the L4-L5 (L = Lumbar). This is because the lumbar spine carries most of the body's weight. People between the ages of 30 and 50

appear to be more vulnerable, because the elasticity and water content of the nucleus decreases with age [177].

Figure 2-44: (a) Herniated disc. NP compressing the nerve is schematically depicted in the insert (b) Progression of the herniated disc [195].

The progression to an actual herniated disc varies from slow to sudden based on the loading condition. There are four stages namely (1) disc protrusion (2) prolapsed disc (3) disc extrusion (4) sequestered disc (figure 2-44b). Stages 1 and 2 are referred to as incomplete, where 3 and 4 are complete herniations. The pain resulting from herniation may be combined with a radiculopathy (neurological deficit). The deficit may include numbness, weakness and reflex loss. These changes are caused by nerve compression created by pressure from interior disc material.

Percutaneous nucleotomy (one of the treatment options) is carried out in order to remove the NP from the sequestered disc and thereby alleviate the back pain [208]. In this procedure, a probe is inserted into the center of herniated disc under fluoroscope monitoring and NP is removed through the probe. The analysis for (i) volume aspiration of the NP fluid with respect to the time for different external suction pressures (figure 2-45a), and (ii) the pressure drop in NP fluid with respect to the time (figure 2-45b) is reported by Ghista *et al.* [209]. Our recommendation to this problem is delineated in chapter 6, which consists of using a prosthetic disc nucleus, in order to preserve the role of NP in containing the disc deformation under increasing loading. The removal of the nucleus pulposus relieves pain and the patient recovers from the neurological deficits. However, the biomechanics of the nucleotomised disc changes as the nucleus is removed. Nucleotomised disc is prone to more deformation than the healthy disc that could lead to the disc collapse as a long term effect of nucleotomy. The results for long-term follow-up of patients with nucleotomised disc are not yet available.

Numerous artificial discs for total disc replacement are commercially available. These disc designs can be classified into four categories (1) low friction sliding surfaces, (2) spring-hinge-systems, (3) fluid filled chambers, and (4) discs of rubber and elastomers. The first two categories have high fatigue-resistant characteristics and the later two categories attempt to exhibit some visco-elastic characteristics. As this dissertation deals only with the comparison of the biomechanics of the healthy disc and nucleotomised disc highlighting the role of the nucleus pulposus and intrinsic feature of the annulus (i.e. exhibiting stress-stiffening material property), a comprehensive design review of the artificial discs is not provided here. Nevertheless, based on the biomechanical role of

nucleus pulposus as delineated in chapter 5, provides a case for further research on fluid filled chambers as they could closely mimic the healthy disc.

Figure 2-45: (a) NP evacuation time vs. NP volume for different suction pressures ($=14, 0, -14$ psi in a, b, c) (b) NP evacuation time vs. pressure drop around the probe for 50%, 70% and 90% of evacuation for different probe length/diameter ratios [208]. Symbols used for this graph are diameter of the probe ' d ', length of the probe ' l ', pressure of the NP ' p ', volume of the NP ' V_o ', viscosity of the

NP ' μ '. The evacuation time ' t ' is given by the equation $t = \frac{1}{AC} \ln \left(\frac{B}{B - C\bar{V}} \right)$ where

$$A = \frac{158.652d}{\mu l}, \quad B = 30 - p, \quad C = 30/V_o \quad \text{and} \quad \bar{V} = V_o - V \quad [209].$$

Chapter 3

Structural analyses and finite element modelling of bone-plate assembly, for optimal bone fracture fixation

Axial compressive load is more prominent in the fractured fixed long bones and it is not hazardous as more interfragmentary compression at the fracture site is achieved. However, due to the eccentric load from the central axis of the bone-plate and the curvature in the long bone (especially femur), bending moment is also applied to the fracture-fixed bone. Bending moment will induce both tensile and compressive stresses across the fracture site, and open up the fracture, leading to the reduction in the stability of the fixation. From an engineering perspective, fracture fixed bone assembly is the weakest in bending.

In this chapter, first using the composite beam theory of strength of materials, an analytical model is developed to calculate the forces in the screws used in fracture fixation by a plate. Based on the forces in the screws, force in the plate, and the bone, an optimal selection criterion of plate is offered for necessary and sufficient stress shielding. Second, employing the finite element method, the use of stiffness graded plate as a potential substitute to the homogeneous stainless steel bone plate is analysed, to determine the extent of stress-shielding.

3.1 Analysis of forces in the screws of an internally-fixed bone under axial load

When a plate is fixed (with the help of screws) to a fractured long bone, for fracture healing the bone-plate assembly can be analysed as a behavior of composite beam sharing the load between the plate and the bone. In case of a bone-plate assembly, remodelling removes most of the stress concentration effects of the screw holes. However, the transfer of load between bone fragments is through screws and plates, until the fracture is healed completely. Only axial load is considered for the sake of simplicity (although the stress state of bone is multi-axial due to flexural and torsional loadings). In figure 3-1 the axial load ' P ' is applied on the fracture-fixed bone, where the distance between screws is ' s '. The elastic calculation shows that the load transferred by screws ' a ' and ' b ' in axial loading condition is based on the geometrical and material properties of the bone and plate. The free body diagram of the load transfers among the bone, plate and screw is shown in figure 3-2.

Figure 3-1: Free body diagram of bone and plate fixation

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-2: Free body diagram with detailed representation of forces. 't' is the thickness of the plate and 'd_b' is the outer diameter of the bone.

The plate and bone are assumed to have the same amount of uniform axial strain (based on compatibility), and it is assumed that the screws do not bend. In figure 3-2, it is shown that Q_2 denote that part of applied load ' P ' diverted by screw ' a ' (in figure 3-2) through the bone, and the remaining load i.e. Q_1 is the load transmitted to the remainder of the plate through screw ' b ' into the bone. Thus $Q_1 + Q_2 = P$, and this is represented in figure 3-2(b).

The internal forces applied by the bone on the screws are shown in figure 3-2(c). The plate and bone are deemed to be held firmly together by screws. In other words, it is assumed that the force P applied to the plate-screw-bone assembly gets distributed into Q_1 and Q_2 in the plate and bone (through the screws), as illustrated in figure 3-2a. Hence, if

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

the axial strain in the plate and the bone segments is such that the screw is not deformed by the bending moments exerted on it (as illustrated in figure 3-2c), then

$$\begin{aligned} \frac{Q_1}{A_p E_p} &= \frac{Q_2}{A_b E_b} \text{ or } \frac{Q_1}{bt E_p} = \frac{4(P - Q_1)}{\pi d_b^2 E_b} \\ \Rightarrow \frac{Q_1}{P} &= \frac{A_p E_p}{A_b E_b + A_p E_p}, \text{ or } \frac{Q_1}{P} = \frac{\bar{A} \bar{E}}{1 + \bar{A} \bar{E}} \end{aligned} \quad (1)$$

where $\bar{A}$ is the non-dimensional cross-sectional area = A_p/A_b (i.e. ratio of cross-sectional area of plate to cross-sectional area of bone) and $\bar{E}$ is the dimensionless modulus = E_p/E_b (i.e. ratio of plate modulus to bone modulus). Figure 3-3 provides a graphical representation of equation 1. The proportion of force 'P' diverted by screw 'a' into the bone is substantial for a normal plate dimension (of thickness 2mm and width 10mm), and of the order of 90% for $\bar{E} = 10$.

Figure 3-3: Influence of $\bar{E}$ and $\bar{A}$ on the shear force on the screw in axial loading condition. For example, $t=2\text{mm}$ and width is 10mm and outer diameter of the bone is 40mm yields $A_p=20\text{mm}^2$, $A_b=1256\text{mm}^2$ and $\bar{A}=0.0156$

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

From equation 1, it is observed that for a bone-plate assembly under uniaxial tensile/compressive load the load transferred by the screws is independent of their separation distance. Upon substituting representative values of $t = 2$ mm, $b = 10$ mm, and $d_b = 40$ mm in equation 1, Q_1 is $P/7$. Since Q_1 is less than half the value of force ' P ', it indicates that the transfer of loads is not the same in both screws, and screw ' b ' transfers less of plate force ' P ' than screw ' a '. The amount of load transferred by the screw depends on the ratio of the cross-sectional area and material properties of bone and the plate, as depicted in figure 3-3.

It is shown analytically that the two screws cannot equally share the applied load. This is because, as seen in figure 3-3, for $Q_1 / P = 0.5$, $\bar{A}$ is 0.1 for a representative value of $\bar{E} = 10$. That is for $E_p = 10E_b$, A_p should be $0.1A_b$, hence $A_p = 125.6 \text{ mm}^2$ for a representative value of $A_b = 1256 \text{ mm}^2$, and for a plate of width 10 mm , t will be 12.5 mm . From a bending moment consideration, this will make the plate too bulky and flexurally stiff, and cause substantial stress-shielding. It is to be noted that the above elastic analysis is applicable for only infinitesimal strains. The irregular geometry of the bone is not taken into account. In general, the metallic implant can bend by forming a plastic hinge, screws can pull out and screws can fail by shear under increased loads.

3.2 Structural analysis of plate-reinforced bone under bending, to determine the forces applied by the screws

After fracture fixation, the plate shields the bone from tensile stresses at the fracture interface (site 1) and away from the fracture interface (site 2), as shown in figure 3-4a.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

While the tensile stress shielding at fracture interface is necessary to promote healing, that away from the fracture can cause osteoporosis and reduction in bone strength [86]. This problem may be resolved by satisfying two objectives: (i) designing for the neutral axis (NA) at fracture interface to be at the plate-bone interface, to ensure that no tensile stresses are transferred to the callus while it is being formed; and (ii) designing for the NA away from the fracture interface to be as far into bone as possible, so that the bone is subjected to the normally prevalent tensile stresses. These two requirements can be satisfied by careful tailor-made design of the plate modulus and geometry.

3.2.1. Bending analysis of the bone and plate assembly: for stresses in bone and plate

When a bone-plate assembly-beam is subjected to bending moment (as shown in figure 3-4a), the material above the neutral axis is subjected to tensile stresses and the material below the neutral axis bears the compressive stresses [92-93, 210]. For a fractured bone, the plate is preferably fixed on the tension side of the bone, as per tension band principle. The compatibility criterion for the bending analysis is that the curvature or bending strain should be the same in the plate and bone along the contact (bone and plate) interface. The bone-plate assembly (in internal fixation) is assumed to behave as a composite beam during and after healing; because the plate is assumed to be perfectly bonded to the bone. In order to identify the role of the screws under bending, the total moment taken up by the plate and the force in the screws need to be calculated.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

The normal stress distribution on the plate-bone transverse section for the applied moment (M) is shown in figure 3-4b, where σ_1 , σ_2 , σ_3 and σ_4 are the stresses at top surface of the plate, bottom surface of the plate, top surface of the bone and bottom surface of the bone respectively. As shown in figure 3-4(c and d), the stress in the plate can be looked upon to consist of (i) an axial stress $(\sigma_1 + \sigma_2)/2$ due to an axial tensile force (F_p), and (ii) a bending stress $(\sigma_1 - \sigma_2)/2$ due to bending moment, M_p . Similarly, the stress in bone is due to an axial compressive force, F_b , and a moment, M_b .

The total normal stresses are state is given by the following equations [93]

$$\sigma_1 = \frac{ME_p C}{S} \quad (2)$$

$$\sigma_2 = \frac{ME_p (C - t)}{S} \quad (3)$$

$$\sigma_3 = \frac{ME_b (C - t)}{S} \quad (4)$$

$$\sigma_4 = -\frac{ME_b (d_b + t - C)}{S} \quad (5)$$

where $S = E_p I'_p + E_b I'_b$, $I'_p = I_p + A_p y_1^2$ and $I'_b = I_b + A_b y_2^2$; S is the equivalent flexural stiffness of the plate-bone assembly, C is the distance between neutral axis (NA) and the top surface of the plate, y_1 is the distance between NA and center of plate, y_2 is the distance between NA and center of bone.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-4: (a) Fracture fixation by plate under bending moment (b) Normal stress distribution for bone-plate assembly under bending moment (c) the stresses in figure 3-4b are a combination of the stresses due to axial forces and bending moment (d) representation of the axial and bending moment acting on the fracture fixation.

The moments and the axial forces that are shared by the plate and bone are given by

$$M_p = \frac{MI_p' E_p}{S} \quad (6)$$

$$M_b = \frac{MI_b' E_b}{S} \quad (7)$$

$$F_p = \frac{ME_p (2C - t)(bt)}{2S} \quad (8)$$

$$F_b = \frac{\pi(ME_b)(2C - 2t - d_b)d_b^2}{8S} \quad (9)$$

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

3.2.2 Analysis for four screws (two on each side of bone callus): determination of forces in screws

Now the bone and the fixator plate is relaxed, and they are assumed to be held together by means of four screws: two on either side from the mid span. Structural analysis of the plate and the bone under the action of the moments M_p and M_b (equations 6 and 7) and the axial forces F_p and F_b (equation 8 and 9), due to forces (W) exerted on the plate and bone by the inner screws and the forces (R) exerted on them by the outer screws, as illustrated in figure 3-5 is carried out. Further, it is assumed that the two extreme screws rigidly fix the bone and plate assembly by applying forces R , as shown in figure 3-5.

With moments M_p and M_b sustained by the plate and bone, the deflections in plate and bone will be different. Under this loading, the compliant bone deflects more than the plate. Hence, in order for the bone and plate to deflect by the same amount, forces have to be applied through screws on the plate and bone. Let the forces through the screws be represented as ' W '. The screw forces W on the plate and bone are equal in magnitude and opposite in direction, and conform the plate and the bone to have the same amount of deflection. The free body diagrams of plate and bone are shown in figure 3-5. As illustrated therein, ' W ' is the force acting on plate through the screw to increase the plate deflection; similarly, W is the force imposed on the bone by the screw to restrict its deflection.

At the site ($x=0$) of the outer screw forces, the deflection between the plate and bone is assumed to be zero. Hence, at $x=a$ from either end, the force (W) applied by the screws are considered to be indeterminate, whose values are obtained by equalizing the mid-span deflection of the plate and bone caused by the forces (W) acting on the plate and

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

bone. Because the outer screws are holding the plate and bone together, the outer screws are in tension. On the other hand, the inner screws are being compressed by the plate and bone (because of their unequal curvatures, due to the bone being more flexible than the plate). The generalized bending moment on the plate and the bone (between the screws) are obtained as follows

$$\text{on plate: } E_p I_p \frac{d^2 y}{dx^2} = M_p + Rx - F_p y \quad \text{for } x < a \quad (10)$$

$$\text{on bone: } E_b I_b \frac{d^2 y}{dx^2} = M_b - Rx + F_b y \quad \text{for } x < a \quad (11)$$

Figure 3-5: Free body diagram of bone and plate as clamped boundary condition. Two independent structures, held together by (i) forces $R=(W)$ applied by the two outer screws and (ii) forces W applied by the two inner screws.

The deflections on the plate and bone can be obtained by solving the above equations with the clamped boundary conditions i.e. deflection and slope are zero at $x=0$. Now making the deflections on the plate and bone at screw location (i.e. $x=a$), the force in the screws are obtained from the equation

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

$$W = \frac{\frac{M_b}{F_b} \left(1 - \frac{e^{a\sqrt{\frac{F_b}{E_b I_b}}} + e^{-a\sqrt{\frac{F_b}{E_b I_b}}}}{2} \right) + \frac{M_p}{F_p} \left(1 - \cos \left(a \sqrt{\frac{F_p}{E_p I_p}} \right) \right)}{\frac{a}{F_p} - \frac{a}{F_b} - \frac{E_b I_b}{2F_b^{3/2}} \left(e^{a\sqrt{\frac{F_b}{E_b I_b}}} + e^{-a\sqrt{\frac{F_b}{E_b I_b}}} \right) - \frac{E_p I_p}{F_p^{3/2}} \cos \left(a \sqrt{\frac{F_p}{E_p I_p}} \right)} \quad (12)$$

The free body diagram of the in Figure 3-6 illustrates the applied bending moment (M_b), axial compressive force (F_b), internal screw forces (W) on bone, and the variation of the bending moment on the bone. The following expressions provide the normal stress distribution across the bone callus cross-section at site 1 and bone section at site 2, due to the applied bending moment M ,

Tensile stress at the top surface of bone callus at site 1

$$\left(\frac{(M_b - Wa)d_b}{2I_b} - \frac{F_b}{A_b} \right) \quad (13)$$

Compressive stress at the bottom surface of the bone at site 1

$$\left(-\frac{(M_b - Wa)d_b}{2I_b} - \frac{F_b}{A_b} \right) \quad (14)$$

Tensile stress at top surface of bone at site 2

$$\left(\frac{(M_b)d_b}{2I_b} - \frac{F_b}{A_b} \right) \quad (15)$$

Compressive stress at the bottom surface of the bone at site 2

$$\left(-\frac{(M_b)d_b}{2I_b} - \frac{F_b}{A_b} \right) \quad (16)$$

As a case study, let us assume that the modulus of callus (E_c) in the initial stages of healing is $\sim 0.005E_b$. The bending moment bearing capacity is governed by the weakest material in the beam. Hence, E_c (callus modulus) is used for calculating all the parameters (i.e. $\sigma_1, \sigma_2, \sigma_3, \sigma_4, M_p, M_b, F_p, F_b$) in equations (2 to 9) instead of E_b (bone modulus). The

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

computed stresses are given by equations (13 to 16). The parameters assigned for the calculations are as follows: bone outer radius 12mm, bone inner radius 6mm, plate of 15 mm width and 60 mm length, distance between the screws 40mm and a bending moment of 1Nm, $E_b=21\text{GPa}$, $E_c=0.1\text{GPa}$, $E_p=210\text{GPa}$, on the bone-plate assembly. With the applied bending moment on the fracture-fixed bone-plate assembly (along with the above mentioned bone and plate geometrical dimensions and moduli), equation 12 yields the force value of 30.2 N (extreme screws are in tension and inner screws are in compression) in the screw for a 5mm thick plate. The stresses in bone at fracture site are given by equations (13 and 14), and tabulated in Table 3-1.

