Biomaterials in Orthopaedic Surgery

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About the image on the title page:
The three sets of circular lines symbolize the main components that contribute to advancements in biomaterials: the atom, the continuous search for improvements, and the scientific evolution of newer biomaterials.

To my wife, my four sons, and my daughter for their understanding, patience and support.

To the memory of two outstanding and brilliant surgeons:
Professor Ángel Martinez-Villarreal, M.D.
Professor Carlos de la Garza-Páez, M.D.

To my Professors of The University of Texas at Austin:
Professor Robert N. Little, Ph.D., D.Ed
Professor Stephen J. Gage, Ph.D.
Professor Kenneth M. Ralls, Sc.D.
Professor William R. Upthegrove, Ph.D.

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Foreword

Being invited by Dr. Federico Ángel Rodríguez to contribute the foreword to his book is an honor. It is greatly appreciated, since this work represents the culmination of his dreams and his many years of hard work and research.

Biomaterials are the keystone of our time; a "dreamed matter." *Matter* because they are handled and felt on a daily basis, and *dreamed* because we expect them to be magical structures that will fulfill and resolve all of our needs. Much advancement has been achieved and many dreams have come true in recent times. A brief look at what has happened in the last century shows how the new materials have contributed to surgery and to the well-being of many people.

Knowledge of biomaterials is fundamental to their appropriate use in medicine. How many times the profession traumatology has been compared to that of a carpenter or a hardware dealer!

Orthopaedic surgery and traumatology have been marked by the instruments of the profession. Luminaries such as Danis, Kuntscher, Charnley, Müller, and so many others have contributed greatly to the field, and their names are associated with specific designs and materials. I am referring to skeletal biomaterials, but their importance in heart surgery, general surgery, urology, and in many other medical specialties should not be forgotten.

Biomechanics is also concerned with the study of biomaterials; for that reason it is important to review some of the basic concepts; as it is done in this book. The technical principles for the application of biomechanics are inherent in the results of mechanical tests. Much has been learned about the possibilities of a material when looking at results as well as failures.

Failures, such as fracturing and corrosion, have helped surgeons improve their techniques and engineers improve their designs. The path has always been walked along with patients who have agreed to try out new designs believed to improve upon the previous ones.

At the end of the nineteenth century, ivory implants were used. Later on screws and metallic plates were implanted with a basic and insufficient

anesthesia, with low quality materials, without mechanical principles that supported their placement, and with a high risk of infections. Those factors eliminated many brilliant ideas. The improvement of anesthesia techniques, the understanding of mechanics applied to biology, and the incorporation of advanced metals, metallic alloys, polymers, ceramics, and composites, on top of safer antibiotic therapies are the factors that have made orthopaedic surgery move forward.

We now have resistant materials to replace bones, and elastic materials capable to act as soft tissue substitutes. Stainless steels, commercially pure titanium, titanium base alloys, cobalt chrome alloys, polyethylene or methyl-methacrylate are essential items in orthopaedic surgery and traumatology.

Also, the establishment of bone and tissue banks has contributed to extend the possibilities of biomaterials. Bone or ligament grafts are organic biological materials with an inert structure similar to the one to be replaced and with the same integration problems as the rest of the biomaterials. Research and the observation of the established rules for the tissue banks allow having grafts of all kinds and probably, in a near future will allow a fast integration of grafts coming from other species, obtained *in vivo,* to be implanted.

We are in the world of coatings, metals combined with biological substances in search of a better incorporation to the organism. In addition, we are experiencing a new period with reabsorbable materials that fulfill their function during a period of time and then gradually undergo reabsorption. Intelligent biomaterials are another emerging possibility.

Nowadays, an interesting period has begun involving materials implanted with cellular cultures. A material should no longer be only inert or active, but may require that cells adhere to the surfaces and differentiate and proliferate in the interior. Growth factors that stimulate cellular differentiation can be incorporated to the material to be considered live material.

The world of biomaterials, after years of sustained knowledge increase, is showing a new impulse and many possibilities are open; many investigations are needed. All this will be possible if history of the development of the different materials is spread, and if we have the basic knowledge offered by books like this one. This book has been written by Professor Federico Ángel Rodríguez thanks to his educational activity and a lifetime dedication to the mechanical study of materials. Professor Rodríguez has been studying biological integration of biomaterials in the organism, and he has been transmitting and shaping his knowledge in a didactic way, as the reader may note.

This book aims to satisfy the knowledge of doctors and engineers who, after finishing their professional studies, would like to enter their neighbor world and continue developing new implants.

Implantation of new materials will benefit patients and will contribute to solve some of the exciting challenges that many branches of surgery currently have.

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Preface

Biomaterials in Orthopaedic Surgery is directed to residents entering the specialty in orthopaedics and traumatology as well as to those professionals who wish to update their knowledge in the very extensive field of application of biomaterials in orthopaedics.

This book will be useful to professionals associated with orthopaedic devices, especially those involved in their design and manufacture.

Surgical practice in orthopaedics requires a strong interaction of different disciplines of science, such as biology, biomechanics, metallurgy, materials science, chemistry and, quite recently, biotechnology and nanotechnology.

The structure of the table of contents in this book is intended to help the reader obtain, through his learning process, a strong and firm grasp of the fundamental principles of biomechanics and biomaterials; both are essential to the study and comprehension of joint physiology and the issues dealing with their application in orthopaedic surgery.

This book will also help the reader have a clear frame of reference regarding the current state of science and infer the future direction of research needed to solve some of the remaining problems of biomaterials that are strongly linked to orthopaedics.

Every chapter except Chapter 8, "Clinical Cases," has a number of bibliographic references, a list of books for further reading, and an enumerated set of educational objectives that serve as a teaching tool and are aimed to reinforce the content presented in each chapter.

The creation of this book was possible only with the support and help from many people. I wish to thank and acknowledge the following colleagues for their support and valuable assistance:

- **Professor Carlos de la Garza-Páez M.D.,** former Chairman of the Orthopaedics and Traumatology Service of the Dr. José E. González University Hospital and of the Faculty of Medicine of the Universidad Autónoma de Nuevo León, for his extraordinary and enthusiastic support throughout the writing of the book.

- **Oscar F. Mendoza-Lemus M.D.,** current Chairman of Orthopaedics and Traumatology Service, for his great and continuous support
- **Carlos Cuervo-Lozano M.D.,** Graduate Advisor of the Orthopaedics and Traumatology Program, for his direct advice, valuable suggestions, and great contributions of many clinical cases.
- **Eduardo Álvarez-Lozano M.D., Ph.D.,** general coordinator in charge of the Bone and Tissue Bank of University Hospital, for his extraordinary advice regarding internal and external bone fracture fixation.
- **Professor Francisco Forriol-Campos M.D., Ph.D.,** for writing the Foreword, which provides an excellent description of the book.
- **Victor Manuel Peña-Martínez M.D.,** for his eager contribution and advice in external bone fracture fixation.
- **Pedro M. Reyes-Fernández M.D.,** for his advice in the cervical spine prosthesis and cervical and lumbar spine implants.

I also value the assistance received from many other distinguished orthopaedic surgeons that collaborated with their very extensive experience in the clinical cases.

Equally appreciated is the assistance of Professors Guillermo Elizondo-Riojas M.D. and José Bernardo Gutiérrez-Sánchez M.D., Ph.D., radiologists of The University Center for Diagnostic Images, for their revision and comments to the manuscript for the section "Artifacts of Metallic Implants in Magnetic Resonance Imaging (MRI)" presented in Chapter 9.

This book has been developed from the notes for a series of lectures given at the Dr. José E. González University Hospital. I want to express deep gratitude to the orthopaedic surgeons at the University Hospital.

Also, I wish to thank the ASM International publishing staff, including Mr. Scott Henry, Mr. Charles Moosbrugger, Ms. Pam Brown, Ms. Ann Britton, and Ms. Madrid Tramble, for their valuable assistance before and during the printing process of the book. My great appreciation to the reviewers for giving me critical advice of a constructive nature, I am also very grateful to individuals, institutions, and organizations that gave permission to use their data and illustrations, including ASTM International, The Hip Society, and the American Association of Tissue Banks. Full credit is given to the appropriate sources.

I also wish to acknowledge Mr. Carlos Limón and Mr. Omar Robles for their time spent in preparing the extensive number of figures.

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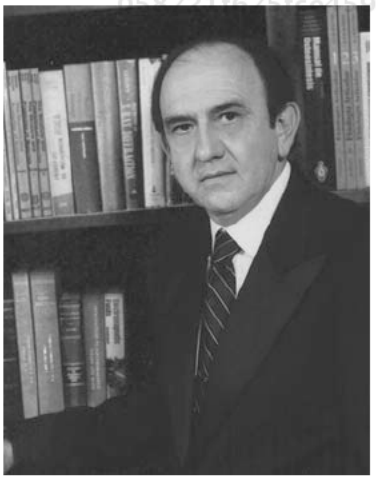

Federico Ángel Rodríguez-González, Ph.D., FASM, is a Professor and a Research Scientist with the Orthopaedics and Traumatology Service of the Dr. José E. González University Hospital of the Faculty of Medicine of the Universidad Autónoma de Nuevo León, México.

He received his B.S. in Physics from the Instituto Tecnológico y de Estudios Superiores de Monterrey, in Monterrey, México, his M.S. in Nuclear Science from The University of Michigan at Ann Arbor, Michigan, and his Ph.D. in Mechanical Engineering from the University of Texas at Austin.

His background combines research in application of the neutron activation analysis technique to study the interstitial oxygen in niobium-titanium solid solution alloys in order to determine the effect of interstitial oxygen on the superconductive transition temperature of these materials; industrial research in steelmaking using sponge iron as feedstock in electric arc furnaces to produce low carbon steels; and the optimization of the steelmaking process.

His teaching experience includes courses in nuclear and experimental physics, metallurgy, materials science, and biomaterials.

Dr. Rodríguez has presented papers related with his research work in national and international forums. He has also been a consultant for several industrial companies.

His current research interests include implant wear in hip and knee joint replacements, loosening of femoral stem components, acetabular cup and femoral stem component coatings, massive bone allograft mechanic properties sterilized with gamma radiation, design considerations of some joint prosthetic devices, and therapy in soft and hard tissue tumors.

