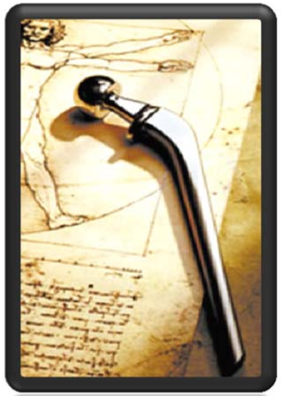
UC: PROJECTO DE DISPOSITIVOS MÉDICOS

CURSO: ENGENHARIA BIOMÉDICA

LECTURE (CU): DESIGN OF MEDICAL DEVICES

CARRER: BIOMEDICAL ENGINEERING



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Escola Superior de Tecnologia e Gestão

CURRICULAR UNIT - SYLLABUS

- Subject: Design of Medical Devices.
- Course Speciality: Biomechanics and Rehabilitation.
- Main Scientific area: Orthopaedics and Rehabilitation (ORE).
- Classes: 60 h/Semester PL (Practice and Laboratory).
- Cycle: 2º (Master degree of Science).
- Year / Semester: 1º year/ 2nd Semester.
- Learning outcomes and competences:
  - Understand design problems of orthopaedic devices used for rehabilitation;
  - Analyse and design the functionality of orthopaedic medical devices;
  - Acknowledge and understanding security and safety issues of medical devices;
  - Optimizing previous or developed medical devices;
  - Design of implants, Orthopaedic devices and technical aids for persons with disabilities .

CURRICULAR UNIT - SYLLABUS

- Prerequisites:
  - Understand musculoskeletal functionality for orthopaedic and rehabilitation.
  - Understand static and dynamic behaviour of deformable and rigid bodies.
  - Apply solid stress and fluid flow analysis principles in simple systems.
  - Select biomaterials for biomedical applications.

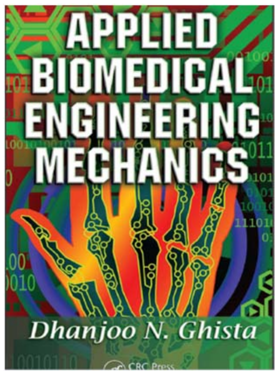
CURRICULAR UNIT - SYLLABUS

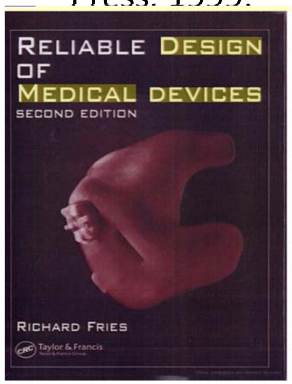
- Course contents (Extended version):
  - Introduction to design:
    - Introduction to medical devices;
    - Medical devices definition;
    - Introduction to design;
    - Tissue Engineering;
    - Biomaterials for devices;
    - Materials wear and corrosion;
    - Medical devices regulatory issues;
  - Device Design Principles :
    - Concept of collapse or failure;
    - Concept of device safety;
  - Medical devices regulation and standards:
    - Incomplete.
    - Incomplete.
  - Case studies in orthopaedic engineering mechanics:
    - Internal bone fracture-fixation plates;
    - Human spinal vertebral body;
    - Intervertebral disc as optimally design human body structure.

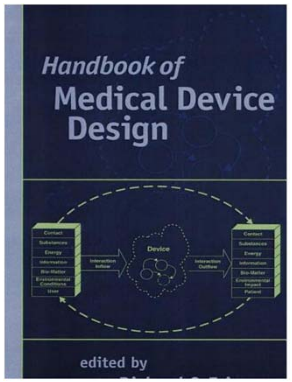
CURRICULAR UNIT - SYLLABUS

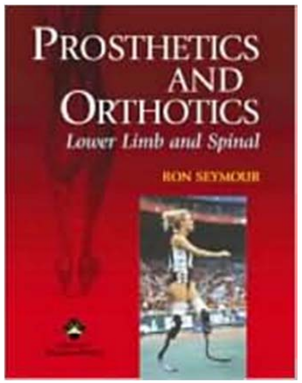
- Teaching and learning methods:
  - Theoretical and practical exposition of the fundamental concepts should be presented at classes, complemented with practical exercises. The remaining period should be used to solve working projects.
  - Out of classes, students are invited to solve problems and prepare poster sessions.
- Suggested bibliography:
  - Suggested documentation: Power point slides;
  - Other references:

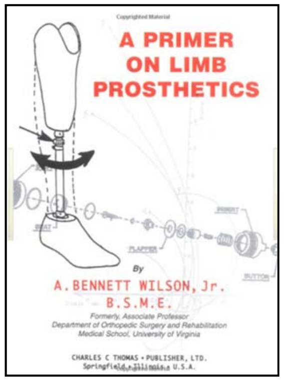
    - Dhanjoo N. Ghista, "APPLIED BIOMEDICAL ENGINEERING MECHANICS", CRC Press, USA, 2008.
    - Richard Fries; "Reliable Design of Medical Devices"; CRC Taylor and Francis, 2006.
    - Richard C. Fries; "Handbook of medical device design", Marcel and Dekker, 2001.
    - D.G. Shurr, J.W. Michael; “Prosthetics and Orthotics”, 2nd edition. Prentice Hall, 2001.
    - A. Bennett, Jr. Wilson; “A Primer on Limb Prosthetics”, Charles C. Thomas Pub Ltd, 1998.
    - Y. H. An, R.A. Draughn (Eds); “Mechanical Testing of Bone and the Bone-Implant Interface”, CRC Press, 1999.

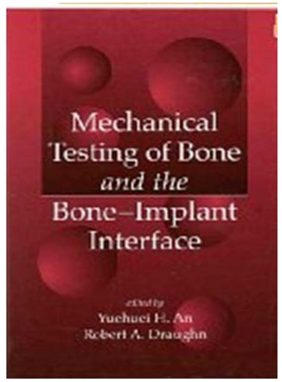






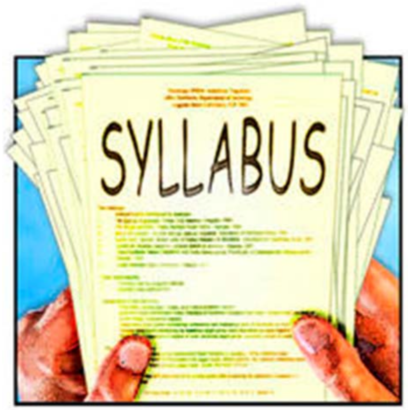






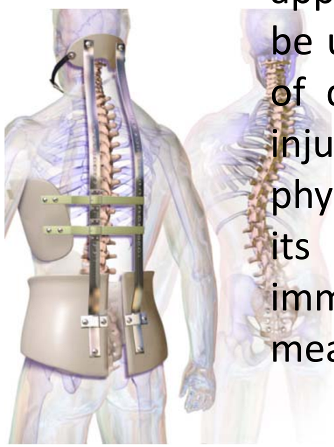
CURRICULAR UNIT - SYLLABUS

- Assessment:
  - Final season (EF):
    - continuous assessment with working projects to be presented at classes (oral presentations with power point slides, with written reports in word format;
    - Labor students with special statute may require Exam during final season.
  - Appeal season (ER): Exam;
  - Special season (EE): Exam;
- Language of classes: Portuguese and English



INTRODUCTION TO MEDICAL DEVICES

- Medical Device [Decreto-Lei n.º 78/97, de 7 de Abril] (In Portuguese):
  - “Qualquer instrumento, aparelho, equipamento, material ou outro artigo utilizado isoladamente ou combinado, incluindo os acessórios e suportes lógicos necessários ao seu correcto funcionamento destinado pelo fabricante a ser utilizado em seres humanos para fins de diagnóstico, prevenção, controlo, tratamento ou atenuação de uma doença, lesão ou deficiência, para fins de estudo ou de substituição ou alteração da anatomia ou de um processo fisiológico ou para fins de controlo da concepção, e cujo efeito principal pretendido no corpo humano não se alcança por meios farmacológicos, imunológicos ou metabólicos, mas cuja actuação possa ser apoiada por esses meios .”
- Medical Device [Directive 2007/47/ec of the European Parliament]
  - “instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Devices are to be used for the purpose of: Diagnosis, prevention, monitoring, treatment or alleviation of disease; Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; Investigation, replacement or modification of the anatomy or of a physiological process; Control of conception. This includes devices that do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.”



MEDICAL DEVICES DEFINITION

- Active Medical Device [DL n.º 78/97, de 7 de Abril]:
  - "Medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity."

- Active Implantable Medical Device [DL n.º 78/97, de 7 de Abril]:
  - "means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure. "

- Custom-Made Device [DL n.º 78/97, de 7 de Abril]:
  - "means any active implantable medical device specifically made in accordance with a medical specialist's written prescription which gives, under his responsibility, specific design characteristics and is intended to be used only for an individual named patient."
- Device Intended for Clinical Research [DL n.º 78/97, de 7 de Abril]:
  - "means any active implantable medical device intended for use by a specialist doctor when conducting investigations in an adequate human clinical environment."

INTRODUCTION TO DESIGN

- Design of a new medical device has a reasonable expectation:
  - Regarding that should not be an improvement in an existing device;
  - No need to build the device;
  - Written report should be sufficient for a patent disclosure.
- Description of the device should include:
  - Dimensions;
  - Materials;
  - A working model or three dimensional model may be possible;
  - Computer simulation may also be possible.
- Description of the functionality of the device.
- Diagram of the device in working place and conditions.
  - If it is an implant, should describe how to fixed to host tissue / organ;
  - Instrumentation if required.

United States Patent **6,034,296**
Elvin, **et al.** **March 7, 2000**

Implantable bone strain telemetry sensing system and method

Abstract

An implantable self-powered sensing system for a bone fixation device, which includes a self-powered strain sensor mountable on or in a bone fixation device, is disclosed. The sensor is capable of measuring strain in the bone fixation device by generating a strain signal in response to stresses produced thereupon. The system also includes a telemetry unit powered by the generated strain signal and in communication with the sensor. The telemetry unit is activated by the sensor when the strain signal reaches a predetermined value and then transmits the strain signal from the sensor to an external receiver. The sensing system can also include a buffer unit in communication with the sensor and the telemetry unit for collecting and storing the strain signals for transmission by the telemetry unit as a cumulative strain measurement. The method of monitoring healing in a bone and measuring strain in a bone fixation device using the sensing system of the present invention includes the steps of subjecting a patient to a predetermined set of dynamic exercises which vary stresses exerted on the bone fixation device and tests the integrity of the bone fixation device and then measuring the strain resulting from the stresses imposed upon the bone fixation device via the implanted self-powered sensor attached to the bone fixation device, which generates a charge in response to the stresses imposed on the bone fixation device, which then powers the implanted telemetry unit in order to transmit the charge generated by the sensor unit to an external receiver as a corresponding strain measurement signal.

Inventors: **Elvin; Niell** (1110 W. Gate Apartments 550 Memorial Dr., Cambridge, MA 02139); **Elvin; Alex** (1110 W. Gate Apartments 550 Memorial Dr., Cambridge, MA 02139); **Spector; Myron** (921 Seaver St., Brookline, MA 02146)

Appl. No.: **984957**

Filed: **December 4, 1997**

INTRODUCTION TO DESIGN

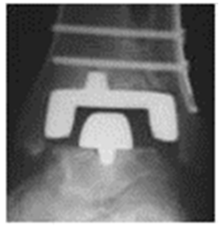
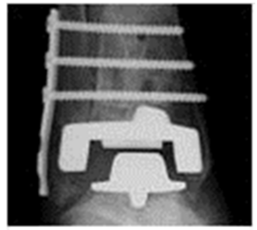
- Engineering:
  - Allows product development using knowledge.
- Science:
  - Process of acquiring new knowledge.
- Technology:
  - Means of producing the product.

- The problem of a missing organ:
  - Irreversible injury (destroys organ functionality);
  - Basic therapies for the missing organ (transplantation, passive implant,...);
  - Clinical problems that may have not been solved adequately.

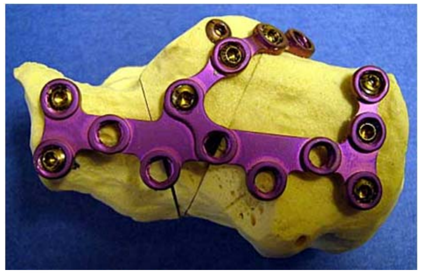
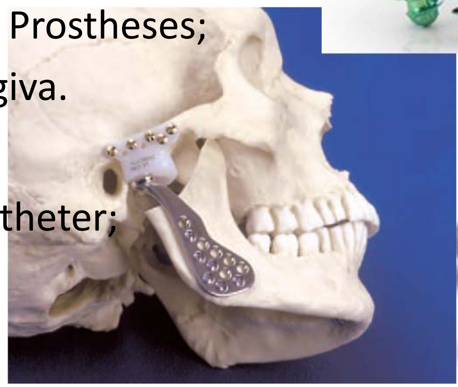
- Design strategy (Prof. Myron Spector, Harvard Medical School:
  - Analyse problem of irreversible injured organ, identifying tissues in organs that regenerate spontaneously (regenerative) and those that do not (non-regenerative).
  - Designer should focus attention on non-regenerative tissues, rather than planning a new device to substitute the entire organ.

MEDICAL DEVICE DESIGN PROJECTS

- Connective tissue:
  - Musculoskeletal System:
    - Joint Replacement Prostheses:
      - Ankle prosthesis;
      - Prosthesis for intervertebral disk regeneration .
    - Fracture fixation device :
      - "Smart" bone plate.
    - Bone Substitute Material;
    - Tendon/Ligament Replacement ;
    - Meniscus Replacement ;
    - Articular Cartilage Prosthesis.
  - Oral, Maxillofacial, and Otologic:
    - Dental Implants;
    - Temporomandibular Joint Prostheses;
    - Ossicular Replacement Prostheses;
    - Augumentation of Gingiva.
  - Cardiovascular System:
    - Angioplasty Balloon Catheter;
    - Heart Valve;
    - Vascular Prosthesis.



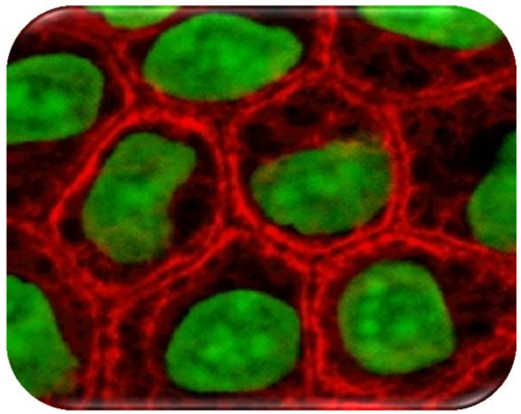
APPLICATIONS OF MEDICAL DEVICES

Medical devices for clinical purposes		Number used per year in USA	Number used per year in Portugal Registry started June 2009
Population		303 007 997	10 617 575
Orthopedic	Hips (THA)	200 000	(?,SPOT) 10 000
	Knees (TKA)	60 000	(?,SPOT) 12 000
	Shoulders, finger joints	50 000	(?)
Reconstructive	Breast prostheses	100 000	(?)
	Dental	20 000	(?)
Cardiovascular	Pacemakers	130 000	(?)

rpa
Registo Português de Artroplastias
Portuguese Arthroplasty Register

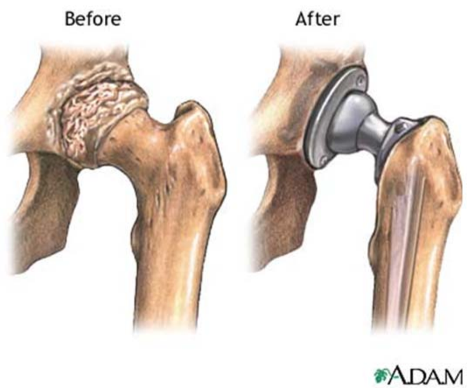
ERAS OF MEDICAL DEVICES

- 1920-1970:
  - Age of new devices:
    - Fracture fixation;
    - Joint replacement;
    - Spine Instrumentation.
- 1970-
  - Age of Biomaterials:
    - Bone graft subsitute materials.
- 2000-
  - Age of Tissue Engineering:
    - Porous absorbable materials to be seeded with cells.
- 2010-
  - Age of Gene Terapy (?):
    - Materials as delivery systems for genes.



PASSIVE IMPLANTS (PROSTHESIS / ORTHOTICS)

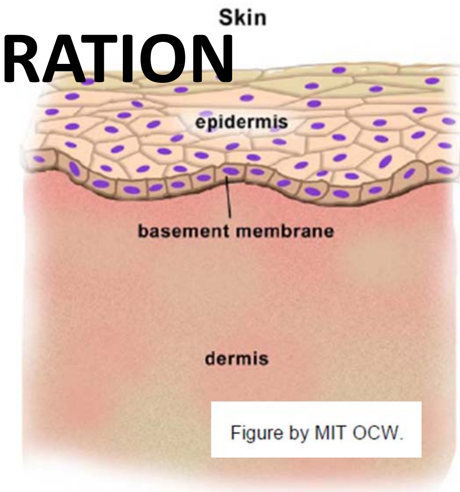
- Metallic's / plastics /ceramics are often used in device fabrication.
- Devices will play or not a long term function with host.
- Problems when host attacks implant:
  - Migration of prosthesis;
  - Abrasion of materials;
  - Tissue fluid may attacks electronic devices.
- Problems when implant attacks host:
  - Bone loss cause by stress shielding (According to Wolff's law, as a result of removal of normal stress from the bone by an implant).



DEFINITIONS

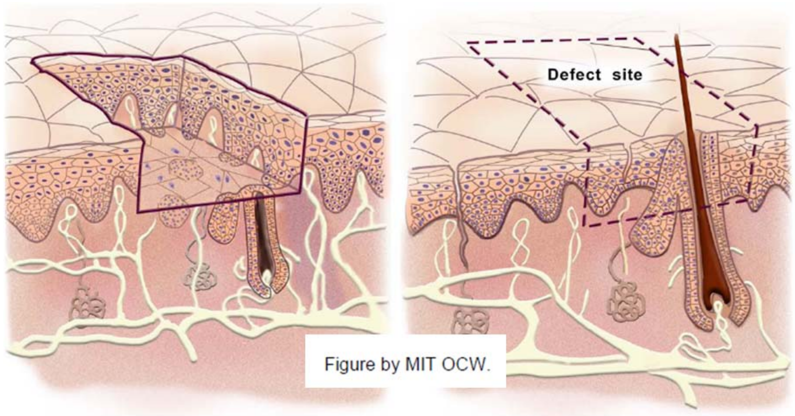
- Implant:
  - A device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more.
- Tissue:
  - An aggregation of similarly specialized cells united in the performance of a particular function. Cells serving the same general function and having the same extracellular matrix.
- Biomaterial:
  - Any substance (other than a drug) or combination of substances, synthetic or natural in origin, which can be used at any period of time as a whole or in part of a system which treats, augments or place any tissue, organ or function of the body (J. W. Boretos and M. Eden, <u>Contemporary Biomaterials, 1984).</u>
  - A non-variable material used in a medical device intended to interact with biological systems (D. F. Williams, <u>Definitions of Biomaterials, 1987).</u>

TISSUE TRIAD AND TISSUE REGENERATION

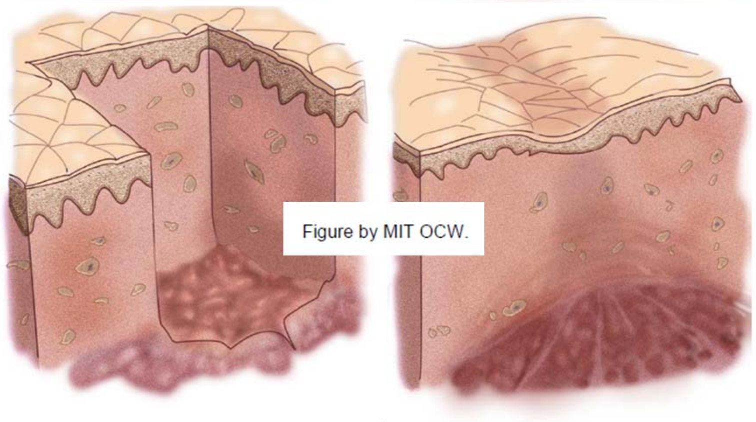


- Epithelia:
  - 100 % cells, no matrix, No blood vessels.
- Basement membrane:
  - No cells, 100 % matrix, No blood vessels.
- Stroma (connective tissue):
  - Cells, Matrix, Blood vessels.

The epidermis is regenerative:
LEFT: a controlled injury (e.g. stripping or blistering) which leaves the dermis intact. RIGHT : the epidermis recovers completely at the defect site. Hair follicles are lined with epidermal tissue and also regenerate.
Epithelia and basement membrane are synthesized from remaining epithelia cells.

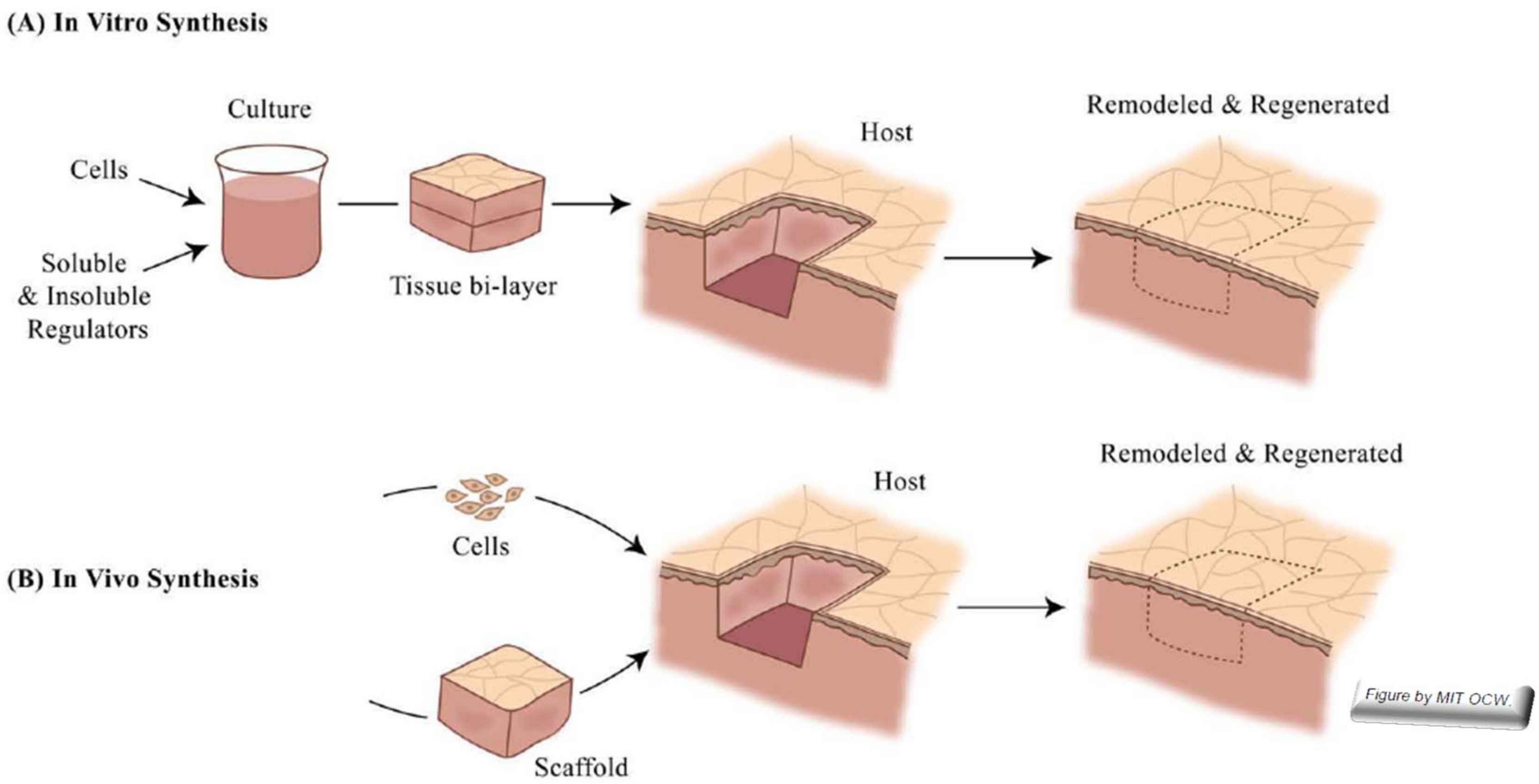


The dermis is nonregenerative:
LEFT: Excision of the epidermis and dermis to its full thickness. RIGHT: Wound edges contract and close, while scar tissue forms.
Stroma is not synthetized from remaining cells.



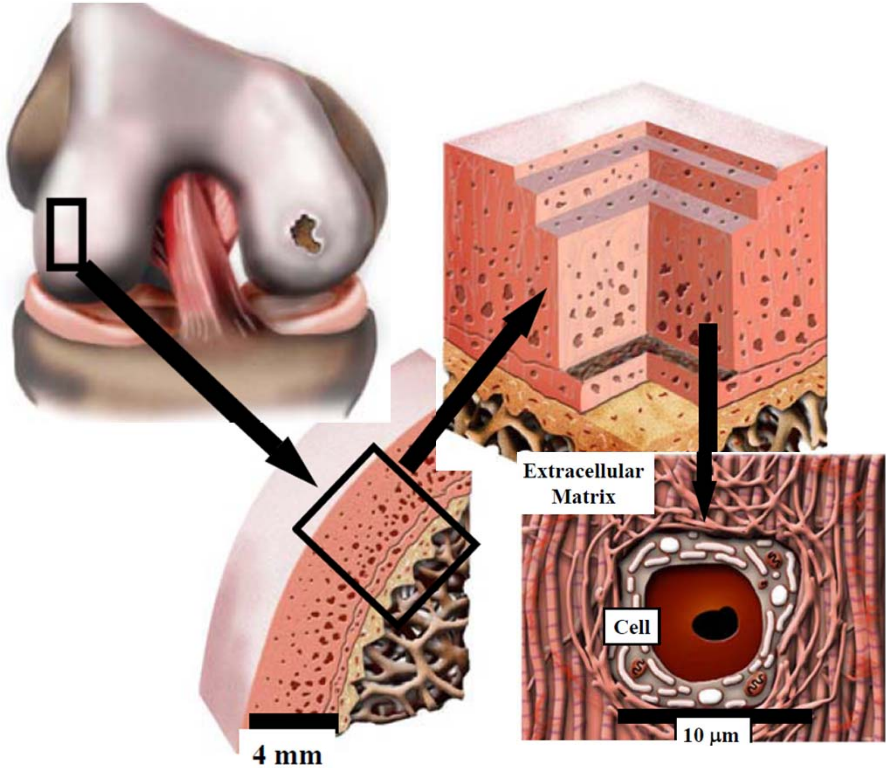
TISSUE REGENERATION

- In vivo and in vitro tissue synthesis:

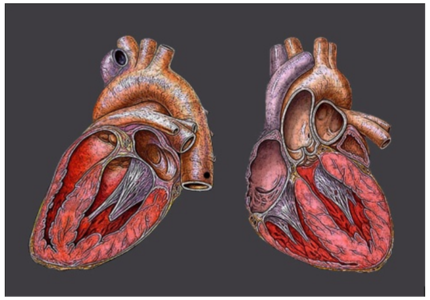


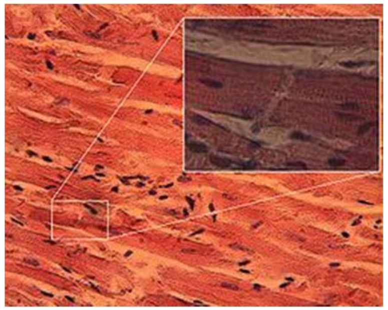
TISSUE AND ORGAN

- Tissue is defined as:
  - Biological structure made up of cells of the same type:
    - Cells of the same phenotype (same genes expressed);
    - An aggregation of morphologically similar cells and associated extracellular matrix acting together to perform on or more specific functions in the body.
  - There are 4 basic types of tissue: muscle, nerve, epithelia and connective.
- Organ is defined as:
  - Any structure made up of 2 or more tissues.
- Example:
  - Main tissue in the heart is the myocardium



Figures by MIT OCW.