Figure 3-6: Bending moment diagram on the bone for a fracture fixed by plate.

From table 3-1, it is noticed that in case 1, to have NA inside the plate at site 1, and maximum tensile stress in the top layer of the bone at site 2, the thickness of the plate should be at least 3mm. Similarly in case 2, the plate thickness should be 4mm. However, for the modulus of plate to be less than 50 GPa (case 3), the NA is shifted into the bone and thus causes some tensile stress in the upper layer of bone (i.e. at site 1) leading to delayed

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

healing. Hence, the optimal plate should have a modulus 210 GPa and thickness of 3mm, for the cases considered.

Table 3-1. Design parameters of plate and calculated stress values in the bone callus at sites 1 and in the bone at site 2.

Modulus of callus (GPa)		Modulus of plate (GPa)	Thickness of plate (mm)	Magnitude of forces in each screw (N). Outer screws are in tension and inner screws in compression.	Stress at site 1 on the top surface of the bone callus (N/mm ²)	Stress at site 2 on the bone top surface (N/mm ²)
Case 1	0.1	210 (316L Stainless steel)	2	25.12	0.20	0.64
			3	26.72	-0.19	0.43
			4	29.07	-0.30	0.27
			5	30.2	-0.32	0.17
Case 2	0.1	110 (Titanium alloy: Ti-6Al-4V)	2	18.86	0.38	0.72
			3	24.81	0.08	0.56
			4	28.44	-0.12	0.40
			5	29.42	-0.39	0.29
Case 3	0.1	50 (CFRP)	2	12.2	0.41	0.77
			3	18.21	0.36	0.68
			4	25.72	0.26	0.55
			5	26.32	0.11	0.43

Ideally, it is preferable that the NA to be located at the plate-bone interface and the stress in the bone underneath the plate be zero (so that there is no tensile stress) in the callus; at the same time, the plate should not overly stiff, so that there is no compressive stress in it (due to the NA being inside it). However, since the plate thicknesses are standardized, what is being implied from Table 3-1 is that the stainless steel plate of 3mm thickness yields the best option for (i) the callus to be totally in compression, with the stress underneath the plate being minimal, (ii) the bone away from the callus fracture-site to have the maximal tensile stress. An extension of the proposed approach is detailed in the

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

later sections (i.e. section 3.2.3) for calculation of the forces in three screws on either side of the fracture under bending loading condition.

3.2.3 Analysis for six screws (three on each side of bone callus)

In the previous section (i.e. section 3.2.2), an analysis for calculating the moments and the forces shared by plate and bone is developed, when the assembly (plate and bone are perfectly bonded and behave as a composite beam) is subjected to bending moment with the plate placed on the tension side of the bone. Later, the bone and plate are assumed to be held together by means of four screws: two on either side from the mid span at which bone callus is located. By equating the deflection of the bone and plate at the screw location the forces in the inner screw are calculated. The same approach is now used in this section, for the fracture fixation involving six screws, i.e. three screws on either side of the bone callus.

The free body diagrams of the plate and bone with the forces in screws (six screws i.e. three screws on either side of the bone calls) are represented in figure 3-7. The outer screws are assumed to held both the plate and bone assembly rigidly fixed. The screw near to the callus site (screw 1) is designated to be at distance ‘ b ’ from the extreme screw (screw 3). Also the distance between screw 2 and screw 3 is designated to be ‘ a ’. Let W_1 be the force in screw 1, W_2 be the force in screw 2, and R be the force in screw 3. According to the representation of forces in figure 3-7, ‘ W_1 and W_2 ’ are the forces acting on the plate and bone through the screws to make the plate and bone congruent (i.e. have similar deflections). To calculate the forces in the screws, the vertical force balance gives

$$W_1 + W_2 = R \quad (17)$$

The generalized bending moment equation on plate (for $x < a$) is given by

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

$$E_p I_p \frac{d^2 y}{dx^2} = M_p + Rx - F_p y \quad (18)$$

Also, the generalized bending moment equation on plate (for $x < b$) for is given by

$$E_p I_p \frac{d^2 y}{dx^2} = M_p + Rx - W_2(x - a) - F_p y \quad (19)$$

Similarly, the generalized bending moment equation on bone (for $x < a$) is given by

$$E_b I_b \frac{d^2 y}{dx^2} = M_b - Rx + F_b y \quad (20)$$

and, the generalized bending moment equation on bone at (for $x < b$) is given by

$$E_b I_b \frac{d^2 y}{dx^2} = M_b - Rx + W_2(x - a) + F_b y \quad (21)$$

The deflections on the plate and bone can be obtained by solving the above equations (18 to 21) with the boundary conditions (i.e. deflection and slope are zero at $x=0$). Now making the deflections on the plate and bone at screw location (i.e. $x=a$ and $x=b$), and solving them with equation 17, the forces in the screws (i.e. R , W_1 , W_2) are obtained.

Figure 3-7: Free body diagram of bone and plate as a beam with six screws. From the calculations, it is noted that screw 1 (W_1) is in compression, while screw 2 (W_2) and screw 3 (R) are in tension.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

By way of an example, the following data are adopted: modulus of plate (E_p)=210GPa, modulus of bone (E_b)=21GPa, modulus of callus (E_c)=0.1GPa, moment of inertia of plate (I_p)=156 mm⁴, bone outer radius 12mm and internal radius 6mm, plate of 15 mm width and 5mm thickness, b =40mm, a =20mm. R =26.8N, W_1 =29.96N and W_2 = 3.16N.

The stresses in bone at fracture interface and away from it are tabulated in Table 3-2, and the forces in the screws are given in Table 3-3. The analysis is done only for a stainless steel plate (SS), as SS plates usage is more common in clinical practice. The optimal plate thickness is still 3mm, even with the increase in the number of screws to six from four. However, it is to be noted that the magnitude of the force in each screw is less in six-screw fixation than four-screw fixation.

Table 3-2. Design parameters of the plate and calculated stress values in the bone callus at site 1 and in the bone at site 2.

Modulus of callus (GPa)	Modulus of SS plate (GPa)	Thickness of plate (mm)	Stresses at site 1 on the top surface of callus (N/mm ²)	Stresses at site 2 on the bone top surface(N/mm ²)
0.1	210	2	0.20	0.64
		3	-0.17	0.43
		4	-0.30	0.27
		5	0.31	0.17

Table 3-3. Forces in the screws for six screw fixation.

Thickness of plate (mm)	Force in the screw 1 (W_1) in N. (Compressive)	Force in the screw 2 (W_2) in N. (Tensile)	Force in the screw 3 (R) in N. (Tensile)
2	23.17	1.38	21.78
3	25.73	2.41	23.31
4	28.24	2.61	25.63
5	29.96	3.16	26.80

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

As described in the literature review (i.e. section 2.2.5), bone does form when the callus is subjected to the tensile stresses. However in this study, it is considered that only compressive stress at the fracture site is helpful for bony tissue formation and hence imposed this constraint in the analytical model for predicting the optimal thickness of the plate and the number of screws. This could be treated as a case for primary healing without micro-motion.

3.3 Finite-element analysis of bone fracture fixation

3.3.1 Representation of constitutive properties of callus and plate for the finite element method

The objective of the section is to address the role of the plate stiffness for optimal fracture fixation, using the ABAQUS[#] finite-element package. Both two and three dimensional models are employed. The methodology will be illustrated only for bending moment (as bending is deemed to be the predominant load that opens the crack), applied onto a fractured long cylindrical bone and plate assembly. The usefulness of stiffness-graded plate in reducing stress-shielding is also carried out. In this model, the callus at fracture site is considered to be homogeneous and isotropic, with its modulus varying from 1% of bone modulus (grown after fracture) to 100% of bone modulus at full healing [93].

Bone is a cellularic material. It is reasonable to model cortical bone as an orthotropic linear elastic solid [149,150]. The material properties of bone used in finite element

[#] ABAQUS Version 6.3, HKS., Rhode Island, USA

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

simulations is given in section 3.3.4. The plate, screws and callus, can be simply modeled as linearly isotropic elastic materials [93], which require the knowledge of only two material properties (viz. Young's Modulus and Poisson's ratio) are required to specify their constitutive behavior (material properties are given in section 3.3.2 and 3.3.4).

3.3.2 Two-dimensional analysis of internally-fixed fractured bone under bending, using stiffness-graded plate in comparison with stainless steel plate

The biomechanical factors, governing the healing efficiency of fractured bone treated by plate and screws, are: (1) the degree of bone contact developed at the fracture interface, (2) stability provided to the fractured bone in terms of reduced movement at the fracture interface, and (3) necessary and sufficient stress-shielding of the bone at fracture interface as well as away from it. Hitherto, conventional high-stiffness stainless-steel (SS) plates have been employed for long-bone fracture-fixation. However, the large difference in modulus between the plate and bone as well as the compressive stresses occurring between the plate and the bone (due to over-tightening of screws) disturb the vascularity of the bone underneath the plate, causes bone resorption underneath the plate and reduction in its strength as a long term effect.

In recent years, there has been considerable awareness and discussion on the need for using less-stiff plates to improve fracture healing and prevent bone weakening due to stress-shielding [39, 63,69,72]. It is not entirely correct to say that bone-plates with high Young's modulus ' E ' cause excessive stress-shielding, because flexural stiffness of the plate is characterized by the product ' E ' and moment of inertia of the plate cross-section;

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

hence the plate geometry also has a bearing on the stiffness and thereby on the stress-shielding of the bone [72]. Nevertheless, for a uniform plate geometry, plates with a lower E will offer less stress shielding than the plates with higher Young's modulus.

Figure 3-8: Schematic of bending stress distribution in bone without and with plate.

The undesirable consequence of using high stiffness bone plate is schematically illustrated in figure 3-8. The normal-stress distribution in a healthy bone under a bending load is shown in figure 3-8a, where the NA lies at the geometrical central axis of the bone. When a stiff plate (with $E_p \gg E_b$) is attached to the bone (as in figure 3-8b), the neutral axis is closer to the plate-bone interface. As a result, the bone underneath the plate is inadequately stressed, and can become osteoporotic due to de-mineralization or cortex thickness reduces.

With the use of FEM, it is illustrated (in figure 3-9a) that the stresses at the fracture interface vary, with an increase in callus stiffness due to the fracture healing (in figure 3-10). In the early stages of healing, when the callus modulus is 1% of the bone modulus (wherein bone is modeled is assigned with the Young's modulus of 20GPa), the neutral axis (NA) is located inside the plate, and the callus interface is in compression. As healing proceeds (the callus modulus increases), the NA shifts down into the bone, allowing the

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

callus to also bear some tensile stress. In this way, the total tensile stress borne by the plate decreases with increase in the callus modulus.

Figure 3-9: (a) Schematic representation of dimensions (mm) and loading conditions used for FEA (b) uniform stiffness plate (c) stiffness graded plate in length (d) stiffness graded plate in thickness.

Functionally graded materials (FGMs) are currently being used for a range of mechanical and structural applications. FGMs (made from a mixture of ceramics and metals) are characterized by a smooth and continuous change of the mechanical properties from one characteristic surface to the other. Herein, the viability of using stiffness-graded materials as bone plates to reduce the stress shielding effect is studied. FEA (ABAQUS) is used to determine the stress distribution for the fracture-fixed bone-plate assembly, as illustrated in figures 3-9 (a-d), where in the geometry and loading conditions (represented

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

by four-point bending in the FEA) are represented by a bending moment of 1.0 Nmm are shown in figure 3-9a. Then, figure 3-9b represents the case of a 316L stainless steel (SS), figure 3-9c is for the case of a length-wise stiffness-graded plate (SGL), while figure 3-9d is for the case of thickness-wise stiffness-graded plate (SGT).

Figure 3-10: Normal stress distribution at the callus (crack interface) and neutral axis location for different callus and plate properties, as healing progresses (calculated using FE simulations..

In order to make the model continuous at the fracture interface, a callus (of length 1% of the beam length) is assumed at the fracture site. The Young's modulus of the callus is assumed to be 1% of that of bone at the initial stages of healing, while its value is equal to that of bone modulus at the final stages of healing. In figure 3-9b, the Young's modulus of SS is 210GPa. In figures 3-9 (c and d), the Young's modulus of SGL and SGT are varied linearly from 210GPa to 21GPa along the length and thickness of the plate, respectively. The transfer of load between the bone and plate (bypassing the crack) enables the plate-reinforced bone to bear the loading. At the same time, the plate prevents the crack from

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

opening up, and helps to induce compressive stress in the lower portion of the crack interface.

The bone and plate are considered to be completely bonded at the bone-plate interface (using CONTACT PAIR option in ABAQUS, i.e. the nodes on the contact surfaces are glued to each other, to thereby develop uniform strain across the interface). Four noded (quadratic) plane-strain elements are used to discretize the geometry. The computed variations of normal stresses along the plate-bone interface at initial and final stages of healing are shown in figures 3-11 (a) and (b) respectively. It is observed that initially after fracture, all the three types of plates shield the bone, by not allowing any tensile stress in the upper bone layers (underneath the plate) close to the fracture-interface. In other words, at cross-sections close to the fracture-site, the neutral axis is located within the plate. However, about 10 mm away from the fracture site, the neutral axis becomes located into the bone region, and the bone starts bearing the tensile stress. It is also observed that the stress shielding zone size for the SS plate is at least 50% greater than that for the SGL and SGT plates. Qualitatively, it can be seen that with SGT, a higher compressive stress is developed in the top layer at the fracture-interface. It is noted that the stress distribution of SGL follows that of SS plate at fracture site, and that of SGT plate away from the fracture site.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-11: Comparison of the stresses along length of bone-plate interface for SS, SGL and SGT (a) stresses on bone Vs distance at initial stage of healing (b) stresses on bone Vs distance at final stage of healing. These comparisons show that SGL and SGT offers less stress shielding compared to SS.

3.3.3 Two-dimensional analysis of fracture-fixed bone with stiffness-graded material for different screw locations

In the previous case study (in section 3.3.2), the plate was assumed to be perfectly bonded to the bone. The same four-point bending problem is now analyzed by fixing the plate with a maximum of three screws and a minimum of one screw on either side of the fractured callus surface, as shown in figure 3-12. In the FE simulations, the contact surface between plate and bone is assumed to have a coefficient of friction of 0.37 [35]. The transfer of load between the plate and the bone is through screws; to simulate this function, a finite length of 1 mm of plate is held (through tie option) to the bone.

Figures 3-13 to 3-18 depict the computed variations of normal stresses on the bone and across the bone-plate interface for all the six modalities of fixation at the initial and final stages of healing for the six screw fixation (S6), four screw mode-1 fixation (S4-1), four screw mode-2 fixation (S4-2), four screw mode-3 fixation (S4-3), two screws near fracture site (S2N) and two screws away from the fracture site (S2E).

The variation of normal stresses in top layer of the bone for six screw fixation is shown in figures 3-13, for both initial and final stages of the healing. It can be seen that in the early stages of healing, the bone is almost de-stressed at the fracture. However, because the screws are functioning as elements holding the plate and bone together, large variations of normal stresses are seen at the screw sites of the bone. This is understandable because in the initial stage of healing, the bone plate assembly is almost equivalent to that of two separate bone fragments held together by the plate through the screws.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-12: Different screw locations for which FEA is carried out (a) six screws (S6) (b) four screws, mode 1 (S4-1) (c) four screws, mode 2 (S4-2) (d) four screws, mode 3 (S4-3) (e) two screws near fracture site (S2N) (f) two screws extreme from fracture site (S2E) to fracture site. The distance (in mm) between screws is showed in the insert of (a). In (b) insert, an element underneath the plate and on the bone is enlarged to depict the stress notation used in table 4.