CHAPTER 1

Introduction to Biomaterials in Orthopaedic Surgery

1.1 Definition of Biomaterial

A *biomaterial* is a material that interacts with human tissue and body fluids to treat, improve, or replace anatomical element(s) of the human body. Biomaterial devices used in orthopaedics are commonly called *implants*; these are manufactured for a great number of orthopaedic applications. Biological materials such as human bone allografts (transplants of tissue between genetically different individuals) are considered to be biomaterials because they are used in many cases in orthopaedic surgery.

Figure 1.1(a) shows a massive proximal femur bone allograft without a head. It replaces a patient's proximal femur. Figure 1.1(b) shows a femoral stem component of a hip replacement device, which is put in place of the massive femur allograft; this system is called hip alloprosthesis.

1.2 Interaction of Biomaterials with the Human Body

Clinical results in orthopaedics have demonstrated that a great need exists to find new and better biomaterials that will help satisfy the minimum requirements for orthopaedic devices to perform correctly on a long-term basis. The main fundamental requirements that orthopaedic devices must fulfill in order to function adequately are summarized in this section.

1.2.1 Biocompatibility

Biocompatibility is the primary characteristic that a medical device should have in any orthopaedic application; that is, it must not adversely affect the

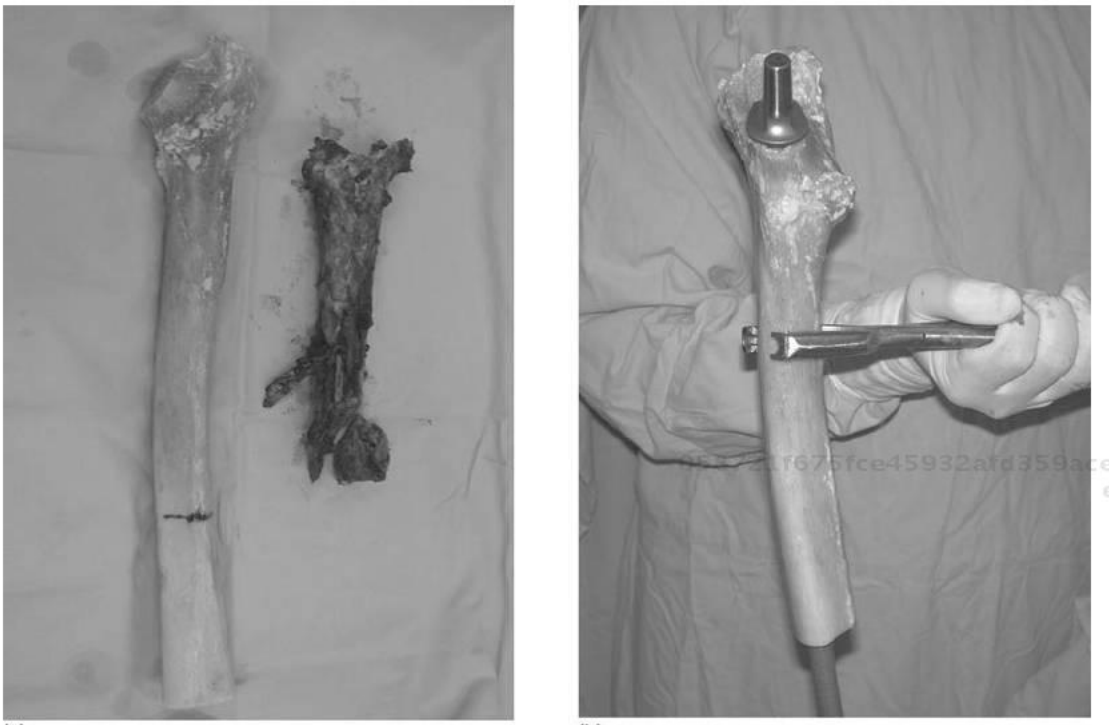

Fig. 1.1 Hip alloprosthesis. (a) Massive proximal femur replacement allograft and patient's femur. (b) Femoral stem component in place. Courtesy of Carlos Cuervo-Lozano M.D.

local and systemic host environment of interaction (bone, soft tissues, ionic composition of plasma, as well as intra- and extracellular fluids).

1.2.2 Appropriate Design and Manufacturability of Implants

Finite element analysis is a powerful analytical tool used in the design of joint replacement prostheses. Currently modern manufacturing processes are necessary to guarantee the quality needed in orthopaedic devices.

1.2.3 Mechanical and Biological Stabilities

The orthopaedic surgeon should seek the biomechanical stability of the implant, and the human body will take care of the biological stability.

1.2.4 Properties of Biomaterials

Some of the most important properties of biomaterials that should be carefully studied and analyzed in their applications are tensile strength, yield strength, elastic modulus, corrosion and fatigue resistance, surface finish, creep, and hardness.

1.2.5 Resistance to Implant Wear and Aseptic Loosening

Implant wear and aseptic loosening are very important failure problems that should be taken into consideration when dealing with long-term prosthetic devices.

1.2.6 Corrosion Resistance

Corrosion of metallic implants that occur within the human body constitutes an ion source that may potentially affect the local and systemic host environment. Therefore, an important property that must be considered is the corrosion resistance of the metallic implants.

1.3 Biomaterial Types in Orthopaedics

It is important for orthopaedic surgeons to understand the nature of biomaterials, their structural configurations, and their properties, as well as the effects of their interaction with soft and hard tissues, blood, and intra- and extracellular fluids of the human body.

The orthopaedics field has benefited from the great efforts of many orthopaedic surgeons, experimental surgery laboratories, and research centers and from research work at universities, academies, societies, scientific organizations, and many interdisciplinary groups. However, many challenges remain to be conquered in the development of new biomaterials that will improve the long-term performance of clinical results in orthopaedic surgery.

The main biomaterials used in orthopaedic surgery are divided into two groups: metals and nonmetals.

1.3.1 Metals

The use of metals in therapeutic procedures dates back several centuries. Metallic implants were used in the 17th century. In the 18th century a metal screw implant was used for the first time.

The majority of elements in the periodic table are metals. Metallic biomaterials have their main applications in load-bearing systems such as hip and knee prostheses and for the fixation of internal and external bone fractures. It is very important to know the physical and chemical properties of the different metallic materials used in orthopaedic surgery as well as their interaction with the host tissue of the human body.

The metallic implants most widely used in orthopaedic surgery are:

- Low carbon grade austenitic stainless steels: 316L
- Titanium and titanium-base alloys: commercially pure titanium (CP Ti), Ti-6Al-4V, and other titanium-base alloys
- Cobalt alloys: Co-Cr-Mo, and other cobalt-base alloys

1.3.2 Nonmetals

Three main subgroups make up this category: polymers, ceramics, and composites.

1.3.2.1 Polymers are organic materials that form large chains made up of many repeating units. Polymers are extensively used in joint replacement components. Currently the polymers most widely used in joint replacements are:

- Ultrahigh molecular weight polyethylene (UHMWPE)
- Acrylic bone cements
- Thermoplastic polyether ether ketone (PEEK)
- Bioabsorbables

1.3.2.2 Ceramics are polycrystalline materials. The great majority are compounds made up of metallic as well as nonmetallic elements; they generally have ionic bonds or ionic with some covalent bonds.

The main characteristics of ceramic materials are hardness and brittleness. They work mainly on compression forces; on tension forces, their behavior is poor.

The main ceramics in orthopaedic surgery and their applications are:

- Alumina, Al_2O_3, used for acetabular and femoral components
- Zirconia, ZrO_2, used for acetabular and femoral components
- Hydroxyapatite, $Ca_{10}(PO_4)_6(OH)_2$, used for coating stem femoral components to integrate the surface material to the bone

1.3.2.3 Composites. Composite biomaterials are made with a filler (reinforcement) addition to a matrix material in order to obtain properties that improve every one of the components. This means that the composite materials may have several phases. Some matrix materials may be combined with different types of fillers. Polymers containing particulate fillers are known as particulate composites.

The following composites are considered in the orthopaedic devices:

- Fiber-reinforced polymers
- Aggregates to polymethyl methacrylate (PMMA)

1.4 Bone Allografts

Bone allografts are commonly used as implants in orthopaedic surgery. They are procured using aseptic techniques and are preserved according to their storage needs:

- *Freeze dried/lyophilized:* tissue dehydrated for storage by changing the water content of frozen tissue to a gaseous state in a vacuum that extracts moisture

- *Fresh:* bone allograft stored for a maximum of 1 week at a temperature of 4 °C
- *Frozen:* bone allograft stored for up to 5 years at a temperature of −70 or −80 °C
- *Cryopreserved:* tissue frozen with the addition of, or placed in a solution containing, a cryoprotectant agent such as glycerol or dimethylsulfoxide
- *Demineralized:* demineralized bone matrix that is osteoconductive and is mainly used for filling bone and/or cavitary defects, not used for structural purposes

1.5 Orthopaedic Implants

Orthopaedic implants can be divided into four main groups:

- Osteosynthesis (stabilization and fixation of bone)
- Joint replacements
- Nonconventional modular tumor implants
- Spine implants

1.5.1 Osteosynthesis

In 1949 Professor Robert Danis M.D. of the Brussels Faculty of Medicine, published his book *Théorie et Practique de L'ostéosynthèse*. His main and most remarkable contribution was the rigid fracture fixation by compressive forces of the main bone fragments previously reduced and then mechanically stabilized with a plate, resulting in an early bone fracture consolidation.

The evolution of modern osteosynthesis started with the publication of Professor Danis. He made great contributions to the scientific development of internal bone fracture fixation. Maurice E. Müller M.D., Martin Allgöwer M.D., Robert Schneider M.D., Hans R. Willenegger M.D., and other colleagues made up a team to extend the basic concepts published by Professor Danis. In 1958 the group Arbeitsgemeinschaft für Osteosynthesefragen (AO) was founded, and in 1984 the Association for the Study of Internal Fixation (ASIF) was constituted. The AO group published in 1969 the first edition of the *Manual of Internal Fixation*. In 1979 the second edition was published; both editions have been reprinted. The third edition was published in 1991.

The main implants used in osteosynthesis are screws, plates, nails, and pins, in a number of different shapes and forms to fulfill the required characteristics to successfully consolidate internal and external bone fracture fixation. Relevant contributions of many orthopaedic surgeons have extended their applications, including stabilizing multitraumatized patients and correcting deformities and longitude discrepancies, among others.