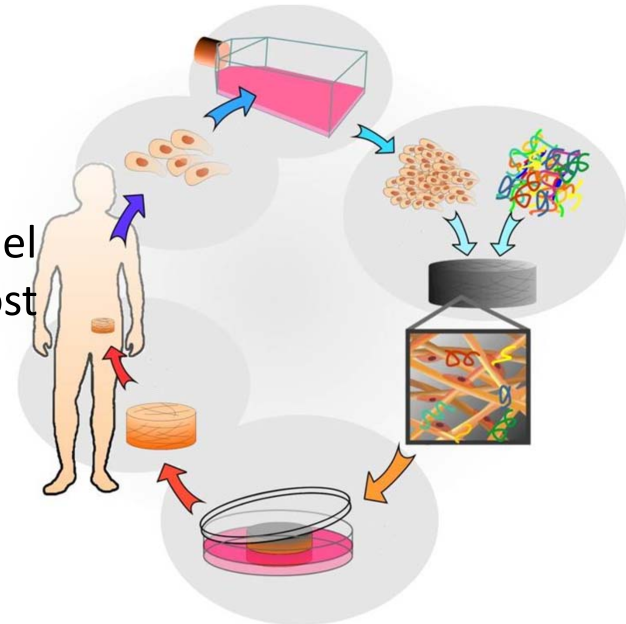


TISSUE FORMATION PROCESSES

- Embryonic tissue formation.
- Remodelling (degradation-formation).
- Healing (repair versus regeneration):
  - Repair: defect in the tissue fills with “scar” (generally fibrous tissue)
  - Regeneration: defect fills with tissue that is indistinguishable from the original tissue.
    - Factors that can prevent regeneration:
      - Size of defect (eg: bone does not regenerate in large defects);
      - Collapse of the surrounding tissue (eg: periodontal defects);
      - Excessive strains in the reparative tissue (eg: unstable fractures).
- Response to permanent and absorbable implants:
  - Tissue formation in the gap (micrometer scale) between the implant and surrounding host tissue;
  - Tissue formation in pores of porous implants.

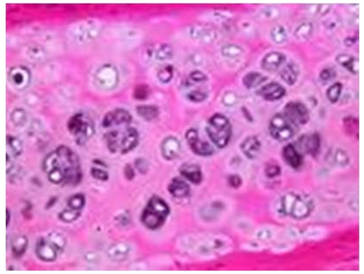
TISSUE ENGINEERING

- Definition:
  – Production of tissue in vitro by growing cells in porous, absorbable scaffolds (matrices).
- Required in certain conditions:
  – Tissues that can not regenerate when injured or diseased;
  – Tissues that can regenerate but not completely due to large defects (example: bone);
- Problems in tissue engineering:
  – Most tissues can not be reproduced in vitro;
  – Implants of tissues produced in vitro may not remodel in vivo and may not become integrate with host tissue.
- Partial solution:
  – Scaffold-based regenerative tissues.

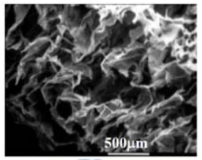


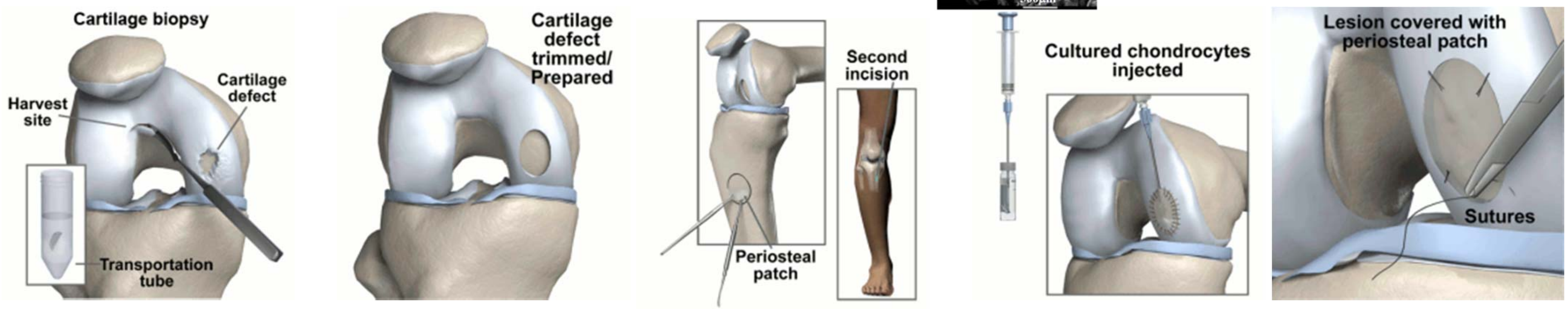
Adaptado de Julian H S George et al
http://www.centropede.com/UKSB2006/ePoster

TISSUE ENGINEERING MILESTONES



- 1980 : Yannas, Artificial skin.
- 1984 : Wolter and Meyer, first use of tissue engineering.
- 1991 : Cima and Vacanti and Langer, Chondrocytes in a polyglycolic acid scaffold.
- 1993 : Langer and Vacanti, Scientific paper on Tissue Engineering; cells in matrices for tissue formation in vitro.
- 1994 : Brittberg and Peterson, Carticel.





Step 1: Biopsy.
Medical assessment of the extent of cartilage damage.

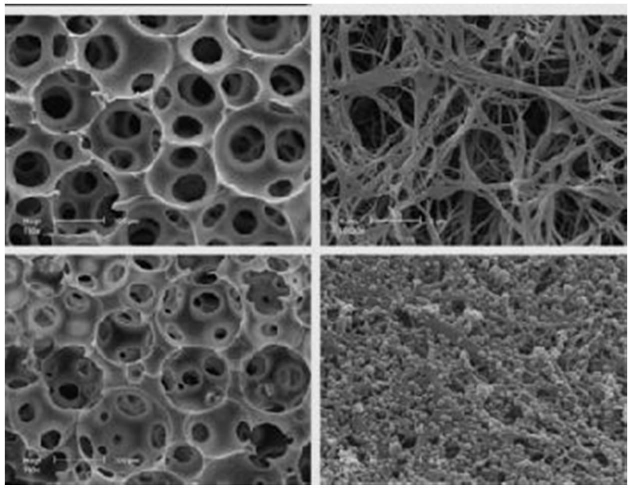
Step 2: Implantation .
Medical incision to expose knee and remove any dead or damaged tissue from the injury.

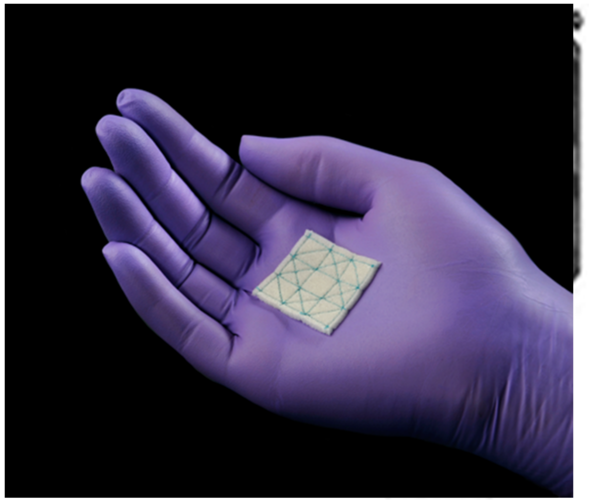
Step 2: Implantation .
Removal of a small piece of tissue from shin bone and sews it securely over the injury.

Step 2: Implantation .
Medical injection of CARTICEL under the patch.

BIOMATERIALS

- Tissue engineering is proving to be a revolution in biomaterials.
- In the past, biomaterials were used for the fabrication of permanent implants to replace tissue function (eg., total joint replacement prostheses).
- In the present and near future, the principal role of biomaterials will likely be to serve as as scaffolds/matrices for tissue engineering and cell and gene therapies.





CLONING RESOURCES

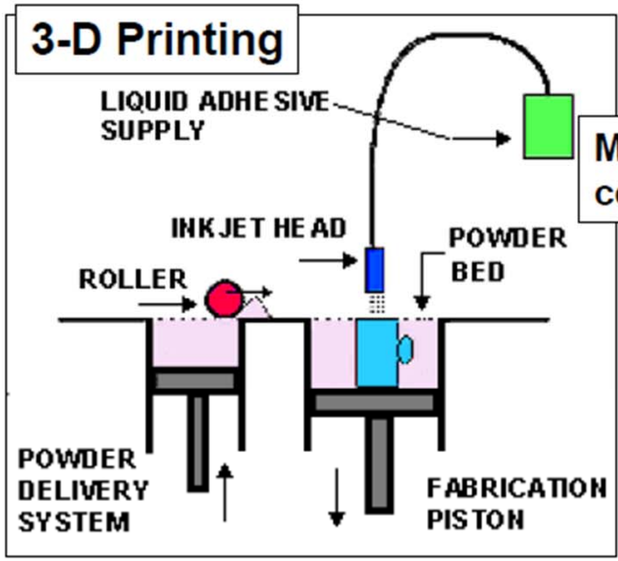
BIOMERIX™

Society For Biomaterials

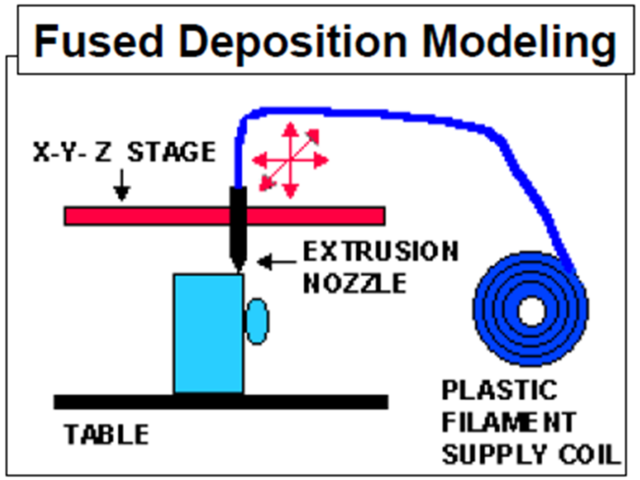
SCAFFOLDS - BIOMANUFACTORING

- Synthetic Polymers:
  - polylactic and polyglycolic acid;
  - Self-assembling proteins,
  - Other.
- Natural Polymers:
  - Fibrin;
  - Collagen;
  - Other.

Solid Free-Form Fabrication Technologies



Multiple inkjet heads; print cells as cells aggregates or individual cells



BIOMATERIAL APPLICATIONS AND EXAMPLES

- Non absorbable materials for the fabrication of permanent implants.
- Absorbable materials for the production of scaffolds for tissue engineering and regenerative medicine.

- Metallic biomaterial:
    - Stainless Steel [Fe, Cr (17-20) %, Ni (10-17)%, Mo, C, others].
    - Cobalt Chromium Alloy [Co, Cr (27-30)%, Mo, Ni, others].
    - Titanium Alloy [Ti, Al(5.5-6.5)%, V(3.5-4.5)%, others].

Oral, maxillofacial, dental, plastic surgery implant : maxillo facial set. Materials: SS or Ti Alloy

Seattle Stainless Steel Safety Knee:
Product weight: 524 [g]
Weight limit: 100 [kg]

Trulife

Distal tibia anatomical plate
Suitable for : osteotomy of distal tibia screw : 4.0 mm x 5.0 mm profile : 20/13.5 x 4.0 mm
distance between hole : 18 mm
Materials: SS or Ti Alloy

4mm cancellous locking screw
Materials: SS or Ti Alloy

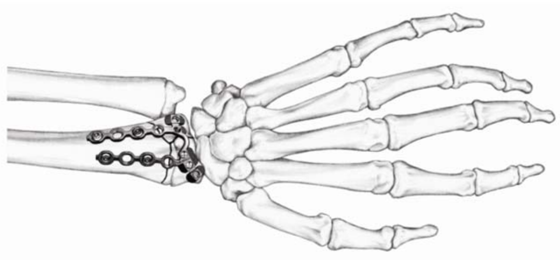
Short description HIP PROSTHESIS
dia : 35 mm to 55 mm (diff 1.0 mm)
Materials: SS or Ti Alloy

SPCPL

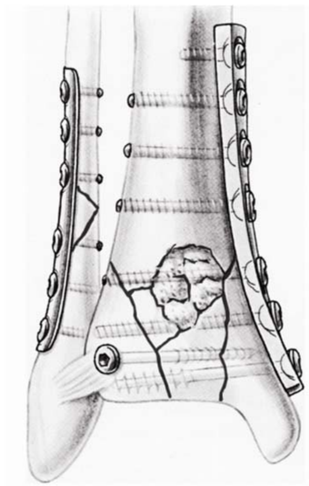
BIOMATERIAL APPLICATIONS AND EXAMPLES

- Stainless steel plate for fracture fixation of proximal tibia
  - Ductility is important , because plate must be deformed in the operating room, to conform the bone shape.

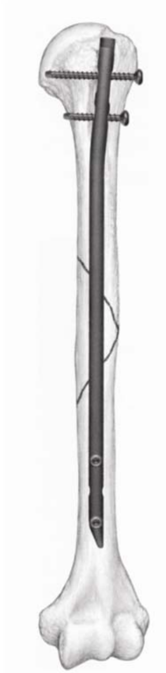
- Pure titanium fixation plate for distal fractures of the radius.



- Fracture of the distal tibia and fibula fixed by a single plate on each bone

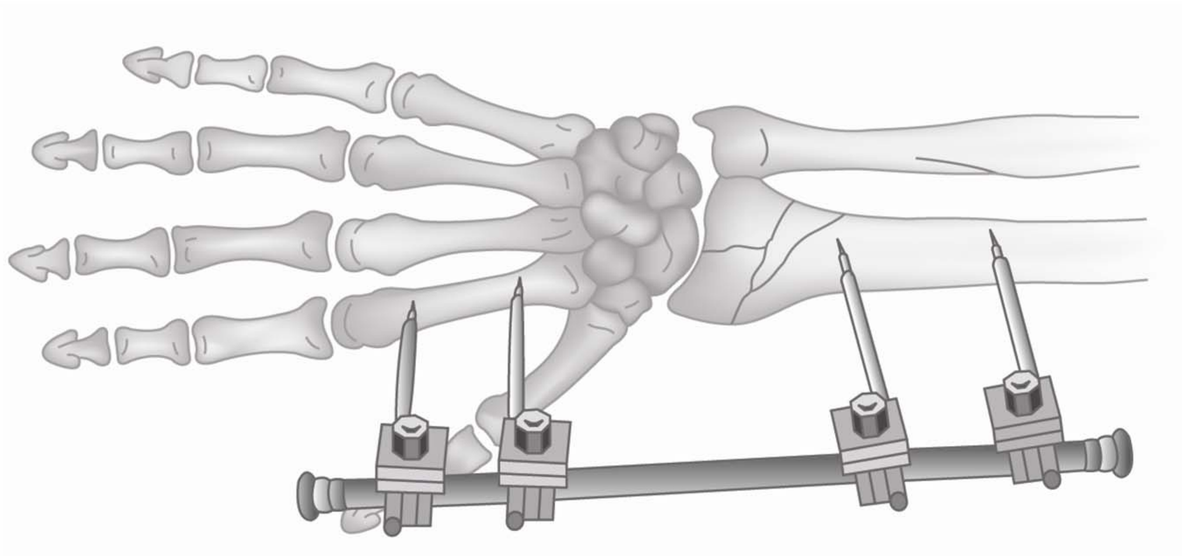


BIOMATERIAL APPLICATIONS AND EXAMPLES



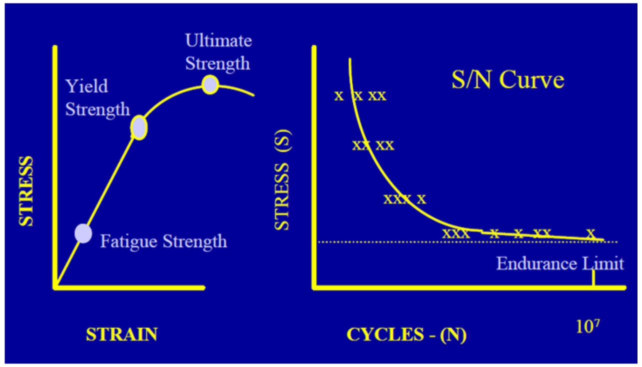
- Fracture of the humeral shaft.
  - Fixed by a locked intramedullary rod.
  - Use of transverse screws through holes in the ends of the rods.

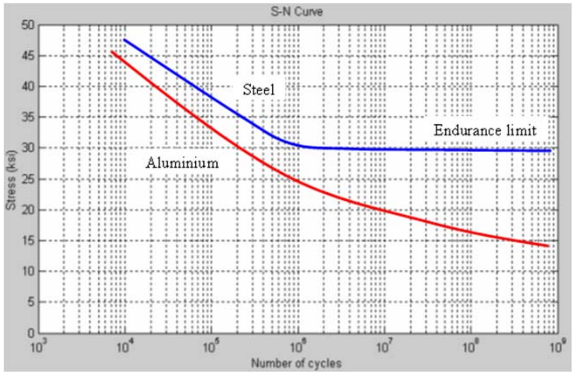
- External fixator for a fracture of distal radius



BIOMATERIALS MECHANICAL PROPERTIES

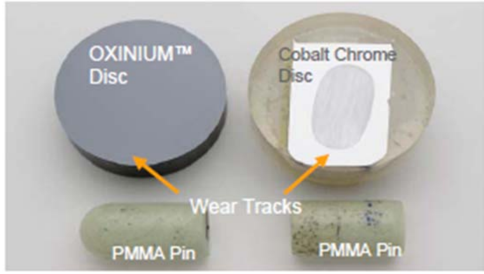
Biomaterial	ASTM DESIGNATION	Condition	Elastic Modulus [GPa]	Yield Stress [MPa]	Ultimate stress [MPa]	Fatigue Limit Stress [MPa]
Stainless Steel	F55/F56	Annealed	190	331	586	241-276
Stainless Steel	F138/F139	Cold Forged	190	1213	1351	820
Cobalt Alloy	F75	Cast./Annealed	210	448-517	655-889	207-310
Cobalt Alloy	F799	Hot forged	210	896-1200	1399-1586	600-896
Cobalt Alloy	F90	Annealed	210	310	860	-
Cobalt Alloy	F562	Hot forged	232	965-1000	1206	500
Titanium Alloy	F67	Cold worked	110	485	760	300
Titanium Alloy	F136	Annealed	116	896	965	620
Oxinium			50	455	378	

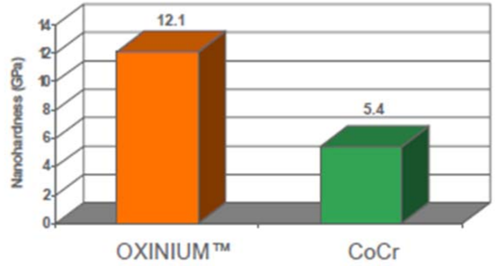


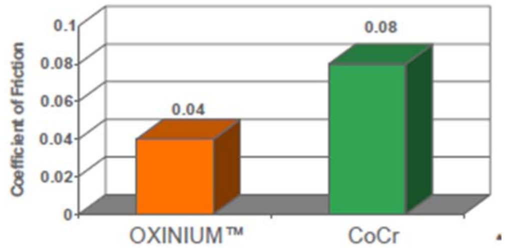


CERAMIC BIOMATERIAL

- Most comoun ceramics:
  - Alumina (aluminum oxide);
  - Zirconia (zirconium oxide);
  - Oxinium (recent developed material; new metal alloy (zirconium-Niobium) that presents a ceramic surface, produced by an oxidation process).
- Advantages:
  - Dense and hard (good against scratch resistance);
  - High quality external surface.

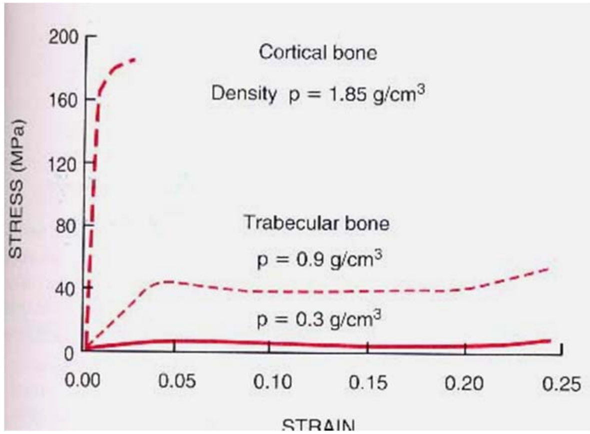






BIOMECHANICS OF MATERIALS

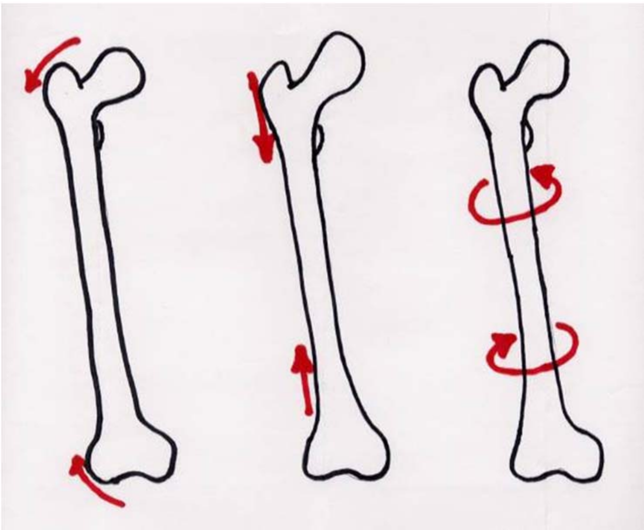
- Anisotropic
  - Mechanical properties dependent upon direction of loading.
  - Bone is anisotropic - its modulus is dependent upon the direction of loading.
  - Bone is weakest in shear, then tension, then compression.
  - Ultimate Stress at Failure Cortical Bone:
    - Compression < 212 N/m2
    - Tension < 146 N/m2
    - Shear < 82 N/m2

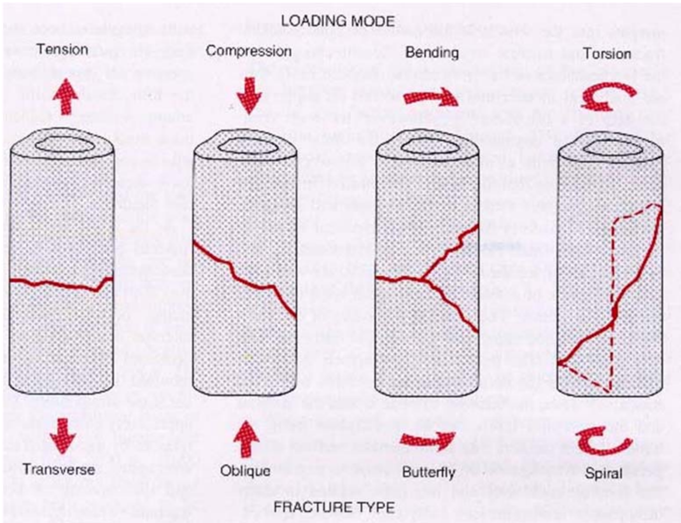


- Viscoelastic
  - Stress-Strain character dependent upon rate of applied strain (time dependent).
  - Ex: Ligaments.

INTRODUCTION TO DESIGN

- FAILURE, COLLAPSE:
  - Load to Failure
    - Continuous application of force until the material breaks (failure point at the ultimate load, ULS).
    - Common mode of failure of bone and reported in the implant literature.
  - Fatigue Failure
    - Cyclical sub-threshold loading may result in failure due to fatigue.
    - Common mode of failure of orthopaedic implants and fracture fixation constructs.



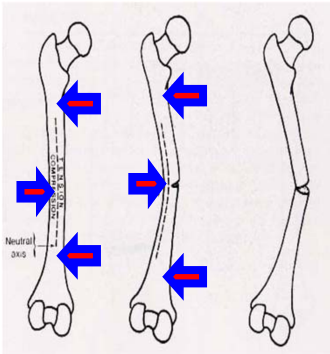


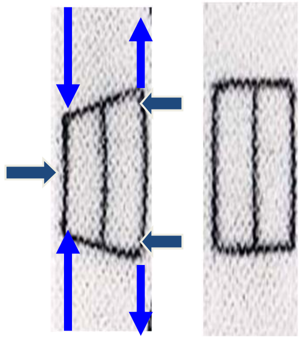
Browner et al: Skeletal Trauma 2nd Ed, Saunders, 1998.

BIOMECHANICS OF FRACTURES AND FIXATION

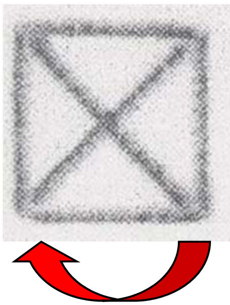
- Fracture mechanics:
  - Bending load: As compression resistance is grater than tension, bone fails in tension

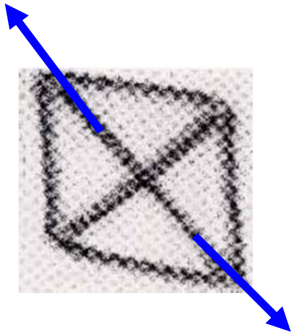
Tencer. Biomechanics in Orthopaedic Trauma, Lippincott, 1994.