In the final stages of healing, the neutral axis becomes relocated from the plate to within the bone. At this stage, the screws are not playing such a major role in maintaining the integrity of the bone, as in the early stages of healing. Hence (as seen in figure 3-13),

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

the magnitudes of the stresses at the screws near the fracture site are considerably less than those at the initial stage of healing. From figures 3-13 to 3-18, it is noted that the stress-distribution associated with fixation by models S6, S4-1, S4-2 and S2E give largest stress-shield zones. On the other hand, fixation by two screws close to the fracture (S2N) provides minimum stress-shield zone. The participation of the length of the plate in bending moment is governed by the extreme screws. Also model S4-3 provides a smaller stress-shielding zone.

The stress-shielding zone is dependant on the working length of the plate, which depends on the location of the screws. In fixation modes S4-3 and S2N, the entire length of the plates (S4-3 and S2N) is not utilized, as the extreme screws are not used. If extreme screws are not used, the ends of the plates are not held to the bone, and will be loose and disturb the soft tissues around the bone. Hence, S4-3 and S2N are avoided in clinical practice. Fixation by just two screws at the fracture site may not provide enough stability; hence S2E is not clinically applicable. However, fixation modes S4-1 and S4-2 of plate with two screws on either side of the fracture are clinically relevant.

Now, coming to the effect of plate stiffness on the stress distribution, it is noticed that the SGL plate simulates the SS plate stress-distribution closer to the fracture zone, but simulates the SGT plate further away from the callus. The level of stress shielding is not significantly affected by the variation in plate modulus. This implies that the screw location on the plate rather than the stiffness of the plate has a more dominating role in minimizing the stress-shield zone. The shear stress near the screw and the maximum compressive stress in the callus for various screw fixators is summarized in Table 3-4. From the table, it can be observed that the six-screw fixation gives minimal central deflection at fracture site and

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

minimum shear stresses in the screws. For four-screw fixation design, the recommendation (based on Table 3-4) for minimal deflection is that one screw should be close to the fracture site and the other should be as far as possible from the fracture site.

Table 3-4: Central deflection, shear stresses at the screw (at bone-plate interface), and the maximum compressive normal stress at the fracture site for two, four and six screw fixation illustrated in figure 3-12. SS: stainless steel, SGL: Stiffness graded along length, SGT: Stiffness graded along thickness.

Mode of fixation	Central deflection (mm) at fracture-site (10^{-5})			S _{xy} -Shear stress at screw (MPa)				Maximum compressive stress in callus (10^{-4} MPa)		
	SS	SGL	SGT	Screw number from fracture-site	SS	SGL	SGT	SS	SGL	SGT
S6	68	70	72	1	-0.0037	-0.0025	-0.0025	-56	-59	-69.2
				2	0.0038	0.00557	0.007			
				3	0.0263	0.0178	0.0196			
S4-1	69	71	73	1	-	-	-	-57	-58	-69
				2	0.009	0.003	0.0068			
				3	0.0254	0.0172	0.0193			
S4-2	69	72	74	1	0.002	0.00007	0.00009	-56	-59	-70.1
				2	-	-	-			
				3	0.0274	0.0193	0.0221			
S4-3	80	86	87	1	0.00075	0.00098	0.0033	-58	-61	-70.6
				2	0.026	0.0213	0.0200			
				3	-	-	-			
S2N	96	98	100	1	0.0314	0.0267	0.0123	-86	-83.4	-90
				2	-	-	-			
				3	-	-	-			
S2E	69	71	75	1	-	-	-	-57.3	-61.2	-71
				2	-	-	-			
				3	0.025	0.018	0.023			

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-13: Normal stresses at the top face of bone in contact with the plate for S6: (a) at initial stages of healing (b) final stages of healing. It can be seen that the bone is under compression stress at the fracture site underneath the plate. Upon complete healing, the bone bears some tensile stress at fracture site.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-14: Normal stresses at the top face of bone in contact with the plate for S4-1 (a) at initial stages of healing (b) final stages of healing. Even in this fixation configuration, upon complete healing the bone bears some tensile stresses at the fracture site.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-15: Normal stresses at the top face of bone in contact with the plate for S4-2. (a) at initial stages of healing (b) final stages of healing. Here too, upon complete healing the bone bears some tensile stresses at the fracture site.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-16: Normal stresses at the top face of bone in contact with the plate for S4-3. (a) at initial stages of healing (b) final stages of healing. It is to be noted that the stress shielding zone is reduced in this fixation configuration. The stress shielding zone is dependent on the working length of the plate, which depends on the location of the screw.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-18: Normal stresses at the top face of bone in contact with the plate for S2E. (a) at initial stages of healing (b) final stages of healing. In this fixation configuration, bone is shielded from stresses for the entire length of the plate due to the usage of the extreme screws. The extreme screws dictate the stress shielding zone of the bone.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

3.3.4 Three-dimensional modelling of fracture-fixed bone-plate assembly

In this section, a three-dimensional finite element analysis (using ABAQUS) is carried out, to identify the stress state in a bone-plate assembly with six screws, under bending loads (simulated by four-point bending). The bone is modeled as a circular tube (figure 3-19b). The plate has a cross-section that resembles a rectangle, with curvature underneath the plate such that the plate exactly matches the bone outer surface (figure 3-19a). The screw is assumed to have only two threads, in such a way that one thread is in the upper material portion of the bone and the other in the lower material portion of the bone. The screw head matches the tapered hole of the bone plate (figure 3-19 c).

The geometries of bone with threaded holes, plate with tapered holes and screw with two threads are separately drawn, using the Pro/Engineer (Pro/E) geometrical modelling package (version 2001), as shown in figure 3-19. These 3D geometries are imported from Pro/E to ABAQUS with the help of CAD translator “STEP”. The imported geometries are then assembled in ABAQUS, as shown in figure 3-20.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-19: Models developed in Pro/E (a) plate with dimensions (mm), (b) bone with dimensions in the insert, (c) screw with two threads. All the dimensions are in mm.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-20: Assembly of plate, screw and bone in ABAQUS.

3.3.4.1 Geometrical Details and Material Data

The plate is taken to be a thin rectangular block (with a curvature on the bottom side of the plate that matches the bone outer diameter, as shown in the insert of the figure 3-20) of 100x12x5 mm, with six tapered holes drilled in it at equal spacing for the purpose of fixing it on to the bone (of 24 mm in outer diameter with 6mm cortex thickness and 200mm long with a 1mm wide transverse fracture) by means of threaded screws. The geometries of the threaded holes in the bone and of the tapered hole in the plate exactly mate (match) with the screw dimensions (as depicted in figure 3-19c). The main function of screw thread is to prevent the screw from being moved along its axial direction, due to its holding capacity (holding capacity is defined as the maximum force that the screw can sustain before being pulled out along its axis). To model this function and to limit the

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

number of elements in the analysis, only two threads are incorporated, as shown in figure 3-19c. This simulation is not aimed at modelling the failure mode of screw itself, but to identify the role of screw and plate in shielding the bone from stress. This kind of approach is able to capture the essential mechanics of the problem. It is to be noted that Fan *et al.* [212] have used a single thread for the screw connection in steel sheeting under static shear.

In the simulation, the screw is assumed to be made of titanium alloy Ti-6Al-4V, with Young's modulus of 105 GPa and Poisson's ratio of 0.3. The bone-plate is "fabricated" with 316L stainless steel, having Young's modulus value of 200 GPa and Poisson's ratio of 0.3. The bone is considered to be of orthotropic material, The nine independent elastic constants of bone (used in ABAQUS⁺) in 3D model are: D_{1111} , D_{2222} , D_{3333} , D_{1212} , D_{1313} , D_{2323} , D_{1122} , D_{1133} , D_{2233} are: 14.1 (GPa), 18.4 (GPa), 25 (GPa), 7.0 (GPa), 6.3 (GPa), 5.28 (GPa), 6.34 (GPa), 4.84 (GPa), 6.44 (GPa) respectively [150]. The 1, 2, 3 directions are as shown in figure 3-20. A 1mm thick callus region is modeled at the center of the femur and it is assigned Young's modulus 0.2GPa and Poisson's ratio of 0.3. For the SG Plate, the Young's modulus value at the center of plate is 200GPa (at fracture site) and decreases linearly towards the ends of the plate to 20GPa, while a constant Poisson's ratio of 0.3 is assumed throughout the length. The analysis is restricted to elastic limit with non-linear geometry.

⁺ as per the option available in property module in ABAQUS

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

3.3.4.2 Contact interfaces

When the assembly (bone, plate, and screw assembly) is subjected to a bending moment, the bone, plate and screw will come into contact and compress each other. Appropriate contact interfaces between the plate and the bone, between the screw and the bone, between the screw and the plate have been created in the ABAQUS software under interaction module. To model the interactions of these contacts, contact elements (surface to surface contact) are used, and consequently appropriate friction conditions are assigned for these interfaces. These contact elements use a “master surface” and a “slave surface” to form a contact pair. This setting requires the surface having higher stiffness to be assigned as the master surface. The master surface is allowed to penetrate the slave surface, but not the reverse. Therefore, six contact pairs (three contact pair on upper sections of the bone and three contact pairs at the lower section of the bone) are defined for bone and screw contact, three contact pairs are defined for plate and screw contact and one contact pair is defined for plate and bone contact (figure 3-21).

Sticking contact conditions **FRICITION***, 0.9; **SURFACE BEHAVIOR***, NO SEPERATION and **HARD CONTACT*** options are assigned for bone and screw contact. Contact interaction between plate and bone is carried but by **FRICITION*** (0.37) and **CONTACT PAIR*** (SMALL SLIDING). In order to simulate self-locking mechanism between the plate and screw, the screw is fixed to the plate through the **TIE*** option. TIE option maintains the contact interaction with a coefficient of friction of 1.

* option available in the interaction module of ABAQUS CAE

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-21: Bone plate assembly depicting the contact surfaces

3.3.4.3 Boundary and loading conditions

The boundary and loading conditions are defined by two steps namely: initial step and step-1 (in the step module of ABAQUS CAE) respectively. In the initial step, boundary conditions (to simulate four-point bending) were assigned; in step-1 the load (displacement) are assigned (as in figure 3-22). In the analysis step-1, a NLGEOM option is switched on, to account for anticipated geometrical nonlinearity (due to the excessive deformations that can occur on the bone near screw thread) during the analysis.

The geometrical and loading symmetry associated with four-point bending are employed to reduce the computational geometry of the problem: one quadrant of the geometry is sufficient to analyze. The model is symmetric about the 1-2 plane at fracture

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

site and at 2-3 plane at the screw axis longitudinal axis (refers to figure 3-22). Symmetric conditions are enforced by constraining the displacements of nodal points on these planes to be zero in the direction normal to symmetry plane. The symmetric condition applied about the 1-2 plane at the fracture site is ZSYMM⁺ (i.e. $U_3=UR_1=UR_2=0$), and the symmetric condition applied about the 2-3 plane at the screw axis longitudinal axis is XSYMM⁺ i.e. $U_1=UR_1=UR_2=0$ (refer to figure 3-22 for the co-ordinate convention).

In order to simulate four-point bending, the end of the bone (1-2 plane at the end of the bone as in figure 3-22) is simply supported, such that displacement along axis 2 is zero i.e. $U_2=0$. In step-1, the nodes located at a distance of 20mm (location of the loading condition is shown in figure 3-22) from the end of the bone are displaced by a magnitude of 0.5mm along the axis 2 (i.e. $U_2=0.5$), such that the plate is subjected to tensile stresses. Then, the force obtained at the nodes multiplied by the distance from the end of the bone produce the equivalent bending moment of 2 Nm. In other words, the bending moment is applied such that the fracture gap closes.

⁺ option available in load module of ABAQUS CAE, U represents displacement and UR represents rotation. The number followed by U or UR represents the axis

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-22: Boundary conditions and loading conditions for 3D model. All dimensions are in mm. U and UR represent the displacement and rotation respectively. With the 1-2 plane at the end constrained $U_2=0$ and the loading condition $U_2=0.5\text{mm}$ applied to the nodes at 20mm from the end simulates the four point bending moment.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Three dimensional (brick) continuum elements with eight nodes and reduced integration (C3D8R) are used to discretize the assembly (as illustrated in figure 3-23a). In order to more accurately account for the contact interactions, a finer mesh has been adopted at the contact of two surfaces. The results of several trial meshes have been compared to choose the final mesh i.e. mesh sensitivity analyses (as shown in figure 3-23b). When a mesh size refinement barely influences the results and the stress contours in the model, that size has been adopted. The variation of the bending moment with the number of elements used in the analyses is shown in figure 3-23b, the convergence of the model (i.e. fracture fixed by a plate and three screws) is obtained at 7933 elements.

Figure 3-23: (a) Mesh for fracture fixed bone by plate and screw. Elements used for meshing is C3D8R (8 node linear brick, reduced integration) (b) the variation of moment with the number of elements used in the analyses, the convergence is obtained at 7933 elements.

3.3.4.4 Results

The Von-Mises stress values (effective stress) within the bone and plate are shown in Figures 3-24 and 3-25 for fixation with stainless steel (SS) plate, and in figures 3-26 and 3-27 for fixation with stiffness graded (SG) plate. The stresses in the plate are maximum in the screw hole located close to the fracture site, and the stress value is noted to be 582MPa

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

for SS plate (figure 3-24a) and 609MPa for SG plate (figure 3-26a). This raises the need to improve the plate design, such that plate will not fail at screw hole near to the fracture.

Maximum stresses in the bone are obtained at the screw holes due to the concentrated contact stresses (Figure 3-25a for a SS plate fixation, and figure 3-27a for SG plate fixation). Higher stresses at the bone cavities will initiate bone remodeling process and the bone density surrounding the screw will increase, which in turn will contribute to the better holding of the screws (some times the holding capacity deteriorates if the stresses are more than the sustainable limits of the bone). However, the screw becomes loose in the initial stages of healing due to its micro-motion under normal loading. The importance of the bending stiffness of the screw is also identified from the analysis; it can be seen from figures 3-24(b and c) and 3-26(b and c) that the screws are subjected to bending moments, with the maximum bending stress in them occurring at the top screw thread.

Table 3-5 summarizes the main features of SG and SS plate fixations. The SG plate generates relatively higher compressive stresses in the callus zone compared to SS plate, thereby providing better bone-healing potential and offers better stability to the fixation at fracture site. In the SG plate assembly, the location of the NA after the first screw with SG plate assembly is nearer to the bone neutral axis when compared with the NA location with SS plate assembly. Thus, the SG plate reduces the stress shielding of the bone by generating higher stresses in the bone, and hence preserves its density and strength.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Table 3-5. Effectiveness of stiffness graded plate compared with stainless steel plate

Fixator plate material	Computed values for the bone	Crack Interface	In cross-section at first screw	In cross-section at second screw	In cross section at third screw
Stainless-steel plate	Maximal tensile stress (MPa)	2.6	11.00	15.00	22.3
	Minimum compressive stress (MPa)	-10.57	-16.20	-20.9	-21.88
	Neutral Axis from top of the bone (mm)	4.8	9.1	9.9	11.5
Stiffness-Graded Plate	Maximal tensile stress (MPa)	2.9	12.49	16.17	23.94
	Minimum compressive stress (MPa)	-11.5	-16.3	-21.19	-25.00
	Neutral Axis from top of the bone (mm)	4.9	10.1	10.5	11.7

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-24: Analysis of fixation with Stainless-steel plate (a) Von-mises stresses (MPa) in the plate (b) Stresses (S_{22}) in screws (MPa) along the axis of the screws (c) Stress (S_{22}) (MPa) developed in the screws while loading (in 2-3 plane)

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-25: Analysis of fixation with Stainless-steel plate (a) Von-mises stresses (MPa) in the bone (b) Normal stress distribution (MPa) in bone at various cross-sections.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-26: Analysis of fixation with Stiffness-graded plate (a) Von-mises stresses (MPa) in the plate (b) Stresses (S_{22}) in screws (MPa) along the axis of the screws (c) Stress (S_{22}) (MPa) developed in the screws while loading (in 2-3 plane)

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

Figure 3-27: Analysis of fixation with Stiffness-graded plate (a) Von-mises stresses (MPa) in the bone (b) Normal stress distribution (MPa) in bone at various cross-sections.

Chapter 3 Structural Analyses and Finite Element Modelling of Bone-Plate Assembly

From these analyses, it is observed that the bone away from the fracture interface is stressed more with the usage of stiffness graded (along the length) plate than in the case of stainless steel plate. However, the screw holding capacity is not improved through the application of stiffness graded plates. Ideally, fracture-fixation by plates requires reduced stress-shielding and improved holding capacity.

The summarized remarks of this chapter are (i) using analytical and numerical methods bone-plate assembly is analyzed under axial tensile and bending loading conditions, (ii) based on the composite beam theory proposed, for a given number of screws the optimal plate thickness can be obtained, (iii) the use of compliant or stiffness-graded plate as an alternative for 316L stainless steel plates is explored using finite element analysis. The above mentioned analyses to the bone-plate assembly are indeed original contribution. Because of the several assumptions made in the analytical and numerical work, it is beyond the scope of this project to make any comparisons with clinical work. The fractured bone is modeled as an orthotropic material (in finite element analysis) and appropriate contact conditions (between the plate-screws, plate-bone, screw-bone and bone-bone at fracture interface) are used wherein the bone in the analytical model is treated as isotropic material with low modulus callus at fracture interface. These different conditions make the finite element model and the analytical model different from each other. Thus the comparison between them was not performed. The next chapter discusses the helical plating technique, to address both the stress-shielding problems and offer improved holding capacity.