Patient diagnosis, surgical technique, and application of biomechanical and biomaterials knowledge are the fundamental aspects to achieve bone

fracture consolidation. Depending on each clinical case, once these systems (for example, a plate and its screws, a blocked nail, etc.) have consolidated bone fractures, the devices might be removed.

1.5.2 Joint Replacements

Prosthetic devices are implanted in the human body to replace the affected joint in order to eliminate pain and restore its normal function. This manuscript considers mainly hip and knee joint replacements because they are by far the most widely used in orthopaedic surgery. It is well known that femoral stem joint replacements have a mean useful life which, among other factors, is intimately linked to wear particles.

1.5.2.1 Hip Joint Replacements. In the first half of the 20th century, a total hip replacement was designed and used in patients; however, the initial results were not completely satisfactory. The main concerns at that time, besides the implant design, were the surface bearing materials of the metal-on-metal and the metal-on-polymer femoral-acetabular component types. Also, methods for implant fixation (cemented and cementless femoral stem components) needed to be established.

Sir John Charnley did not use the metal-on-metal femoral acetabular component because of frictional torque in the bearing of metallic surfaces. In 1962, he found a high-density polyethylene to be a more adequate bearing surface. For the femoral stem fixation, Dr. Charnley used PMMA bone cement and finger packing as the cement insertion technique. The postoperative problems were the femoral stem subsidence.

In 1979, Carl Zweymüller, M.D., started to use a cementless tapered titanium femoral stem. A great number of total hip replacements, cemented and cementless prosthetic devices, have been developed since the relevant early design of Dr. Charnley's total hip replacement prosthetic device.

The femoral-acetabular component types currently used are:

- Metal-on-polyethylene
- Metal-on-metal
- Ceramic-on-polyethylene
- Ceramic-on-ceramic

An excellent publication that considers cemented, cementless, and hybrid implants with different designs is *The Swedish Total Hip Replacement Register* (see "References for Further Reading"). It incorporates very important clinical results of implant survival in patients with an index diagnosis of osteoarthritis, with revision due to aseptic loosening as the end point.

Currently, persistent problems remain to be solved with total hip replacements, including implant wear, aseptic loosening, and osteolysis.

1.5.2.2 Knee Joint Replacements. There are two types of the knee joint replacement: total and unicondylar.

Types of total knee replacements are:

- Nonconstrained knee replacements
- Semiconstrained knee replacements
- Constrained knee replacements

The unicondylar knee replacement is usually called half replacement. It is recommended when half of the damaged joint is to be replaced.

The implant biomaterials used in total knee replacements are titanium-base alloys, cobalt-chromium alloys, ceramics, and cross-linked ultrahigh molecular weight polyethylene. The improvements on implant materials and manufacturing processes have made great contributions to the long-term performance of these prosthetic devices.

1.5.3 Nonconventional Modular Tumor Implants

The fundamental objective in cases of oncology orthopaedics is the preservation of the affected parts. In these cases the use of bone allografts, the tumor modular prosthesis, or a combination of both is usually required. The main nonconventional modular tumor implants are:

- Nonconventional modular tumor implants with femoral replacement
- Nonconventional modular tumor implants with tibia replacement

For cases of children and adolescents who are still growing and have bone sarcoma tumors in the lower extremities, and where there is a length discrepancy, both noninvasive or invasive extendible tumor modular prosthesis can be used.

The technological development of orthopaedic implants has been extremely important in the successful results of many clinical cases. However, there is still a lot of work left to reach the expected results, which means the continuous search for new and better biomaterials to satisfy the day-to-day needs in orthopaedic surgery.

1.5.4 Spine Implants

Thanks to the instruments designed by Paul Harrington M.D., modern spine surgery started in 1950. From then on, it has been used to correct neuromuscular defects, especially those associated with poliomyelitis. Since the beginning of the 21st century there has been an increase in the manufacturing of sophisticated implants to treat different spine pathologies.

1.6 International Standards for Orthopaedic Devices

The preparation and publication of material standards is an important activity. Test protocols were established by different institutions in different

countries such as ASTM International and the International Organization for Standardization (ISO). The main efforts of all institutions are directed to obtain biocompatible and inexpensive orthopaedic devices, as well as safe and affordable material that responds to the medical requisites of the surgeon and, most important, to the needs of the patient.

Many publications, worldwide conferences, and society and academy meetings have presented clinical results of implants used in orthopaedic surgery. The final results indicate a growing interest and considerable activity in the extraordinary and expanding field of biomaterials in orthopaedic surgery.

1.6.1 ASTM Standards for Orthopaedic Devices*

The ASTM Committee F04 on Medical and Surgical Materials and Devices was created in 1962. The Committee, with a membership of approximately 880 members, currently has jurisdiction of over 250 standards, published in the *Annual Book of ASTM Standards,* Volume 13.01. Committee F04 has 34 technical subcommittees that have jurisdiction over these standards.

The technical subcommittees of F04 collectively encompass the following five primary areas:

- *Resources:* addresses standards for materials such as ceramics, metals, and polymers; it also includes standards to address the information needed on biocompatibility, test methodology, and magnetic resonance imaging.
- *Orthopaedic Devices:* focuses on methods and practices for osteosynthesis, arthroplasty, and spinal devices.
- *Medical and Surgical Devices:* pertain mostly to cardiology, neurology, audiology, gastroenterology, and plastic surgery.
- *Tissue Engineered Medical Products (TEMPs):* focuses on materials needed in, and practices and methods for, the development and applications of TEMPs technologies.
- *Computer-Assisted Orthopaedic Surgical Systems (CAOS):* writes standards for system accuracy.

1.6.2 ISO Standards for Orthopaedic Devices**

The International Organization for Standardization, known as ISO, is an International-standard-setting body composed of representatives from various national standards organizations. ISO was founded on February 23, 1947, and its headquarters is in Geneva Switzerland. The word ISO is based on the Greek word isos meaning equal and is applied for any country

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and in any language. ISO has 157 national members out of the 195 total countries in the world. The ISO catalog includes more than 17,000 published International Standards.

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EDUCATIONAL OBJECTIVES

1. In your own words define a biomaterial. Compare it with the definition given in the book.
2. What is the first and most important property of a biomaterial? Explain.
3. What metallic biomaterials are the most widely used in osteosynthesis?
4. What metallic alloy used in hip and knee replacements is called "the work horse"?
5. What is the most widely used polymer surface bearing material in hip and knee replacements?
6. What are the two main characteristics of the Co-Cr-Mo femoral head components that are usually preferred over other metallic alloys?
7. Which of the bone allografts mentioned in Chapter 1 is osteogenic? Explain.
8. Are bone allografts considered to be biomaterials? Explain.
9. Compare and contrast metallic alloy and a composite biomaterial
10. What metallic biomaterial is the most biocompatible with the human body? Explain.

11. What is the meaning of CP Ti and how many grades of unalloyed titanium are used in orthopaedics?
12. After succeeding with metal on polyethylene as bearing surfaces in the femoral-acetabular components on cemented hip stems, what was the usual problem that Dr. Charnley always had in cemented stems? Explain.

CHAPTER 2

Structures of Solids and Phase Diagrams

Electrons orbiting around the atomic nucleus in their different energy levels are quantum mechanical particles. Their behavior and the electron space distribution depend on the laws of quantum mechanics. The laws governing these orbital electrons govern the bonding of the interacting atoms in solid structures. It is not the purpose of this chapter to completely review this field of study, which is well beyond the scope of this book; however, a simple and brief explanation of the different bond types in biomaterials is pertinent.

The bond types in solids are *primary* and *secondary* bonds. *Primary* bonds are represented by covalent, ionic, and metallic bonding; *secondary* bonds are weaker than the primary bonds and are found in atoms and molecules.

Secondary bonds are represented by *permanent dipole* (directional) bonds and *fluctuating dipole* (nondirectional) bonds, also called van der Waals bonds. The latter type is particularly important in the study and application of polymers used in orthopaedic devices.

For a well-grounded understanding of biomaterials used in orthopaedic applications, the reader needs to have good knowledge not only of the types of surgical and prosthetic devices used in orthopaedic surgery, but also of the metallic and molecular bonding in solids, the use of phase diagrams, and the mechanical, magnetic, and chemical properties of biomaterials.

2.1 Crystal Geometry

A *crystal* is a solid consisting of atoms or molecules arranged in a pattern that is repetitive in three dimensions. The arrangement of the atoms or molecules in the interior of a crystal is called its *crystal structure.* The specific arrangements of solid metals represented in a three-dimensional space are known as *space lattices.*

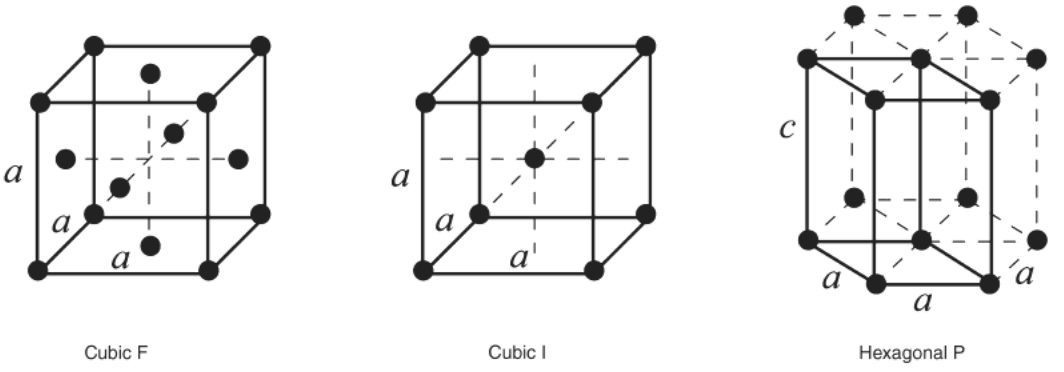

Fig. 2.1 Two cubic unit cells and one hexagonal P cell

A space lattice is a definite arrangement of points distributed in space. Each unit cell in the space has identical arrangements of points, making up the lattice points of the crystal structure.

The lattice points are arranged in 14 different ways, called the Bravais lattices. The repetitive units that make up these structures are called unit cells.

Three unit cells relevant to metallic implants are shown in Fig. 2.1. The unit cell cubic F arrangement is called face-centered cubic (fcc); it contains four lattice points per unit cell. The unit cell cubic I arrangement is body-centered cubic (bcc); it contains two lattice points per unit cell. The lattice points are the centers of the atoms. The hexagonal P (primitive) cell is shown with solid lines.