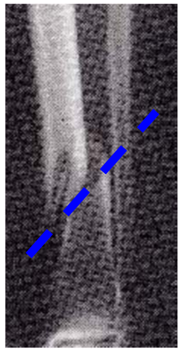




  - Torsion: The diagonal in the direction of the applied force is in tension – cracks perpendicular to this tension diagonal. Spiral fracture 45º to the long axis

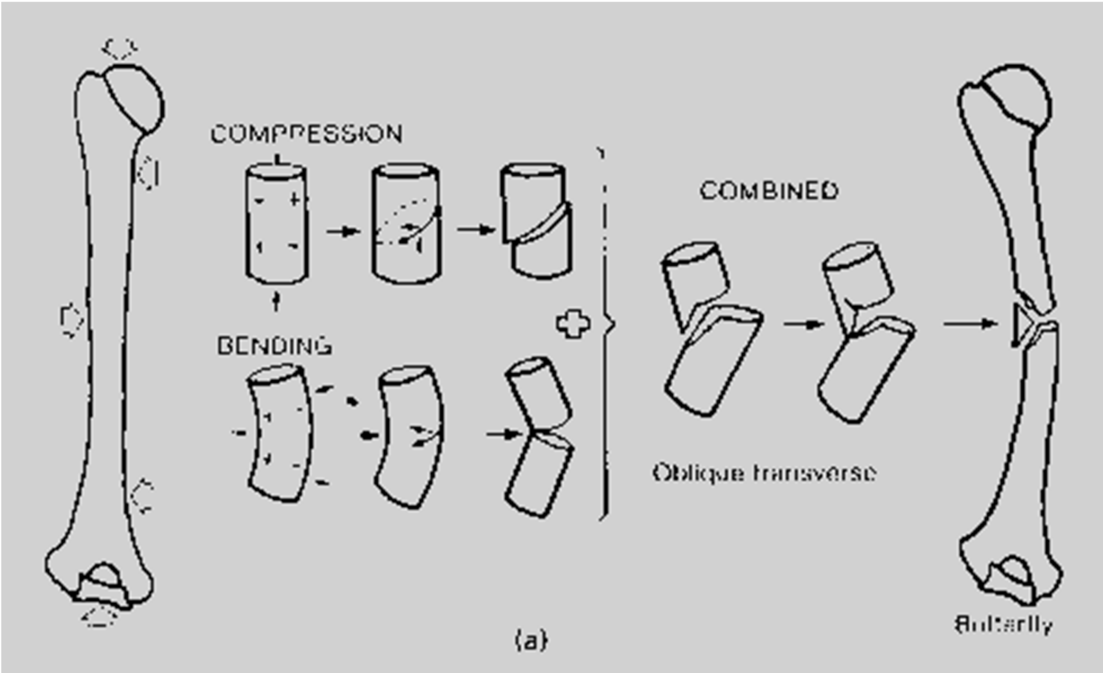






BIOMECHANICS OF FRACTURES AND FIXATION

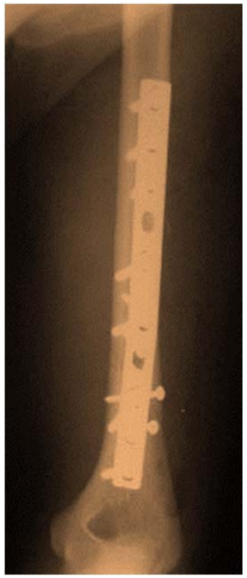
- Fracture mechanics:
  - Bending and axial load: Leads to oblique fracture and Butterfly fragment

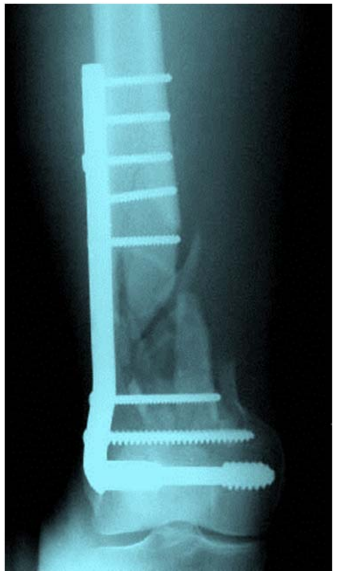


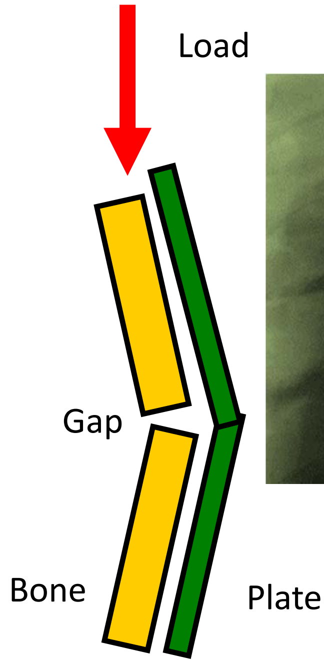
Tencer. Biomechanics in Orthopaedic Trauma, Lippincott, 1994.

BIOMECHANICS OF FRACTURES AND FIXATION

- Function of the plate:
  - Internal splint and Compression.
- Unstable constructs:
  - May lead to severe fragmentation, bone loss, poor quality bone and poor screw technique.
- Fracture Gap:
  - Allows bending of plate with applied loads.
  - Fatigue failure. Even stable constructs may fail from fatigue if the fracture does not heal due to biological reasons.



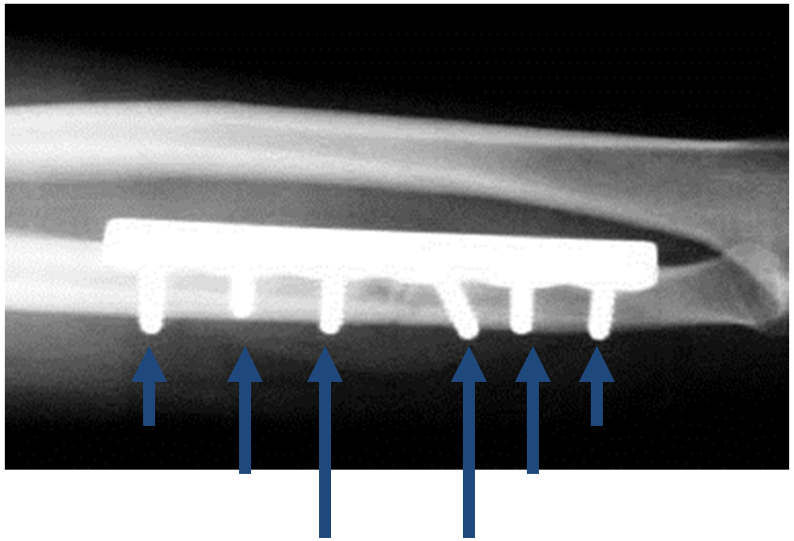




BIOMECHANICS OF FRACTURES AND FIXATION

- The screws closest to the fracture see the most forces.
- The construct rigidity decreases as the distance between the innermost screws increases.
- Number of screws (cortices) recommended on each side of the fracture:

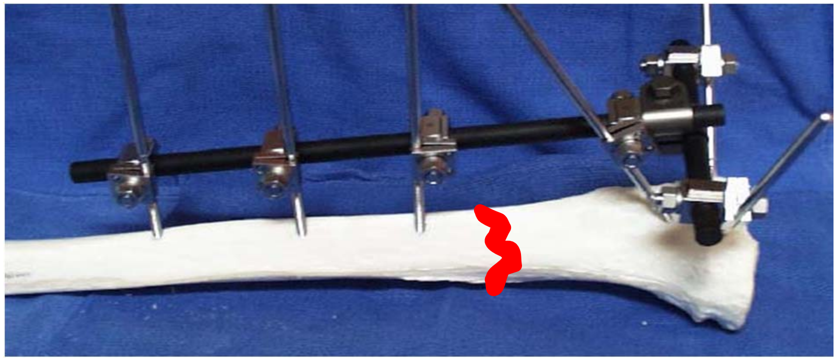
– Forearm	3	(5-6)
– Humerus	3-4	(6-8)
– Tibia	4	(7-8)
– Femur	4-5	(8)

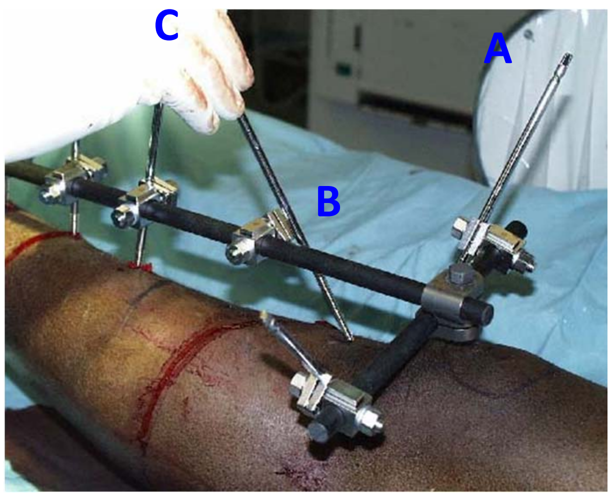


Screw Axial Force

BIOMECHANICS OF EXTERNAL FIXATION

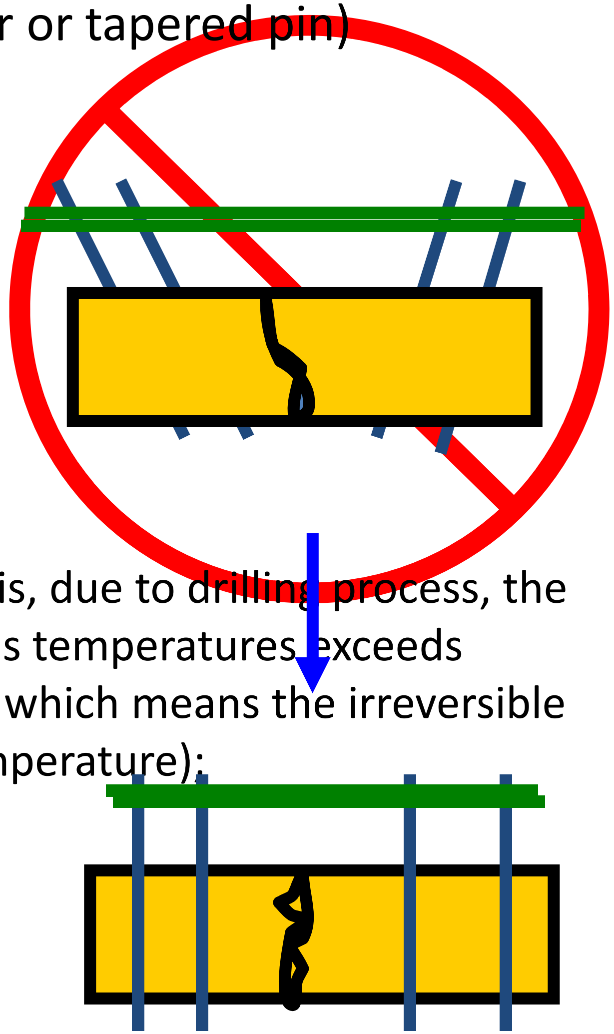
- Pin Size
  - Radius. Most significant factor in frame stability.
- Number of Pins
  - Two per segment. Third pin: (C) out of plane of two other pins (A & B) stabilizes that segment.
- Pin Location
  - Avoid zone of injury or future ORIF, Pins close to fracture as possible. Pins spread far apart in each fragment.





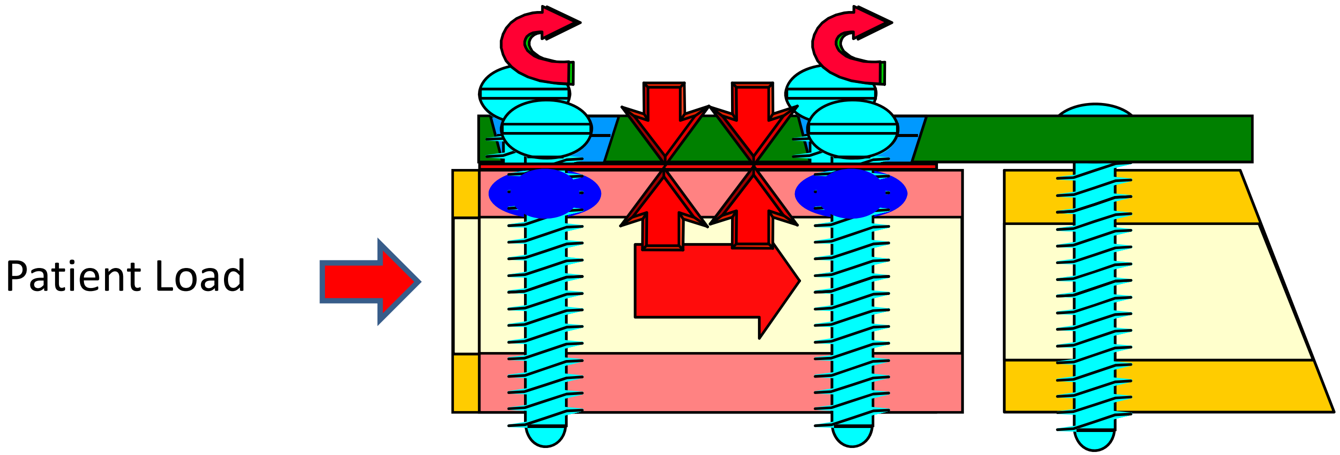
BIOMECHANICS OF EXTERNAL FIXATION

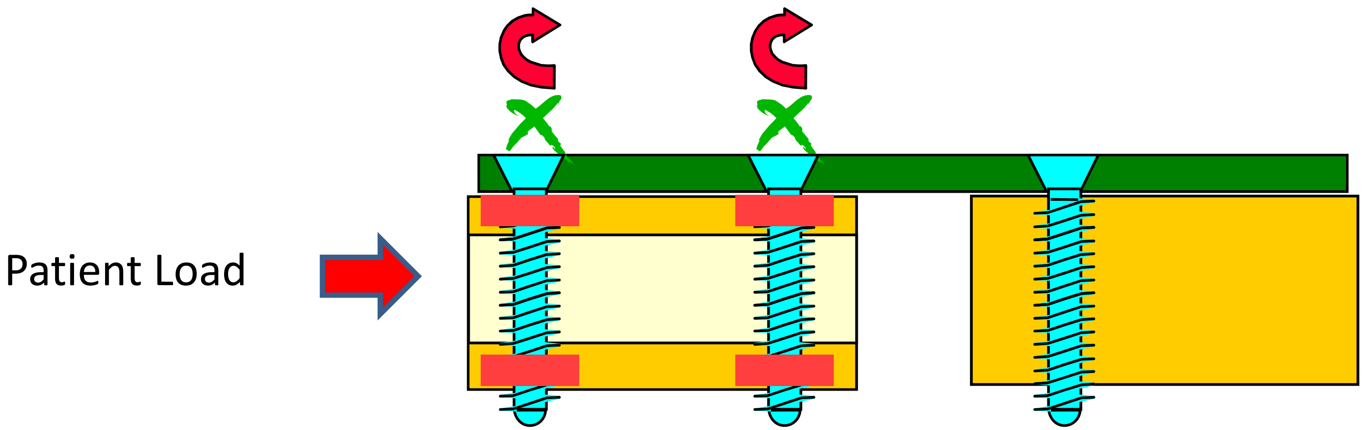
- Pin Bending Preload:
  - Bending preload not recommended
- Radial preload (predrill w/ drill < inner diameter or tapered pin)
  - may decrease loosening and increase fixation
- Increase stability by:
  - Increasing the pin diameter;
  - Increasing the number of pins;
  - Increasing the spread of the pin;
  - Multi-planar fixation;
  - Reducing the bone-frame distance;
  - Pre-drilling and cooling (reduces thermal necrosis, due to drilling process, the surrounding bone tissue is heated, and when this temperatures exceeds critical limit, this may result in thermal necrosis, which means the irreversible death of the bone cells exposed to that high temperature);
  - Radially preload pins,
  - 90º tensioned wires;
  - Stacked frames.



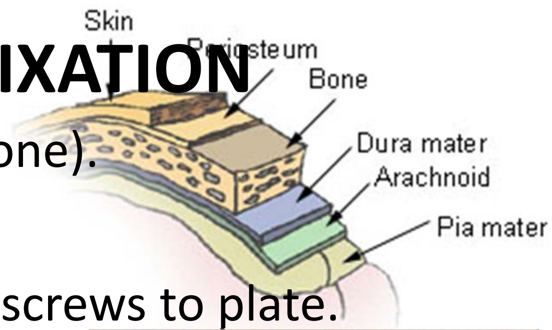
BONE–FIXATOR PLATE

- Good plate fixation procedure:
  - When patient load is smaller than friction force.
  - When patient load is smaller than compressive Strength of the Bone.

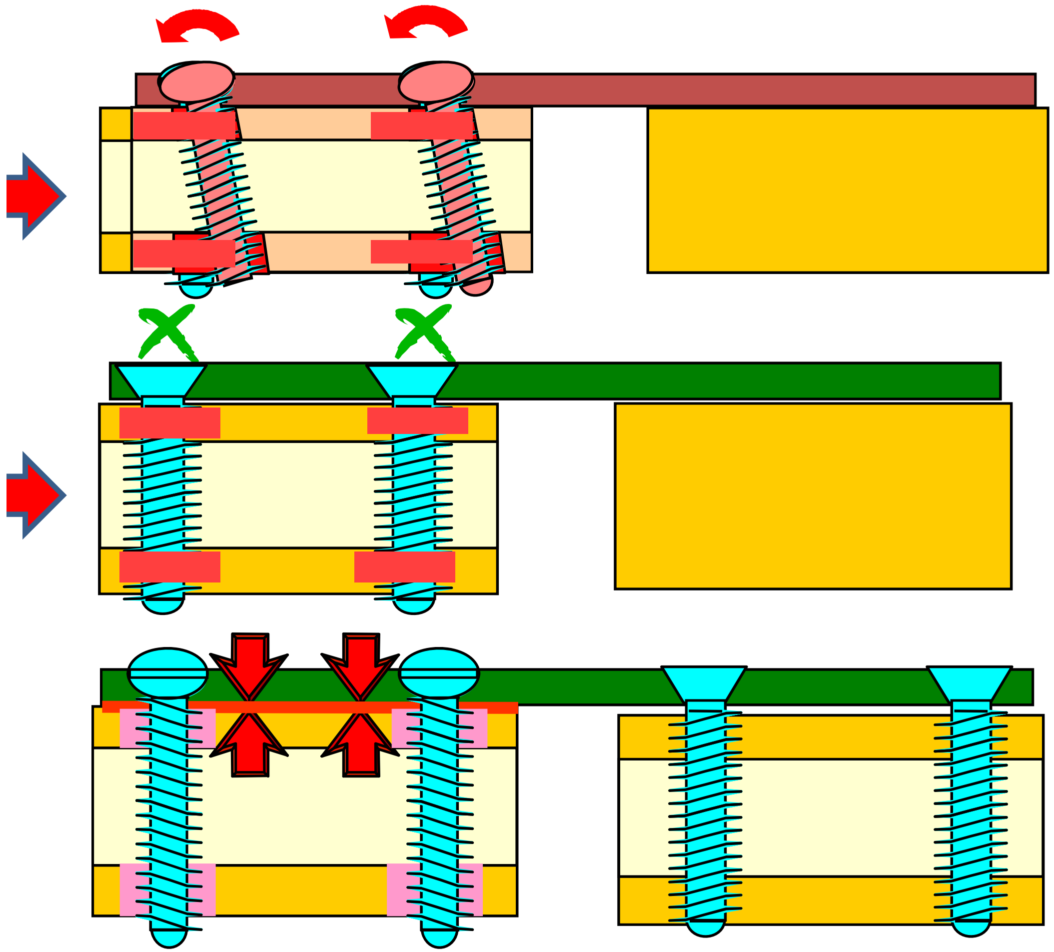




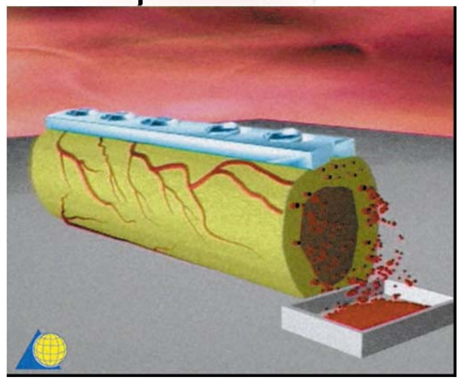
ADVANTAGES OF LOCKED PLATE FIXATION



- Purchase of screws to bone not critical (osteoporotic bone).
- Preservation of periosteal blood supply.
- Strength of fixation rely on the fixed angle construct of screws to plate.



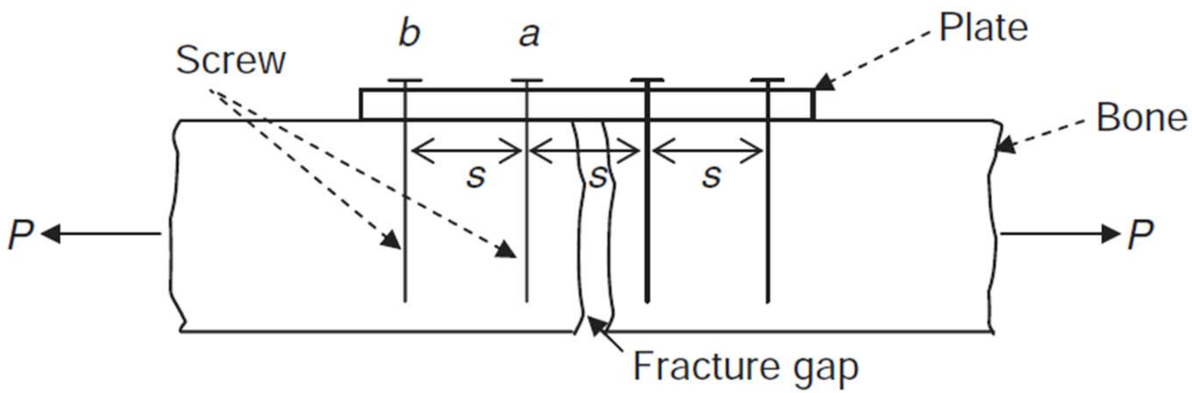
Conventional plating Loced plating

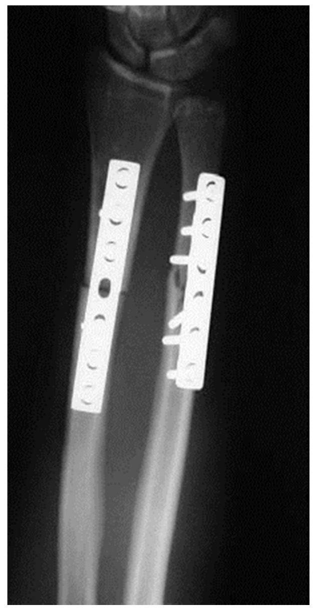


- Conventional plating:
  - Bone is pre-stressed;
  - Periosteum strangled.
  - Contour of plate is important to maintain anatomic reduction
- Locked plating:
  - Plate (not bone) is pre-stressed;
  - Periosteum preserved.
  - Contour of plate not as important.
  - Reduce fracture prior to applying locking screws.

ANALYSIS OF INTERNAL FIXATION OF A FRACTURED BONE BY MEANS OF BONE–FIXATOR PLATE

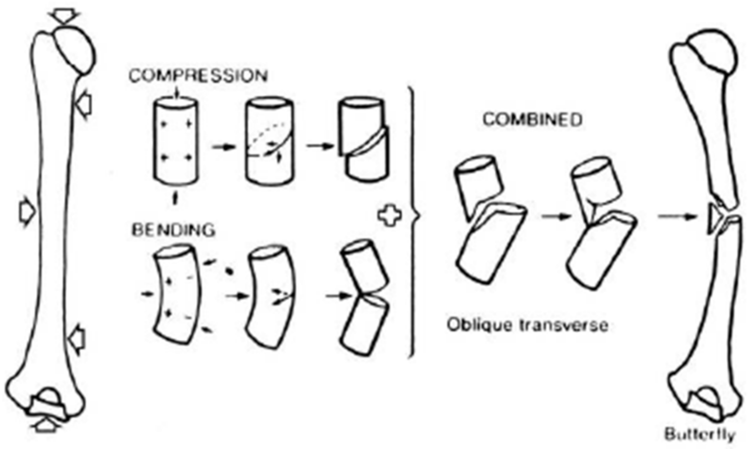
- Introduction and Scope:
  - Fracture-fixed long bones are submitted to axial load and bending loads, due to eccentricity. This last load tends to open fracture, leading to the reduction in the stability of the fixation.
  - Analytical model to predict forces to be applied in the screws, stresses in the bone and plate.
  - Optimal plate selection to minimize deformation of the fractured bone, as well as introducing stress shielding into account.
  - Advanced calculation method (FEA) to analyze stiffness graded plate, against homogeneous stiffness, to determine the extent of increased stress shielding.

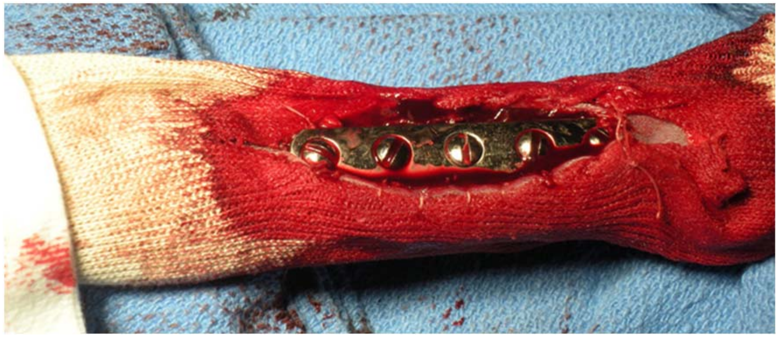




BONE–FIXATOR PLATE - ANALYSIS MODEL

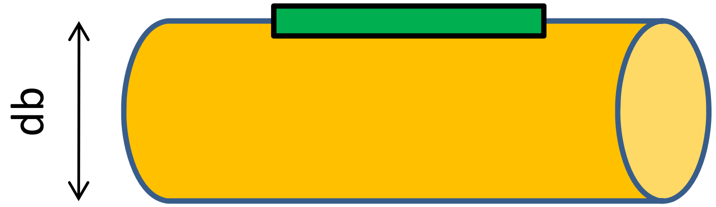
- Bone plate assembly:
  - Considered as composite beam;
  - Remodelling eliminates most part of the stress concentration effect of the screw holes;
  - The service load and load transfer will be process through plate and screws, until the fracture is healed.