Chapter 4

New modality of fracture fixation using a hemi-helical plate: Optimality considerations

This chapter discusses the improvements in oblique fracture-fixation by means of hemi-helical plate, that provides the bone-plate-screw (BPS) assembly (i.e. bone-fracture fixed by the plate and the screws) with enhanced (and somewhat flexible) holding capacity, while the individual components involved in the fracture-fixation are stiff/rigid (i.e. plate and screws being made with stainless steel). In particular, the hemi-helical plate (HHP) is conceived to provide stable fixation for helical cracks (caused by torsion), such that the bone interfaces at the crack are brought into apposition and compressive strains are applied at the cracked interfaces. The HHP wraps around the bone, and hence is also suited for fixation of commutated fractures. This is because, instead of employing multiple screws across the cracks, the HHP holds the bone fragments together.

This chapter is divided into three parts. Part 1 discusses the experimentation on the fracture-fixed bone in bending to determine (i) the forces in the screws, (ii) stiffness of the BPS assembly (fracture-fixation), and (iii) the energy to failure for all possible screw configurations (on straight plate) i.e. convergent (CSO), divergent (DSO), alternating (ASO) and perpendicular orientation (PSO). Part 2 develops the special capabilities of HHP with respect to its enhanced holding capability, in comparison to CSO, DSO, ASO, PSO. Part 3 provides the finite element analysis of HHP, to elucidate its efficacy in terms of (i) fracture gap movement and closure, and (ii) the flexibility of the fracture-fixation for compressive, bending moment and torsional loads.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Bone fracture fixation, for the healed bone to retain its pre-fracture stiffness and strength, continues to pose an immense challenge to mankind. There are several methods to treat bone fractures. These include external immobilization and fixation techniques (such as plaster casting and multiple percutaneous transcortical pins or internal fixation techniques using intra-medullary rods and/or plates). The current chapter addresses the unique features of Hemi-Helical Plate (HHP) internal bone fracture fixation, wherein screws are used to anchor a hemi-helical plate onto the fractured bone. This is a relatively new concept in internal fracture fixation.

The screws provide bridge transferring forces between the plate and fractured bone. Consequently, these screws may be subjected to relatively large shear stresses during movement of the fractured limb. In addition, the bone surface adjacent to the screw could be subjected to the trauma of insertion, which may cause some temporary bone necrosis. These factors can lead to loosening and subsequent ‘pulling-out’ of the screws, thereby destabilizing the entire assembly of bone fracture fixation [64, 66, 108, 110]. Such phenomenon is commonly observed in straight-plate fixation, where the screws are oriented normal to the plate in the same plane. Therein, inclination (i.e. angling) of the screws is thought to be a possible solution to mitigate the loosening of bone fracture fixation (as shown in figure 4-1). Apart from the possibility of screw loosening, the straight-plate also induces undue stress-shielding of the fractured bone. This is because the straight-plate fixture is fastened onto the tensile surface of the fractured bone (thereby distressing of the bone beneath the plate), and the plate material Young’s modulus, which is $\sim 200\text{GPa}$ for 316L stainless steel is typically an order-of-magnitude higher than that of bone, which is about 20GPa .

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-1: (a) perpendicular screw (b) convergent (c) divergent (d) alternating. All the inclinations are 15° normal to the axis of the bone.

In this chapter, **three specific issues** pertaining to internal bone fracture fixation are addressed. **First**, we perform four-point bending experiments on a straight plate fixation assembly, for four different screw configurations - convergent (CSO), divergent (DSO),

Chapter 4 New modality of fracture fixation using a hemi-helical plate

alternating (ASO) and perpendicular (PSO) are carried out to determine (a) the forces present in the screws, (b) the stiffness of the fixation assembly, and (c) the energy-to-failure. **Secondly**, the concept of hemi-helical plate fixation is explored, by conducting pull-out experiments with the aim of comparing the holding strengths between a straight and hemi-helical plate for various screw configurations mentioned above. **Thirdly**, Finite Element Analysis (FEM) for three fracture fixation configurations (i.e. straight plate, 90° helical plate and 180° helical plate), under uniaxial compression, bending moment and torsional loading are performed to compare the overall stiffness of the various assemblies and the fracture gap movement.

4.1 Four-point bending test on fracture fixed bone, by means of a dynamic compression plate

Material and methods

A six-hole Dynamic Compression Plate (DCP, 110mm long) was attached onto the tensile surface of a transversely fractured Synthes* femur bone segment, using two 4.5 mm cortical screws on each side of the fracture location. The fracture gap was about 2 mm. In total, four different screw orientations were employed. As depicted in figure 1, these were the *perpendicular (PSO)*, *convergent (CSO)*, *divergent (DSO)* and *alternating (ASO)* screw orientations. In the perpendicular-screw orientation (PSO) setup, the screws were arranged such that plate axis is perpendicular to the screw axis (as shown in figure 4-1a). In the convergent screw orientation (CSO) set-up, the screws were inclined 15° (to the normal of the bone axis) *towards* the fracture location (as shown in figure 4-1b). In the divergent

* Synthes bones from Mathys Ltd

Chapter 4 New modality of fracture fixation using a hemi-helical plate

screw orientation (DSO) set-up the screws were inclined 15° (to the normal of the bone axis) *away* from the fracture (see figure 4-1c). In the alternating screw orientation (ASO) set-up, the inner screws were inclined at 15° away from the fracture, while the outer screws were inclined 15° towards the fracture interface (see figure 4-1d). In all of the above configurations the screws were placed in the first, second, fifth and sixth screw holes (counted from the left hand side of the bone plate) of the DCP.

Figure 4-2 shows an experimental arrangement of the (dynamic compression) straight plate bone fracture fixation assembly, employed for four-point bending experiments (before loading). Two bolt gauges were placed on each test specimen along the axis of the screws corresponding to the 1st and 2nd holes of the DCP (as shown in figure 4-3), to determine the forces in each screw bending. In addition, three strain-gauges (from Tokyo Sokki Kenkyulo co. Ltd) were used to monitor the nature of the stresses at various locations in the fracture fixation assembly: One strain gauge was near the 6th hole of the DCP, second strain gauge was placed on the lateral side of the Synthes femur bone, and third strain gauge was attached to the compression side of the femur bone (figure 4-3). All bolt and strain gauges (from Tokyo Sokki Kenkyulo co. Ltd) and were connected to a data logger. Retort stands were used to grip the bone and prevent it from rotating during loading due to the irregular geometry of the bone. Four-point bending tests were conducted on all four configurations (i.e. PSO, CSO, DSO and ASO), using an Instron testing machine under displacement control at a loading rate of 5 mm/min.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-2: Bending experiments setup of the fracture fixed bone before loading

Figure 4-3: Position of strain gauges on synbone and plate. 1st and 2nd are bolt gauges, 3rd is strain gauge for stainless steel; 4th and 5th are strain gauge for plastics.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Results and Discussion

Muscle forces applied to the bone and compressive loading on the fracture interface often gives rise to bending due to the natural curvature of bones. Hence, bending tests were carried out (on convergent, divergent, alternating and perpendicular screw configurations) to determine the relative (a) strengths (b) bending stiffness and (c) energy-to-failure of the respective straight-bone-plate fracture fixation assemblies. Figure 4-4 shows the load-displacement curves for perpendicular, convergent, divergent, alternating screw configurations of fracture-fixation assemblies. The slopes of these load-displacement curves indicate that the alternating and perpendicular screw configurations offer, respectively, the greatest and lowest bending stiffness for the bone-fracture fixation assembly. The convergent and divergent screw configurations result in similar but intermediate levels of bending stiffness as shown in Table 4-1.

Table 4-1. Stiffness and energy to re-fracture for perpendicular screw orientation (PSO), convergent screw orientation (CSO), divergent screw orientation (DSO) and alternating screw orientation (ASO) configurations

Screw orientation	Stiffness fracture fixation (kN/m)	Energy to re-fracture of fracture fixation (J)
PSO	126	2.66
DSO	135	2.10
CSO	140	2.92
ASO	201	2.69

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-4: Bending tests: Load displacement graph for PSO, CSO, DSO, ASO specimen configuration. The slope of the load-displacement curve represents the stiffness of the assemblies and the area of the load-displacement curve represents energy to re-fracture.

The areas under the respective load-displacement curves indicate that the convergent and divergent screw configurations result, respectively, in the greatest and lowest energy-to-fracture or toughness for the bone-fracture fixation assembly. The perpendicular and alternating screw configurations result in similar but intermediate levels of energy-to-fracture or toughness. This suggests that the alternating and convergent screw configurations appear to provide the best compromise of bending stiffness and toughness for the bone-fracture fixation assembly, compared to those of perpendicular and divergent screw configurations (from the values depicted in Table 4.1). Strain gauge measurements verified that bone-fracture fixation assembly behaved as a composite beam with the DCP subjected to tensile strains.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figures 4-5a and b show, respectively, plots of the “measured load transfer vs the applied moment” in the innermost and outermost screws in the bone-fracture fixation assembly. One of the primary roles of the screws is to ensure that the bone-fracture fixation assembly (comprising the bone, plate and screws) deforms in an integrated fashion when subjected to loading. As depicted in figure 4-5c, the outermost screws at the fracture interface experience predominantly tensile forces in the process of keeping the plate fixed on to the bone, while the innermost screws experience predominantly compressive forces in the process of ensuring that the plate and bone deform in an integrated manner (i.e. the inner screws push onto the plate for more deformation).

At any given load, the magnitude of force transfer by the innermost screws is the greatest in the divergent screw configuration and lowest in the perpendicular screw configuration. The convergent and alternating screw configurations provide intermediate levels of force transfer in the innermost screws. In contrast, the magnitude of force transfer by the outermost screws is the greatest in the convergent screw configuration and lowest in the perpendicular screw configuration. The divergent and alternating screw configurations provide intermediate levels of force transfer in the innermost screws.

Overall, our experimental results suggest that angling the screws improves the load transfer between the plate and fractured bone during bending. The divergent and convergent screw configurations appear to provide best compromise for improved load transferred between the plate and fractured bone for the outer and inner screws.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-5: Force in each screw vs moment applied for PSO,DSO, CSO, ASO configurations. (a) For the screw near to the fracture interface (b) for the screw farthest from the fracture interface (c) schematic of the forces in the screws. Extreme screw holds the plate on to the bone while subjected to bending. Hence, the extreme screws are in subjected to tensile force, while inner screws maintain the bone and plate to deform the same amount (i.e. deflection at the mid span of the plate equal). Thus, inner screws are subjected to compressive force.

4.2 Hemi-helical versus straight-plate bone fracture fixation: Pull out experiments observations

Material and methods

In this section, we experimentally analyze the concept of hemi-helical plate fixation, by conducting pull-out experiments with the aim of comparing the holding strengths between a straight bone plate (with various screw orientations) and a hemi-helical bone plate. Figure 4-6 illustrates the nomenclature of a helical plate. The 'axis' is defined as a straight line along the length of the bone, while the 'radius' is defined as the distance from the axis of the bone to the outer surface of the bone (at mid shaft). The 'effective length' is the distance between the ends of the plate along the axis of the bone and the 'pitch' is degree of rotation (or twist) of the plate. For example, 1-pitch represents a 360° twist of the plate, $\frac{1}{2}$ -pitch represents a 180° twist of the plate and $\frac{1}{4}$ -pitch represents a 90° twist of the plate.

Figure 4-6. Terminology for a helical plate. Insert shows the side view of the helical plate, depicting the $\frac{1}{2}$ pitch of the plate.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Fernandez [146] was the first to clinically moot the idea of fracture fixation using helical bone plates. In particular, his anatomical study postulated the advantage of helical plates for treating fractures on the humerus. Bone fracture fixation using a 360° or 270° helical plates is not considered due to the clinical application constraints. Hence, 180° and 90° helical plates are considered in the present investigation. In the current experiments, a twelve-hole Zimmer Dual Compression Contourable Plate (DCCP), with 4.5 mm cortical screws, was fixed onto a Synthes* femur bone specimen by screws located at the 1st, 4th, 9th and 12th hole-positions.

Experiments were conducted to determine the axial pull-out strengths of both (a) hemi-helical and (a) straight bone plates with perpendicular (PSO), convergent (CSO), divergent (DSO) and alternating (ASO) screw orientations as in figure 4-7 in accordance with ASTM F1691-96. The experimental set up for the pull out experiments is shown in figure 4-8. Special grippers were designed and built (seen in figure 4-8) to hold the ends of the femur bone specimens and comply with ASTM F1691-96 test techniques. Each bone-fracture fixation assembly was loaded by a 5kN Instron testing machine under displacement control at a loading rate of 5 mm/min. It is to be noted that experimentation is confined to one sample of each configuration (i.e. PSO, ASO, CSO, DSO and Hemi-helical fixation assembly) due to limited bone specimens. The saw bones are not reusable as they fracture after the test eventhough the plates remain the elastic state.

* Synthes bones from Mathys Ltd

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-7: Pull out tests: Inclined screw orientations (i) straight plate fixation with (a) PSO (b) CSO (c) DSO (d) ASO configuration (ii) helical plating (e) hemi-helix~180° Helical plate. In the hemi-helical plate fixation set-up, it is to be noted that the screws are oriented in different planes, compared to all the screws being in the longitudinal plane in straight plate fixation.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-8: Set up for the pull-out test of 180° helical plate and bone fixation held by four cortical screws with newly designed grippers holding the assembly.

Results and Discussion

Figure 4-9 shows the load-displacement responses for the hemi-helical and straight bone plates (with four different screw orientations) during pull-out testing. These pull-out tests enable assessment of the holding capacity of the plate and screws on the fractured bone. As shown in Figure 4-9, four distinct peaks were observed in the load-displacement curves of straight bone plates (with various screw orientations). These peaks reflect sequential screw pull-out where the screws located at the 4th hole loosens initially, followed by progressive loosening of the 9th, 1st and 12th hole in the bone plate (see Figures 4-8 and 4-10a). In contrast, no sequential screw pull-out was observed in the hemi-helical bone plate fixation (refer to figure 4-10b-c). It is also noteworthy that the holding strength of the hemi-helical bone plate fixation is higher than that of the straight bone plate with perpendicular (PSO), convergent (CSO), divergent (DSO) and alternating (ASO) screw orientations. Moreover, no screw loosening was observed in the hemi-helical bone plate fixation (see Figure 4-10b-c).

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Pull-out strength test: Load (N) Vs extension of the load cell (mm)

Figure 4-9: Pull out tests; Load Vs Extension curves for all the configurations of fixations shown in figure 4-7. An insert depicts the four peaks in the curve that represents the screw pull out for the CSO configuration. Similar screw pull out patterns were observed for PSO, ASO and DSO configurations. The stiffness of the assembly is the slope of the load vs extension curve and the area under the load vs extension curve till the initiation of pullout represent the energy to pullout.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-10: (a) Sequential pull-out of straight plate PSO, CSO, DSO, ASO configurations, (b) The holding power of HHP is high, such that sequential screw pull-out is not observed, (c) However, the bone failed before screw pull-out, indicating that the fixation is stiff enough so that screw loosening does not occur.

The gradients of these load-displacement curves (figure 4-9) indicate that the straight bone plate with alternating and divergent screw configurations offer, respectively, the greatest and lowest stiffness for the bone-fracture fixation assembly, for bending loading. Convergent and perpendicular straight plate screw configurations as well as hemi-

Chapter 4 New modality of fracture fixation using a hemi-helical plate

helical bone plates result in similar intermediate levels of stiffness (shown in Table 4-2). The areas under the respective load-displacement curves indicate that the hemi-helical and straight bone plates (with divergent screw configurations) result, respectively, in the greatest and lowest energy-to-fracture (or toughness) for the bone-fracture fixation assembly. The perpendicular, alternating and convergent screw configurations for straight plate fixation result in similar intermediate levels of energy-to-fracture (shown in Table 4-2).

Table 4-2. Stiffness, energy to initiate pull-out and peak pull-out for PSO, CSO, DSO ASO and hemi-helix configurations.

Screw orientation	Stiffness of plate fixation (kN/m)	Energy to pull-out of plate fixation (J)	Peak pull-out load of plate fixation (N)
PSO	55.1	7.17	796
ASO	58.0	9.67	900
CSO	49.3	10.12	924
DSO	44.7	6.88	679
Hemi-Helix	55.4	10.83	1000

The hemi-helical plate also confers the highest pullout-strength in the bone fracture fixation assembly, compared to the straight plate configurations with four different screw orientations. **Overall, these results suggest that hemi-helical bone plate fixation provides the optimal combination of strength, stiffness and toughness compared to straight bone plates with different screw orientations.** In addition, there is the risk of loosening and sequential screw pull-out in the straight bone plates, since the axes of the screws are all in the same plane (as seen from cross-sectional views along the longitudinal plane of the bone fracture fixation assembly, see Figures 4-7a-d). In contrast, the axes of the screws in the hemi-helical bone fracture fixation assembly are all in different planes

Chapter 4 New modality of fracture fixation using a hemi-helical plate

(intersecting one another as shown in Figure 4-7e), thus eliminating or minimizing the problem of loosening and progressive sequential pull-out of screws.