2.2 Bond Types in Atoms and in Molecules

It is important to mention that real materials may have a combination of bonds.

2.2.1 Primary Bonds

The three primary bonds are: covalent, ionic, and metallic.

2.2.1.1 Covalent Bonding. The covalent bond in solids is characterized by the *sharing of a pair of electrons between adjacent atoms.* This type of bond is directional, which means that it has a specific direction in the crystalline structure. The cubic structure of diamond is the best example of covalent bonding. Its structure is very rigid in its three dimensions.

Diamond. The diamond structure has a stable covalent bond because each carbon atom is bonded in a tetrahedral direction with its four closest adjacent atoms. See Fig. 2.2. The unit cell of diamond is the fcc structure. Diamond is the hardest natural material that exists.

Graphite. In graphite each carbon atom is covalently bonded to three adjacent atoms that are in a flat hexagonal structure. The bonds between

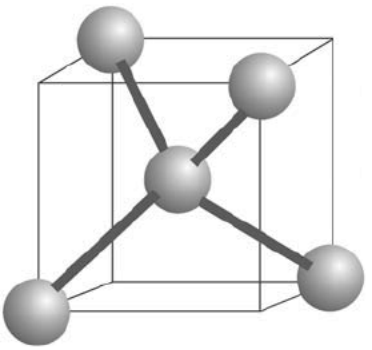

Fig. 2.2 Bonding in carbon atoms. The carbon atom is bonded in a covalent way to its four closest adjacent atoms. The bond angle is 109.5° between any carbon atoms.

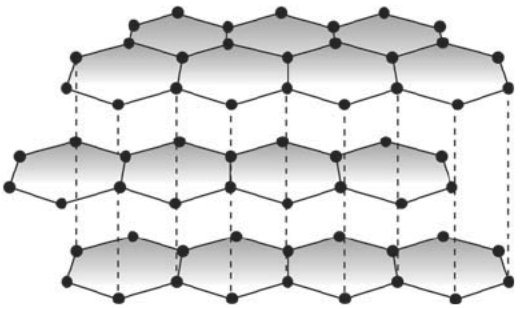

Fig. 2.3 Graphite structure

flat parallel structures are van der Waals bonds; these two bonding types are responsible for the anisotropy of graphite. The low friction coefficient of graphite is attributed to the weak bond that exists between planes; this characteristic accounts for the use of graphite as a lubricant. See Fig. 2.3.

2.2.1.2 Ionic Bonding. The ionic bond is nondirectional, and its strength resides in the electrostatic attraction between the opposite charges of the ions. Electrostatic attraction as well as electrostatic repulsion obey Coulomb's Law. This law establishes that electrostatic forces of attraction and/or repulsion are directly proportional to the product of the ion electric charges and inversely proportional to the square of the distance between charges.

In common table salt (NaCl), a typical ionic compound, the sodium releases its outermost electron, becoming a cation (Na^+), and the chlorine ion gains this electron, becoming an anion (Cl^-). In this manner these two ions (Na^+ and Cl^-) are electrostatically attracted. Other examples are MgO and SiO_2. See Fig. 2.4.

The formation of different lattices of ionic substances takes into account:

- Different charges of each ion
- The different sizes of the ions

Ionic compounds in the solid state exhibit the following main properties and characteristics:

- They have high melting points.
- They are hard and brittle.
- They have very high resistivity.

Aluminum oxide, Al_2O_3, is an ionic compound with a corundum crystalline structure (hexagonal close-packed, or hcp). Oxygen ions are localized at

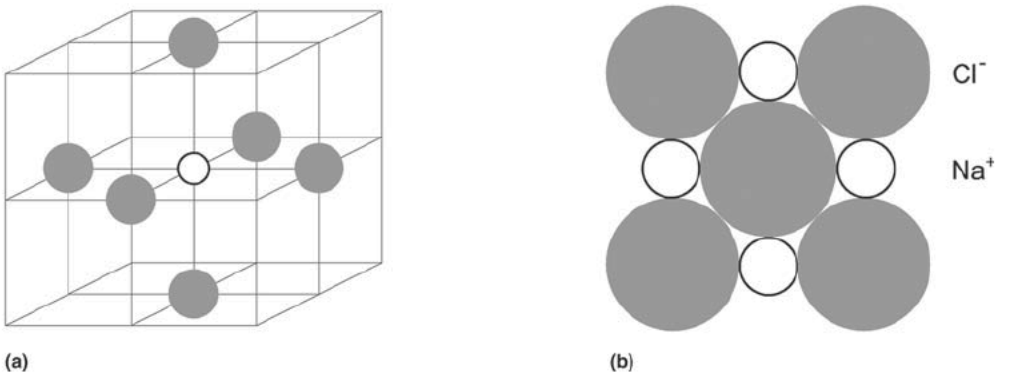

Fig. 2.4 Ionic bonding in sodium chloride (NaCl). (a) The Na^+ ions in the crystalline structure are surrounded by six nearest neighbors of opposite sign, and these nearest neighbors represent the coordination number of the NaCl structure. The rest of the Na^+ and Cl^- ions can be localized by arranging the ions in an alternatively manner at the lattice points of the cubic structure. (b) One face of the six faces of the fcc unit cell of NaCl

the lattice points with the aluminum ions at the central octahedral sites. High-purity dense aluminum oxide is used for surgical implant applications.

2.2.1.3 Metallic Bonding. Most of the elements of the periodic table are metals with valence electrons (outer shell electrons from the bonding nucleus) that are practically free to move around the crystalline network. Therefore, the main metal characteristics are electrical conductivity and thermal conductivity. Metallic bonds in these elements are nondirectional. Atoms in these elements are bonded into very stable structures.

Elements present in the different alloys of prosthetic devices include iron (Fe), chromium (Cr), nickel (Ni), zirconium (Zr), titanium (Ti), molybdenum (Mo), niobium (Nb), and cobalt (Co). The unit cells of these elements are shown in Fig. 2.1.

The Fe, Ti, Co, and Zr elements are *allotropic*; that is they have different crystalline structures at different temperatures. By convention, these different structures are identified by Greek letters:

Element	Structure (symbol)	Structure (symbol)
Fe	bcc (α, δ)	fcc (γ)
Ti	hcp (α)	bcc (β)
Co	hcp (α)	fcc (β)
Zr	hcp (α)	bcc (β)

bcc, body-centered cubic; fcc, face-centered cubic; hcp, hexagonal close-packed

Figure 2.5 shows the cubic and hexagonal close-packed crystal structures of these elements. The allotropy of pure metallic elements, such as iron, titanium, cobalt, and zirconium, where temperature is the only variable, is considered to be a *one-component system*.

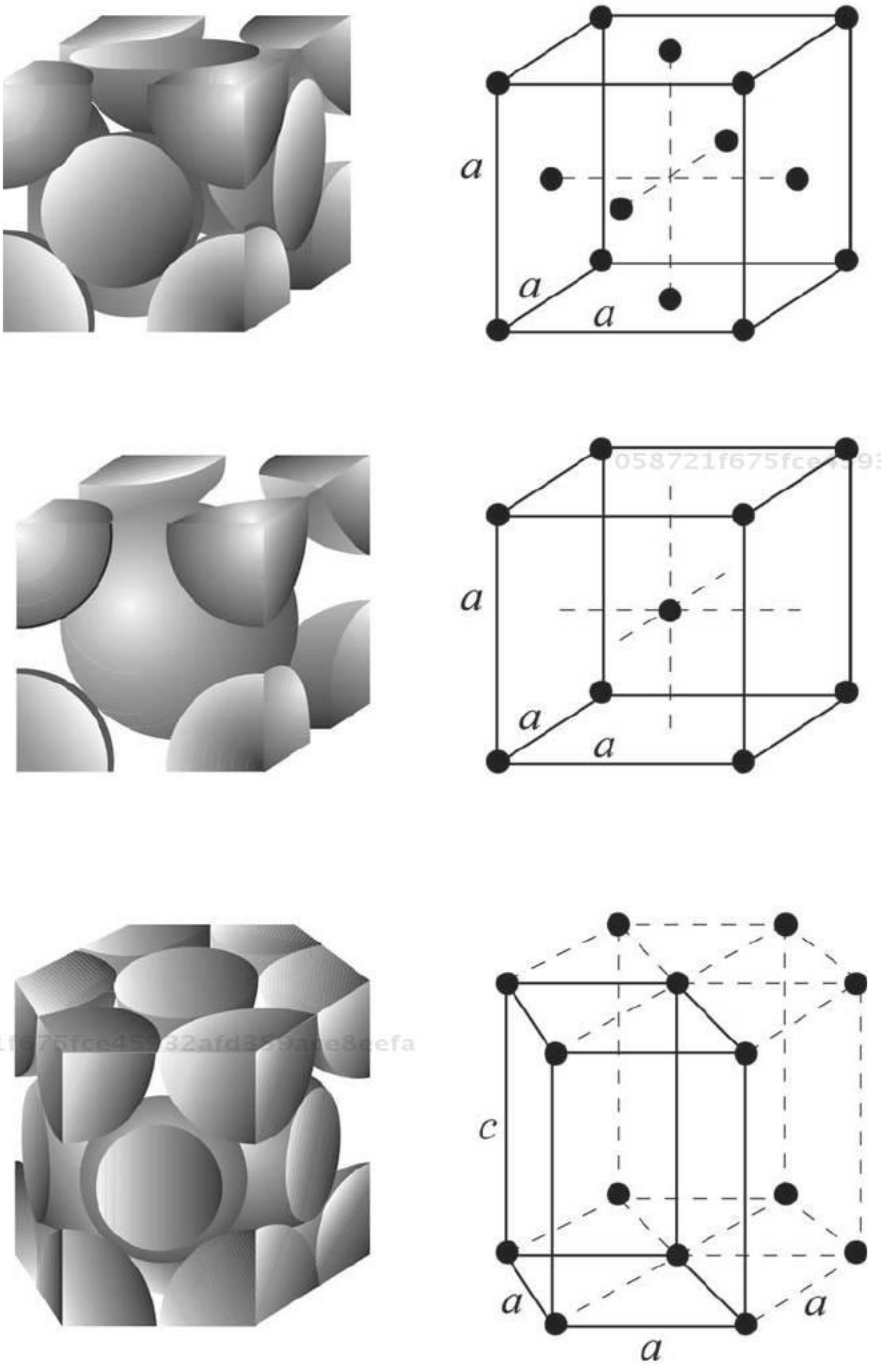

Fig. 2.5 Face-centered cubic (top) and body-centered cubic (middle) crystal structures show that the center of the atoms coincide with the lattice points of the fcc and bcc unit cells; however, in the hexagonal close-packed (hcp) crystal structure (bottom) the centers of the atoms do not coincide with its lattice points.