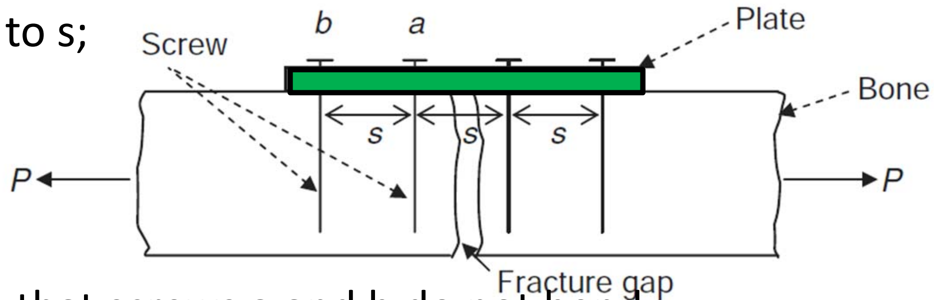




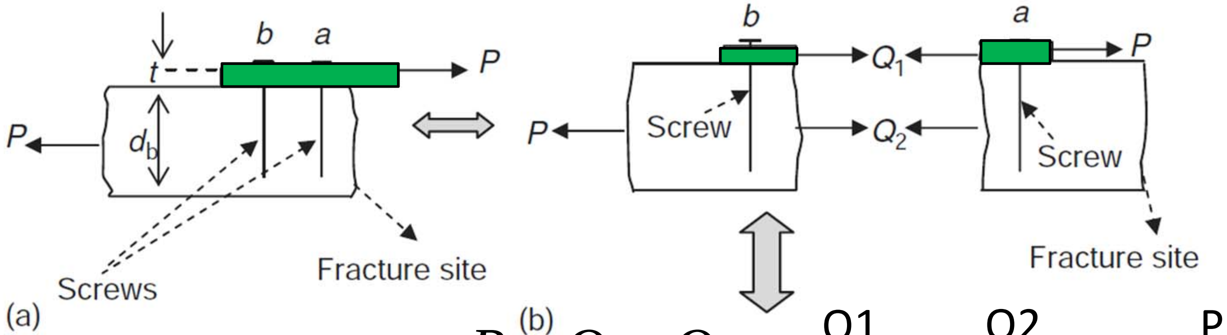
BONE–FIXATOR PLATE - LOADS

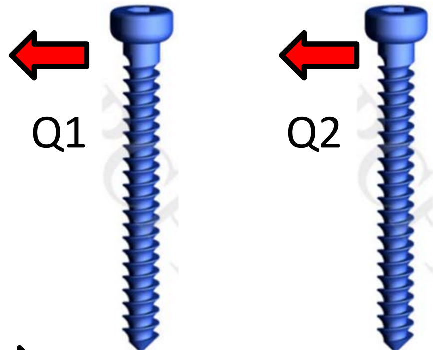
- Bone: Weak in tension, strengthen in compression.
- Loads: Service load produces internal forces: Normal, bending, torsion and shear.
- **Load case 1 (axial load), Perfect Bond between the Bone and the Plate :**
  - Assume axial force P;
  - Space between screws equal to s;



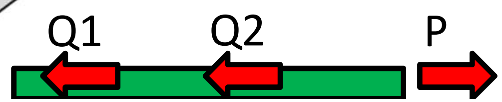


  - Free body diagram, assuming that screws a and b do not bend:
    - Q2 is part of the load P diverted by screw "a";
    - Q1 is the remainder force deliver by the plate, through screw "b" to the bone.



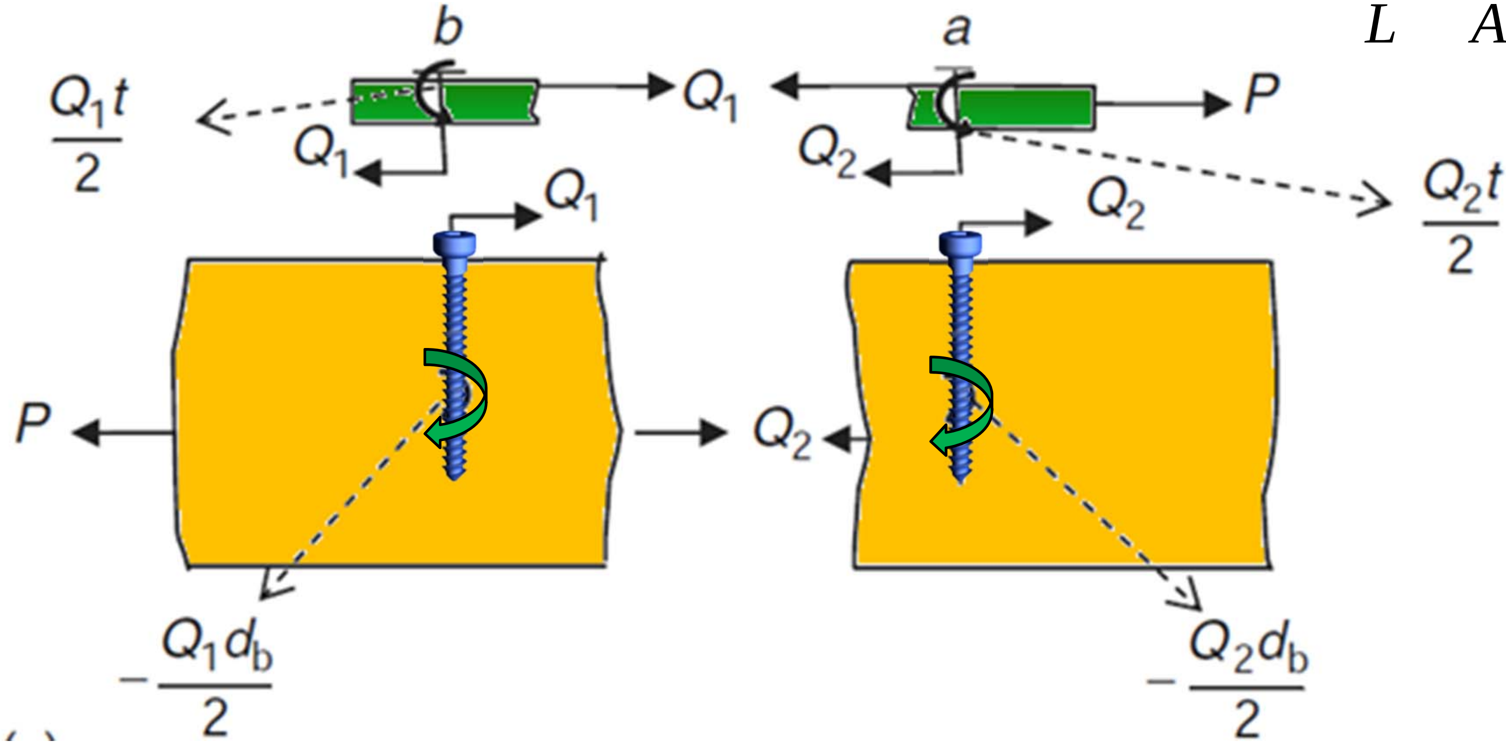


$$P = Q_1 + Q_2$$



BONE–FIXATOR PLATE – STRAIN COMPATIBILITY

- The internal forces applied by the screws on bone:
  - If 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;
  - The plate and the bone are deemed to be firmly held together;
  - Assuming strain calculation of uniform element as function of the cross-section area A, and elastic modulus E, when subjected to axial force F: $\varepsilon = \frac{\delta}{L} = \frac{F}{AE}$



  - The following conditions verifies: $\varepsilon_p = \varepsilon_b$

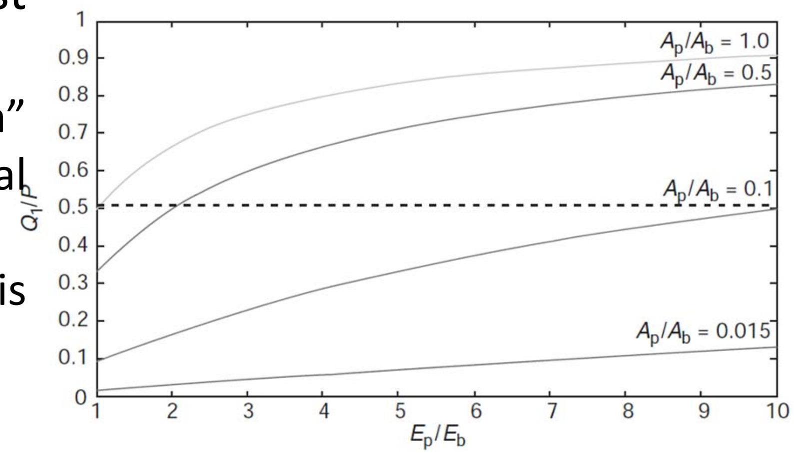
BONE–FIXATOR PLATE – STRAIN COMPATIBILITY

- Strain compatibility for bone–plate assembly under uniaxial tensile=compressive load :
  - Allows to determine internal forces, as function of an non-dimensional cross section and non-dimensional elastic modulus.

$$\varepsilon_p = \varepsilon_b \Leftrightarrow \frac{Q_1}{A_p E_p} = \frac{Q_2}{A_b E_b} \Leftrightarrow \frac{Q_1}{P} = \frac{\frac{A_p E_p}{A_b E_b}}{1 + \frac{A_p E_p}{A_b E_b}} \Leftrightarrow \frac{Q_1}{P} = \frac{\overline{A}\,\overline{E}}{1 + \overline{A}\,\overline{E}}$$

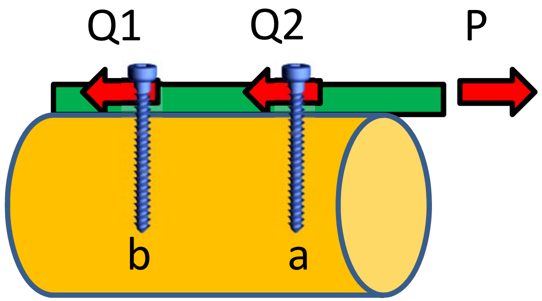
$$\varepsilon_p = \varepsilon_b \Leftrightarrow \frac{Q_1}{P} = \frac{A_p E_p}{A_b E_b + A_p E_p}$$

- From graphical representation of the last equation :
  - The proportion of force P diverted by screw “a” into the bone depends on non-dimensional area and elastic modulus;
  - The load transferred by the screws is independent from their spacing “s”.



BONE–FIXATOR PLATE – SCREWS

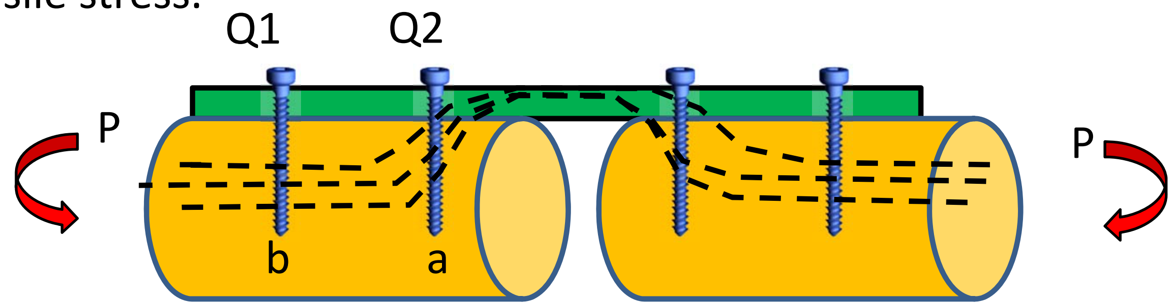
- Substituting representative values for bone and plate dimensions, as well as for the elastic modulus, (b= 10 [mm], t= 2 [mm] and db=40 [mm]; Ep/Eb=10).
  - Q1 is less than half the value of force P;
  - Screw “b” transfers less of plate force P than screw “a” proximal to the fracture site.



- From the analytical point of view:
  - Two screws can not equally split the applied load, because:
    - Ap/Ab would be equal to 0.1, for a representative value of Ep/Eb=10. This leads us to a unpractical dimensional of “t”.
  - The analysis is only valid for small strain values.

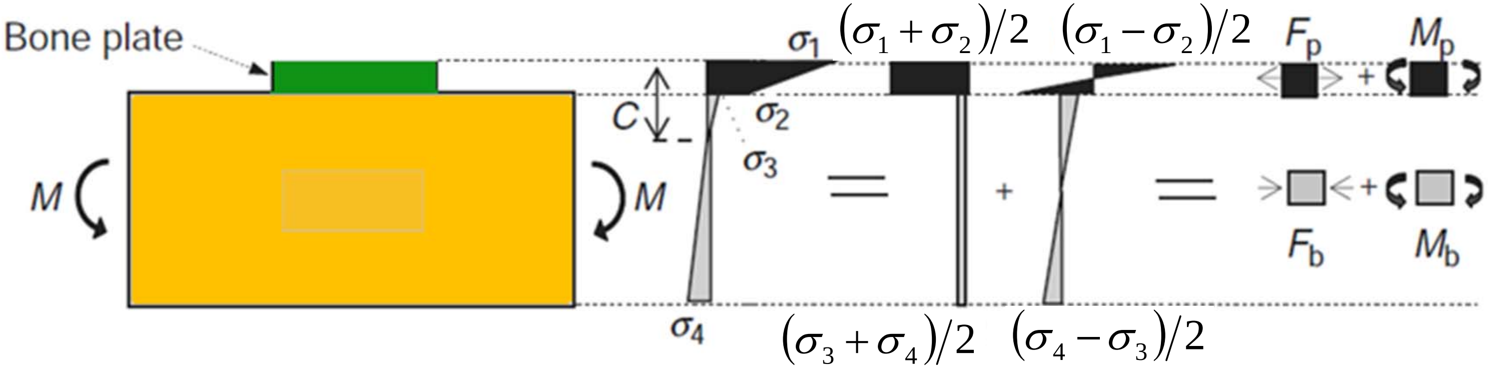
BONE–FIXATOR PLATE - LOADS

- **Load case 2 (Bending load), Perfect Bond between the Bone and the Plate:**
  - After fracture fixation and when tensioned, the plate shields the bone from tensile stresses at the fracture interface.
- Problem:
  - Shielding is important to promote healing, while shielding away from fractured zone can cause osteoporosis and reduction in bone strength.
- Solution:
  - Good design should promote neutral axis to be at plate-bone interface, near the fracture zone, to ensure that no tensile stresses are transferred to the callus while it is being formed;
  - Good design should promote neutral axis to be into the bone, away from the fracture zone, to ensure that bone is subjected to the normally prevalent tensile stress.



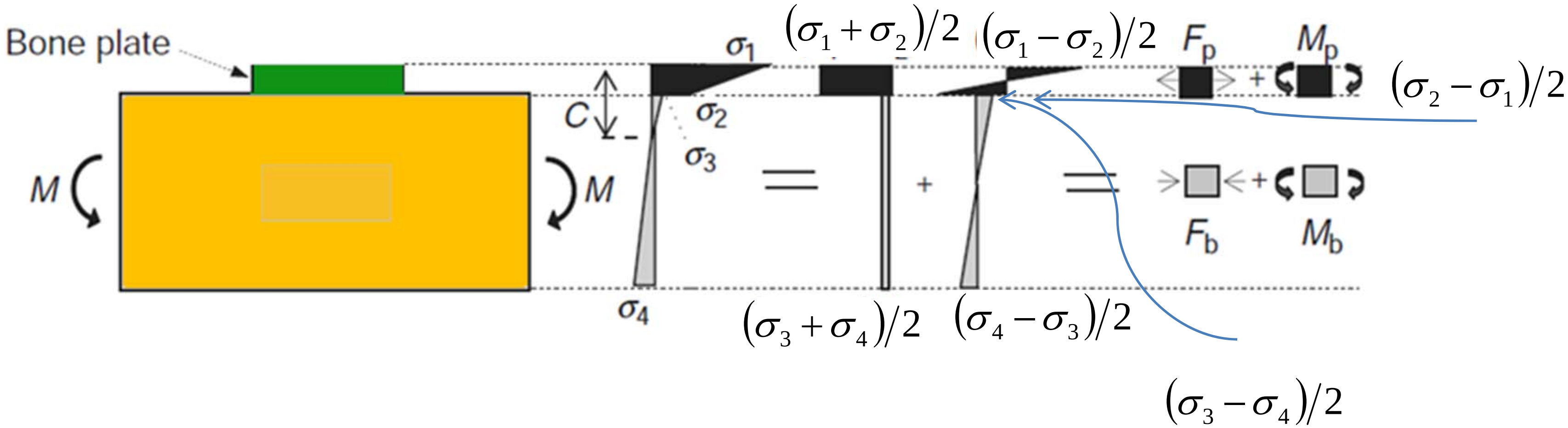
BONE–FIXATOR PLATE – COMPOSITE BEAM THEORY

- When Bone-Plate assembly is subjected to bending:
  - The material above neutral axis is subjected to tensile stresses;
  - The material bellow neutral axis is subjected to compressive stresses.
- Principle:
  - For a fractured bone, the plate is preferably fixed on the tension side of the bone.
- Strain compatibility:
  - The curvature or bending deformation should be the same in the plate and the bone, along the contact (bone and plate) interface.
  - To identify the role of the screws, verify the normal stress distribution:
    - $\sigma 1$ and $\sigma 2$ = normal stress at top and bottom surface of the plate, respectively;
    - $\sigma 3$ and $\sigma 4$ = normal stress at top and bottom surface of the bone, respectively.

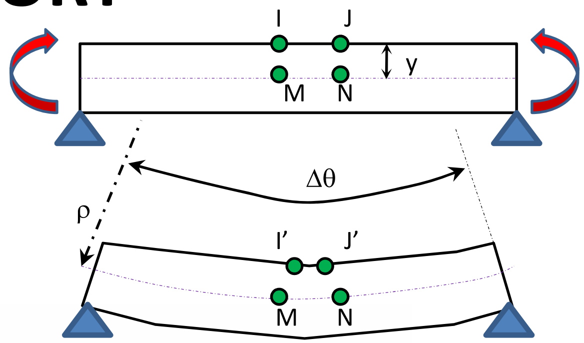


BONE–FIXATOR PLATE – COMPOSITE BEAM THEORY

- Stress in plate:
  - Axial stress due to an axial tension force Fp: (σ1+σ2)/2;
  - Axial stress due to bending moment Mp, with maximum stress equal to: (σ1-σ2)/2.
- Stress in the bone:
  - Axial stress due to an axial compressive force Fb: (σ3+σ4)/2;
  - Bending stress due to a bending moment Mb, with maximum stress equal to: (σ3-σ4)/2;
- Stress at the interface is different because:
  - materials present different Elastic Modulus. $\sigma_2 = E_p\ \varepsilon$ $\sigma_3 = E_b\ \varepsilon$



COMPOSITE BEAM THEORY

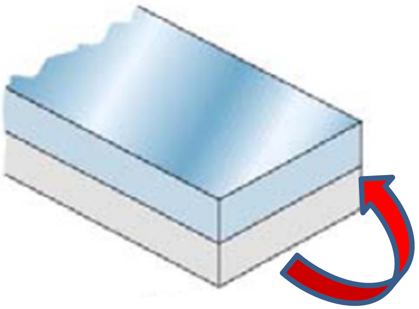


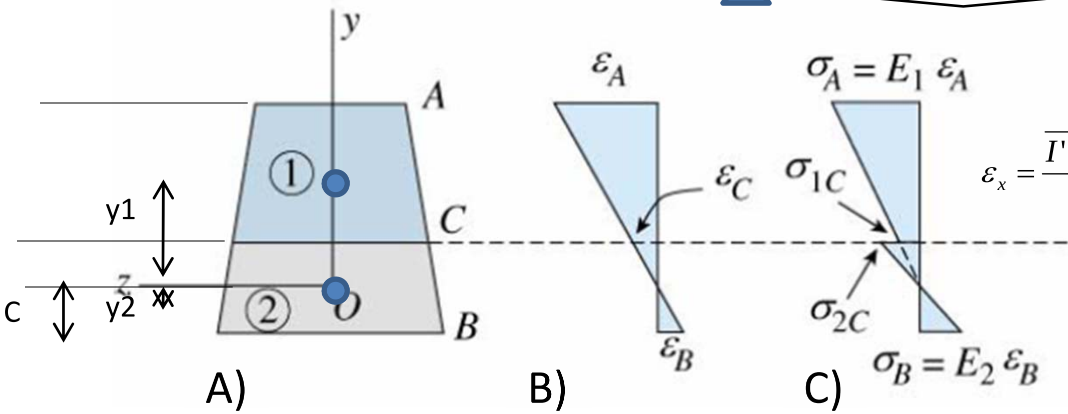
$$\overline{I'J'} = (\rho - y)\Delta\theta$$

$$\overline{MN} = \rho\Delta\theta$$

$$\varepsilon_x = \frac{\overline{I'J'} - \overline{IJ}}{\overline{IJ}} = -\frac{y}{\rho} = -ky$$

- Composite beam with two different materials:
  - A) Generic cross-section ;
  - B) Normal strain distribution;
  - C) Normal stress distribution, case when E2>E1.





  - Beam theory:

$$\sigma_A = E_1\varepsilon_A \qquad \varepsilon = -\frac{y}{\rho} \qquad \sigma_{x1} = -E_1\, k\, y$$

$$\sigma_B = E_2\varepsilon_B \qquad \sigma_{x2} = -E_2\, k\, y$$

1st order moment of each area respect to neutral axis

  - Neutral axis: $\int_{A_1} \sigma_{x1}\, dA_1 + \int_{A_2} \sigma_{x2}\, dA_2 = 0 \Leftrightarrow \int_{A_1} -E_1 ky\, dA_1 + \int_{A_2} -E_2 ky\, dA_2 = 0 \Leftrightarrow -E_1 k \int_{A_1} y\, dA_1 - E_2 k \int_{A_2} y\, dA_2 = 0$
  - Moment curvature relationship: $\Leftrightarrow -E_1(y_1 A_1) - E_2(y_2 A_2) = 0$

$$M = -\int_A \sigma_x\, y\, dA = -\int_{A_1} \sigma_{x1}\, y\, dA_1 - \int_{A_2} \sigma_{x2}\, y\, dA_2 = k\, E_1 \int_{A_1} y^2\, dA_1 + k\, E_2 \int_{A_2} y^2\, dA_2 = k(E_1 I_1 + E_2 I_2)$$

$$k = M/(E_1 I_1 + E_2 I_2)$$

BONE–FIXATOR PLATE – COMPOSITE BEAM THEORY

- Normal stresses for composite beams (theory):

$$\sigma_A = -E_1 k y = -E_1 y \frac{M}{E_1 I_1 + E_2 I_2} \qquad \sigma_B = -E_2 k y = -E_2 y \frac{M}{E_1 I_1 + E_2 I_2}$$

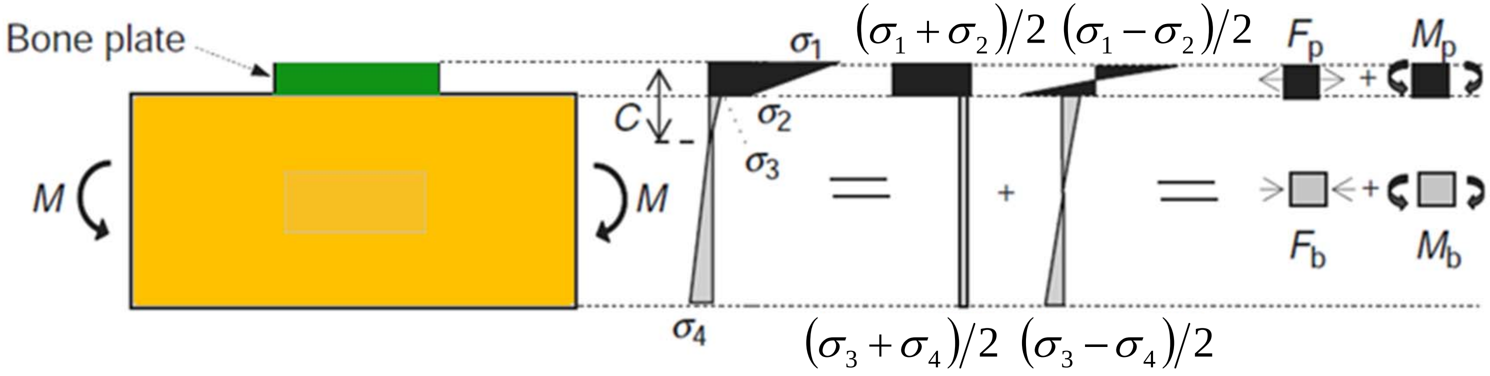
- For the case of bone-fixator plate:

$$\sigma_1 = \frac{M E_p C}{E_p I'_p + E_b I'_b} \qquad \sigma_2 = \frac{M E_p (C-t)}{E_p I'_p + E_b I'_b} \qquad I'_p = I_p + A_p \times y_1^2$$

$$I'_b = I_b + A_b \times y_2^2$$

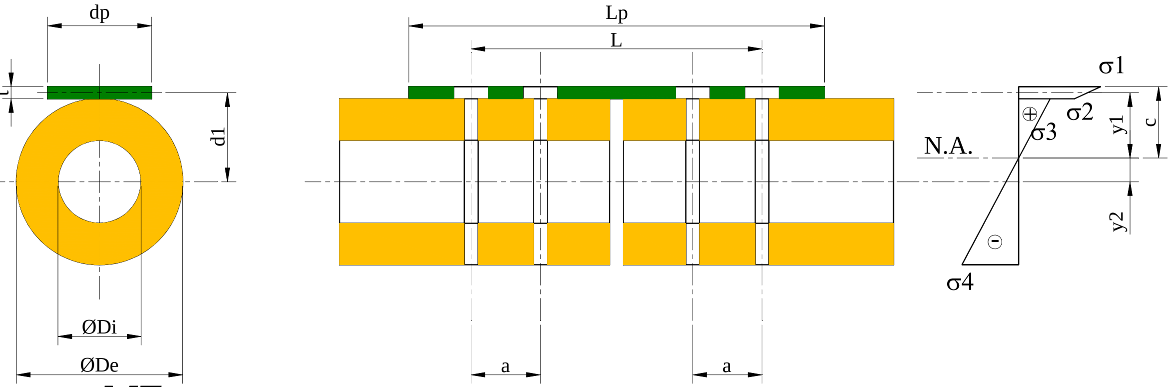
$$\sigma_3 = \frac{M E_b (C-t)}{E_p I'_p + E_b I'_b} \qquad \sigma_4 = -\frac{M E_b (d_b + t - C)}{E_p I'_p + E_b I'_b}$$

  - At contact level, stresses are different because the elastic modulus are different;
  - Y1 represents the distance between neutral axis and the centre of the plate;
  - Y2 represents the distance between neutral axis and the centre of the bone.