The primary aim of fixation is to promote swift healing of the fractured bone and restore the strength to that of the intact bone. The results from this study show that the properties of assembly stiffness and the energy required to re-fracture or pull-out are dependent on the orientation of the plate and thereby on the inclinations of the screw. They indicate that not all types of inclined screw configurations are beneficial, only CSO and ASO configurations show significant improvement over PSO and DSO configurations in stiffness and energy for re-fracture; the CSO and ASO configurations allow bone fracture fixation to fail only at higher load (1.16 times and 1.13 times respectively) and absorb more energy (1.41 times and 1.35 times) respectively higher than PSO respectively. It is also apparent that inclining the screws enhances the load transferring capability between the plate and the bone.

The pull out strength test has also shown the superior capability of angled (inclined) screw fixation over the usual perpendicular screw fixation. Similarly, convergent and alternating screw orientations give more holding strength between the plate and bone. However, there is still a chance of sequential pull out (which is undesirable to the progress of fracture healing), as the axis of each screw is still in the longitudinal plane (figure 4-7a-d). On the other hand, the 180° helical plate performs better than any inclined screw configuration (because of the multiplanar planes of screw fixations), and thus it solves the problem of sequential pull out, because the axis of each screw is oriented in different planes (Figure 4-7e). **Thus, the helical plate provides much higher holding strength than any straight plate fixations.**

4.3 Hemi-helical verses straight-plate bone fracture fixation: Finite element analysis

From the earlier sections, it can be observed that the helical plating has an improved load holding capacity, which is necessary to avoid implant loosening (which is more prominent in the osteoporotic bones or less quality bones). It is now necessary to also understand the fracture-gap movement characteristics and the assembly (fracture-fixed bone and plate) stiffness of the helical plating with respect to the straight plate. For this purpose, fixation of an oblique fracture (angled 45^0 to the axis of the bone) fixed with a straight plate, a 90^0 helical plate and a 180^0 helical plate under compression, bending and torsion loadings, is analysed numerically using ABAQUS finite element program.

Modelling (geometrical and material) of the fracture fixation

The bone with screw holes is modelled as a hollow cylinder (of outer diameter 24mm, inner diameter 16mm, length 170mm and eight screw holes), and the eight screws are considered to be cylinders (of diameter 3.5mm), in order to reduce the number of elements required for screws meshing (as screw threads require finer elements for meshing) and for plates (i.e. straight plate, 90^0 helical plate and 180^0 helical plate). The plate dimensions are 12mm width, 4mm thick, 140mm effective length, while the radius of the helix is 12mm. In order to ‘produce’ a helical plate, the straight plate is curved, such that it exactly fits the outer diameter of the bone. The distance between the screw holes are equal in all the plate configurations.

All the modalities of fixation (i.e. straight plate, 90^0 helical plate and 180^0 helical plate) are modeled by commercial software UNIGRAPHICS. The finite element (FE)

Chapter 4 New modality of fracture fixation using a hemi-helical plate

models are depicted in figure 4-11a-c. The modelled parts (i.e. plate, bone and screws) are imported to the ABAQUS (Finite Element Analysis software) from UNIGRAPHICS through a standard CAD translator i.e. STEP format. After importing these parts into ABAQUS, the bone is modified to incorporate the fracture gap of 2mm at its mid span, angled 45^0 to the axis of bone (as shown in figure 4-11d). The screws are positioned such that they are always perpendicular to the top surface of the plate.

The bone is modeled as a transversely isotropic material, with a modulus of $E_1=14.5(\text{GPa})$, $E_2=14.5(\text{GPa})$, $E_3=19.7(\text{GPa})$, $G_{12}=7.0(\text{GPa})$, $G_{13}=7.0(\text{GPa})$, $G_{23}=5.28(\text{GPa})$, $\nu_{12}=0.285$, $\nu_{13}=0.285$, and $\nu_{23}=0.265$ (the directions 1,2,3 are shown in figure 4-12) [150]. The plate and screws material are in elastic state with in applied loading and assigned 200 GPa Young's modulus (316L stainless steel) and 0.3 Poisson's ratio values. In order to simulate the locking-screw mechanism during analysis, the screw head and the contoured surface of the plate are tied⁺ together. Similar contact conditions are assigned for cylindrical screw and bone, so that the screw holds the bone during loading. A coefficient of friction of 0.37 is assigned between bone and plate contact; and of 1 between the broken bone fragments (i.e. at fracture interface). The strain-displacement is assumed to be non-linear for all the materials (finite strain) by imposing NLGM option on in the ABAQUS program.

Loading and boundary conditions imposed on fracture-fixed bone

Compressive, torsion and bending loadings are applied on obliquely fractured bones fixed by straight plate, 90^0 helical plate and 180^0 helical plate. In order to apply a compression load of 150 N, one end of the fracture fixed bone is fixed (with the

⁺ by means of a `contact` option available in ABAQUS

Chapter 4 New modality of fracture fixation using a hemi-helical plate

displacements defined in figure 4-12 as $U1=U2=U3=UR1=UR2=UR3=0^*$ as boundary conditions) and a compressive force of 150N in the U3 direction is applied on the reference plane (as the loading condition) that is fixed to the free end of the bone (as shown in figure 4-12a).

Figure 4-11: Finite element models in ABAQUS (a) straight plate model (b) 90° helical plate model (c) 180° helical plate model (d) oblique fracture fixed by a helical plate. The bone axis (depicted in the figure) is along coordinate 3.

* U and UR represent displacement and rotation respectively, as per ABAQUS notations

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-12: Loading and boundary conditions applied on the 180° helical plate fixation on the simulated fractured bone (with 45° oblique fracture: (a) compressive load (b) bending load and (c) torsional load. Similar loading conditions are applied on the straight plate and the 90° helical plate fixations. U and UR represent displacement and rotation respectively and the numbers in the suffix denote the direction of loading.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

This loading condition on the reference plane is modified to make the displacement $UR3 = -0.05$ radians to simulate the torsional load, while the boundary conditions (of the free end (i.e. $U1=U2=U3=UR1=UR2=UR3=0$) are maintained (figure 4-12c). A four-point bending loading has been simulated, by applying the boundary condition ($U1=U2=U3=0$) on one-half of the edge of the bone ends and the loading condition $U2=0.15\text{mm}$ at 10mm from the bone ends, as shown in figure 4-12b.

Mesh sensitivity

In all the models, tetrahedron (C3D4) elements are used for meshing. The variation of the deflection, bending moment and torsion with the number of elements used in the analyses is shown in figure 4-13. The number of elements used in straight plate fixation for compression, bending moment, and torsion are 55463, 55762, 55463 respectively. The convergence to these numbers of elements are chosen, as the variations in the results are less than 0.33% with the increase in the number of elements. Likewise, in 90° helical plate fixation, we have converged to 60823, 61218, 60823 elements for compression, bending moment and torsion loads. Similarly, in 180° helical plate fixation we have converged to 61291, 61812, 61291 elements for compression, bending moment and torsion loads. The mesh was graded such that finer mesh was chosen at regions of high strain concentrations.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-13. Mesh sensitivity analyses on a straight plate fixation (a) Deflection variation with the number of elements in compression loading condition; convergence is obtained at 55463 elements (b) Bending moment variation with the number of elements in bending loading condition; convergence is obtained at 55762 elements (c) Torsion variation with the number of elements in torsional loading condition; convergence is obtained at 55463 elements.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Results and Discussion

Stiffness of the assembly

In both compression and bending, it is observed that the stiffness of the fracture fixation (slope of the load deflection curves for the fracture fixed assembly) is lowest for 180^0 helical plate, second lowest for 90^0 helical plate and highest for straight plate, as shown in figure 4-14 a and b. In other words, it is minimum for 180^0 helical plate and maximum for straight plate. In torsion, the stiffness is lowest for straight plate, second lowest for 90^0 helical plate and highest for 180^0 helical plate, as in figure 4-14c. This means that with the increase in the degree of contouring in helical plating, the compression and flexural stiffnesses reduce, where as the torsional stiffness increases. As discussed in the Chapter 2 (i.e. literature review), the objective is in making the assembly (fractured bone fixed by the plate and screws) flexible in compression and bending (so as to minimize stress-shielding in bending) without compromising on torsional stiffness, by using helical plating.

Relative fracture gap movement

Figure 4-15 illustrates the bone cross-section at the fracture site. From the finite element analysis, the relative movements (i.e. the combined movements of the both fracture fragments) at the fracture gap along the three axes (1, 2 and 3) at all the locations A, B, C, D (figure 4-15), for the bone-plate fracture-fixation (with straight plate, 90^0 helical plate and 180^0 helical plate) under axial, bending and torsion loadings are computed and depicted in figures 4-16, 4-17 and 4-18, respectively.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-14. Comparison of stiffness of bone-plate assembly: (a) Compressive load Vs. deflection of the reference plane (depicted in the figure) (b) bending moment Vs deflection at the mid span of the top surface of the plate (c) Torsion Vs rotation of the reference plane (depicted in the figure). Helical plate fixations offer less stiffness than the straight plate fixation in compression and bending loadings. In torsional loading helical plate fixation provides maximum stiffness. Oblique fractures produced by torsion have been a big concern for fixation by straight plates. Our helical plate provides a solution for this long-standing problem.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-15: Different locations considered in the finite element analyses, for computing fracture gap movement. Location A is on the bone on the fracture gap and underneath the plate. Location D is on the bone at fracture gap but on the opposite side of the plate. Locations B and C are on the bone on the fracture gap and between locations A and D. Note: for better presentation of the fracture gap, the left bone fragment was made invisible.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-16. Relative movement along axis 3 at A, B, C and D location on the fracture gap (a) for compressive load (b) for bending moment (c) for torsional load. Fracture gap closure is maximum in the 180° helical plate. It is seen that the fracture gap closes for all the plates, in compression and bending loadings. However, in the case of torsion, the fracture gap closes for the helical plate only and opens up for the straight plate. '+' displacement means gap closure, '-' displacement means opening up.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-17: Relative movement along axis 2 at A,B,C and D location on the fracture gap (a) for compressive load (b) for bending moment (c) for torsional load. The movements in helical plate along axis 2 are maximum in all the loading conditions indicating that the shear is maximum in helical plate along with the maximum gap closure.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-18. Relative movement (in shear) along axis 1 at A,B,C and D location on the fracture gap (a) for compressive load (b) for bending moment (c) for torsional load. It is seen that the 180° helical plate has minimal shear displacement compared to the straight plate and 90° helical plate.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

It is observed that the fracture gap movement (or closure) along axis 3 (at locations A, B, C and D) is maximum for 180^0 helical plate fixation, followed by 90^0 helical plate, and then the straight plate in compression and bending (figures 4-16 and 4-17). **Hence, it is perceived that a near-uniform gap closure along the fracture site can be achieved through the helical plating.** Uniform gap closure enhances the bone healing [10, 53]. Further, it is noted that the uniformity in gap closure increases with the increase in the degree of contouring in helical plate, for all the loading conditions considered in this study.

Based on the FEA, for torsional loadings both 90^0 and 180^0 helical platings mitigate torsion of the bone-plate assembly, and this fracture gap closure can enhance bone healing [213]. On the other hand, the fracture gap opens up for fracture fixation by a straight plate (figure 4-18). Thus, straight plate fixation is not seen to be at all useful when the fracture-fixation assembly (plate, screws and bone) is subjected to torsion.

The gap-closure causing lateral movements of the fracture gap (i.e. gap closure movements along axes 1 and 2) are maximum for 180^0 helical plate, followed by 90^0 helical plate and straight plate fixation (as in figure 4-16, 4-17 and 4-18). The lateral movement at the fracture gap increases with the increases in the degree of helical plate contouring. The lateral movement could eventually lead to contact of the fractured surfaces, causing compression and shear at the fracture gap. Whereas, compression is definitely conducive to bone healing, the role of studies on the role of shear at the fracture gap is controversial [214]. According to Russel [52], the shear at the fracture gap delays the healing, whereas Park *et al.* [214] report that shear at the fracture gap enhances the fracture healing. Nevertheless, based on the fracture gap movement for oblique fracture, it can be

Chapter 4 New modality of fracture fixation using a hemi-helical plate

concluded that the helical plate fixation offers gap movements that enhance healing for compression, bending and torsional loading conditions, when compared to straight plate fixation. This means that the callus formed during the phases of healing will be subjected to both compressive and shear stresses (i.e. at all the locations shown in figure 4-15), which will provide consolidation of callus into bone and later the remodelling of the bone.

Stresses on the plate and screws

It is perceived that in all the loading conditions, the plate is highly stressed near the screw hole at the fracture site (approximately eight times more than the stresses at the extreme ends of the plate). Hence, the plate failure (if it initiates) would be expected to take place at the screw hole near the fracture site.

For 180° helical plate fixation, the screws nearest to the fracture site are stressed three times more than the farthest screws, while loaded in compression. Similarly in torsion for 180° helical plate fixation, the screws nearest to the fracture site are stressed ten times more than the farthest screws. In the case of bending for 180° helical plate fixation (such that the fracture gap closes), the screws farthest from fracture site are stressed three times more than the nearest screws to the fracture.

For 90° helical plate fixation, the screws nearest to the fracture site are stressed four times more than the farthest screws while loaded in compression. Similarly in torsion, the screws nearest to the fracture site are stressed twelve times more than the farthest screws. In the case of bending, the screws farthest from fracture site are stressed three times more than the nearest screws to the fracture.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

For straight plate fixation, the screws nearest to the fracture site are stressed three times more than the farthest screws, when loaded in compression. Similarly in torsion, the screws nearest to the fracture site are stressed fifteen times more than the farthest screws. In the case of bending, the screws farthest from fracture site are stressed three times more than the nearest screws to the fracture.

As regards stress-shielding of the bone, the location of the neutral axis (NA) for bending moment loading indicates the stress shielding offered by the plate on the bone. As discussed earlier, the optimal fracture fixation will not allow the fracture site to be in tension, i.e. the neutral axis (NA) should at most be at the plate-bone interface. Away from the fracture interface, the NA should be located into the bone, so that the bone also bears tensile stress. Figure 4-19 depicts the location of the NA on the bone cross-section at the fracture site, and at the first, second, third and fourth screws for straight plate, 90° helical plate and 180° helical plate fixations. The location of NA is also tabulated in Table 4-3, from which it is noted that the NA shift (away from fracture interface) into the bone for helical plate fixation is more than the straight plate. Further, the amount of the shift in NA axis is also a function of the degree of contouring of helical plate.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-19. Locations of the neutral axis (NA) on the bone cross-section at different places along the length of the bone for straight plate, 90° helical plate, and 180° helical plate fixations, subjected to bending moment. The change of color from grey to black represents the NA. Figure (a) depicts the locations considered for the neutral axis along the length of the bone (b) depicts the cross-sections of bone showing NA at different locations along the length of the bone fixed by the straight plate (c) cross-sections of bone showing NA at different locations along the length of the bone fixed by the 90° helical plate (d) cross-sections of bone showing NA at different locations along the length of the bone fixed by the 180° helical plate.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Table 4-3. Location of the neutral axis at different sites along the length of the bone. *The effectiveness of helical plate compared with stainless steel plate is that; away from the fracture site the neutral axis is near to the axis of the bone (i.e. deep into the bone). The guiding principle should be that at fracture site the NA is at plate-bone interface (callus of increasing stiffness as healing proceeds) interface while away from fracture site the NA is as deep into the bone as possible.*

Fixation type	Computed values (for the bone) of the NA location	At fracture site	At cross-section at first screw	At cross-section at second screw	At cross section at third screw	At cross section at fourth screw
Straight plate	Neutral Axis from top of the bone (mm)	Located inside the plate	1.5	2	2	2.5
90 ⁰ helical plate	Neutral Axis from top of the bone (mm)	Located inside the plate	2	2.6	3.2	4
180 ⁰ helical plate	Neutral Axis from top of the bone (mm)	Located inside the plate	2.8	4.3	5.5	6.8

4.4 Clinical application of hemi-helical plate

Clinical application is simultaneously carried by Dr. Khong Kok Sun (who is one of the mentors in this dissertation) after this experimental and finite element analyses. A 68 year old female patient was admitted at National university hospital, Singapore; with a humerus fracture (X-ray of the fracture is provided in figure 4-20a) due to a malignant bone marrow disease (myeloma). The bone was osteoporotic and there was a short joint block in the distal humerus with bone loss at the medial (inner) cortex. The helical plating technique (helical plate fixation is provided in figure 4-20b) allowed fixing the distal block with the

Chapter 4 New modality of fracture fixation using a hemi-helical plate

minimum number of screws i.e. 2 and spanning the rest of the humerus which was also studded with the tumour. It was impossible to use intramedullary nail and conventional plate would not have been secure. Her fracture was uniting, but she died of her extensive diseases within about 3 months. During these three months, the fixation did not fail. This case demanded the advantage of having improved holding capacity of the fixation (which helical plate provides) with the least number of screws as the bone is osteoporotic and having tumour. This case study further confirms the efficacy of helical plate fixation for complex situations.