2.2.2 van der Waals Bonds

The secondary van der Waals bonds are nondirectional and weaker. These bonds result from the attractive interaction of *fluctuating dipole* moments between atoms. The dipole moment takes place when the charge distribution at a given time in an atom is eccentric; that is, the center of the given charges (positive and negative) do not coincide. These bonds are important in the study and applications in orthopaedic surgery of organic materials such as polyethylene and acrylic bone cement.

2.3 Melting of Metals

Different systems are used to melt metals for the manufacture of surgical and metallic orthopaedic devices. Some of these systems require special gases to be used in the chamber where the melting takes place to obtain very clean alloys that are free of unwanted elements. Vacuum induction melting (VIM), investment casting, vacuum arc remelting (VAR), and copper hearth melting (plasma or electron beam) are processes widely used in the manufacture of metallic orthopaedic devices. Hot isostatic pressing (HIP) is a powder metallurgy (P/M) technique used in the manufacture of certain metallic alloys. This technique is useful for the manufacture of total hip and total knee joint replacements.

2.4 Solid Solutions

When two- or three-element alloys occur in a solid state, they form what is known as solid solutions. They exist in two different forms, the substitutional solid solution and the interstitial solid solution. The element that is more abundant is called the solvent; the one that is less abundant is called the solute. In Fig. 2.6 and 2.7, it is easy to distinguish between the solvent and the solute.

2.4.1 Substitutional Solid Solutions

The solute atoms occupy the lattice points of the unit cubic cell, as seen in Fig. 2.6.

2.4.2 Interstitial Solid Solutions

The solute atoms that are found at the interstitial sites of the solid structures differ considerably in size from the solvent atoms that occupy the lattice points. A typical example of this is the carbon in iron (steel). The carbon atom is so small that it cannot occupy a place in the lattice points of the crystal structure. See Fig. 2.7.

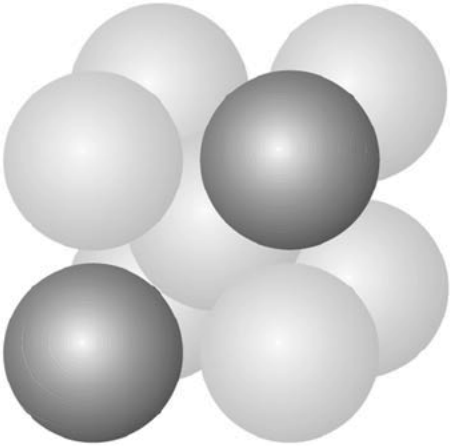

Fig. 2.6 Substitutional solid solutions

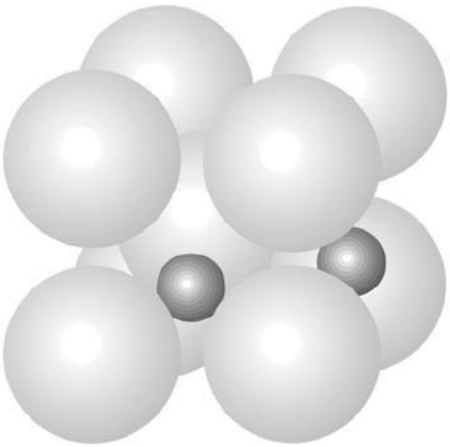

Fig. 2.7 Interstitial solid solutions

2.5 Phase Diagrams

Phase diagrams are important in the study, application, and manufacture of metallic alloys. Phase diagrams represent the relation of the chemical composition of a material with temperature and microstructure. Phase diagrams usually represent the composition limits of phase fields in an alloy system as they exist under conditions of thermodynamic equilibrium; in this case they are known as *equilibrium diagrams*.

On the microstructure level, regions of the metal with same structure and a similar chemical composition are called phases or grains. Generally, microstructures with smaller grains are stronger.

When two-component elements are alloyed a *binary* phase system is formed. When three-component elements are alloyed a *ternary* phase system is formed.

In orthopaedic devices the alloys are usually described on the basis of composition of the matrix elements, for example, titanium-base alloys and cobalt-base alloys.

2.5.1 Binary Solid Solution Diagram

The Cu-Ni phase diagram in Fig. 2.8 bears importance because it shows only one phase (α) for all the proportions of the elements copper and nickel. Starting from left to right, the nickel content goes from 0% to 100%. This means that the Cu-Ni binary phase diagram shows a complete substitutional solid solubility. The copper and nickel elements have the same fcc crystalline structure. Additional examples of a complete solid solution, besides the Cu-Ni (fcc) alloys, are the Ag-Au (fcc) and the Cr-Fe (bcc) systems.

Complete substitutional solid solutions can occur in all proportions for two-component systems under certain conditions known as the Hume-Rothery rules. Without going into detail, these rules require that the

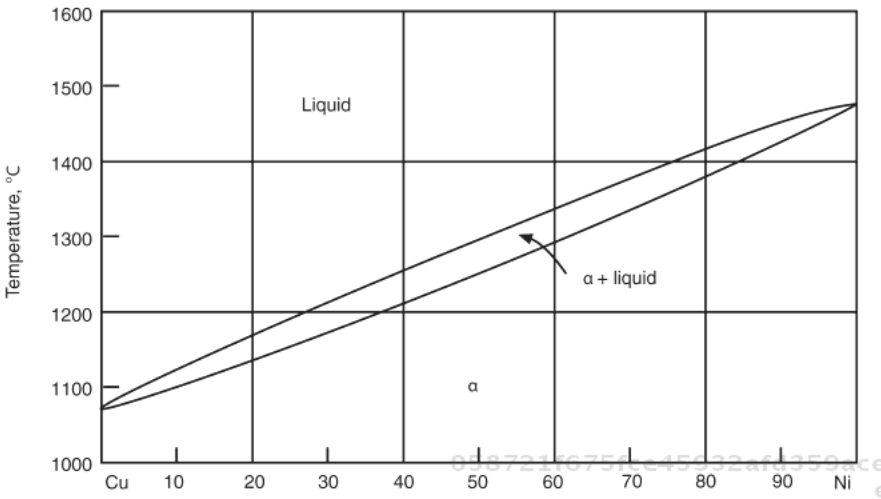

Fig. 2.8 Copper-nickel phase diagram. Element concentrations are in weight percent. Adapted from *Metals Handbook,* 8th ed., *Metallography, Structures and Phase Diagrams,* American Society for Metals, 1973, p 291

elements in these systems are close in atomic size, have small difference in electronegativity, have the same valence, and have the same crystal structure.

It is unusual to find a good number of binary solid solutions mainly due to their differences above the upper limits of the atomic size given by the Hume-Rothery rules.

2.5.2 Binary Eutectic Diagram

A good example is the Ag-Cu binary eutectic diagram. Silver and copper have an fcc crystalline structure.

The eutectic temperature that is reached in binary phase diagram occurs at the *eutectic point,* that is, the lowest point where liquid L phase temperature coincides with the α and β solid phases. See the Ag-Cu phase diagram in Fig. 2.9(a).

In the Ag-Cu alloy shown in Fig. 2.9(a), the solid solubilities are limited; that is, 8.8 wt% Cu is dissolved in the fcc structure of silver at 779.4 °C, and 8.0 wt% Ag is dissolved in the fcc structure of copper at the same temperature. An example of Ag-Cu alloy with eutectic composition is the Mexican silver coins used at the beginning of last century, see Fig. 2.9(b).

2.5.3 Intermediate Phases

It is possible to have crystal structures or phases that are different from those of their elemental components. Such structures are called intermetallic compounds; they occur in a number of solid solution alloy systems. An example is the Fe_3C (iron carbide) phase in the iron-carbon phase diagram shown in Fig. 2.10.

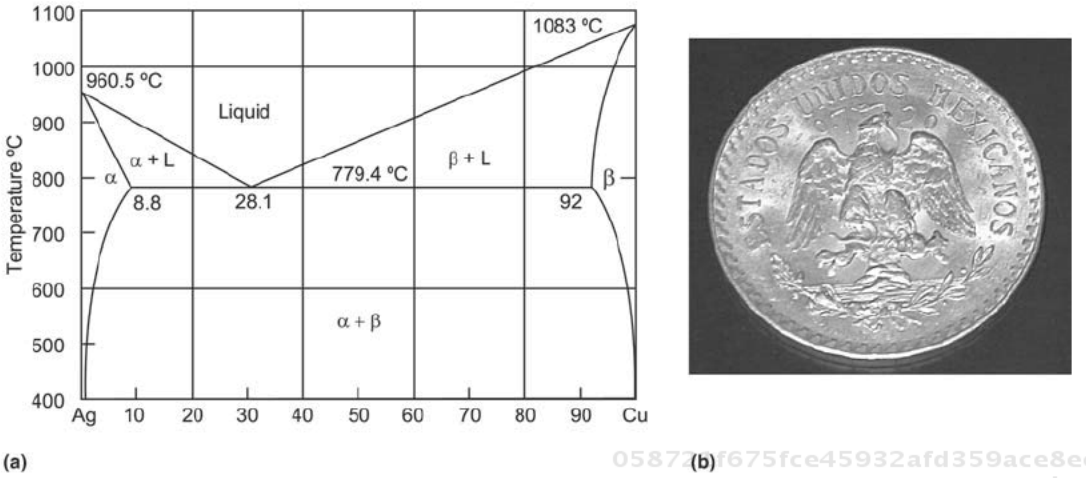

Fig. 2.9 Silver-copper alloys. (a) The Ag-Cu phase diagram. Element concentrations are in weight percent. Adapted from *Metals Handbook,* 8th ed., *Metallography, Structures and Phase Diagrams,* American Society for Metals, 1973, p 253. (b) Silver-copper coin (71.9 wt% Ag)