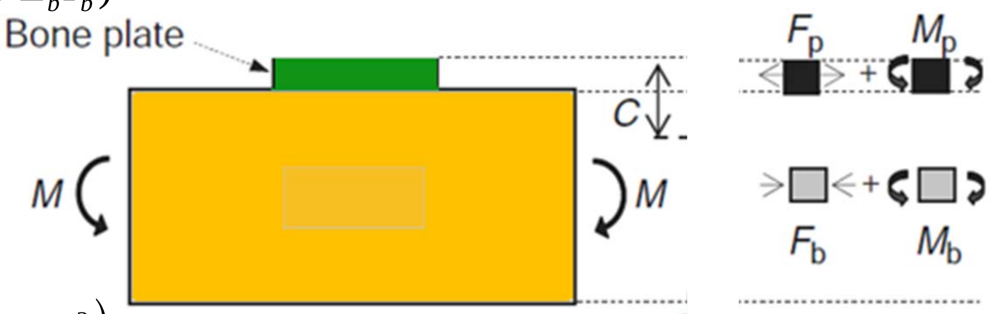
BONE–FIXATOR PLATE – COMPOSITE BEAM THEORY

- Moments and axial forces shared by the plate and bone may be calculated according to:
  - Plate:



$$F_p = \left[\frac{\sigma_1 + \sigma_1}{2}\right] \times A_p = \frac{ME_p(2C - t)}{2(E_p I_p^{'} + E_b I_b^{'})}(d_p t)$$

$$M_p = \left[\frac{\sigma_1 - \sigma_2}{2}\right] \times \frac{I_p^{'}}{\frac{t}{2}} = \frac{ME_p t}{2(E_p I_p^{'} + E_b I_b^{'})}\frac{I_p^{'}}{\frac{t}{2}} = \frac{ME_p}{(E_p I_p^{'} + E_b I_b^{'})} I_p^{'}$$



  - Bone:

$$F_b = -\left[\frac{\sigma_3 + \sigma_4}{2}\right] \times A_b = -\frac{ME_b(2C - 2t - D_e)}{2(E_p I_p^{'} + E_b I_b^{'})}\frac{\pi}{4}(D_e^{2} - D_i^{2})$$

$$M_b = \left[\frac{\sigma_3 - \sigma_4}{2}\right] \times \frac{I_b^{'}}{\frac{D_e}{2}} = \frac{ME_b(D_e)}{2(E_p I_p^{'} + E_b I_b^{'})}\frac{I_b^{'}}{\frac{D_e}{2}} = \frac{ME_b}{(E_p I_p^{'} + E_b I_b^{'})} I_b^{'}$$

- Neutral axis:

$$\Leftrightarrow -E_p(y_p A_p) - E_b(y_b A_b) = 0$$

$$\Leftrightarrow -E_p\left(-(C - \frac{t}{2})A_p\right) - E_b\left((\frac{D_e}{2} + t - C)A_b\right) = 0$$

$$\Leftrightarrow C = \frac{\overline{EA}\, t + 2t + De}{2(\overline{EA} + 1)}$$

SECOND ORDER BEAM THEORY

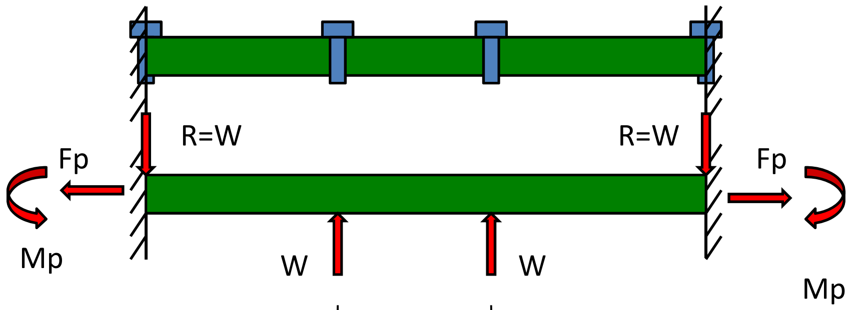
- **Second Order Theory of Deflections for the Linear Elastic Isotropic Beams**
  - the second order theory enables to include directly the influence of the normal forces along the beam on its deflection function.
  - From the mathematical point of view, the differential equation adequate to the deflection function is written on the deformed configuration of this beam, so that the normal forces can play significant role in the beam strength.
- For more information, please read information about in maple software - application center - user community

BONE–FIXATOR PLATE – SCREW DESIGN

- Consider the fixed end plate and bone model to determine screw load, based on the following free body diagram and equilibrium in the deformed shape:
  - For the plate and x<a:

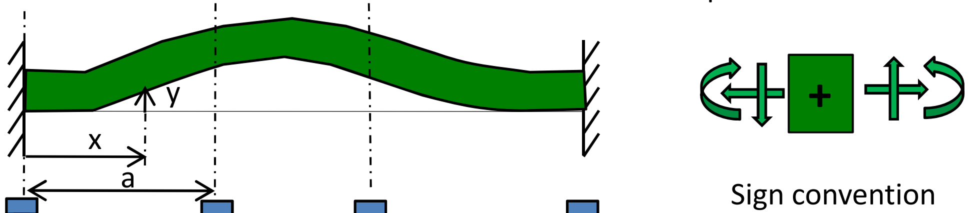
$$M_{fp} = -M_p - Wx + F_p y_p$$

$$\frac{d^2 y_p}{dx^2} = \frac{M_{fp}}{EI}$$



  - Boundary conditions:

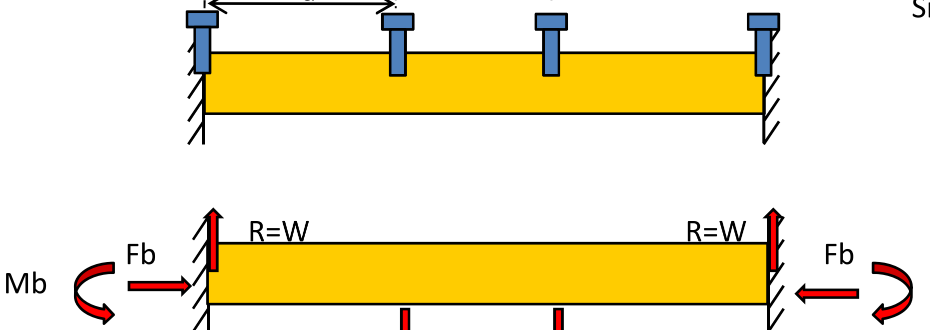
$$x = 0 \Rightarrow y_p = 0 \quad \wedge x = 0 \Rightarrow \frac{dy_p}{dx} = 0$$



  - For the bone and x<a:

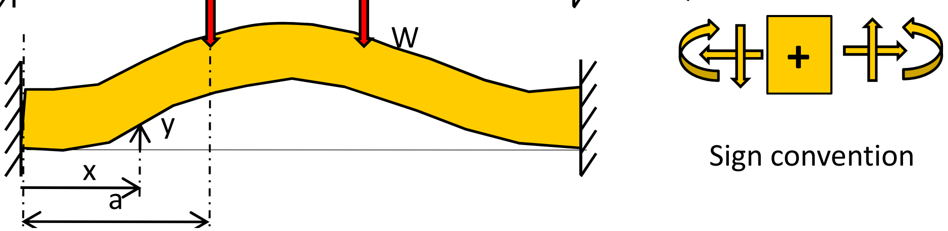
$$M_{fb} = -M_b + Wx - F_b y_b$$

$$\frac{d^2 y_b}{dx^2} = \frac{M_{fb}}{EI}$$



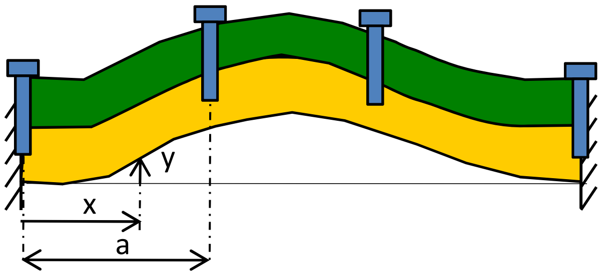
  - Boundary conditions:

$$x = 0 \Rightarrow y_b = 0 \quad \wedge x = 0 \Rightarrow \frac{dy_b}{dx} = 0$$



BONE–FIXATOR PLATE – SCREW FORCES

- Assuming the compatibility criteria for strain at the contact level, for the composite beam during and after healing.
- The screw forces "W" on the plate and on the bone are equal in magnitude and opposite in direction, and conform the plate and the bone to have the same amount of deflection. Under this loading, the compliant bone would deform more than the plate. Screws have to apply a residual force W, to conform plate and bone to have the same amount of deflection.
  - Forces W, exerted at the plate and bone by the inner screws;
  - Forces R, exerted at the plate and bone by the outer screws.



- Imposing the deflection criteria for x=a, and using MAPLE symbolic manipulator.

$$y_p(x=a) = y_b(x=a) \quad \Leftrightarrow$$

ODE SYMBOLIC SOLUTION FOR SCREW FORCES WITH MAPLE

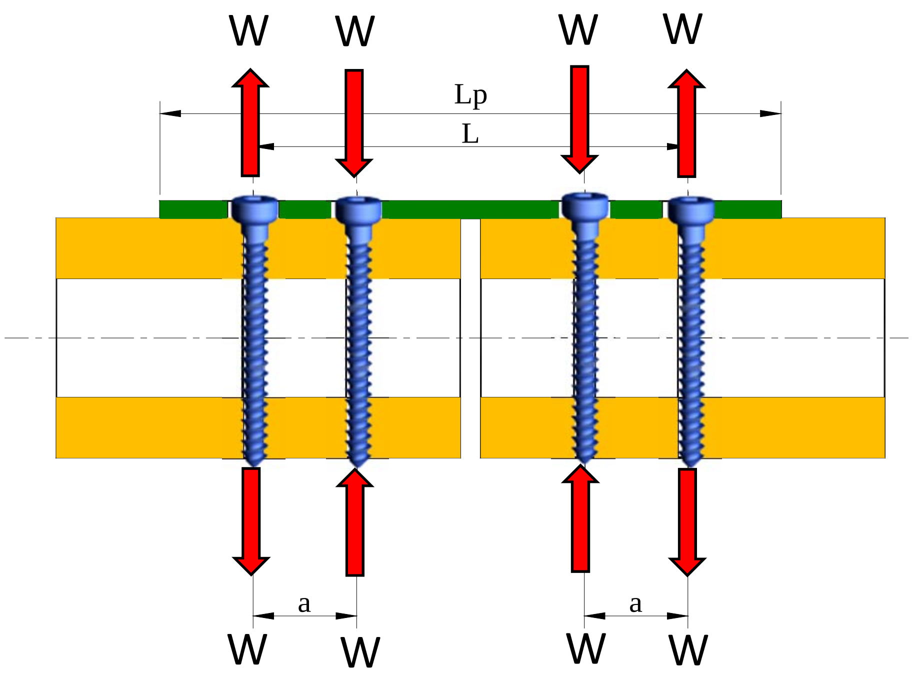
Maple 13 The Essential Tool for Mathematics and Modeling

```
> restart;
> M := M;
> Eb := Ebc;
> Ep := Ep;
> Et := Ep/Eb;
> De := De;
> Di := Di;
> t := t;
> dp := dp;
> Ip := Ip;
> Ap := dp*t;
> Ab := Ab;
> d1 := (1/2)*De+(1/2)*t;
> At := Ap/Ab;
> Ib := Ib;
> It := Ip/Ib;
> C := (De+2t+AtEt*t)/(2*(At*Et+1));
> W := W;
> Ipl := Ip+dp*t*(C-(1/2)*t)^2;
> Ibl := Ib+Pi*((1/4)*De^2-(1/4)*Di^2)*(d1+(1/2)*t-C)^2;
> y1 := C-(1/2)*t;
> y2 := d1+(1/2)*t-C;
> Mp := Mp;
> Mb := Mb;
> Fp := Fp;
> Fb := Fb;
> a := a;
> > with(DETools);
> ode1 := Ep*Ip*(diff(diff(yp(x), x), x)) = -Mp-W*x+Fp*yp(x);
> dsolve({ode1, yp(0) = 0, (D(yp))(0) = 0}, yp(x)); assign(%);
> solyp := eval(subs(x = a, yp(x)));
> ode2 := Eb*Ib*(diff(diff(yb(x), x), x)) = -Mb+W*x-Fb*yb(x);
> dsolve({ode2, yb(0) = 0, (D(yb))(0) = 0}, yb(x)); assign(%);
> solyb := eval(subs(x = a, yb(x)));
> eqn := solyp = solyb;
> solve(eqn, W);
```

ODE SYMBOLIC SOLUTION FOR SCREW FORCES WITH MAPLE

- Solution for screw forces “W”:

$$W=-\frac{\left[\left(e^{\frac{\sqrt{Fp}\,a}{\sqrt{E_pI_p}}}+e^{-\frac{\sqrt{Fp}\,a}{\sqrt{E_pI_p}}}\right)F_bM_p-2F_bM_p-2F_pM_b+2\cos\left(\frac{\sqrt{F_b}\;a}{\sqrt{E_bI_b}}\right)M_bF_p\right]\sqrt{F_p}\sqrt{F_b}}{\left[e^{\frac{\sqrt{Fp}\,a}{\sqrt{E_pI_p}}}F_b^{3/2}\sqrt{E_pI_p}-e^{-\frac{\sqrt{Fp}\,a}{\sqrt{E_pI_p}}}F_b^{3/2}\sqrt{E_pI_p}-2\sqrt{F_p}F_b^{3/2}a-2\sin\left(\frac{\sqrt{F_b}\;a}{\sqrt{E_bI_b}}\right)\sqrt{E_bI_b}F_p^{3/2}+2\sqrt{F_b}F_p^{3/2}a\right]}$$



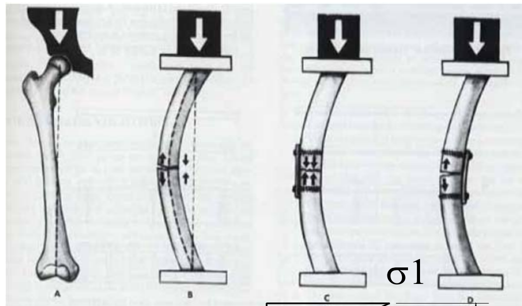
Compression / Tension

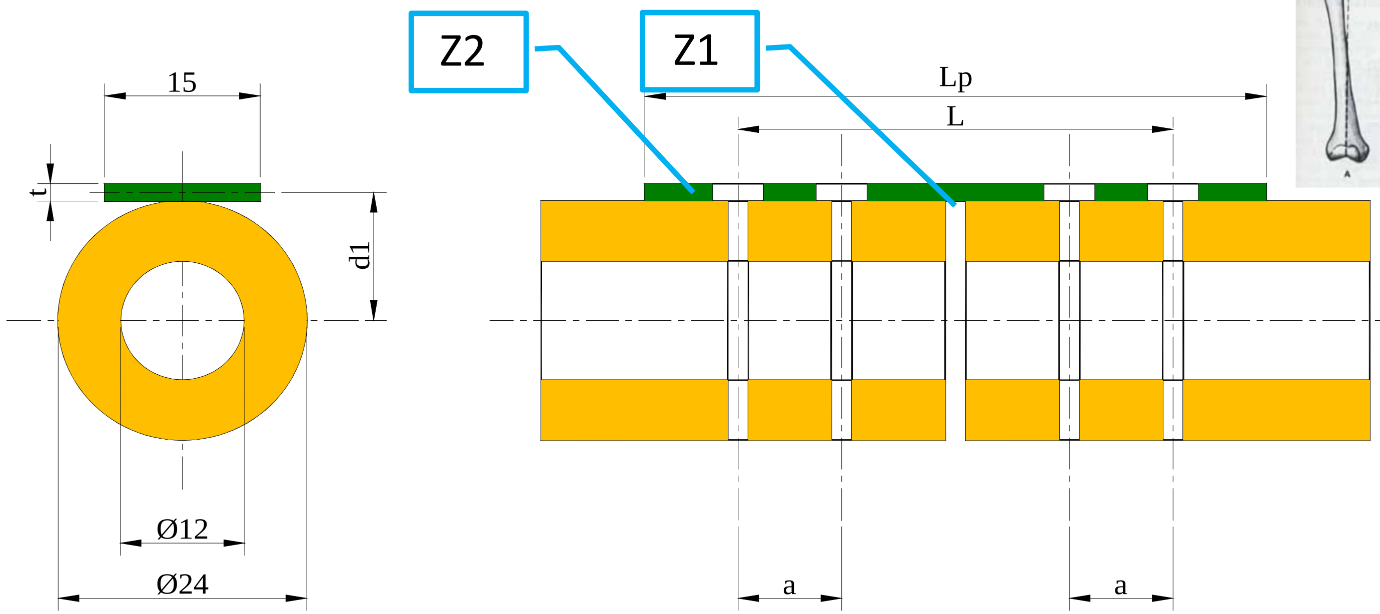
BONE–FIXATOR PLATE: CONCLUSION

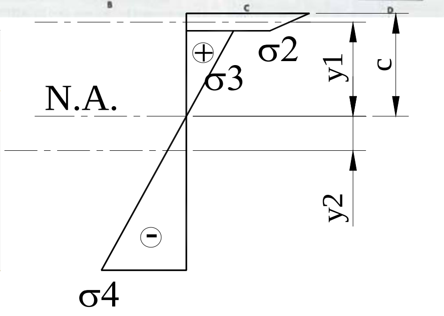
- Neutral axis should be located at the plate bone interface;
- Normal stress at surface bone, underneath the plate, should be zero in the callus (so that there is no tensile stress);
- Stiffness of the plate should not be excessive, otherwise compressive stresses will appear, due to the fact of having neutral axis inside the plate;

BONE–FIXATOR PLATE 4 SCREWS IN BENDING

- Working Project 1:
  - Assume plate in stainless steel material, with Ep=210 [GPa], width dp=15 [mm] , thickness t=2,3,4,5 [mm], Lp=60 [mm],
  - Assume bone healing process, with callus formation, around fracture. This means to use Ebc=0,005 Eb , 50% Eb and 100% Eb. (Eb=21 [GPa])
  - Load: M=1, 10, 20, 30 [Nm].
  - Calculate screw forces and axial stress S3, in callus zone (Z1) and away from callus zone (Z2).
  - Assume a=10 [mm] and L= 60 [mm].

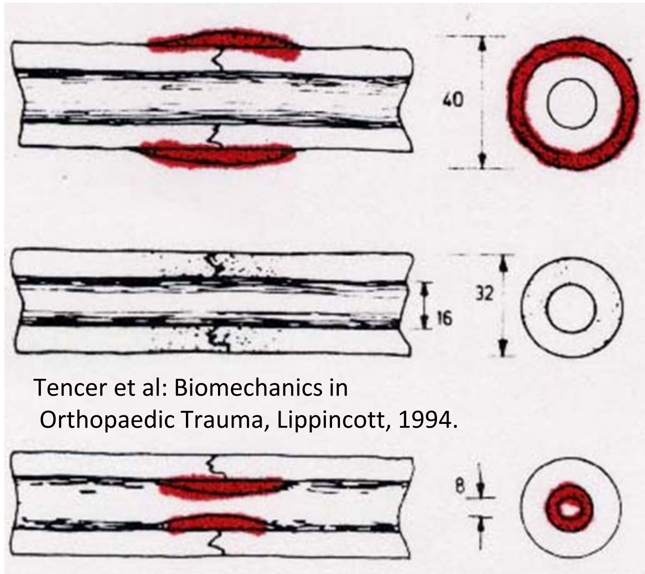




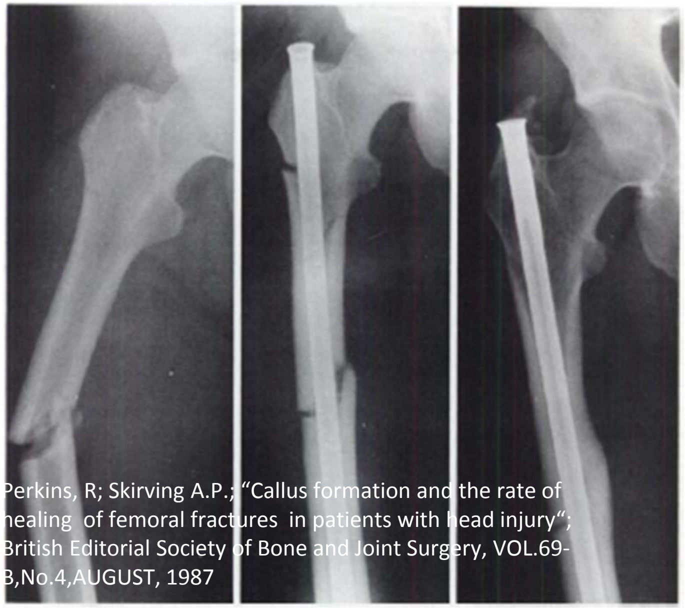


HEALING PROCESS – CALLUS FORMATION

- Callus formation (healing process):
  - Moment of inertia proportional to r4
  - Increase in radius by callus greatly increases moment of inertia.
  - The stiffness is proportional to “Ebc” and the moment of inertia “Ib”.
  - Resistance to bending, twisting, compression or tension of an object is a function of the section shape geometry.
- Time of Healing:
  - Callus increases with time.
  - Stiffness increases with time, near normal stiffness at 27 days.



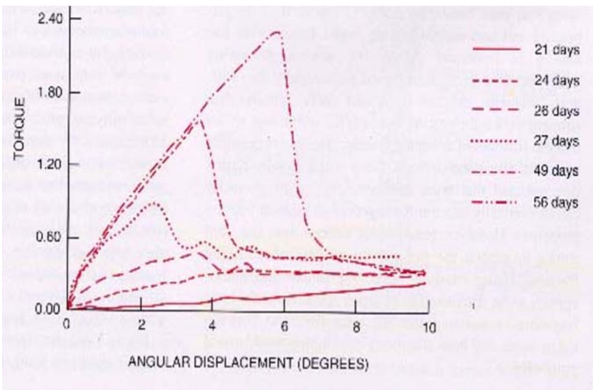
Tencer et al: Biomechanics in Orthopaedic Trauma, Lippincott, 1994.

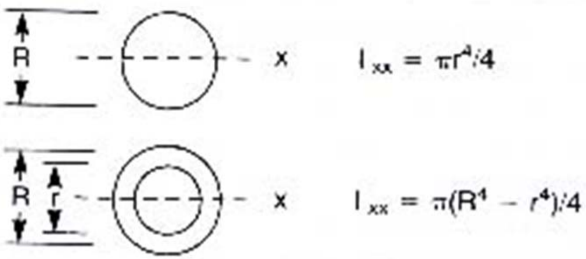


Perkins, R; Skirving A.P.; “Callus formation and the rate of healing of femoral fractures in patients with head injury“; British Editorial Society of Bone and Joint Surgery, VOL.69-B,No.4,AUGUST, 1987

Fig. 4 Fig. 5 Fig. 6

Figure 4 – A fractured femur with no associated head injury. There is also an undisplaced fracture at the upper end. Figure 5 – After fixation. Figure 6 – After union, with small callus response.





BONE–FIXATOR PLATE 6 SCREWS IN BENDING

- HOME WORK:
  - Assume plate in stainless steel material, with Ep=210 [GPa], width plate moment of inertia Ip=156 [mm4] , thickness t=2,3,4,5 [mm], Lp=60 [mm],
  - Assume bone healing process, with callus formation, around fracture. This means to use Ebc=0,005 Eb instead of Eb=21 [GPa].
  - Load: M=1, 10, 20, 30 [Nm].
  - Calculate screw forces and axial stress S3, in callus zone (Z1) and away from callus zone (Z2) and the optimal thickness of the plate.
  - Assume a=20 [mm] and b= 40 [mm].

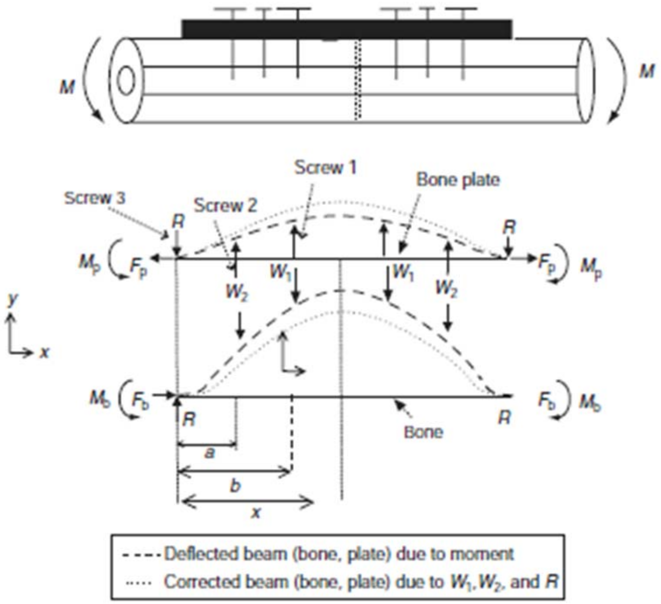


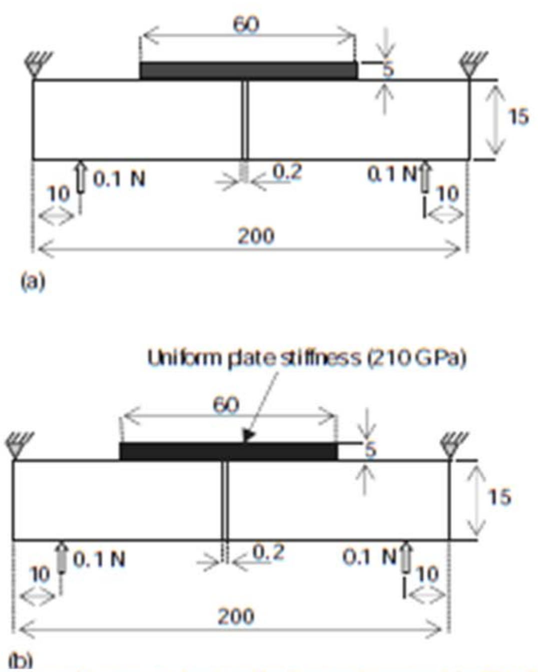
FIGURE 11.6
Free body diagram of bone–plate assembly with six screws holding the bone and the plate together, three on either side of the fracture site. From the calculations, it is noted that screw 1 (W_1) is in compression, while screws 2 (W_2) and 3 (R) are in tension.