Figure 4-20: Clinical application of hemi-helical plate (a) distal humerus fracture due to myeloma (b) fracture fixation using a helical plate. Courtesy Dr. Khong Kok Sun.

4.5 Remarks on hemi-helical plate

The advantages offered by helical plates are:

1. Nearly uniform fracture gap closure is obtained at all locations of the fracture interface for all the loading conditions and the uniformity of

Chapter 4 New modality of fracture fixation using a hemi-helical plate

fracture gap closure improves with the increased contouring of the plate i.e. increasing the pitch

2. In bending moment loading, the neutral axis (NA) is located inside the plate at fracture site (similar to that of straight plate); away from the fracture site, due to the helical shape of the plate, the NA shifts into the bone (as shown in the figure 4-19) and can hence allow the bone to take on both normal tensile and compressive stresses; also the location of NA is dependent on the degree of contouring of the plate
3. In torsional loading, the bone elements are subjected to tensile stresses on the long diagonal planes. Because the axis of helical plate will be parallel to the orientation of the tensile stress (as schematically shown in figure 4-21), the helical plate will absorb the tensile stresses caused by the torsional loading; this is not the case with straight plate fixation, wherein the tensile stresses open up oblique fracture gap; thus the helical plate can be optimally employed for treating spiral fractures
4. Also, from the clinical point of view, helical plates have freedom at the entry point, during minimally invasive surgery according to Fernandez [146]
5. The screw holding power for helical plate fixation will be high, as the screws are inclined at different orientations (as in Table 4-2), thus avoiding sequential screw loosening.

Chapter 4 New modality of fracture fixation using a hemi-helical plate

Figure 4-21: Schematic of a fracture-fixed bone by a 180⁰ helical plate under torsion

Apart from the advantages the helical plate fixation offer, helical plates are not commercially available. Thus, currently, we need to contour a straight plate into a helical plate as a temporary solution. As discussed earlier, the procedure for contouring a straight plate to a helical plate is as follows: The straight plate is bent to form a semi circular sector of a ring, and then its ends are twisted in opposite sense to form a helical plate.

However, the repeatability of contouring the straight plate into a helical plate is questionable. During contouring, excessive screw holes deformation could take place and hence hamper easy insertion of the screws during surgery. The situation is even worse if we contour the Locking compression plate (LCP), because the locking mechanism will be damaged due to excessive deformation at screw hole during contouring. Residual stresses can also develop in the helical plate while contouring, and this might can have an impact

Chapter 4 New modality of fracture fixation using a hemi-helical plate

on the fatigue property of the helical plate. Similarly, excessively deformed screw hole acts as a stress raiser, and the plate will tend to fail at the screw hole during contouring itself. Thus contouring the plates should be replaced by manufacturing the helical plates.

While this study demonstrates the advantages offered by helical plate fixations, more anatomical locations for helical plating need to be explored. Thus, this experimental and finite element analysis has opened a new arena of study in modern fracture fixation through helical plates.

Chapter 5

Intrinsic features of the spine vertebral body and intervertebral disc as optimal structural design

In this chapter, spine vertebral body is analysed as a hyperboloid shell for its optimal shape in weight bearing. Also, the spinal intervertebral disc is analysed as an intrinsically optimal structure based on its load-deformation characteristics. A comparison of the deformations in a healthy disc and nucleotomized disc is provided for compressive loading condition.

5.1 Optimal design of the vertebral body

5.1.1 Structural analogy of the VB to the cane stool

The analyses (provided in the chapter 2, pages 55-64) illustrate how the intrinsic hyperboloid shape design of the vertebral body enables the loadings to be transmitted as axial (compressive/tensile) forces through the generators of the HP shell. In this regard, the VB can be compared to a hyperboloid cane stool (shown in figure 5-1a), which is an ideal high-strength and light-weight structure. This is because all the loading exerted on it (by a person sitting on it) is transmitted (to the ground) as axial forces in the cane generators. Now a bar structure (such as a cane) is strongest in compression (provided its length is less than the buckling length). This makes the cane stool a high-strength and high load-bearing structure.

If these two sets of canes are tied at all their intersecting points (as shown in figure 5-1a), their functional lengths are reduced, and this further enhances the strength and load-carrying capacity of the cane stool. Further, the cane stool is very light as it is just made up of discrete canes (as generators of the hyperboloid structure). This structural configuration makes the cane stool a very simple but effective load-bearing high-strength and light-weight structure. This concept of a hyperboloid made of two sets of generators was used in building the Shabolovka radio tower (Moscow), which needed just 2200 tons of steel to build a 350m high tower (figure 5-1b) [218].

Figure 5-1: A couple of man-made hyperboloid structures (a) the humble cane stool (with permission from www.exbali.com) weighting 2.5kg but capable of bearing 5000N in compression (b) The Shabolovka radio tower, Moscow needed just 2200 tons of steel to build a 350m high tower [218].

Now, the spinal VB cortex has similar structural configuration and properties as the cane stool, to also make it an efficient load-bearing and load-transmitting high-strength and light-weight structure. The VB cortical wall can be deemed to be primarily comprised of the two sets of generators. Just as in the case of cane stool (figure 5-1), the VB wall transmits all the loading as axial forces through its generators. Further, in the case of the VB, the generators are also intrinsically tied at their interesting points, so as to reduce their effective length. This is the basis for a high-strength and light-weight vertebral body design.

5.1.2 Optimization of the hyperboloid shape of the VB

Now the spinal VB has a definitive value-range of the hyperboloid shape parameter β , and hence of its hyperboloid shape. In order to determine the structural basis of this β value, the combined axial force in its generators is to be minimum. In that case, this optimised VB structure will be able to sustain maximal loading, before the ultimate failure load of its generators is reached.

The VB is subjected to the combined compression, bending-moment and torsional loadings. Under this combined loading, the forces in the generators given by the equations (provided in the chapter 2, page 55-64) can be combined, using the principle of linear superposition. For its optimal intrinsic design with respect to its hyperboloid shape parameter β , to sustain the combined loadings, it can be put down as

$$\frac{d}{d\beta} [\text{Combined forces in the generators}] = 0 \quad (1)$$

Hence from equations (17, 28 and 32 in chapter 2, page 55-64),

$$\frac{d}{d\beta} \left(\frac{C}{2n \cos \beta} + \frac{M}{na \cos \beta} + \frac{T}{2na \sin \beta} \right) = 0$$

or,

$$\left(\frac{\sqrt{R^2 - a^2}}{H} \right)^3 \left(\frac{C}{2} + \frac{M}{a} \right) = \frac{T}{2a} \quad (2)$$

Equation (2) gives the relation between the applied loading and the geometry of the VB. Interestingly, the value of ' a ' is not found in the literature [182-185]. However, for a

specific set of values of R and H and functionally occurring ratios of the loading values (of C, M, T), the value of the hyperboloid shape parameter ' a ' can be calculated from equation (2), for the intrinsic design of the VB. In equation (2), considering the representative functional values of $M/C=0.003m$ and $T/C=0.003m$ along with $R=21.6mm$ and $H=14.75mm$, based on Guo *et al.* [219] and Zhou *et al.* [184], $a \approx 20.3mm$. Hence, from equation (5), $\beta = 26.5^\circ$.

Figure 5-2: MRI of lumbar vertebrae. $H/R = 0.7$ (average of L2 to L5) and a/R is 0.91 (average of L2 to L5).

Hence, the optimal light-weight high-strength spinal VB geometry is given by $\beta = 26.5^\circ$, with $a/R=0.939$ (for $H=14.75mm$). The a/R value of 0.91 measured from a typical lumbar vertebrae MRI scan, shown in the figure 5-2, confirms the validity of this optimal-design analysis. Thus, the intrinsic design of the VB hyperboloid geometry is such that it bears the combined loadings of compression, bending-moment and torsion by minimising the axial

forces in the generators. In other words, it can sustain and transmit maximal values of the loadings with minimal amounts of material, because of all the loadings being transmitted as axial forces through the hyperboloid generators. This analysis demonstrates that the VB shape and material distribution are modeled by the loading to be an optimal high-strength and light-weight structure.

5.2 Conceptual idea of biomimic anterior fixator

A totally new design insight for an anterior fixator is proposed based on the optimal design analysis of the VB as a hyperboloid shell structure. It is made up of two ring plates, to which generators can be attached, as illustrated in figure 5-3. These ring plates can be first attached to the top and bottom intact VBs (or even its adjacent discs). These rings can have slots for the attachment of the bars, to constitute the hyperboloid generators. By adjusting the inclination and length of the generators, the height of the fixator can be adjusted. Alternatively from the hyperboloid shell analysis performed on the VB and equations (provided in the chapter 2, page 52-62), it is known that the force in the generator for compressive force ‘ C ’ is given by $F_c = C/2n\cos\beta$, the force in each generator for bending moment ‘ M ’ is given by $F_m = M/n\cos\beta$ and the force in each generator for torsion ‘ T ’ is given by $|F_{cT}| = T/2na\sin\beta$.

Figure 5-3: Biomimetic anterior fixator. (a) Ring plate design. It consists of spikes and a screw hole which allows to hold the VB. It also contains the slots for inserting the generators upon fixing the ring plates to the VB. (b) The fixator is to be shaped as a hyperboloid formed of two sets of generators. The height of the fixator can be expanded or reduced by the inclination of the generators. Hydroxyapatite (HA) slurry can be injected into this constructed hyperboloid cage, which will act as a biological bridge between the intact VBs.

In that respect, the above mentioned fixator mimics the actual VB and hence constitutes an optimally designed structure for bearing and transmitting compression, bending and torsion loadings. It is proposed to inject hydroxyapatite slurry into the fixator as schematically shown in figure 5-3, so as to solidify the fractured VB fragments. The advantages of this biomimic fixator would be that (i) it biomimically simulates the shape of the intact VB and hence transforming all forces axially through its generators, (ii) it is a stable implant in compression, bending and torsion as it directly bears all these loadings and transmits them as axial forces in its generators, (iii) it is a symmetric implant, (iv) it is easy to handle, (v) forms a biological bridge due to the presence of hydroxyapatite.

5.3 Intervertebral disc stress deformation characteristics

The intervertebral disc's stress-deformation characteristics have been effectively analyzed by finite element analysis [196-204,207,210]. However, herein our objective is to biomechanically demonstrate why and how the intervertebral disc (IVD) can contain its deformation under increased loading, and thereby demonstrate its inherent optimal design feature. Herein, an elasticity model of the disc as a closed thick-walled fluid-filled cylinder is employed to determine its stress and deformations under uniaxial compressive loading, and demonstrate the role of NP in containing the disc deformations. It is also demonstrated that the nucleotomised disc will undergo larger deformations than the normal disc, for the same levels of loading, thereby drawing attention to whether it is efficacious to treat a ruptured disc (and associated back pain) by nucleotomy.

The stress dependant Young's modulus of the disc annulus can be represented as [210]

$$E = E_0 + 375.3\sigma^{0.473} \quad (3)$$

where E_0 (the residual Young's modulus) = 4.2MPa and the stress σ is expressed in MPa. This constitutive equation is employed to determine the E value for the uniaxially compressed disc. This constitution of the spinal disc, wherein the stress-dependant Young's modulus of its annulus encloses the nucleus pulposus, gives it a key self-reinforcing design property. The closest man-made self-reinforcing structure is a car tyre, which makes it lighter as well as lends it a shock-absorbing property.

The disc annulus is assumed to be isotropic, so that $E_z=E_r=E_\theta=E$. As the disc gets compressed (by increasing the applied compressive force F), the annulus stresses (σ_z , σ_r , σ_θ) keep increasing. For each updated value of E for enhanced stress state (in response to increasing values of the compression force F on the disc), the σ (in equation 3) is taken to

be equal to the maximum value of the principal stress (which happens to be the axial stress σ_z). For this relationship, as the disc is loaded, the annulus stress state $\sigma = (\sigma_z)$ increases. Correspondingly, its E increases, so as to thereby contain the disc deformations.

In this chapter, the mechanism of disc deformation containment for vertical loading is delineated. Compressive loading (F) on the disc causes compressive axial stress (σ_z) in the annulus and also pressurizes the nucleus-pulposus (NP) fluid, which then exerts hydrostatic pressure (p_i) and hence compressive radial stress σ_r on the annulus. This radial pressure or stress (σ_r) in turn causes circumferential tensile stress (σ_θ) in the annulus. These stresses in turn influence the strain state in the disc through the elastic modulus, and hence the axial and radial deformations of the disc by virtue of equation (3). Hence, the effect of the NP hydrostatic pressure (p_i) is to stress the disc annulus, and enhance the value of its E . This in turn stiffens the disc (according to the equation 3), and enables it to bear heavy loads without large axial and lateral deformations.

5.4 Analysis: Disc stresses, displacements and deformed geometry

The disc is considered to be a thick-walled isotropic cylinder, whose geometry and deformations are depicted in figure 5-4a. In this analysis, linear elasticity formulation of stress-strain constitutive relations has been employed. Under compressive loading of the order of $2000N$, the deformations are of the order of $1mm$. This result has been obtained by Fagan *et al.* [198,207] and is shown in figure 5-4b. Hence, in order to compute the disc deformations under compressive loading, small incremental loadings are adopted, so that the resulting strains are infinitesimal. Likewise, for each incremental load state, (i) the NP pressure is determined, (ii) the incremental stresses are computed, and the total stress state

is computed, (iii) the disc material modulus value is revised as per equation 3, and (iv) the disc deformations are determined, and its geometry is updated.

Figure 5-4: (a) Geometry and deformation variables of the spinal disc, loaded in compressive force F . Note that u is depicted as expansive radial deformation, while w is depicted as shortening axial deformation (b) Comparison of the effects of including linear and non-linear material (M) and geometry (G) solution options on compressive behaviour of the disc [198,207].

Stress equilibrium equations: Let u be the radial displacement and w be the axial displacement, as shown in figure 5-4. Because of the axial symmetry of the disk geometry and loading conditions, the shear stresses and the circumferential displacement are identically equal to zero. Thus, the stress-equilibrium equations are

$$\text{in the radial direction, } \frac{d\sigma_r}{dr} + \frac{\sigma_r - \sigma_\theta}{r} = 0 \quad (4)$$

$$\text{in the axial direction, } \frac{d\sigma_z}{dz} = 0 \quad (5)$$

The strain-displacement relations are

Chapter 5 Intrinsic features of the spine

$$\text{radial strain, } \varepsilon_r = \frac{\sigma_r}{E} - \frac{\nu(\sigma_\theta + \sigma_z)}{E} = \frac{du}{dr} \quad (6a)$$

$$\text{circumferential strain, } \varepsilon_\theta = \frac{\sigma_\theta}{E} - \frac{\nu(\sigma_z + \sigma_r)}{E} = \frac{u}{r} \quad (6b)$$

$$\text{axial strain, } \varepsilon_z = \frac{\sigma_z}{E} - \frac{\nu(\sigma_r + \sigma_\theta)}{E} = \frac{dw}{dz} \quad (6c)$$

wherein the annulus material modulus (E) is adopted to be isotropic.

The disc material's constitutive stress-strain relations in terms of disk material's Young's modulus (E) and Poisson's ratio (ν) are in the radial direction as,

$$\sigma_r = \frac{E}{1+\nu} \left[\frac{\nu}{(1-2\nu)} \left(\frac{du}{dr} + \frac{u}{r} + \frac{dw}{dz} \right) + \frac{du}{dr} \right] \quad (7a)$$

in the circumferential direction as,

$$\sigma_\theta = \frac{E}{1+\nu} \left[\frac{\nu}{(1-2\nu)} \left(\frac{du}{dr} + \frac{u}{r} + \frac{dw}{dz} \right) + \frac{u}{r} \right] \quad (7b)$$

in the axial direction as,

$$\sigma_z = \frac{E}{1+\nu} \left[\frac{\nu}{(1-2\nu)} \left(\frac{du}{dr} + \frac{u}{r} + \frac{dw}{dz} \right) + \frac{dw}{dz} \right] \quad (7c)$$

Note that σ_θ , σ_r , σ_z are adopted to be positive for tensile stress.

Now, by substituting the constitutive relations (7) into the equilibrium equations (4 and 5), two partial differential equations in displacements u and w are obtained, as follows

$$\frac{d}{dr} \left[\frac{\nu}{1-2\nu} \left(\frac{du}{dr} + \frac{u}{r} + \frac{dw}{dz} \right) + \frac{du}{dr} \right] + \frac{1}{r} \left(\frac{du}{dr} - \frac{u}{r} \right) = 0 \quad (8a)$$

Chapter 5 Intrinsic features of the spine

$$\frac{d}{dz} \left(\frac{\nu}{1-2\nu} \left(\frac{du}{dr} + \frac{u}{r} + \frac{dw}{dz} \right) + \frac{dw}{dz} \right) = 0 \quad (8b)$$

The solutions of equations (7 a and b) can be expressed as

$$u = \frac{A}{r} + Br \quad (9)$$

$$w = Cz + D \quad (10)$$

where, A, B, C, D are the constants of integrations. These constants can be determined by applying appropriate boundary conditions.