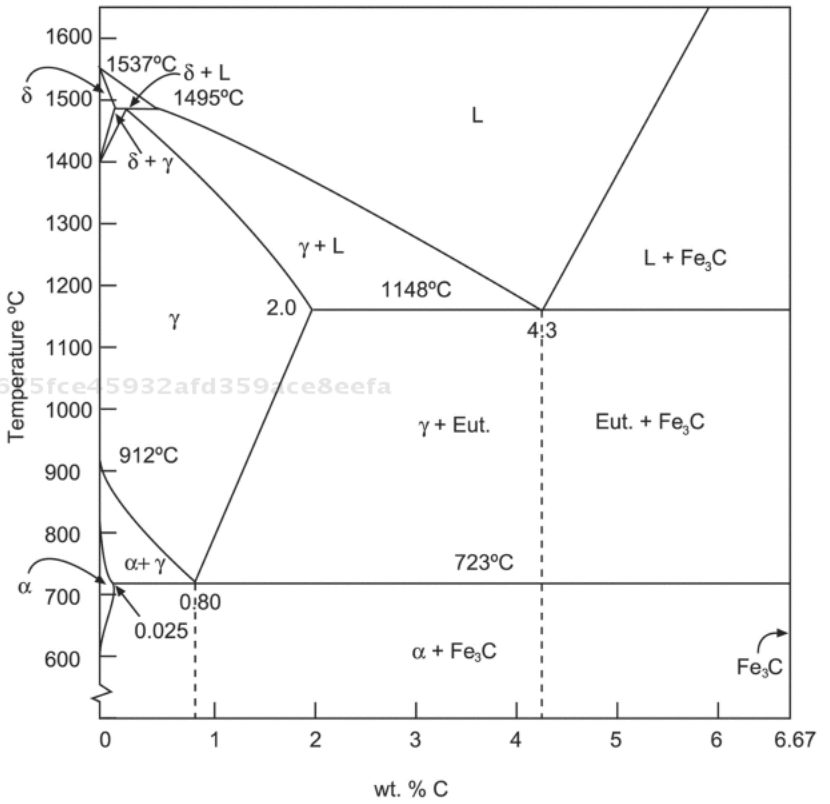

Fig. 2.10 The iron-carbon phase diagram

2.5.4 Three-Phase Reaction Plain Carbon Steels

2.5.4.1 Allotropic Transformations of Pure Iron. To make the best use of alloys, it is important to know the changes that occur in the crystalline structure of metallic biomaterials. These changes influence or are responsible for the intrinsic properties of the alloys, such as tensile strength, ductility, hardness, magnetic susceptibility, and so on. The allotropic forms of pure iron are shown in Fig. 2.11.

2.5.4.2 Phase Diagram for the Fe-Fe_3C System. Commercial steels (plain carbon steels) are alloys containing iron, carbon, and manganese; in addition, they may contain other elements: *natural, residual,* and *additions*. Alloying additions are purposely added to provide or increase desired properties.

2.5.4.3 Phases and Invariant Reactions. The Fe-Fe_3C binary phase diagram is one of the most commonly consulted diagrams, given its importance and the large volume of steel that is handled worldwide. See Fig. 2.10. In this system, four solid phases participate in three invariant reactions:

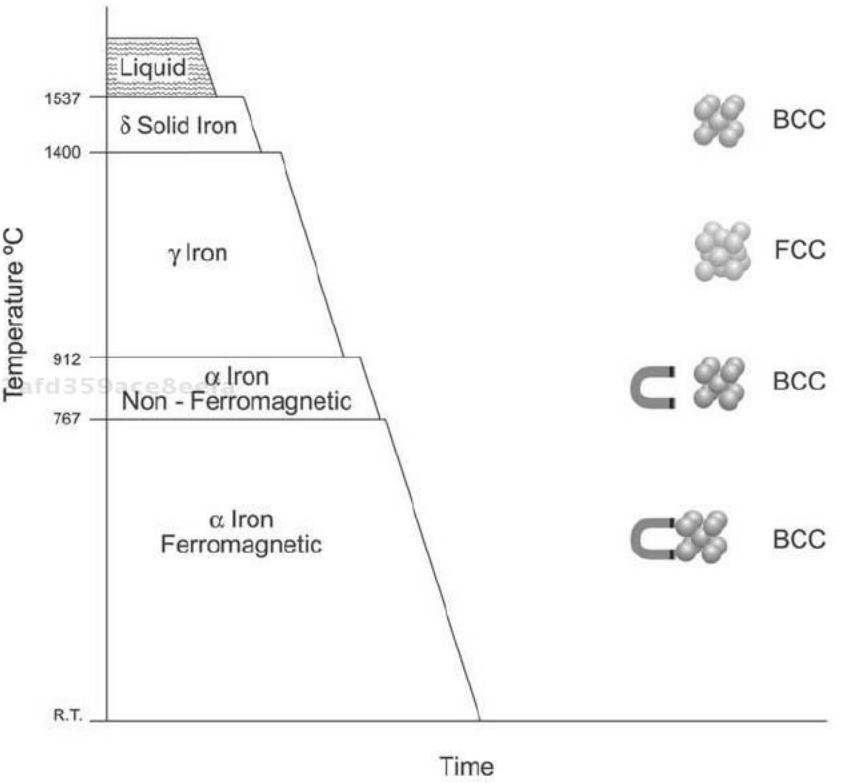

Fig. 2.11 Changes in pure iron as it is cooled from a liquid state at room temperature. Source: ASM International Materials Engineering Institute course, Metallurgy for the Non-Metallurgist, Lesson: Heat Treatment of Steel, ASM International, Fig. 11-1, p 11-2

- Peritectic: $\delta + L + \text{cooling} \rightarrow \gamma$ at 1495 °C
- Eutectic: $L + \text{cooling} \rightarrow \gamma + Fe_3C$ at 1148 °C
- Eutectoid: $\gamma + \text{cooling} \rightarrow \alpha + Fe_3C$ at 723 °C

Three important structures and phases shown in the diagram are austenite, ferrite, and cementite:

- Austenite: (γ phase) fcc structure that dissolves up to 2% C at 1148 °C
- Ferrite: (α phase) bcc structure that dissolves a maximum of 0.025% C at 723 °C
- Cementite: Fe_3C, iron carbide is an intermetallic compound that has an orthorhombic structure that contains 12 iron atoms and 4 carbon atoms (in a three-to-one-ratio) per unit cell; this corresponds to a carbon content of 6.67%.

2.6 Isothermal Time Temperature Transformation Diagram for Eutectoid Steel (0.80% C)

Every branch of applied science needs materials that have certain properties that are necessary to fulfill a specific function. Many materials applications require certain mechanical properties; in steels, these may include specific levels of hardness, ductility, and so on. These requirements can be achieved in different ways. One of those ways is with thermal treatments. Thermal treatments facilitate mechanical property changes that are useful for certain purposes.

A heat treatment may be defined as the process of heating and cooling metallic alloys such as steels to obtain certain mechanical properties. Many different heat treatment processes may be employed, just as there are many specifications for steel types that require certain mechanical property changes. The heat treatment field of steels is very extensive and complex. For illustration and for learning purposes, consider the heat treatment of the eutectoid steel (0.80% C).

1. **Heating procedure for a eutectoid steel (0.80%C).** Take the steel sample to a temperature above 723 °C, for example, 950 °C, and hold it at that temperature for the amount of time it takes for the original structure ($\alpha + Fe_3C$) to change completely to austenite γ phase. This process requires time because of the principle of nucleation and growth, see Fig. 2.12. As soon as the steel sample cools below the eutectoid temperature of 723 °C, the austenitic phase starts its transformation. The changes have to be carefully monitored and controlled. Experiments of isothermal transformation of austenite in plain carbon steels determine what is usually called the C curves, see Fig. 2.13 (A stands for austenite, F for ferrite, and C for carbide).
2. **Three paths of the cooling processes of eutectoid steel (0.80%C).** (The temperature and hardness values are approximated.)

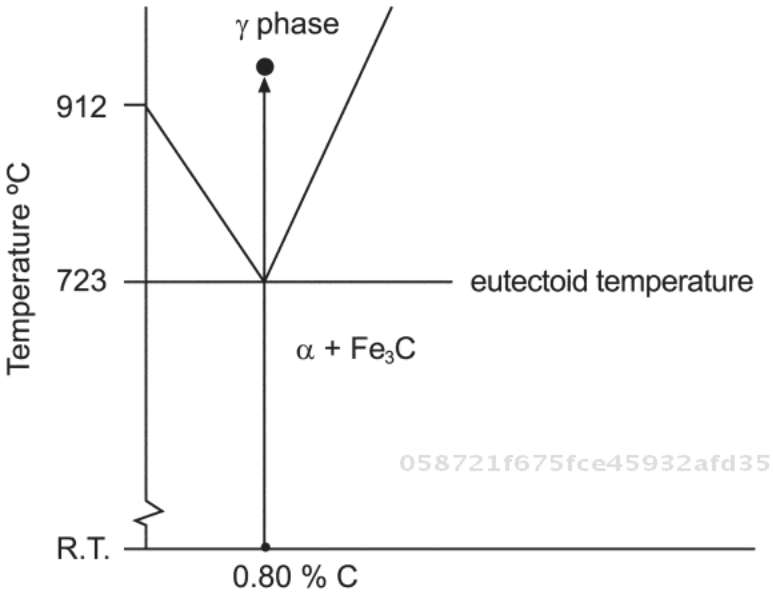

Fig. 2.12 Heating procedure of eutectoid steel

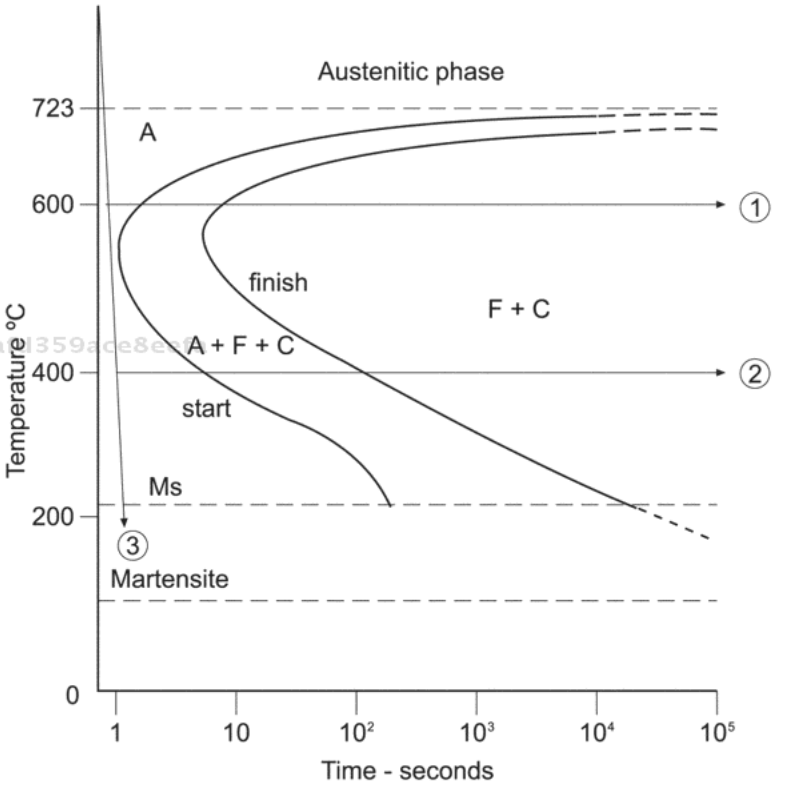

Fig. 2.13 Cooling paths of an isothermal transformation for eutectoid steel. Source: Adapted from the *Atlas of Isothermal Transformation and Cooling Transformation Diagrams,* ASM International, 1977, p 28