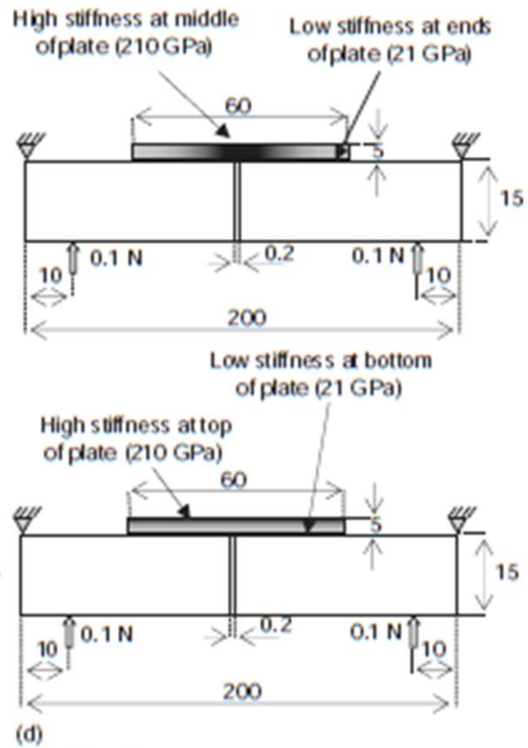
FINITE ELEMENT ANALYSIS OF BONE FRACTURE FIXATION

- Objective:
  - Address the role of functionally graded plate stiffness for optimal fracture fixation, using ANSYS, using plane strain analysis.
  - The purpose is to explore the extent of stress shielding.
  - The callus at fracture site is considered to be homogeneous and isotropic, with its modulus varying from 1% of bone modulus (grown after fracture) to100% of bone modulus at full healing. Eb=21 [GPa] and Ep=210 [GPa].
- 2D analysis:
  - Comparison between FGP (mixture of ceramic and metals) and Stainless Steel plate material, with perfect bond contact between plate and bone.
  - Investigate the reduction in stress shielding provided by stiffness-graded plates.
  - Assume continuous model at the fracture interface, callus (of length 0.1% of the bone length) is assumed at the fracture site.
  - Elastic 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.
  - The transfer of load between the bone and the plate (by passing the crack) enables the plate-reinforced bone to bear the loading. At the same time, the plate prevents the crack from opening up, and helps to induce compressive stress in the lower portion of the crack interface.

FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

- Geometry and boundary conditions are shown in figure a).
- Bending moment equal to 1 [Nmm].
- Case of uniform stiffness, using stainless steel A 316L (figure b).
- Case of length-wise stiffness-graded plate (SGP) (figure c). Elastic modulus varies from 210 to 21 linearly.
- Case of thickness-wise stiffness-graded plate (SGT) (figure d). Elastic modulus varies from 210 to 21 linearly.





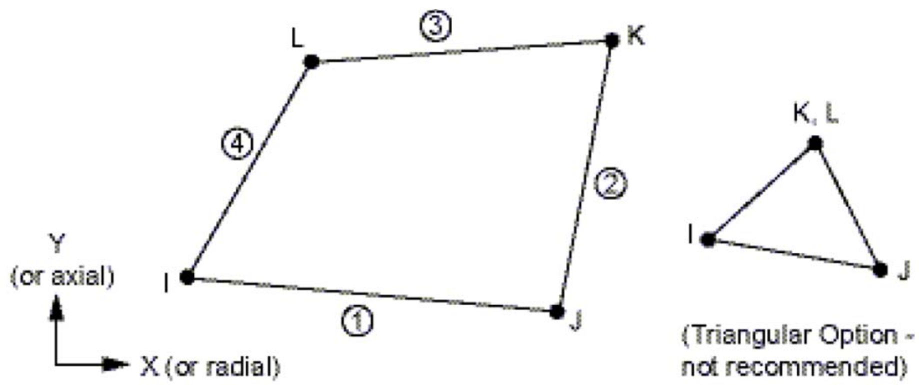
(a) Schematic representation of dimensions (mm) and loading conditions used for FEA; (b) uniform stiffness plate; (c) stiffness-graded plate in length; and (d) stiffness-graded plate in thickness. (From Ramakrishna, K., Sridhar, I., Sivashankar, S., Ganesh, V.K., and Ghista, D.N., *J. Mech. Med. Biol.*, 5, 89, 2005.)

FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

- Working Project 2 - Numerical model:
  - Use 4 node plain strain elements (ANSYS plane 182 with KEYOPT(1) = 3);
  - Calculate axial stress distribution over the plate and bone, for callus zone Z1, for progressive healing:
    - Early stages of healing. Ebc=1% Eb(=20 [GPa]). Neutral axis inside plate. Callus interface is in compression.
    - As healing progresses, the Elastic modulus increases. Neutral axis shifts down into bone material, allowing callus to bear tensile stresses.
  - Testing cases:
    - **Case 1 (Initial healing): Eb=20 [GPa], Ebc(1%)=0,2 [GPa], Ep=210 [GPa] ($\bar{E}$=10,5).**
    - Case 2 (Initial healing): Eb=20 [GPa], Ebc(1%)=0,2 [GPa], Ep=100 [GPa] ($\bar{E}$=5).
    - **Case 3 (Initial healing): Eb=20 [GPa], Ebc(1%)=0,2 [GPa], Ep=20 [GPa] ($\bar{E}$=1).**
    - **Case 4 (progressive healing): Eb=20 [GPa], Ebc(50%)=10 [GPa], Ep=210 [GPa] ($\bar{E}$=10,5).**
    - Case 5 (progressive healing): Eb=20 [GPa], Ebc(50%)=10 [GPa], Ep=100 [GPa] ($\bar{E}$=5).
    - **Case 6 (progressive healing): Eb=20 [GPa], Ebc(50%)=10 [GPa], Ep=20 [GPa] ($\bar{E}$=1).**
    - **Case 7 (final healing): Eb=20 [GPa], Ebc(100%)=20 [GPa], Ep=210 [GPa] ($\bar{E}$=10,5).**
    - Case 8 (final healing): Eb=20 [GPa], Ebc(100%)=20 [GPa], Ep=100 [GPa] ($\bar{E}$=5).
    - Case 9 (final healing): Eb=20 [GPa], Ebc(100%)=20 [GPa], Ep=20 [GPa] ($\bar{E}$=1).

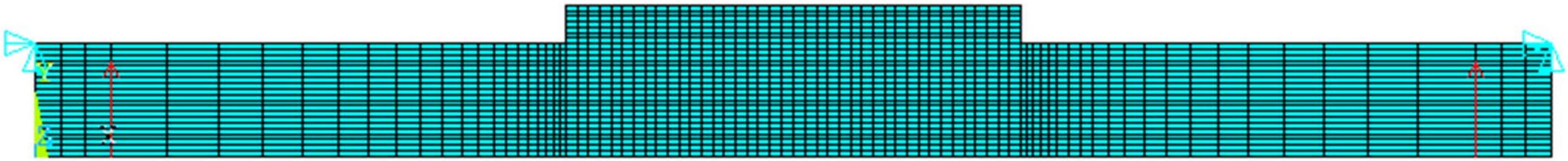
FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

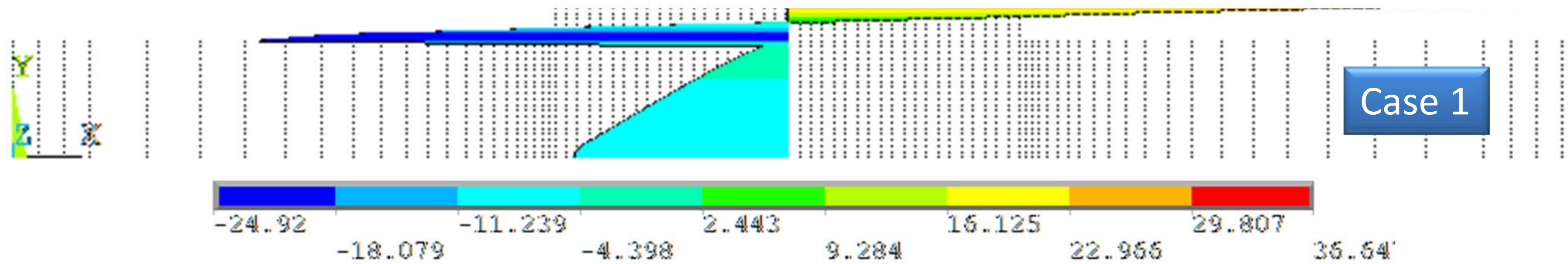
- **PLANE182 Element Description (ANSYS):**
  - PLANE182 should be used for 2-D modeling of this plain model.
  - Can be used as either a plane element (plane stress, plane strain or generalized plane strain) or an axisymmetric element.
  - Four nodes having two degrees of freedom at each node: translations in the nodal x and y directions.
  - The element has plasticity, hyperelasticity, stress stiffening, large deflection, and large strain capabilities.
  - It also has mixed formulation capability for simulating deformations of nearly incompressible elastoplastic materials, and fully incompressible hyperelastic materials

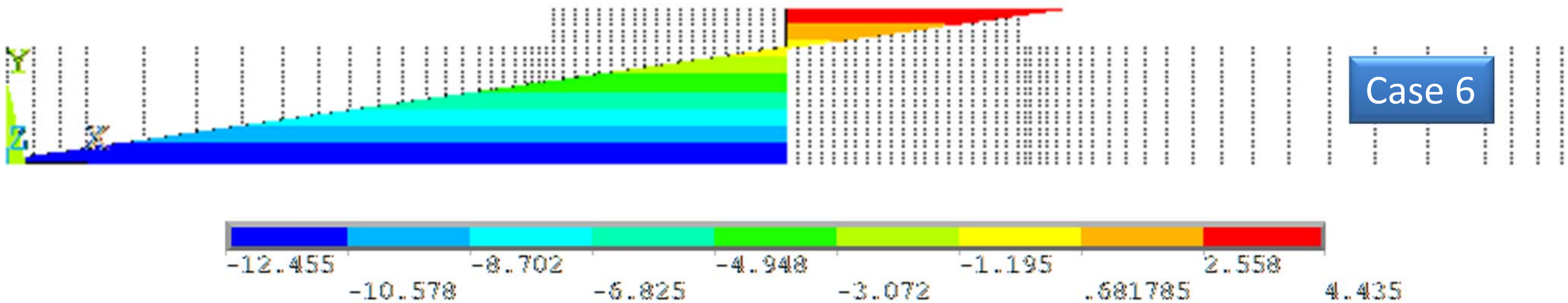


FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

- Case 1 and 6:
  - Mesh and boundary conditions;
  - Results for axial stress SX, over mid span (callus zone Z1).

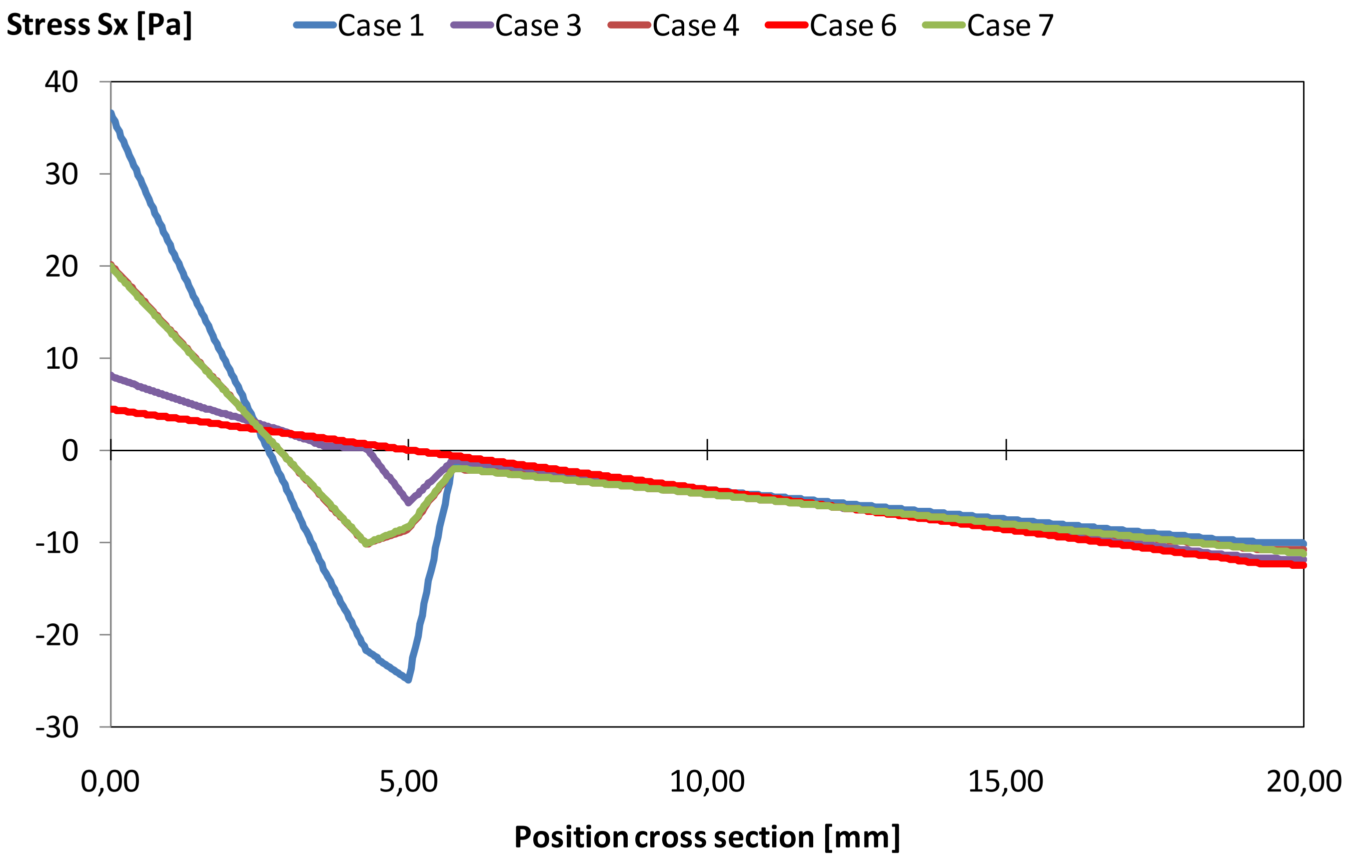






FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

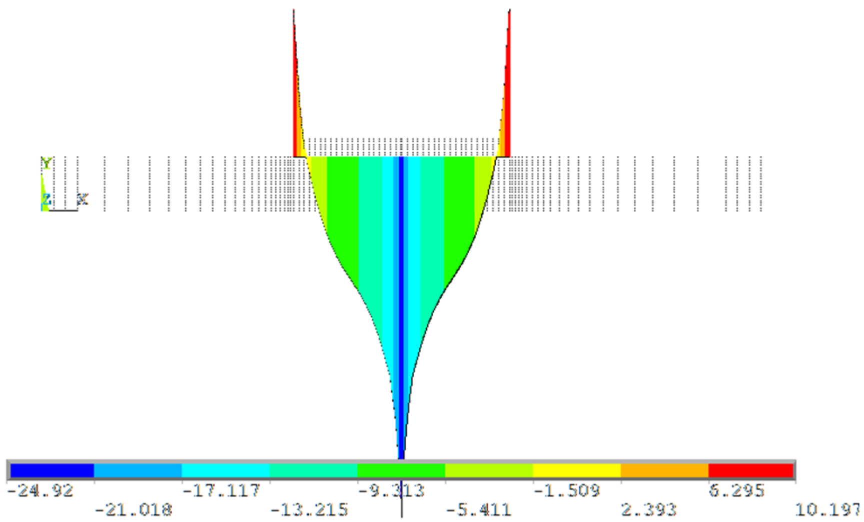
- Normal stress (Sx) distribution at the callus zone (crack interface):
  - For different callus and plate properties;
  - For different healing progress stages.
- Results for cases number 1,3,4,6 and 7.



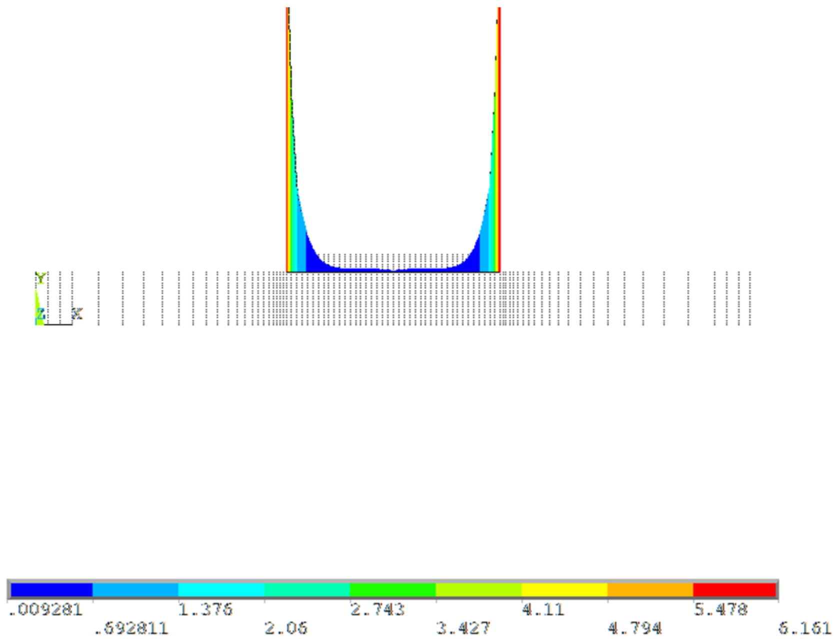
FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

- Case 1 and 6: Results for axial stress SX, along bone plate interface.
  - Case 1: Initial healing process;
  - Case 6: 50 % healing process.

Case 1

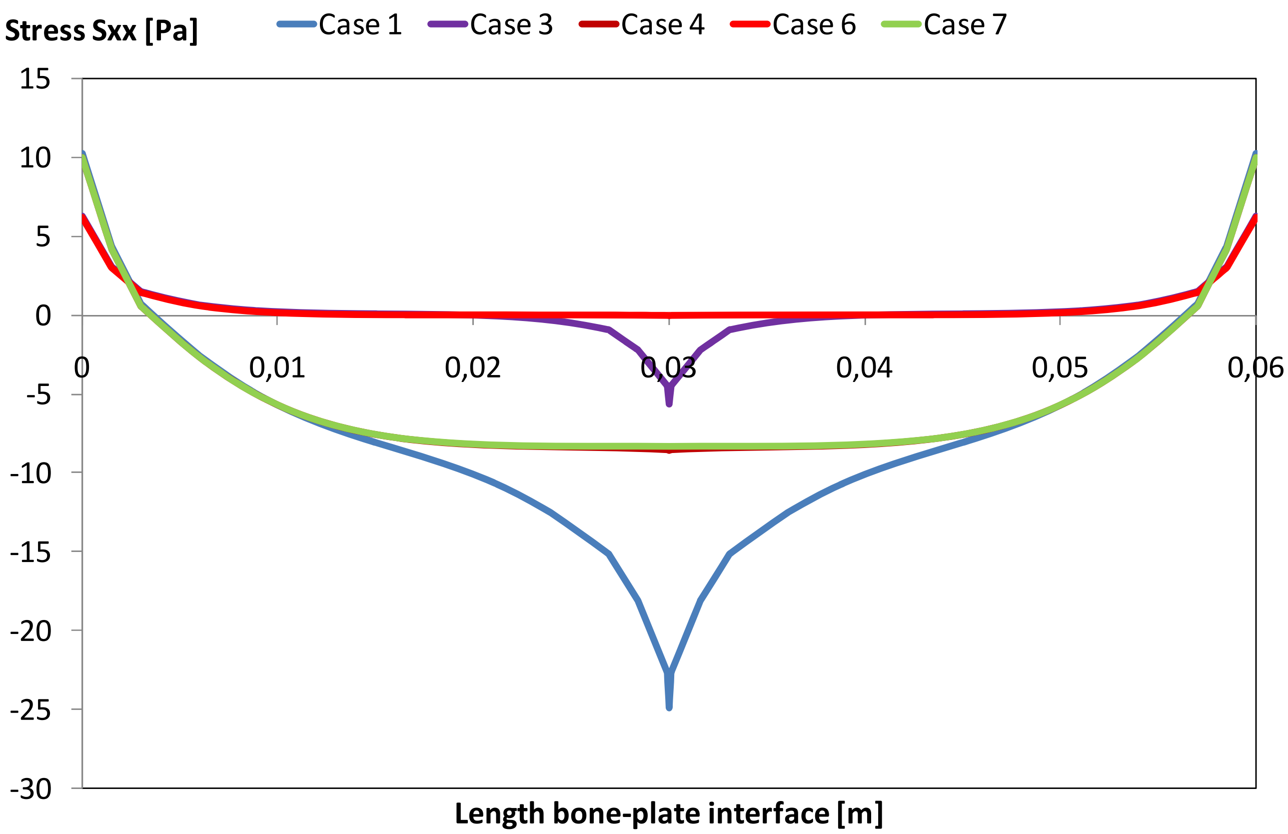


Case 6



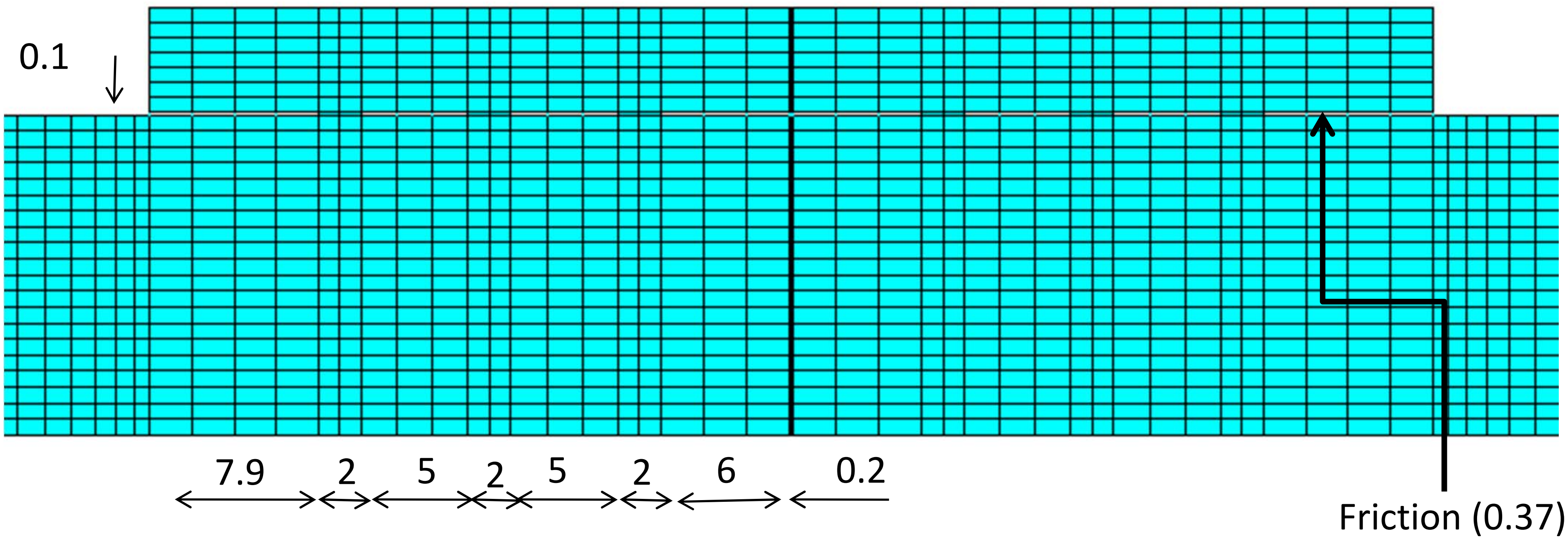
FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

- Normal stress (Sx) distribution along the bone-plate interface:
  - 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, close to the fracture interface.



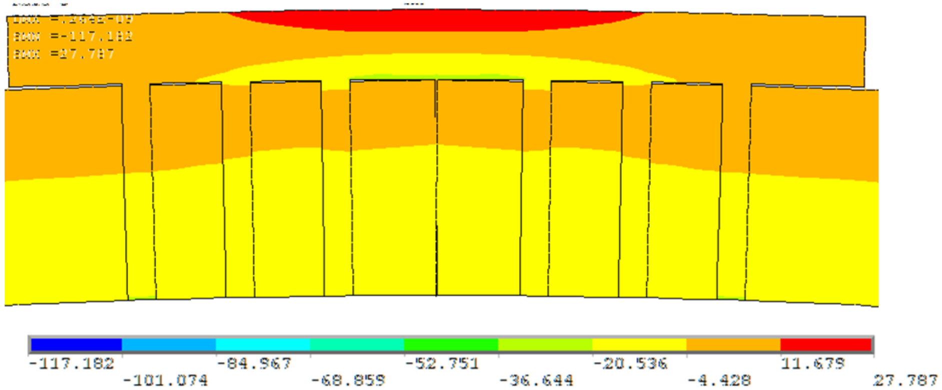
FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

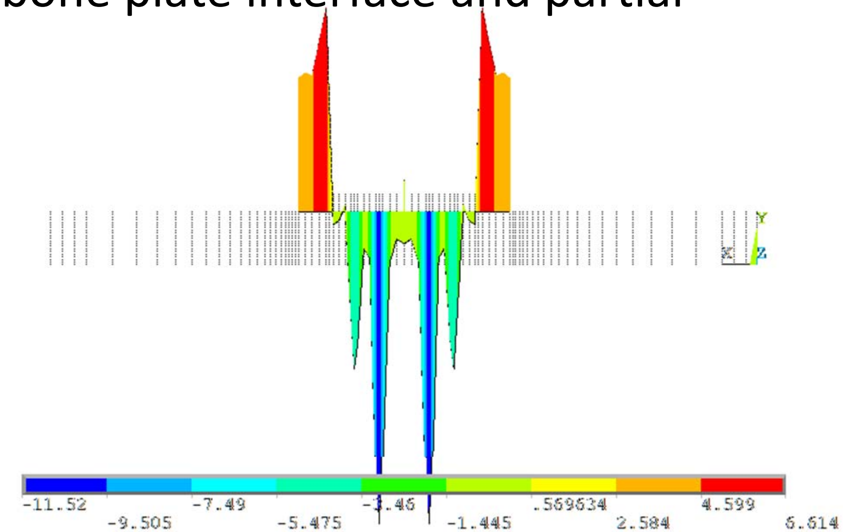
- Detailed analysis of screw fixating systems:
  - Screws can also be modelled by means of a tie, assuming perfect contact between them and the plate, and also between them and the bone.
  - Contact between bone and plate can be modelled using special finite elements (CONTA178) to simulate contact and friction. Assume friction coefficient equal to 0.37 and a distance between nodes equal to 0.1 [mm], see model in figure.