As the NP is incompressible [194], its volume after deformation is unchanged, so that

$$\pi a^2 h = \pi (a + u_a)^2 (h - w_h)$$

This can be simplified, by neglecting higher-order terms ($u_a w_h$ and $u_a^2 w_h$), to yield

$$2\pi a h u_a - \pi a^2 w_h = 0 \quad \text{or,} \quad u_a = \left(\frac{a}{2h} \right) w_h \quad (11)$$

It is to be noted that according to deformation as per figure 5-4a, w_h is the shortening deformation at $z=h$, while u_a is the radial expansion deformation at $r=a$.

The appropriate boundary conditions for solving equations (9 and 10) are hence

$$u_{r=a} = u_a = \frac{A}{a} + Ba \quad (12a)$$

$$\sigma_r = 0 \text{ at } r = b \quad (12b)$$

$$w = 0 \text{ at } z = 0 \quad (12c)$$

$$w = -w_h \text{ at } z = h \quad (12d)$$

Using the boundary conditions from equation (12) and utilizing equations (7, 9 and 10); the constants in equations (9 and 10) are obtained as

Chapter 5 Intrinsic features of the spine

$$A = \frac{(1-2\nu)u_a b^2}{b^2 + a^2(1-2\nu)} \quad (13a)$$

$$B = u_a \left(\frac{a^2(1-2\nu) + 2\nu b^2}{ab^2 + a^3(1-2\nu)} \right) \quad (13b)$$

$$C = -\frac{w_h}{h} = -\frac{2u_a}{a} \quad (13c)$$

$$D = 0 \quad (13d)$$

Using the constants A , B , C and D , the stresses in the equation (7) can now be represented as

$$\begin{aligned} \sigma_r &= \frac{E}{1+\nu} \left(\frac{\nu(2B+C)}{(1-2\nu)} + B - \frac{A}{r^2} \right) \\ &= -\frac{E}{1+\nu} \left(\frac{u_a a(1-2\nu)}{a^2(1-2\nu) + b^2} \right) \left(\frac{b^2}{r^2} - 1 \right) \end{aligned} \quad (14a)$$

$$\begin{aligned} \sigma_\theta &= \frac{E}{1+\nu} \left[\frac{\nu(2B+C)}{(1-2\nu)} + B + \frac{A}{r^2} \right] \\ &= \frac{E}{1+\nu} \left(\frac{u_a a(1-2\nu)}{a^2(1-2\nu) + b^2} \right) \left(\frac{b^2}{r^2} + 1 \right) \end{aligned} \quad (14b)$$

$$\begin{aligned} \sigma_z &= \frac{E}{(1+\nu)} \left(\frac{\nu(2B+C)}{(1-2\nu)} + C \right) = -\frac{2u_a E}{a(1+\nu)} \left[\frac{a^2(1-2\nu) + b^2(1+\nu)}{a^2(1-2\nu) + b^2} \right] \\ &= -\frac{w_h E}{(1+\nu)} \left[\frac{a^2(1-2\nu) + b^2(1+\nu)}{a^2(1-2\nu) + b^2} \right] \end{aligned} \quad (14c)$$

Then, from equations (9 and 12 a and b), the radial displacement is given by

$$u_r = \frac{A}{r} + Br = \frac{u_a}{ar} \left(\frac{a^2 b^2(1-2\nu) + r^2[a^2(1-2\nu) + 2\nu b^2]}{a^2(1-2\nu) + b^2} \right) \quad (15a)$$

and hence u_b (at $r=b$) is given by

$$u_b = \frac{2bu_a}{a} \left(\frac{a^2(1-2\nu) + \nu b^2}{a^2(1-2\nu) + b^2} \right) \quad (15b)$$

It is to be noted (from equation 14c) that the σ_z is uniform throughout the disc, and the minus sign implies that σ_z is compressive.

5.5 Stress analysis of the healthy disc under compression

For an axially applied force F (as illustrated in figure 5-5), the equilibrium equation is

$$F = \pi a^2 \sigma_f - \pi(b^2 - a^2) \sigma_z \quad (16)$$

where σ_f is the hydrostatic pressure in the fluid, and σ_z is the axial stress in the annulus (as shown in figure 5-5). Its sign is taken to be negative in equation (16), because positive σ_z is considered as tensile.

Figure 5-5: Normal stresses σ_f and σ_z under the applied force compressive F .

Because the disc height (h) is small, therefore σ_f is taken to be approximately constant, and hence:

$$\sigma_f = -\sigma_r|_{r=a} = p_i \quad (\text{the pressure in NP}) \quad (17)$$

Based on equations (17) and (14-a),

$$p_i = \frac{E(1-2\nu)}{(1+\nu)} \left(\frac{u_a}{a} \right) \left(\frac{b^2 - a^2}{a^2(1-2\nu) + b^2} \right) \quad (18)$$

Then, substituting for u_a from equation (18) into equation (14-c), we obtain

$$p_i = -\frac{1-2\nu}{2} \left(\frac{b^2 - a^2}{a^2(1-2\nu) + b^2(1+\nu)} \right) \sigma_z \quad (19)$$

The axial stress in the annulus is then obtained by substituting the expression for p_i from equation (19) into equation (16), as

$$\sigma_z = -\frac{2}{\pi} \left(\frac{F}{b^2 - a^2} \right) \left(\frac{a^2(1-2\nu) + b^2(1+\nu)}{2b^2(1+\nu) + a^2(3-6\nu)} \right) \quad (20)$$

Then, from equation (19) and (20), the NP pressure is expressed in terms of the applied compressive force F , as

$$p_i = \frac{1-2\nu}{\pi} \left(\frac{F}{3a^2(1-2\nu) + 2b^2(1+\nu)} \right) \quad (21)$$

From equations (20) and (14-c), by equating the expressions for σ_z , we get the radial deformation at the inner surface, as

$$u_a = \frac{1}{\pi} \frac{1}{E} \left(\frac{F}{b^2 - a^2} \right) \left(\frac{a^3(1-2\nu) + ab^2}{2b^2(1+\nu) + a^2(3-6\nu)} \right) \quad (22)$$

From equations (22) and (11), we get the axial deformation as

$$w_h = \frac{2}{\pi} \frac{1}{E} \left(\frac{F}{b^2 - a^2} \right) \left(\frac{h(a^2(1-2\nu) + b^2)}{2b^2(1+\nu) + a^2(3-6\nu)} \right) \quad (23)$$

By substituting equation (22) into equation (15b), the expression for u_b (the radial deformation at the outer surface of the annulus), under the applied compressive force, is obtained as

$$u_b = \frac{2}{\pi} \frac{1}{E} \left(\frac{F}{b^2 - a^2} \right) \left(\frac{a^2 b(1 - 2\nu) + b^3}{2b^2(1 + \nu) + a^2(3 - 6\nu)} \right) \quad (24)$$

Finally, from equations (14 a and b) and (22), we obtain the expressions for σ_r and σ_θ (in terms of applied load F), as

$$\sigma_r = \frac{1 - 2\nu}{\pi} \left(\frac{F}{b^2 - a^2} \right) \left(\frac{a^2}{2b^2(1 + \nu) + a^2(3 - 6\nu)} \right) \left(1 - \frac{b^2}{r^2} \right) \quad (25)$$

$$\sigma_\theta = \frac{1 - 2\nu}{\pi} \left(\frac{F}{b^2 - a^2} \right) \left(\frac{a^2}{2b^2(1 + \nu) + a^2(3 - 6\nu)} \right) \left(1 + \frac{b^2}{r^2} \right) \quad (26)$$

It is seen that as the disc gets loaded in compression (by the force F), (i) both σ_z and p_i increase, by virtue of equations (20 and 21), (ii) the increased p_i (which is a function of F , as per equation 21) causes both σ_r and σ_θ and u_b to increase by virtue of equations (24, 25 and 26), (iii) the axial (shortening) deformation w_h increases by the virtue of equation (23). Finally, the stresses ($\sigma_r, \sigma_\theta, \sigma_z$) are expressed in terms of F by equations (20, 25 and 26), while the deformations (u_a, u_b and w_h) are expressed in terms of F by means of equations (22, 23 and 24).

5.6 Mechanism and computation of disc deformation

The nucleus pulposus gets pressurized when the load F acts on it, as per equation (21). All the stresses increase with loading as per equations (20, 25 and 26), and so does E according to equation (3). Now E (the elastic-modulus corresponding to the deformed state of the disc under load F) will be greater than its value in the unloaded state of the disc, as

per equation (3). Hence, as per equations (23 and 24), both the axial and radial deformations will be contained.

This is attributed to the disc design, wherein the annulus contains the nucleus pulposus. This dependency of E on p_i , and hence on F and on the disc annulus stress state (represented by the σ_z) is also reported by Shirazi-Adl [210] and Ranu [220,221], based on experimental and finite-element analyses of the annulus. The following procedure has been adopted followed to determine the disc deformation in response to compressive load.

Step 1:

Starting from the unloaded state, $\sigma_{z0}=0$, for which $E=E_0$ as per equation (3).

1. Now an incremental compressive force of $\Delta F_I = 1\text{N}$ is applied on the unstressed disc of dimensions $(a_0, b_0 \text{ and } h_0)$, and the incremental stresses $(\Delta\sigma_{rI}, \Delta\sigma_{\theta I}, \Delta\sigma_{zI})$ are computed based on equations (25, 26 and 20).
2. Next, the maximum value of these three stresses $(\Delta\sigma_{zI}, \Delta\sigma_{rI}, \Delta\sigma_{\theta I})$, which happens to be $\Delta\sigma_{zI}$, is noted. Then, based on $\Delta\sigma_{zI}$, $E=E_I$ is computed according to the relation (based on equation 3): $E_I = E_0(= 4.2) + 373.3\{\Delta\sigma_{zI}\}^{0.473}$.
3. The disc deformations $(w_{hI}, u_{aI} \text{ and } u_{bI})$, corresponding to the incremental stresses are also computed from equations (23, 22 and 24), based on the above calculate value of $E=E_I$.
4. The disc geometry is now updated to $h_I=h_0- w_{hI}$, $a_I=a_0+ u_{aI}$, $b_I=b_0+ u_{bI}$

Step 2:

1. Again, another incremental $\Delta F_2 = 1\text{N}$ is applied on the deformed geometry of the disc (a_1 , b_1 and h_1), and the incremental stresses ($\Delta\sigma_{r2}$, $\Delta\sigma_{\theta2}$, $\Delta\sigma_{z2}$) are evaluated.
2. Next, the maximum value of these three stresses ($\Delta\sigma_{z2}$, $\Delta\sigma_{r2}$, $\Delta\sigma_{\theta2}$) is noted, which happens to be $\Delta\sigma_{z2}$.
3. The stress state is upgraded by adding $\Delta\sigma_{z2}$ to $\Delta\sigma_{z1}$, and E_2 is computed based on equation (3), as: $E_2 = E_0 (= 4.2) + 373.3 \left[\left[\Delta\sigma_{z1} + \Delta\sigma_{z2} \right] \right]^{0.473}$
4. Then, the incremental disc deformations (w_{h2} , u_{a2} and u_{b2}) are determined corresponding to ($\Delta\sigma_{z2}$, $\Delta\sigma_{r2}$, $\Delta\sigma_{\theta2}$), with E_2 as the updated annulus modulus. The total disc deformation is now: $w_{h1} + w_{h2}$, $u_{a1} + u_{a2}$, $u_{b1} + u_{b2}$
5. The deformed disc geometry is now updated to: $h_2 = h_1 - (w_{h1} + w_{h2})$,
 $a_2 = a_1 + (u_{a1} + u_{a2})$, $b_2 = b_1 + (u_{b1} + u_{b2})$

Step 3:

Step 2 is repeated until the total compressive force reaches 2000N, in order to obtain the final deformed geometry at the desired applied load.

The resulting graphs of disc deformations (w_h , u_a and u_b) vs Force (F) are depicted in figures 5-6. The deformed geometries of the disc for $F=500\text{N}$, 1000N , 1500N and 2000N are shown in figure 5-7, so as to depict the “disc-hardening” effect whereby the disc deformations do not increase linearly with F . It is disc-hardening effect that makes it an intrinsically optimal structure.

Chapter 5 Intrinsic features of the spine

(a)

(b)

(c)

(d)

Figure 5-6: (a) Disc vertical deformation vs. compressive force on the annulus (b) radial bulge at $r=a$ vs. compressive force on the annulus (c) Disc radial bulge at $r=b$ vs. compressive force (d) Disc $u_b - u_a$ vs. F . The initial geometric parameters adopted are $a=11\text{mm}$, $b=25\text{mm}$ and $h=11\text{mm}$ and residual modulus E_0 is 4.2MPa

Figure 5-7: Graphical representation of disc deformation from the unloaded state until the compressive load of 2000N is reached. All geometry dimensions are in mm.

5.7 Disc herniation, back pain and nucleotomy

If the load F becomes very large, σ_θ would exceed the sustainable value and cause the annulus to develop radial cracks. Then the NP breaks through the annulus. A herniated disc occurs most often in the lumbar region of the spine, especially at the L4-L5 (L = Lumbar). This is because the lumbar spine carries most of the body's weight. People between the ages of 30 and 50 appear to be more vulnerable, because the elasticity and water content of the nucleus decreases with age. The pain resulting from herniation may be combined with radiculopathy (neurological deficit). The deficit may include numbness, weakness and reflex loss. These changes are caused by nerve compression, created by pressure from interior disc material. Percutaneous nucleotomy is carried out, in order to remove the NP from the sequestered disc, and thereby alleviate the back pain [208,222-224]. For this purpose, a probe is inserted into the centre of herniated disc under fluoroscope monitoring, and the NP is removed through the probe. The analysis for (i) volume aspiration of the NP fluid with respect to the time for different external suction pressures, and (ii) the pressure drop in NP fluid with respect to the time is reported by Ghista *et al.* [209].

5.8 The nucleotomised disc: stresses analysis

For the nucleotomised disc, only the axial equilibrium needs to be satisfied as there is no internal pressure. Note that the radial and circumferential hoop stresses are identically equal to zero. Hence, the solution of equation (4), with the boundary conditions $w = w_{h,nu}$ at $h=z$ and $w=0$ at $h = 0$, is given by

$$w = w_{nu} = -w_{h,nu} \frac{z}{h} \quad (27)$$

Chapter 5 Intrinsic features of the spine

The circumferential strain is related to the axial strain by (the Poisson's ratio) as

$$\varepsilon_\theta = \frac{u_{nu}}{r} = -\nu \varepsilon_z = -\nu \frac{dw_{nu}}{dz} = \nu \frac{w_{h,nu}}{h} \quad (28)$$

Hence, the radial displacements at $r = a$ and $r = b$ for nucleotomised disc are given by

$$u_{a,nu} = \nu \frac{w_{h,nu}}{h} a, \text{ and } u_{b,nu} = \nu \frac{w_{h,nu}}{h} b \quad (29)$$

For a vertically applied force F , the equilibrium of the disc is illustrated in figure 5-8; the minus sign is employed because the axial stress $\sigma_{z,nu}$ (assumed to be tensile) acts on the vertebral end plate and the axial stress $\sigma_{z,nu}$ in the annulus is hence given by

$$\sigma_{z,nu} = -\frac{1}{\pi} \left(\frac{F}{b^2 - a^2} \right) \quad (30)$$

Figure 5-8: Normal stress $\sigma_{z,nu}$ equilibrating the applied force F in a nucleotomized disc.

Using Hooke's law, the axial deformation is related to $\sigma_{z,nu}$ and hence to the applied force F , so that the decrease in disc height

$$w_{h,nu} = \frac{1}{\pi} \frac{1}{E} \left(\frac{Fh}{b^2 - a^2} \right) \quad (31)$$

Then, from equation (29) and (31), the radial expansion of the disc at $r=a$, is given by

$$u_{a,nu} = \frac{1}{\pi} \frac{\nu}{E} \left(\frac{Fa}{b^2 - a^2} \right) \quad (32)$$

Similarly, the radial expansion of the disc at $r=b$ is given by

$$u_{b,nu} = \frac{1}{\pi} \frac{\nu}{E} \left(\frac{Fb}{b^2 - a^2} \right) \quad \text{or} \quad u_{b,nu} = \frac{bu_{a,nu}}{a} \quad (33)$$

5.9 Mechanism of disc deformation in nucleotomised disc

The same procedure as outlined in section 5-6 is used to determine the incremental and final deformations of the nucleotomised disc under an uniaxial compressive load of 2000 N. The resulting graphs of disc deformations $w_{h,nu}$, $u_{a,nu}$, $u_{b,nu}$ vs F and $(u_{b,nu} - u_{a,nu})$ vs F are plotted in figure 5-9, along side the deformations of the normal disc in order to provide a comparison. Also shown in figure 5-10 are the deformed disc geometries for $F=0$, $F=500N$, $F=1000N$, $F=1500N$ and $F=2000N$.