Path 1—Pearlite

- Cooling transformation temperature is 600 °C.
- Pearlite formation starts at the left curve and finishes when it leaves the second curve.
- Pearlite is a lamellar structure composed of ferrite (α) and cementite (Fe_3C), and it goes from coarse (soft) down to fine (hard) pearlite as the temperature goes down.
- Hardness is 38 HRC.

Path 2—Bainite

- Cooling transformation temperature is 400 °C.
- Bainite formation starts at the left curve and ends when it leaves the second curve.
- Bainite is a mixture of ferrite and cementite particles.
- Hardness is 42 HRC.

Path 3—Martensite

- Cooling transformation temperature is 230 °C.
- Martensite starts (M_s) when it reaches a temperature of ~230 °C. This requires a very rapid cooling rate without touching the nose of the left curve, as seen in path 3.
- Martensite: is a carbon oversaturated solid solution in body-centered tetragonal (bct) structure.
- Hardness: This microstructure is the hardest. Hardness (HRC) range is in the upper 50s and low 60s. As observed, the hardness of the steel microstructures increases as the cooling transformation temperature decreases.

It is important to mention that plain carbon steels such as the eutectoid steel are not used in orthopaedic devices. However, it is worthwhile to know some of the fundamental concepts of the heat treatments described.

These same basic concepts apply to heat treatments such as process annealing needed for austenitic stainless steels wires used mainly in osteosynthesis (ASTM F 138, "Standard Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)") and the heat treatments for stainless steels used for surgical instruments (ASTM F 899, "Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments").

2.7 Definitions of Some Additional Heat Treatment Processes Related to Metallic Orthopaedic Devices

Annealing is heating to and holding at a suitable temperature and then holding at a suitable rate, for such purposes as reducing hardness, improving

machinability, facilitating cold working, producing a desired microstructure, or obtaining desired mechanical, physical, or other properties. When applied to ferrous alloys, the term annealing, without qualification, implies full annealing.

Solution annealing is a heat treatment that is applied to austenitic stainless steels in order to acquire a homogeneous microstructure free from carbides; such carbides are detrimental when localized at the grain boundary. Solution annealing is also applied for some cast and wrought alloys for machining purposes.

REFERENCES FOR FURTHER READING

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EDUCATIONAL OBJECTIVES

1. Name the primary bond types of the solid structures.
2. Is the molecular bond as strong as the covalent bond? Why?
3. What are the main applications of solids used in orthopaedics?
4. List the different bonds types, from strongest to weakest.
5. What are the bond types of graphite?
6. Define allotropy in your own words.
7. What are the most common crystal structures found in metallic biomaterials?
8. List two factors that justify the importance of phase diagrams.
9. Name the systems of solid solubility and explain each.
10. In what kind of implants is it useful to know the iron-carbon phase diagram?
11. Explain the difference between residual and addition elements.
12. What are the main purposes of a heat treatment?

CHAPTER 3

Types of Biomaterials in Orthopaedics

3.1 Metallic Biomaterials

The demand for high-quality metallic implants requires state-of-the-art melting systems using inert gas atmospheres. The processes used to achieve the final product are also quite rigorous in order to fulfill ASTM and ISO standards.

The metallic implants addressed in this chapter are stainless steels, titanium, titanium-base alloys, and the cobalt-base alloys.

Some of the melting systems used for the production of the metallic implants are:

- *Vacuum induction melting (VIM)* involves melting the metallic charge under vacuum; the heat source is electromagnetic induction eddy currents in the metallic charge. The vacuum is used in order to prevent the presence of gases such as oxygen and nitrogen, mainly in the production of high-purity metals and/or alloys, which may serve as master alloys for the investment casting process and the production of electrodes for remelting, among other uses.
- *Investment casting* involves casting metal into a mold produced by surrounding, or investing, an expendable pattern with a refractory slurry that sets at room temperature, after which the wax or plastic pattern is removed through the use of heat prior to filling the mold with liquid metal. Investment-cast cobalt-base alloys are used for special applications and in the production of orthopaedic devices. These alloys are strengthened by the presence of carbide formers such as molybdenum or tungsten.
- *Vacuum arc remelting* (*VAR*) is a consumable-electrode remelting process in which heat is generated by an electric arc between the electrode and the ingot. The process is performed inside a vacuum chamber. Exposure of the droplets of molten metal to the reduced pressure reduces the amount of dissolved gas in the metal.

This section describes the grain sizes of metallic microstructures obtained by different melting systems that may be combined with additional mechanical and thermal processes for further improvement of the products.

The Co-Cr-Mo casting products used for orthopaedic devices require very clean casting quality; that is, they must be free of nonmetallic inclusions. The ASTM F 75 standard specifies chemical requirements, product analysis tolerances, and as-cast mechanical property requirements for these products.

The main advantage of as-cast condition is the casting into the desired form. However, cast products show coarse grain microstructures. These reflect lower tensile and fatigue strength compared to wrought and forgeable alloys.

ISO Standard 9584:1993 is concerned with the radiographic examination of cast metallic surgical implants and ISO Standard 15374:1998 with the requirements for production of forgings.

Wrought Co-Cr-Mo alloys with smaller grain size (average grain size No. 5 on the ASTM scale) show better tensile strength and fatigue strength than those in the as-cast condition. ASTM F 1537, "Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants" applies to wrought bar stock, rod, and wire.

Vacuum induction melting and electroslag remelting systems are necessary for the manufacture of cast/wrought products for implants. The forging and hot-worked processes of metallic devices are also important. Another high-purity melting process is cold hearth melting, using plasma or electron beam energy. Thermal spray technology can also be used to produce highly pure materials for coating purposes.

Hot isostatic pressing (HIP) process is a powder metallurgy (P/M) technique used to manufacture orthopaedic devices composed of Fe-Cr-Ni, Co-Cr-Mo, and Ti-6Al-4V, as well as many other high-quality products. The HIP process involves simultaneously heating and forming a compact in which the powder is contained in a sealed flexible sheet metal or glass enclosure, and the powder is subjected to equal pressure from all directions at a temperature high enough to permit plastic deformation and sintering to take place. The simultaneous application of heat and pressure virtually eliminates internal voids and microporosity through a combination of plastic deformation, creep, and diffusion. This process plays an important role in the manufacture of hip and knee total joint replacements.

The main advantages of the P/M process are the fine grain size and homogeneous metallic structure throughout the implant material. Fine carbide distribution is also important.

3.1.1 Stainless Steels

Stainless steels have a great resistance to corrosion because of their high chromium content (above12 wt%). Stainless steels are classified as austenitic, martensitic, and ferritic, according to their structural phases.

3.1.1.1 Fe-Cr-Ni Ternary Phase Diagram. The Fe-Cr-Ni ternary phase diagram (Fig. 3.1) is the starting point in the study and application of stainless steels used in orthopaedic devices. Various classes of stainless steels used for surgical implant and medical instruments are associated with different phases as shown in the phase diagram.

Surgical Implants—Low Carbon Grade Austenitic Stainless Steels. The austenitic γ phase, as shown in Fig. 3.1, is not susceptible to magnetic fields. This phase is achieved by the addition of a strong austenite stabilizer. Nickel is usually the common addition to the basic iron-chromium composition, as it improves its corrosion resistance. The austenitic structure is also achieved by adding manganese/low-nickel to the iron-chromium composition.

In binary phase diagrams the phase changes are easily observed in any given composition as the temperature goes from room temperature to liquid state in the alloy elements.

Several phases are shown in Fig. 3.1 at 650 °C. This is called an isothermal section from the Fe-Cr-Ni system. When comparing isothermal sections

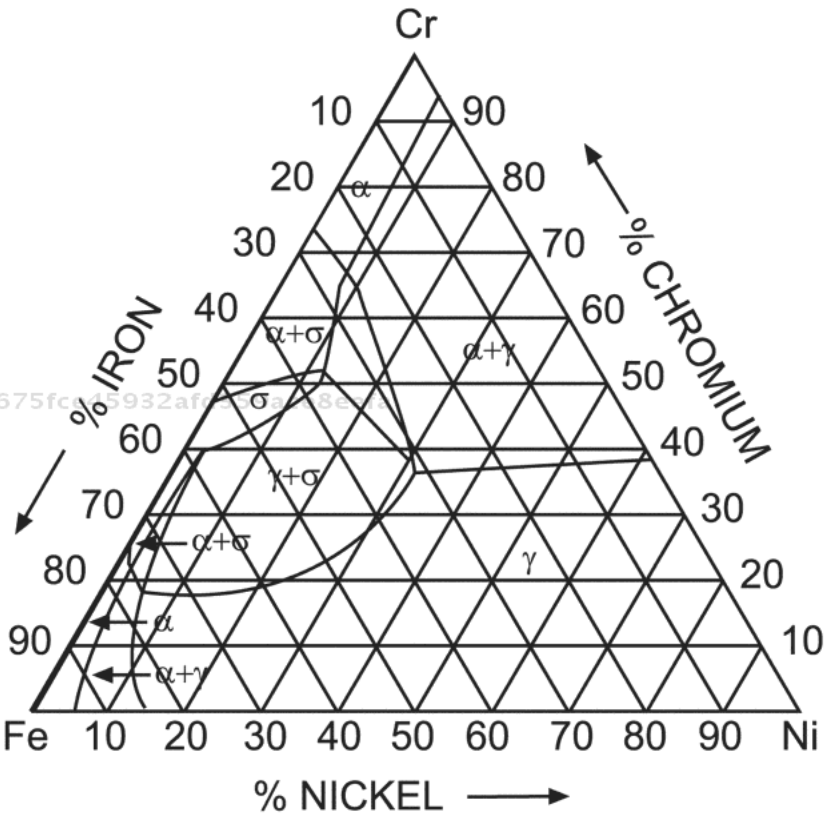


Fig. 3.1 Fe-Cr-Ni ternary phase diagram showing the isothermal section at 650 °C. Source: *Metals Handbook,* 8th ed., *Metallography, Structures, and Phase Diagrams,* American Society for Metals, 1973, p 425