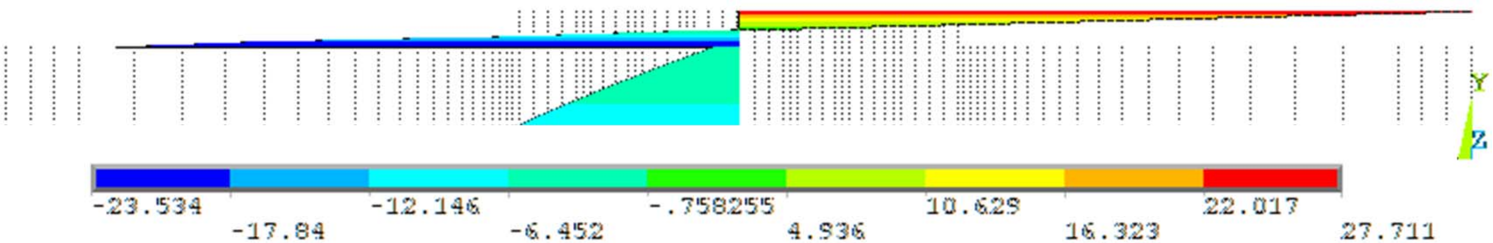
FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

- Case 1: Results for axial stress SX, along bone plate interface and partial domain.
  - Case 1: Initial healing process.





- Case 1: Results for axial stress SX, along callus
  - Case 1: Initial healing process.

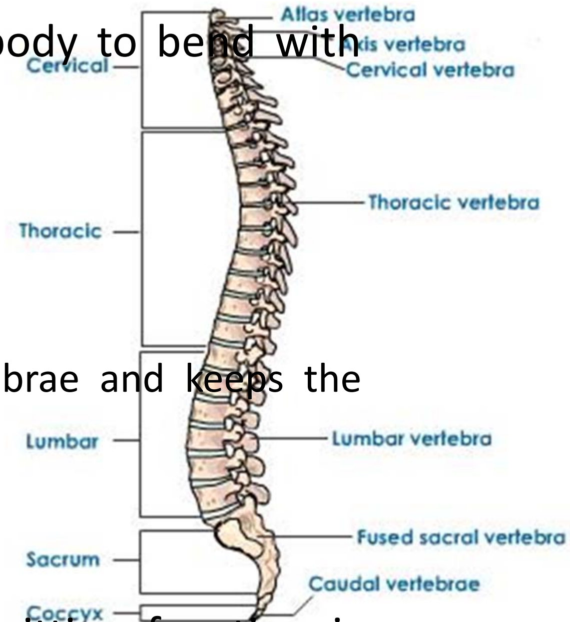


FEM 2D ANALYSIS OF BONE FRACTURE FIXATION

- Conclusions:
  - The early stages of healing, the bone is almost de-stressed at the fracture zone.
  - Large variations of normal stresses are seen at the screw sites of the bone.
  - In the final stages of healing, the NA 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.
  - The screw location on the plate (rather than the stiffness of the plate) has a more dominating role in minimizing the stress-shield zone.

HUMAN LUMBAR VERTEBRAL BODY

- Main objective:
  - Spine gives the body structure, support, and allows the body to bend with flexibility. It is also designed to protect the spinal cord.

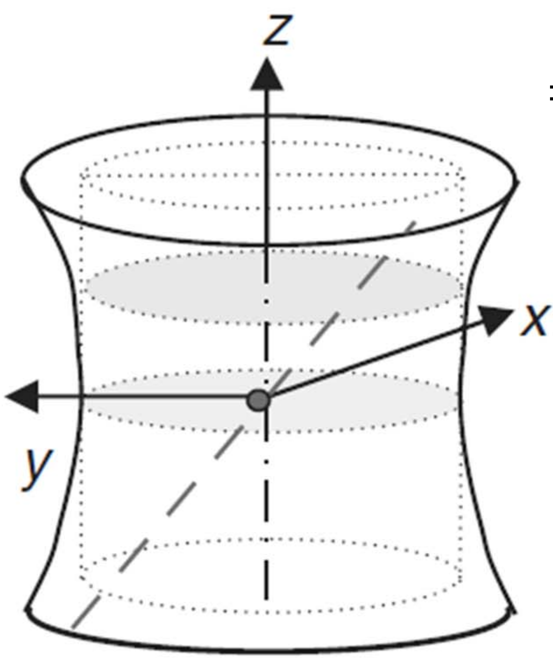


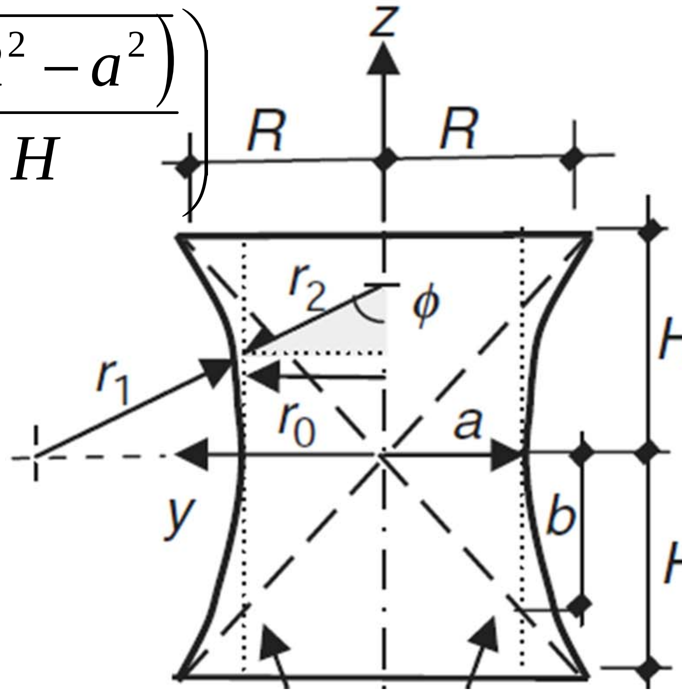
- Structure:
  - Spinal is made up of 24 small bones (vertebrae).
  - Between each vertebra, there is an intervertebral disk
    - Helps to cushion and transmit the load between the vertebrae and keeps the vertebrae from rubbing against each other.
  - Each vertebra is held to the others by groups of ligaments.
  - The normal spine has an‘‘S’’- like curve.
  - In the VB (vertebra body), the load- carrying and transmitting function is primarily done by the cortical VB, whose shape resembles a hyperboloid (HP) shell.
    - All the loadings are transmitted as axial forces.
    - Natural light weight structure.

OPTIMUM HYPERBOLOID SHAPE

- Optimal HP shape and geometry:
  - Anatomical structures are customized to be functionally optimal.
  - Minimizing the sum of the forces in the HP VB generators with respect to the HP shape parameter (angle between pairs of generators).
  - The value of β is determined to be 26.58, which closely matches with the in vivo geometry of the VB based on the magnetic resonance imaging (MRI).

$$\beta = arc\ tg\ (a/b)$$
$$= arc\ tg\left(\frac{\sqrt{(R^2 - a^2)}}{H}\right)$$



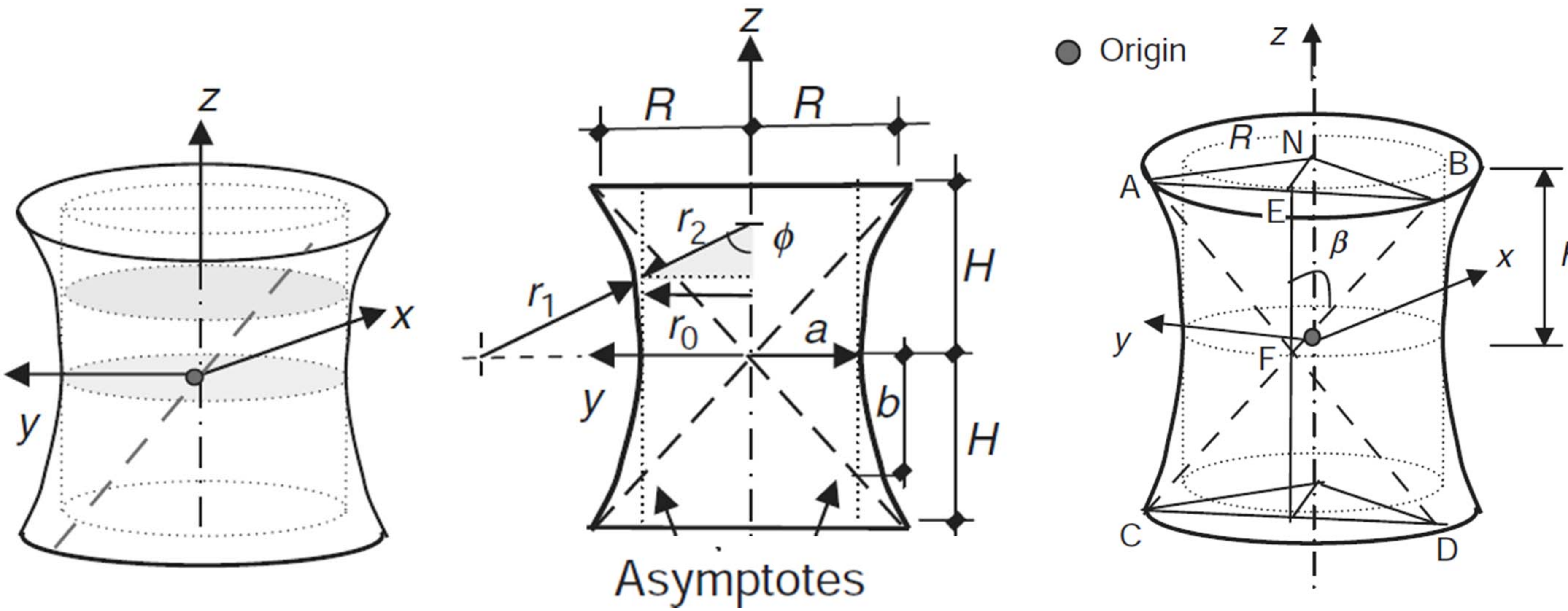


HYPERBOLOID SHAPE OF VERTEBRAL BODY

- Intersecting the HP shell surface with a vertical plane parallel to the yz plane but at x=-a, then the intersecting curves are given by:

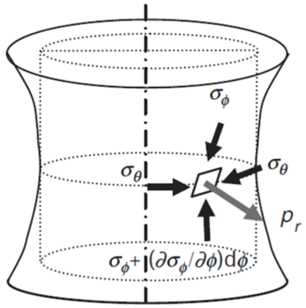
$$\frac{x^2+y^2}{a^2}-\frac{z^2}{b^2}=1 \qquad \Leftrightarrow \qquad \frac{a^2+y^2}{a^2}-\frac{z^2}{b^2}=1 \quad \text{or} \quad z=\pm\left(\frac{b}{a}\right)y$$

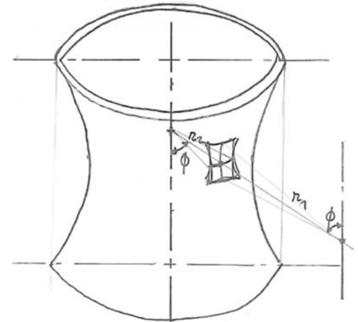
- The primary dimensional parameters of the VB HP are hence (R, a, and H).



MEMBRANE STRESSES IN THE VERTEBRAL BODY CORTEX

- Use the membrane theory of shells to analyze the stresses in the cortical.
- Membrane stresses:
  - Meridian stress σ_ϕ
  - Hoop stress. σ_θ
- Under normal pressure: p_r
- Static equilibrium in radial direction for forces:
  - R2 considered to be positive;
  - R1 considered to be negative.





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

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

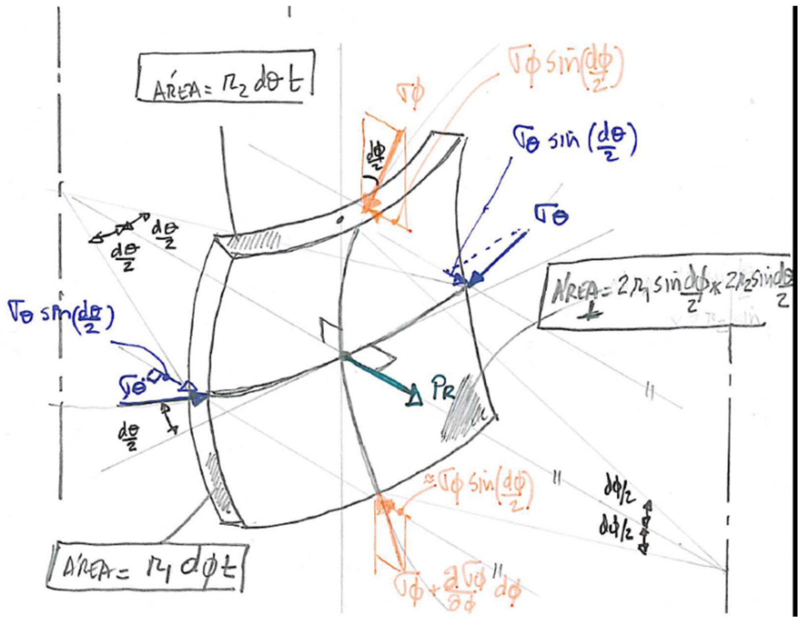
$$-2\sigma_\phi \sin\left(\frac{d\phi}{2}\right)\left[t\, r_2 d\theta\right] + 2\sigma_\theta \sin\left(\frac{d\theta}{2}\right)\left[t\, r_1 d\phi\right] +$$

$$+\, p_r\left[2r_1 \sin\left(\frac{d\phi}{2}\right) \times 2r_2 \sin\left(\frac{d\theta}{2}\right)\right] = 0$$

- For small angle $\frac{d\phi}{2}$: $\sin\left(\frac{d\phi}{2}\right) = \frac{d\phi}{2}$

  $\frac{d\theta}{2}$ $\sin\left(\frac{d\theta}{2}\right) = \frac{d\theta}{2}$

$$\boxed{\frac{\sigma_\phi t}{r_1} - \frac{\sigma_\theta t}{r_2} = p_r}$$



MEMBRANE STRESSES IN THE VERTEBRAL BODY CORTEX

- Assuming the concept of stress per unit of wall thickness:
  - Hoop force per unit of length: N_θ
  - Meridian force per unit of length: N_ϕ
- Equilibrium equation in "r" direction, becomes the membrane equation.

$$\frac{N_\phi}{r_1} - \frac{N_\theta}{r_2} = p_r$$

- If the internal pressure (pr) in the cancellus bone, within the cortical shell is negligible, the equation becomes:

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

- Substituting the geometric value of r1 and r2, $r_1 = \left(b^2/a^4\right) r_2^3$, the relation becomes:

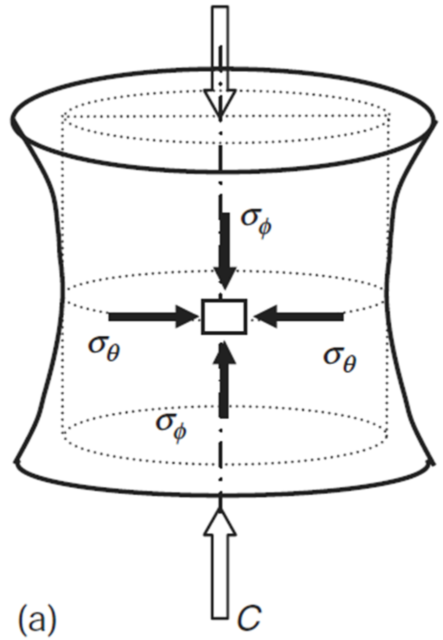
$$N_\phi = \left(\frac{b^2}{a^4} r_2^2\right) N_\theta$$

STRESS ANALYSIS UNDER COMPRESIVE FORCE

- Stress in shell cortex when submitted to compressive force “C”.
  - Force equilibrium in vertical direction holds, for any horizontal section:

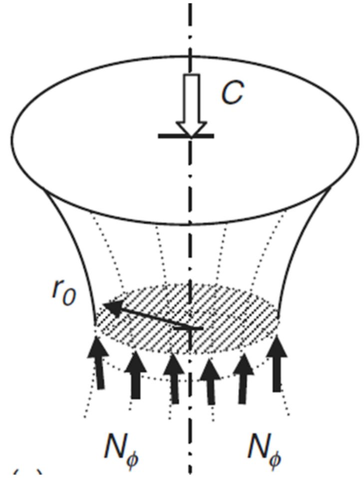
$$N_\phi \sin(\phi)\, 2\pi\, r_0 = C$$

  - For the case of waist circle (r0=a), which means ϕ=90º, the meridian and hoop force per unit of length are compressive in nature and equal to.



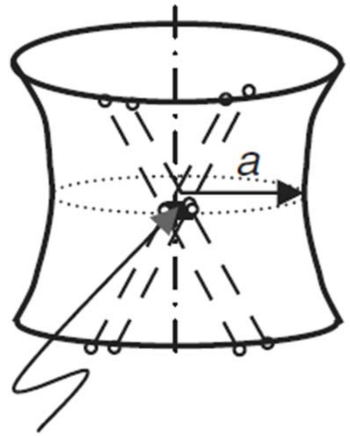
$$N_\phi = \frac{C}{2\pi a}$$

$$N_\theta = \left(\frac{a^4}{b^2}\frac{1}{r_2^2}\right) N_\phi = \left(\frac{a^2}{b^2}\right) N_\phi = \left(\frac{a^2}{b^2}\right)\frac{C}{2\pi a} = \tan^2(\beta)\frac{C}{2\pi a}$$



STRESS ANALYSIS UNDER COMPRESIVE FORCE

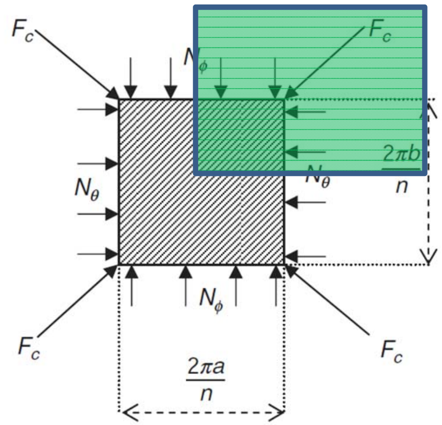
- Assume that there are n fibres (straight bars) placed at equal spacing of $2\pi a/n$ measured at waist circle.
- Assume no developed shear stresses, due to load nature.
- Calculate equivalent resultant compressive force "Fc" developed at fiber generator of the VB HP shell.



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

- The total axial load is transmitted into the HP shell's generators, as compressive forces.

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



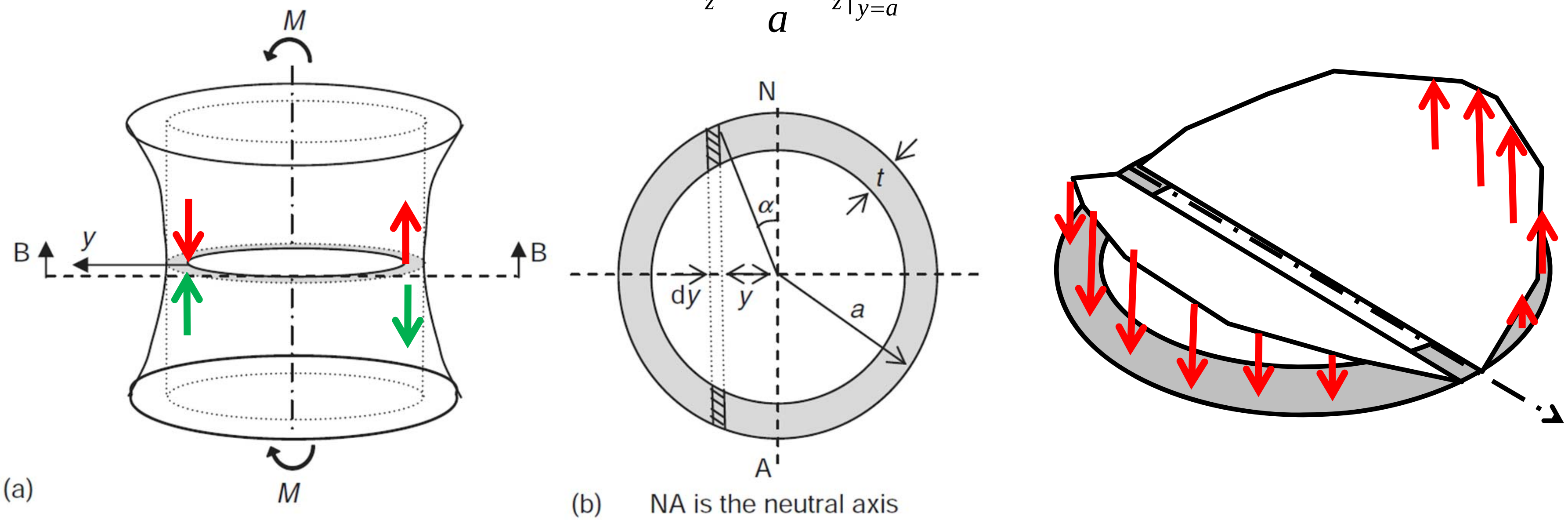
STRESS ANALYSIS UNDER BENDING MOMENT

- When VB is subjected to a bending moment(M), normal stresses (Sz) are developed at the waist circle (r0=a) cross section.
- The bending moment may de determined according to the developed stress field:
  - In Cartesian coordinates:

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

- Stress may be related with the maximum normal stress verified at y=a.

$$\sigma_z = \frac{y}{a}\sigma_z\Big|_{y=a}$$



(a)

(b) NA is the neutral axis

STRESS ANALYSIS UNDER BENDING MOMENT

- Combining both last equations, the bending moment may be determined by:

$$M = 4t\sigma_a \int_0^a \frac{y^2}{a\cos(\alpha)}\,dy$$

- Assuming the change of integration variable:

$$y = a\sin(\alpha) \qquad dy = a\cos(\alpha)\,d\alpha \qquad \int \sin^2(\alpha)\,d\alpha = \frac{1}{2}(\alpha - \sin(\alpha)\cos(\alpha))$$

- The bending moment may be rewritten:

$$M = \pi\,a^2\,t\,\sigma_a$$

- The meridian force per unit of length, at position y=a (waist circle):

$$N_\phi\Big|_a = \sigma_a\,t = \frac{M}{\pi\,a^2}$$

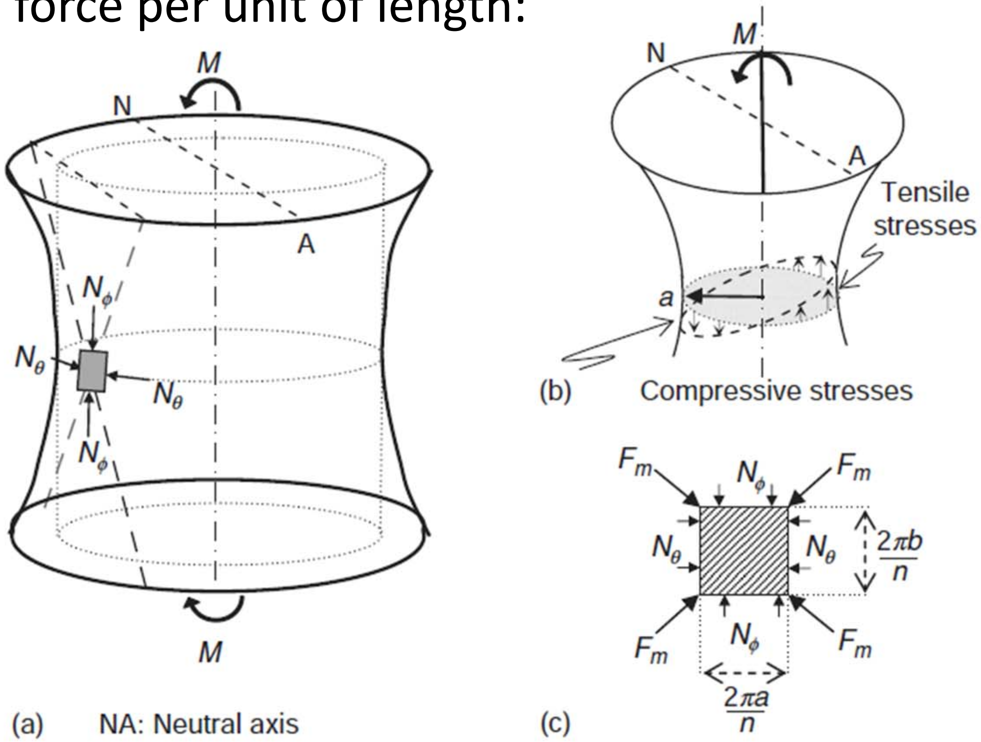
STRESS ANALYSIS UNDER BENDING MOMENT

- Calculate equivalent resultant compressive force “Fm” developed at fiber generator of the VB HP shell:

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

- Upon substituting the Meridian force per unit of length:

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



- Since $tg\,(\beta) = a / b$

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

$$F_m = \frac{M}{na \cos \beta}$$

OBS: May be positive or negative

STRESS ANALYSIS UNDER TORSION MOMENT

- When VB is subjected to pure torsion, shear stresses are developed, while the normal stresses are equal to zero.
  - The Meridian force per unit of length and Hoop force per unit of length will vanish.

$$N_\phi = N_\theta = 0$$

- The equilibrium of a segment of the shell at a horizontal section gives:

$$[(2\pi r_0)N_{\phi\theta}]r_0 = T$$

$$(2\pi r_0^2)N_{\phi\theta} = T$$

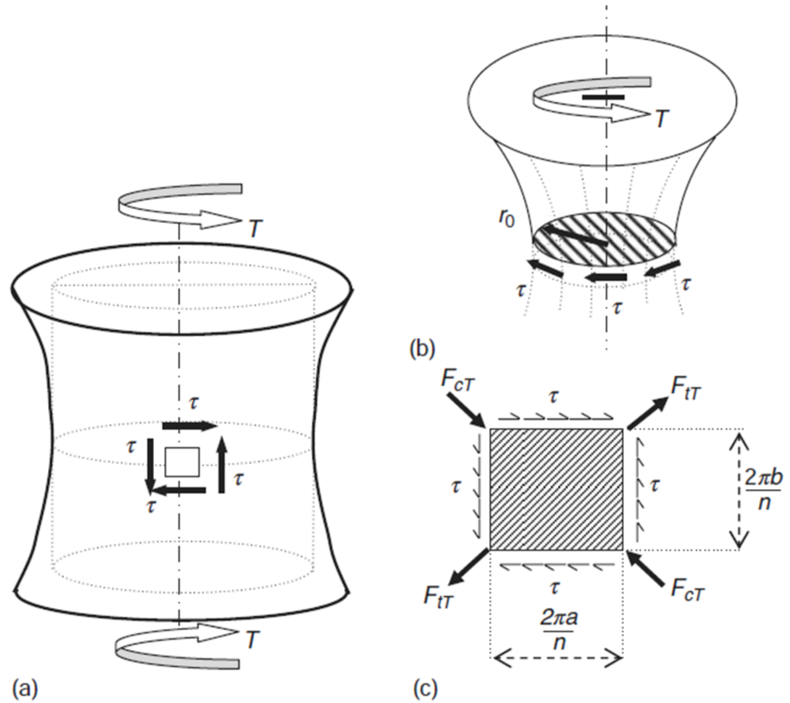
- At the waist circle "r2"="r0"="a":

$$[(\tau \cdot t)(2\pi a)]a = T \qquad \Leftrightarrow \qquad N_{\phi\theta} = \frac{T}{2\pi a^2}$$