It is seen that the nucleotomised disc has considerable greater deformations than the normal disc. These deformations can result in compression of the nerve structures as well as the facet joints. Thus the removal of NP has adverse effects like disc collapse and excessive radial bulging. This trend is experimentally demonstrated by Meakin *et al.* [222] and Judith *et al.* [223].

(a)

(b)

(c)

(d)

Figure 5-9: (a) Disc vertical deformation V_s compressive force on the annulus with and with out NP (b) Disc $u_{a,nu}$ vs. F with and with out NP (c) Disc $u_{b,nu}$ vs. F with and with out NP (d) Disc $(u_{b,nu} - u_{a,nu})$ vs. F with and without NP. The initial geometric parameters adopted are $a=11\text{mm}$, $b=25\text{mm}$ and $h=11\text{mm}$ and residual modulus E_0 is 4.2MPa .

Figure 5-10: Graphical representation of nucleotomized disc deformation from the unloaded state till the compressive load of 2000N. All geometry dimensions are in mm.

5.10 The intervertebral disc as an optimal structure

Based on these results, in order to retain the stress-stiffening characteristic of the disc and mimic the normal disc load-deformation behaviour, it is not advisable to carry out

Chapter 5 Intrinsic features of the spine

nucleotomy on herniated discs. Instead, it is advisable to replace NP with a gel-filled balloon [225] in the case of disc herniation (as shown in figure 5-11).

This chapter clearly illustrates the natural anatomical-physiological design of the intervertebral disc as an optimal load-bearing and deformation-containing structure. This is because of the composite design of the IVD, in which the NP is enclosed by the annulus. Thus, when the IVD is loaded, the NP gets pressurised, its annulus stress increases, the annulus (stress-dependent) modulus increases, and hence the annulus deformation are contained. This is the salient feature of the IVD as an optimal structure, namely its ability to contain its axial and radial deformations under increased loading.

(a)

(b)

Figure 5-11: (a) Prosthetic disc nucleus (b) balloon intervertebral nucleus developed by Disc dynamics, Inc. Minnetonka [225].

Post script

Linear isotropic elasticity theory is used to analyze the IVD as a thick-pressure-vessel and the analysis suggest that nucleotomy will lead to increased deformation of the disc under load. Further assumptions made are the regular circular shape of the disc, uniform deformation through out the length of the disc.

Chapter 5 Intrinsic features of the spine

Symbols

b -outer radius of the annulus, a - inner radius of the annulus, h - height of the annulus, p_i - pressure of the nucleus pulposus, F -compressive load, σ_f -induced fluid pressure, σ_z - compressive stress induced in the annulus, σ_θ - circumferential stress induced in the annulus, σ_r -radial stress induced in the annulus, ν - Poisson's ratio, E - Young's Modulus, ε - strain.

Chapter 6

Conclusions and scope for future work

The summary, conclusions and future work on the present investigation are reported in this chapter. These concluding remarks are made on the basis of work done during the Ph.D. programme.

6.1 Summary

Bone is a self-repairing structural material, able to adapt its mass and shape to the loading state. It protects the soft tissues and organs, supplies the framework for the bone marrow, and transmits the forces of muscular contraction from one part of the body to another during movement. This dissertation is concerned with: (i) the analysis of internal fixation of long bone fracture by means of a plate screwed to the bone, and comparison of stresses along the bone-plate interface for stainless-steel and stiffness-graded plates (ii) analysis of a hemi-helical plate (as a new concept) for internal fixation of a bone with an oblique fracture, (iii) the biomechanics of the optimal shape of the vertebral body and surgical treatment of burst fractures (iv) the biomechanics of the intervertebral disc in relation to the role of nucleus pulposus to contain the intervertebral disc deformation.

(i) A detailed stress analysis of the straight-plate fixation has been carried out, to (a) determine the stress at the fracture interface, as well as the stresses in the bone, plate and forces in the screws, (b) study the influence of the screw placements on the stresses in the bone at the fracture interface, (c) study the stress-shielding on the bone away from the fractured interface for stiffness-graded plates in comparison with stainless-steel plates.

(ii) The developments in the internal fracture fixation of long bones by plates and screws advocate for a good fracture apposition, and the usage of longer plates and fewer screws. As the force transfer between the plate and the bone is through the screws, the screws are subjected to high shear forces. Also, the bone surface adjacent to the screw is subjected to

Chapter 6 Conclusions and scope for future work

the trauma of insertion, causing local temporary necrosis. These factors lead to the loosening and backing out of the screws, thereby jeopardizing the fixation. Hence, plate fixation by screws of fractured osteoporotic bones in the elderly population poses even greater problems of screw backing out. This phenomenon is common to the straight plate fixation, in which the screws are all oriented normal to the plate. Angling of the screw is considered to be a temporary solution to avoid backing of screws. However, most of the existing plate designs limit the inclinations of the screw to a mere 15^0 , which has very little advantage in increasing the holding strength of the fixation.

The hemi-helical plate was proposed in this research as an optimal fixation for oblique fractures (i.e. a short spiral fracture caused by torsion) as well as to prevent screw pull-out. It warps around the fractured bone, and hence holds the fractured fragments more effectively than a straight plate can do so. The finite-element stress analysis of the fractured bone fixed by a hemi-helical plate (HHP) has been carried out to study: (a) the movement at the fracture interface, (b) how the orientations of the screws in different planes (with respect to the bone axis) can enhance the holding capacity of fixation, (c) how the wrapping of the HHP around the fractured bone lowers the neutral-axis of the bone (in bending) into the bone so as to thereby reduce stress-shielding of the bone.

(iii) In the vertebral body, the load carrying and transmitting function is primarily done by the cortical vertebral body (VB). Hence the VB is studied in its natural shape, as a hyperboloid shell, whose geometry and composition is made up of its generators. The forces in the VB generators due to compression, bending and torsional loadings are

Chapter 6 Conclusions and scope for future work

analyzed. It is observed that all the loadings are transmitted as axial forces in the generators. This unique feature of the hyperboloid VB makes it a high-strength structure. Further, because the cortical VB material is primarily made up of its generators, it makes the VB to be a light-weight structure.

The optimal hyperboloid shape and geometry of the VB is obtained by minimizing the sum of the forces (due to compression, bending and torsion) in the hyperboloid VB generators with respect to the hyperboloid shape parameter (angle β between pairs of generators). The value of β is determined to be 26.5° , which closely matches with the in-vivo geometry of the VB based on the Magnetic Resonance Imaging (MRI).

This analysis demonstrates that the VB is an intrinsically functionally-optimal structure as per the concept of optimal design in nature. Despite the optimal shape of the spinal vertebral body (VB), it fails as the load exceeds the sustainable limits. A crushed VB gets displaced posteriorly towards the spinal cord. In order to prevent this herniation, posterior and anterior fixation devices have been developed. The limitations of the devices are studied and a new design of anterior spinal fixator is proposed. The proposed spinal fixator mimics the concept of optimum VB geometry as a hyperboloid shell, and will be studied as a part of the future work.

- (iv) The spinal intervertebral disc needs to have the flexibility to enable the spine to bend and twist. At the same time under loading, its lateral and axial deformations have to be contained, so that it does not herniate and impinge on the spinal-chord. The disc is

composed of a fluid-like nucleus pulposus (NP) contained within an annulus. Hence when the disc is loaded, the NP gets pressurized and stresses the surrounding annulus. Now, because its elastic modulus is stress-dependent, the annulus stiffens under loading, and hence its deformation is contained.

In this way, the spinal intervertebral disc is able to sustain its loading with minimal deformation, and thereby contain its deformation. In this dissertation, the stress and deformation analysis of the spinal disc is carried out, and it is demonstrated that its deformations do not increase in proportion to the load intensity because of the stress-dependant modulus of the annulus.

When the annulus ruptures, the NP oozes out through the cracks and comes in contact with the nerve roots. This causes back pain. The treatment for a ruptured annulus is nucleotomy. However, based on the analyzed role of NP in containing the disc deformation, nucleotomy is not the solution of a ruptured disc. Rather it is proposed to insert some kind of a gel substance contained in it. A polymeric sac within the NP cavity would mimic the structural role of NP in stiffening the annulus and containing its deformation.

6.2 Conclusions

The major conclusions are stated as follows

1. The concept of plate fixation of a fractured bone is based on the plate minimizing the opening of the crack. The state of art on internal fracture fixation by means of plate is critically reviewed.

Chapter 6 Conclusions and scope for future work

2. Under uniaxial loading, it is showed (using engineering mechanics) that the transfer of load by the screws is dependent on the geometry and the material properties of the bone and the plate (section 3.1 of chapter 3).
3. An engineering-mechanics analysis is carried out to show that the variation in the number and the placement of the screws has an effect on the stresses at the fracture interface. Necessary and sufficient stress-shielding on the fractured bone depends on the adroit selection of parameters such as: modulus of the plate,(modulus of bone and callus being patient case specific), geometry of the plate, number and location of the screws (section 3.2 of chapter 3).
4. By finite-element analysis, it is shown that in the early stages when the callus modulus is 1% of the bone modulus, the neutral axis (NA) is located within the plate, and the callus interface is in compression (as per figure 3-10, chapter3). As healing proceeds and the callus modulus increases, the NA shifts down into the bone, with the callus also bearing some tensile stress. Also, the total tension force borne by the plate decreases, and the plate stress-shielding also reduces.
5. Stiffness-graded plates do offer less stress-shielding, but not significant enough as the dependence of stress-shielding is more on the geometry of the plate, number and placement of the screws (section 3.3 and 3.4 of chapter 3).
6. Long bone fractures occur due to a combination of compression, bending and torsional loadings. Straight plate fixation can be justifiably employed for classical bending fractures, by placing the fixation plate on the tension surface of the bone. However, clinically fractures are not ideal bending fractures. In the event of spiral fractures or oblique fractures, using straight plate fixation is not biomechanically

Chapter 6 Conclusions and scope for future work

advantageous. Also, in the case of multifragmentary fractures with crack planes at various orientations, it becomes more difficult to place a straight plate in the ideal location to achieve stability. Similarly, the holding capacity of the fixation needs to be improved while treating fractures with less bone stock. Hence, the hemi-helical plate (HHP) fixation concept is conceived, and features of the hemi-helical plate fixation are discussed (chapter 4).

7. Through the experiments (both pull-out and four point bend), it is observed that the over-all stiffness of the fixation by plates and the holding capacity of the plate in fixation can be somewhat improved through the angling of the screws but more so by the use of a hemi-helical plate (section 4.1 and 4.2, chapter 4).
8. From finite element analysis and experimentation, the advantages of HHP are as follows: Firstly, the HHP will provide the compression at the fracture interface, good resistance to torsional loadings, and relatively less flexural and axial stiffness. The second advantage of HHP fixation is that it envelops the cracked bone. Hence, it ideally bridges the cracks. The third advantage is that the radially-dispersed angulation of plate screws (into a HHP) improves overall resistance against screw pullout and fixation failures. Finally, another benefit of HHP fixation for bending loading is that the HHP placement lowers the neutral axis into the bone away from the fractured surface. Hence, the HHP stress-shields the bone less than the straight plate. Hence, it is envisaged that hemi-helical plating would become a standard option when plating long bone fractures and is expected to avoid the current problems of conventional plating (section 4.3, chapter 4).

9. It is shown that the spinal vertebral body (VB) is modeled as a hyperboloid by nature, as per the concepts of design in nature. A detailed stress analysis on the hyperboloid VB is performed, to demonstrate that the hyperboloid VB's generators are always axially loaded for all types of loading on the VB. An optimal biomimic anterior fixator is proposed for treating burst fractures, based on the stress analysis of the hyperboloid VB (chapter 5).
10. The intervertebral disc is analysed as a thick cylinder with nucleus pulposus, under compressive loading. It is observed from the analysis that the axial and radial deformations in the disc with NP are less (compared to nucleotomized disc), as the function of the NP is to stress the annulus and elevate its (stress-dependant) modulus of elasticity (chapter 5).

6.3 The key contributions of this work

The major contribution from this dissertation are summarized below

1. Analytical analysis for the rationale in the fracture fixation

Fracture-fixation using a plate is increasingly gaining importance with the recent developments in the surgical procedures. Despite these advances, stress-shielding (cortex thinning) and sequential screw failure (essentially loosening of screws and later pullout) are reported. An optimal number of screws and plate Young's modulus should be selected to minimize stress shielding on bone and screw failure (either pull-out or fracture).

The two conditions that a surgeon need to consider while selecting a plate and number of screws for fracture fixation are (1) compressive stress should prevail at fracture interface (2) bone should be subjected to the best possible actual loading conditions away from fracture interface. Based on the above two conditions, an analytical analysis is carried out on a transversely fractured bone under bending loading to determine parameters such as modulus and thickness of the plate, number of screws and their location.

2. Stiffness graded plates in fracture fixation for reduced stress shielding

Stiffness graded plate is conceived to be an alternate option in reducing stress-shielding on the bone. Hence, finite element simulation on fracture fixation by a stiffness graded plate in comparison with a straight plate fixation was carried out. It was reported from the analyses that the stiffness-graded plates offer less stress-shielding. Further, the effect of number and location of the screws on either side of the fracture on stress shielding are investigated.

3. Helical plates for improved holding capacity and reduced stress shielding

Sequential screw pullout can partially be avoided through the inclinations of screws in fracture fixation. Possible screw fixation configurations are (1) converging (2) diverging and (3) alternating. Forces in each screw and the screw holding capacity for the fracture fixed bone assembly was studied through four point bending experiments. These experiments showed that there is an improved load transferring capacity by the inclined screws. However, stress shielding away from fracture site cannot be addressed

through inclinations alone. From the pull out experiments and finite element analysis, it was reported that helical or contoured plates offer less stress shielding and better holding capacity. Also, the fracture gap is always under compression under uniaxial compression, bending and torsional loading conditions. It is envisaged from the analyses that that helical plating will emerge as a surgical procedure.

4. Shape Optimisation of Vertebral body and Intervertebral Disk

Ghista [174] has analysed the vertebral body as hyperboloid body shell under uniaxial compression and torsion. This analysis is further extended to bending loads and optimal geometrical parameters are extracted. This fuller analysis illustrate how the optimal hyperboloid shape design of the vertebral body enables the loadings to be transmitted as axial (compressive/tensile) forces through the generators of the hyperboloid shell at minimum weight. Based on the analysis, the relation between the loading conditions and geometric features was derived.

Intervertebral disk (IVD) is modeled as thick-walled cylindrical shell under uniaxial compressive and internal pressure loading by taking stress stiffening modulus of IVD material. Based on these results, in order to retain the intrinsic feature (stress-stiffening characteristic) of the IVD and mimic the normal disc load-deformation behavior, it is not advisable to carry out nucleotomy on herniated discs. Instead, it is suggested to replace nucleus pulposus with a gel-filled balloon in the case of disc herniation.

6.4 Limitations of this work

The limitations are as follows

1. For graded-plate finite element analysis in chapter 3, the healing progresses with increase in modulus of the callus is assumed.
2. For the finite element analysis of the helical plating (chapter 4), only oblique fracture is considered for the analysis. Hence, the fracture gap movement addressed in this chapter is valid only for oblique fractures.
3. For the vertebral body (chapter 5), the structural optimal analysis primarily concerns the main body (i.e. anterior) shape, and not its posterior elements. The analysis entails optimization of the main anterior body.
4. For the intervertebral disc (chapter 5), a non-linear elastic analysis, is carried out showing how the nucleus pulposus and the stress-stiffening constitutive property of the annulus enables it to sustain increased loading without proportional increase in deformation. The elasticity analysis assumes a cylindrical shape of the intervertebral disc, instead of its precise shape. Further, the analysis does not consider the time-dependent visco-elastic nature of the disc material. Here also, the emphasis is on the optimal aspect of the disc, which enables it to bear increased loading without proportionate deformation increase.

6.5 Future work

The scope of the future work on bone fracture fixation and spine is discussed in the following paragraphs.

Rationale in Hemi-helical plate fixation (HHP)

This involves

- (1) Fixation basis: The biomechanical foundation of HHP fixation (in comparison to straight plate fixation) by finite element analysis is to be developed to show how the screw placement and lengths of the plate influences the distribution of stresses across the fracture interface and stress-shielding of the bone.
- (2) Determination of optimal screw placements for the optimal working length of bone-plate assembly.
- (3) Clinical assessment of fracture-healing of bone fixed by helical and straight plates
- (4) Identification of suitable anatomical locations for placement of fixation plates
- (5) The manufacturing of hemi-helical plates will be explored.
- (6) Jigs for fracture reduction and contouring of the HHP can be designed.

New spinal fixator and treatment of the ruptured disc

The design, manufacturing and testing of the biomimetic-anterior fixator for burst vertebral body will be carried out. Also, the development (material selection and testing) of a polymeric sac (instead of nucleus pulposus) as a filler for the nucleus pulposus will be carried out.

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