- The equivalent resulting force system

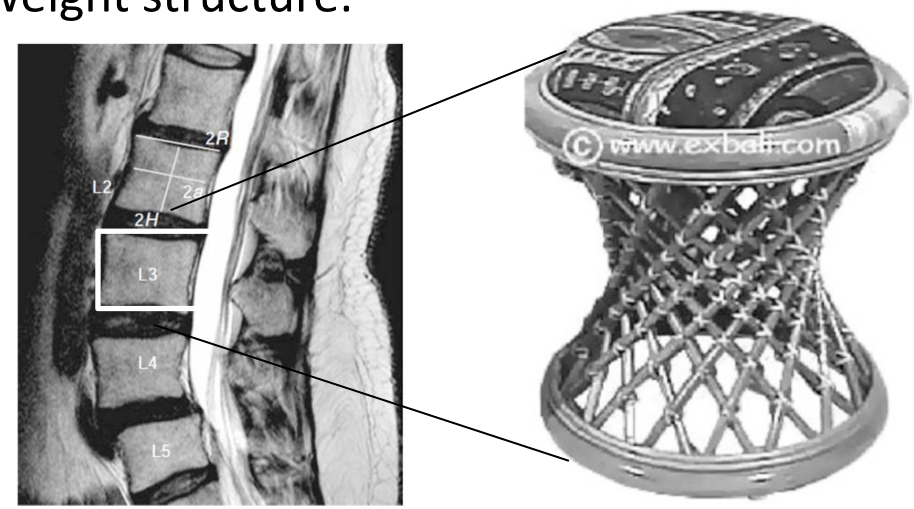
$$F_{cT}^2 = F_{tT}^2 = \left(N_{\phi\theta}\frac{\pi a}{n}\right)^2 + \left(N_{\phi\theta}\frac{\pi b}{n}\right)^2$$

$$|F_{cT}| = |F_{tT}| = \frac{T}{2na\sin\beta}$$



OPTIMAL DESIGN

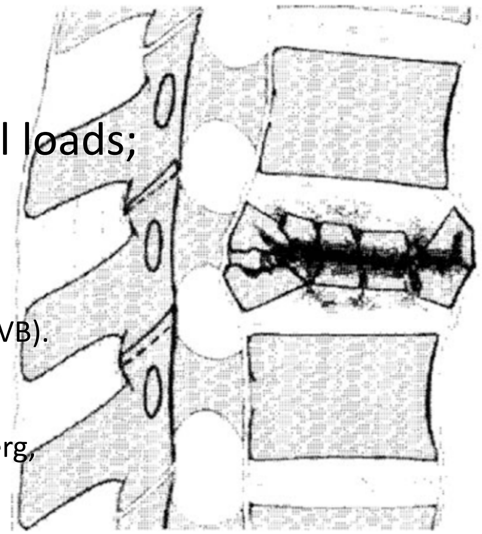
- HP shape design of the VB enables the loadings to be transmitted as axial (compressive = tensile) forces, through the generators of the HP shell.
- The VB can be compared to an HP cane stool, which is an ideal high-strength and light weight structure.
- A cane stool of radius 200 mm and height 175mm has a nominal weight of 2.5kg (or25N), but can easily bear a load of at least 5000 N, which is 200 times its weight.
- The spinal VB cortex has similar structural configuration and properties as that of the cane stool, to make it an efficient load-bearing and load-transmitting, high-strength, light weight structure.
- Optimal design for H=14.75 mm.
  - β=26.5º.
  - a/R=0.939



Magnetic resonance imaging (MRI) of lumbar vertebrae: $H/R = 0.7$ (average of L2 to L5) and a/R is 0.91 (average of L2 to L5).

SURGICAL TREATMENT IN BURST FRACTURE

- Spinal VB fails if the load exceeds the sustainable limits.
- 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.
- 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. Burst fractures cause loss of sensory and neural stimulation below the level of the injury, often resulting in paraplegia.
- The surgical treatment in burst fracture are used to:
  – Achieve pain free and stable spine;
  – Enable neurological recovery;
  – Restore the ability of load beating resistance to physiological loads;
  – Cause minimal resection of injured fragments;
  – Employ small implants.

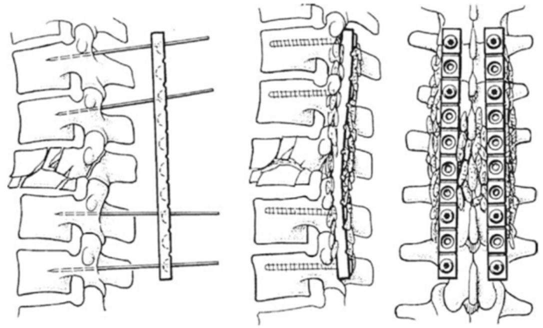


Na axial burst fracture of the vertebral body(VB).

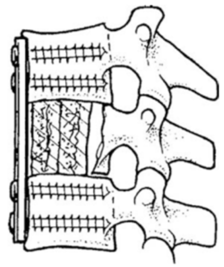
Aebi,M., Thalgott,J.S., andWebb,J.K., AO ASIF Principles in Spine Surgery, Springer, Heidelberg, 1998.

SURGICAL TREATMENT IN BURST FRACTURE

- The surgical methods available are:
  - Posterior technique (with posterior fixators);



  - Anterior technique (with anterior fixators);

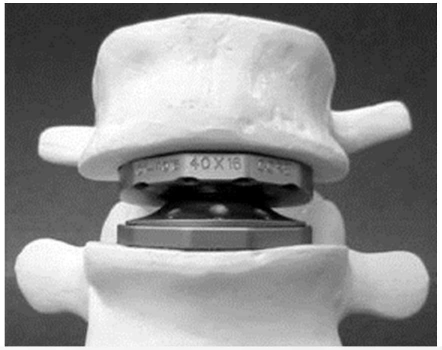


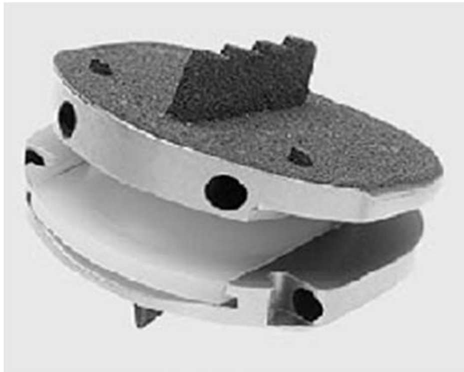
  - Combination of posterior and anterior techniques;
  - Other techniques:
    - Rezaian spinal Fixator: Medical device that is embedded into the end plates of the VB and allows adjustment of the height by the turnbuckle technique.

Rezaian spinal Fixator

TOTAL DISC REPLACEMENTS

- Solutions:
  - Metal-on-Metal
  - Metal-on-Polymer
- Multiaxial loads, motions
- Wear testing required!
- Standard test methods needed!



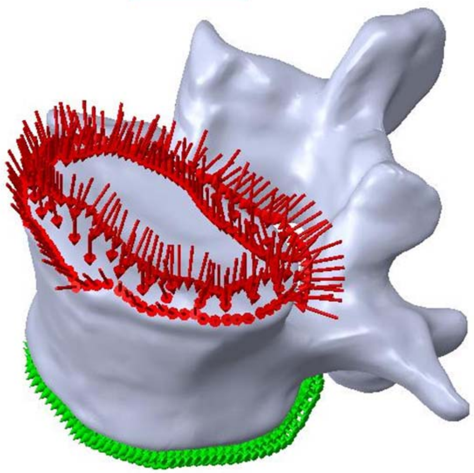


Working Project 3 – Numerical Simulation

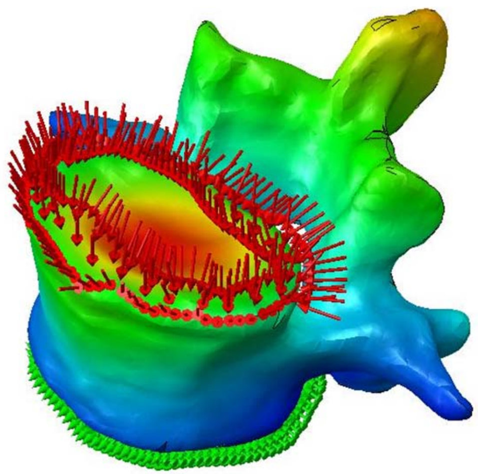
- Consider an STL model of L3 VB or L4 VB and transform it to shell or volume configuration.
- Assume the following loading cases:
  - C=1000 [N];
  - M= 3 [Nm];
  - T=3 [Nm].
- Calculate the Meridian force per unit of length and Hoop force per unit of length and compare the numerical results with analytical results.

$$N_\phi = \sigma_\phi \, t \qquad\qquad N_\theta = \sigma_\theta \, t$$

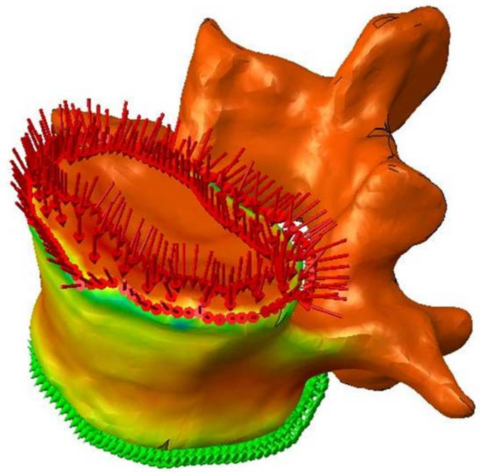
Model



Displacement

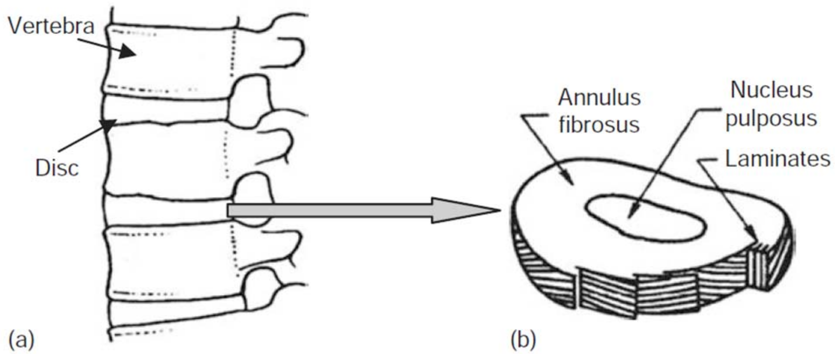


Axial stress



HUMAN SPINAL INTERVERTEBRAL DISC

- The inter-vertebral disc (IVD) consists of:
  - Annulus Fibrosus (AF): stress-stiffening solid similar to a hyper-elastic material. (increase in elastic modulus under loading). The annulus fibers are oriented helically, at almost 30º–50º.
  - Nucleus pulposus (NP).
- Biomechanical behaviour:
  - When the IVD is loaded in axial compression, the NP gets pressurized and transmits radial stress to the AF, which in turn gets stressed.
  - As the IVD gets loaded, its deformation does not increase in the same proportion as the loading.
  - The IVD sustains and transmits axial compression, bending, and torsional loadings.
  - The IVD also functions as shock-absorber component of the spinal unit.

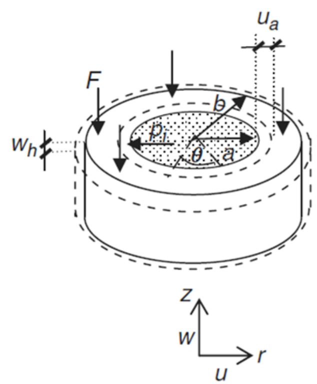


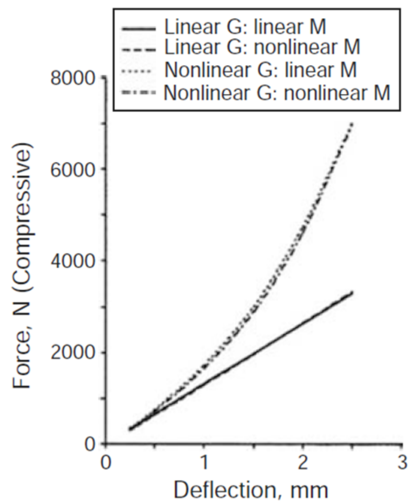
HUMAN SPINAL INTERVERTEBRAL DISC

- Geometry and deformation variables:
  - The biomechanical behaviour is explained when the disc is loaded in axial compression (or bending or torsion), the NP fluid gets pressurized and stresses the surrounding annulus.
  - The annulus under increased loadings, its elastic modulus increases, so that the deformations are contained. Example:

$$E = E_0 + 375.3\sigma^{0.473}$$

    - E0 represents the residual Young's modulus, equal to 4.2 [MPa];
    - σ is taken to be equal to the maximum value of the principal stress (which happens to be the axial stress SZ).
  - The internal pressure causes circumferential hoop tensile stress in the annulus. This stress in turn influences the strain state in the disc through its elastic modulus, and hence the axial and radial deformation.





HUMAN SPINAL INTERVERTEBRAL DISC

- The disc is considered to be a thick-walled isotropic cylinder.
- In order to calculate the disc deformations:
  - 1st: Determine the NP pressure;
  - 2nd: Compute incremental stress, using incremental solution methods. Update total stress field.
  - 3rd: Update material property (E);
  - 4th : Determine disc deformations;
  - 5th: Update geometry.
- Equilibrium equations (because of the axial symmetry of load and geometry, there are not shear stresses). :
  - In radial direction: $$\frac{d\sigma_r}{dr} + \frac{\sigma_r - \sigma_\theta}{r} = 0$$
  - In axial direction: $$\frac{d\sigma_z}{dz} = 0$$
- Strain - displacement relations:
  - Radial strain: $$\varepsilon_r = \frac{du}{dr} = \frac{\sigma_r}{E} - \frac{\nu(\sigma_\theta + \sigma_z)}{E}$$
  - Circumferential strain: $$\varepsilon_\theta = \frac{u}{r} = \frac{\sigma_\theta}{E} - \frac{\nu(\sigma_r + \sigma_z)}{E}$$
  - Axial strain: $$\varepsilon_z = \frac{dw}{dz} = \frac{\sigma_z}{E} - \frac{\nu(\sigma_r + \sigma_\theta)}{E}$$

HUMAN SPINAL INTERVERTEBRAL DISC

- Stress- displacement relations:
  - Radial stress:

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

  - Circumferential (hoop) stress:

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

  - Axial stress:

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

- By direct substitution of the constitutive relations (top of slide) into the equilibrium equations:
  - Radial direction:

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

  - Axial direction:

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

- Solutions for differential equations:
  - Radial displacement, dependent of A and B (constants of integrations): $u = \frac{A}{r} + Br$
  - Axial displacement, dependent of C and D (constants of integrations): $w = Cz + D$

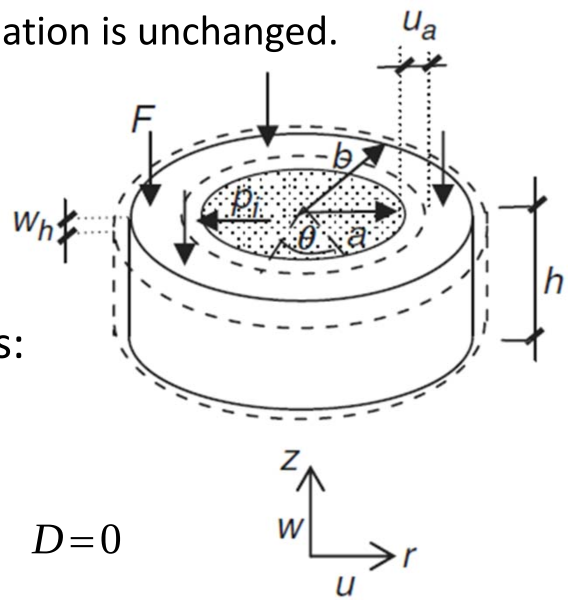
HUMAN SPINAL INTERVERTEBRAL DISC

- Solutions for differential equations:
  - Constants must be determined when applying the appropriate boundary conditions.
  - The IVD displacements “u” and “w” are related:
    - Assuming NP as incompressible, its volume after deformation is unchanged.

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

    - Neglecting higher order terms:

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



  - The boundary conditions allow to determine constants:

$$u_{r=a} = u_a = \frac{A}{a} + B a \qquad \sigma_{r=b} = 0 \qquad w_{z=0} = 0 \qquad w_{z=h} = -w_h$$

$$A = \frac{(1-2\nu) u_a a b^2}{b^2 + a^2(1-2\nu)} \quad B = u_a\left[\frac{a^2(1-2\nu) + 2\nu b^2}{ab^2 + a^3(1-2\nu)}\right] \quad C = -\frac{w_h}{h} = -\frac{2u_a}{a} \qquad D = 0$$

- Solutions for differential equations:
  - Radial displacement:
  - Axial displacement:

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

$$w = \left(-\frac{2u_a}{a}\right) z$$

HUMAN SPINAL IVD UNDER COMPRESSIVE FORCE

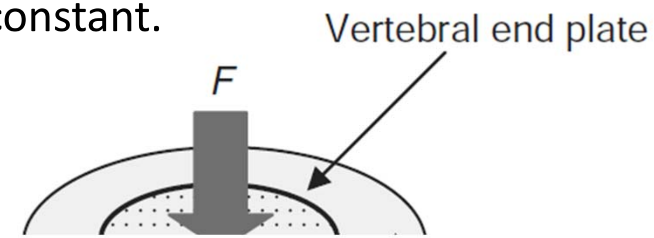
- For an axially applied force F, the equilibrium equation becomes:
  - In axial direction.

    $$F = \pi a^2 \sigma_f - \pi\left(b^2 - a^2\right)\sigma_z$$

    - Where σf represents the hydrostatic pressure in the fluid.
    - And σz represents the axial stress in the Annulus.
  - Because the height “h” is small, Sf is approximately constant.
    - The pressure “pi” equals σf.

    $$\sigma_f = -\sigma_{r=a} = p_i$$

  - Radial and axial displacement:



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

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

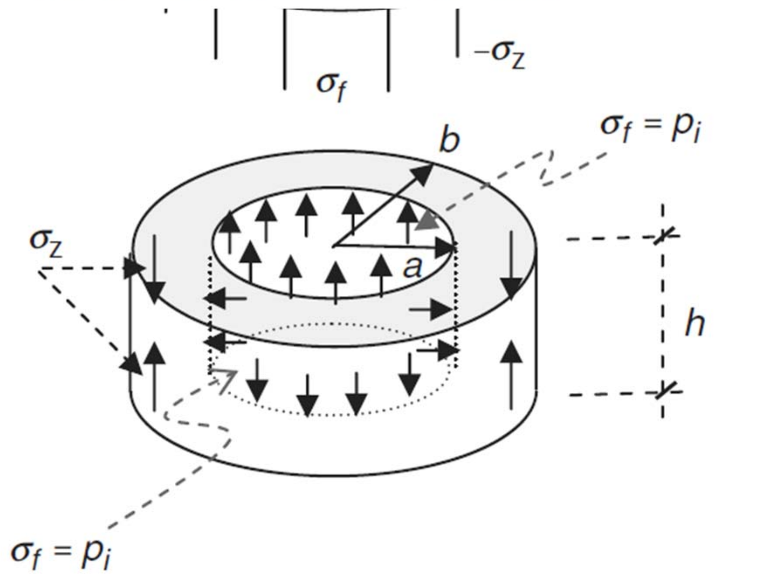
$$w_h = \frac{2}{\pi}\frac{1}{E}\left(\frac{F}{b^2-a^2}\right)\left[\frac{h\left(a^2(1-2\nu)+b^2\right)}{2b^2(1+\nu)+a^2(3-6\nu)}\right]$$

  - Radial, circumferential and axial stress:

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

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

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



HUMAN IVD UNDER COMPRESIVE FORCE

- Non linear geometry solution algorithm (incremental load):
  - Step 1:
    - Start from unloaded condition: $\sigma_z = 0$
    - Material property: $E = E_0$
    - Incremental force: $\Delta F_1 = 1\left[N\right]$
    - Incremental stresses are computed: $\Delta\sigma_{r1},\quad \Delta\sigma_{\theta 1},\quad \Delta\sigma_{z1}$
    - Determine the maximum value of these stresses to update material property: $\Delta\sigma_{z1}$

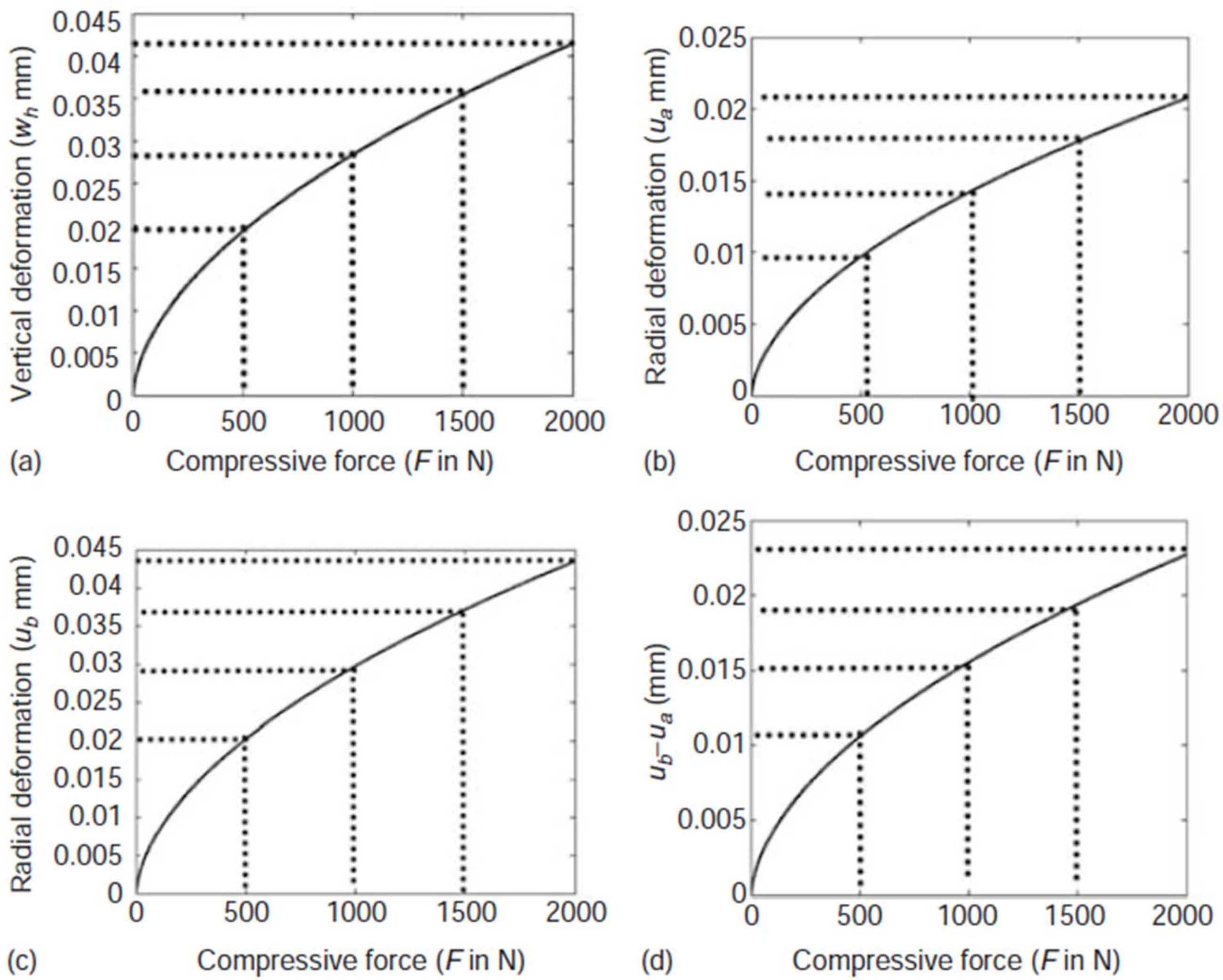
      $$E_1 = 4.2 + 373.3\left[\left|\Delta\sigma_{z1}\right|\right]^{0.473}$$
    - Calculate disc displacement, corresponding to incremental stress state: $w_{h1},\quad u_{a1},\quad u_{b1}$
    - Update disc geometry: $h_1 = h_0 - w_{h1},\quad a_1 = a_0 + u_{a1},\quad b_1 = b_0 + u_{b1}$
  - Step 2:
    - Incremental force applied to the deformed geometry: $\Delta F_2 = 1\left[N\right]$
    - Incremental stresses are computed: $\Delta\sigma_{r2},\quad \Delta\sigma_{\theta 2},\quad \Delta\sigma_{z2}$
    - Determine the maximum value of these stresses to update material property: $\Delta\sigma_{z2}$

      $$E_2 = 4.2 + 373.3\left[\left|\Delta\sigma_{z1} + \left|\Delta\sigma_{z2}\right.\right]^{0.473} = E_0 + 373.3\left[\left|\sigma_{z2}\right|\right]^{0.473}$$
    - Calculate disc displacement, corresponding to incremental stress state:

      $$w_{h1} + w_{h2},\quad u_{a1} + u_{a2},\quad u_{b1} + u_{b2}$$
    - Update disc geometry: $h_2 = h_1 - \left(w_{h1} + w_{h2}\right),\quad a_2 = a_1 + \left(u_{a1} + u_{a2}\right),\quad b_2 = b_0 + \left(u_{b1} + u_{b2}\right)$
  - Step 3: Repeat step 2 until total compressive load reaches the specified value.

HUMAN IVD UNDER COMPRESSIVE FORCE

- Numercial results:



DESIGN OF RIB SPREADER WITH HINGES

- Phase 1: Early Risk Assessment and Concept Approach.
- Phase 2: first design approach, with mechanical system.