Table 3.1 Carbon, chromium, nickel, and molybdenum contents of selected austenitic stainless steels

	Composition, %			
Type	C max	Cr	Ni	Mo
Selected conventional austenitic stainless steels				
302	0.15	17.00–19.00	8.00–10.00	. . .
304	0.08	18.00–20.00	8.00–10.50	. . .
316	0.08	16.00–18.00	10.00–14.00	2.00–3.00
317	0.08	18.00–20.00	11.00–15.00	3.00–4.00
Selected low-carbon grade austenitic stainless steels				
304 L	0.03	18.00–20.00	8.00–12.00	. . .
316 L	0.03	16.00–18.00	10.00–14.00	2.00–3.00
317 L	0.03	18.00–20.00	11.00–15.00	3.00–4.00
ASTM F 138 specification for 316 and 316 L				
316	0.08	17.00–19.00	13.00–15.50	2.00–3.00
316 L	0.030	17.00–19.00	13.00–15.50	2.00–3.00

L stands for extra low carbon. Source: *ASM Handbook*, 9th ed., Vol 3, and ASTM F 138

taken at different temperatures, the number of phases of the stainless steels in Fig. 3.1 may change as well as the border lines between phases. See Appendix I for composition determination.

The main elements composing some of the low-carbon grade austenitic stainless steels are given in Table 3.1.

The 316L low carbon grade austenitic stainless steel is a biomaterial widely used for implants in orthopaedics and traumatology.

ASTM F 138, "Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants," specifies requirements for Grade 1 (316) and Grade 2 (316 L), including mechanical properties and dimensions for bar and wire in hot-worked, annealed, and cold-worked conditions. It also gives the mechanical requirements for fine wire in the annealed and cold-drawn conditions.

The medical practice in orthopaedics and traumatology requires metallic biomaterials to have certain mechanical properties, from the beginning of the operating period, as well as during the surgery. An annealed low-carbon grade austenitic stainless steel wire, which becomes soft and flexible after treatment, will help the surgeon align the strut properly in an osteosynthesis procedure. See Fig. 3.2. Osteosynthesis is considered when screws cannot be placed in a femoral diaphysis fixation. A cable is fixed by the pressure of the lock located on the plate. See Fig. 3.3.

Surgical Instruments—Martensitic Stainless Steels. The martensitic stainless steels are iron-chromium binary alloys. They are susceptible to magnetic fields and are hardened by heat treatment. These stainless steels are designated in the 400 series, and are described in ASTM F 899, "Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments." Martensitic stainless steels applications are used in surgical instruments because of their mechanical properties (tensile strength, fatigue, hardness, impact, and creep) and their great resistance to corrosion.

Fig. 3.2 Minimal osteosynthesis performed with a 1.2 mm diameter 316L monofilament wire with bone allograft cortical struts in an arthroplasty revision procedure of a 45-year-old man. Courtesy of Eduardo Álvarez-Lozano, M.D., Ph.D., and Tomás Ramos-Morales M.D.

Fig. 3.3 Femoral diaphysis fixation with a plate and braided wire, second revision, in a 60-year-old man. Courtesy of Carlos Cuervo-Lozano M.D.

Surgical Instruments—Ferritic Stainless Steels. Ferritic stainless steels are iron-chromium binary alloys. They are susceptible to magnetic fields and not hardened by quenching. However, certain mechanical properties such as ductility and toughness may be reached by annealing and quenching. The 430 F and XM-34 are the only ferritic types described in ASTM F 899.

3.1.1.2 Microstructures and Grain Size. Metallography is the science used to characterize the granular structure of metals and their alloys. The grains in the microstructures represent the crystal structure of the specimen. Microstructure descriptions are related to the mechanical properties of metals and/or alloys under study. The microstructures are observed under a microscope.

The grains that make up such structures are divided in three groups:

- Grains visible to the naked eye, called macroscopic. For example, the thin zinc grains that are observed in the metallic buckets made of galvanized steel
- Grains structures that can only be seen under a light microscope with a typical magnification range of 100×, 250×, or sometimes 1000×
- Grain structures that can be observed only with the use of an electronic microscope, which can provide magnifications up to 100,000×

ASTM E 112, "Standard Test Methods for Determining Average Grain Size," classifies austenitic stainless steels with numbers that go from 1 to 8. (ASTM also provides various plates for grain size comparison.) Grain size number 1 is the largest, and number 8 is the smallest. Grains sizes from 1 to 4 are called coarse grains, 5 and 6 are medium, and 7 and 8 are fine grains.

3.1.1.3 ASTM F Standards for Orthopaedic Devices. Table 3.2 lists the ASTM F standards for stainless steels used in orthopaedic devices. ASTM F 138 standard mentions the microcleanliness of the austenitic stainless steel as determined by ASTM E 45, "Standard Test Methods for Determining the Inclusion Content of Steel." The amount of thin and heavy inclusion types such as sulfides, aluminas, silicates, and globular oxides can be determined by comparison to plates provided by ASTM.

The microstructure of Fig. 3.4 is a low-carbon grade austenitic stainless steel 316L monofilament wire in the annealed condition. This is the same monofilament wire shown in Fig. 3.2. Figures 3.5 to 3.10 show various orthopaedic fixation devices made from 316L stainless steel and microstructures that result from different processing operations.

3.1.1.4 ISO Standards for Orthopaedic Devices. The ISO standards that relate to stainless steels used for orthopaedic devices are ISO 5832-1:2008, "Implants for Surgery—Metallic Materials—Part 1: Wrought Stainless Steels" and ISO 5832-9:2007, "Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel."

Table 3.2 ASTM F standards for stainless steels used for orthopaedic devices

Stainless steels	Standard	Uses in orthopaedics
Fe-18Cr-14Ni-2.5Mo (wrought)	ASTM F 138	Surgical implants
Austenitic (Grades 1 and 2)	ASTM F 138	Surgical implants
Grade 1 (316)	Special Quality	Bar and wire
Grade 2 (316L)	Special Quality	Bar and wire
Austenitic	ASTM F 139	Surgical implants
Grade 1 (316)	Special Quality	Sheet and strip
Grade 2 (316L)	Special Quality	Sheet and strip
Fe-18Cr-12.5Ni-2.5Mo (Cast and solution annealed)	ASTM F 745	Surgical implants
Austenitic, ferritic, martensitic, and precipitation hardening	ASTM F 899	Surgical instruments
Fe-22Cr-12.5Ni-5Mn (Wrought nitrogen strengthened)	ASTM F 1314	Surgical implants
Fe-21Cr-10Ni-3Mn-2.5Mo	ASTM F 1586	Surgical implants

Fig. 3.4 Microstructure of 316L monofilament wire 1.2 mm diameter, austenitic phase, with grain size ASTM No. 8, Hardness: 80 HRB. Twinning is observed. Original magnification: 400×. Courtesy of Laboratorios Fairchild S.A.

Fig. 3.5 Low-carbon grade 316L austenitic stainless steel cancellous bone screw

3.1.2 Titanium and Titanium Alloys

The industrial interest in titanium began in the mid-20th century, when a relatively safe and relatively economical method to produce titanium metal was developed. Rutile (TiO_2) and ilmenite ($FeTiO_3$) are important titanium minerals for titanium ingot production. Rutile and upgraded ilmenite are feedstock materials. See Fig. 3.11. Other minerals containing titanium include anatase and brookite. Ilmenite is considered the most important ore of titanium, while rutile is a commercially common mineral. Titanium is quite expensive as a result of the complex processes to produce it (Fig. 3.11).

Sponge titanium (ASTM B 299) is an important charge to titanium melting units. Titanium scrap and alloying elements to the melting unit are added to conform the chemical composition of the titanium end product.

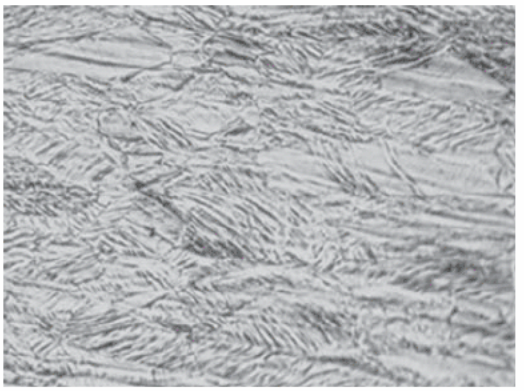


Fig. 3.6 Microstructure of a 316L cortical screw, showing deformed austenitic grains, martensite, and bands due to cold-rolled operation. Hardness: 29 HRC. Original magnification: 100×. Courtesy of Laboratorios Fairchild S.A.

Fig. 3.7 Low-carbon grade austenitic stainless 316L steel plate

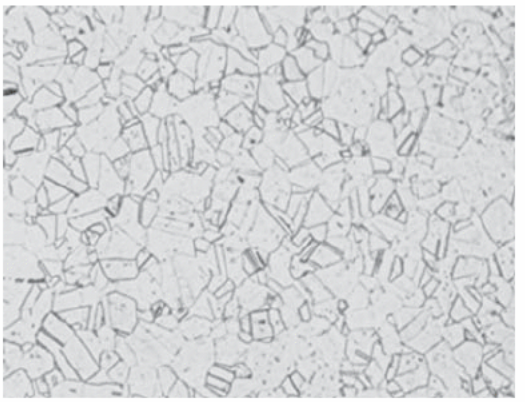


Fig. 3.8 Microstructure of 316L plate austenitic phase with grain size ASTM No. 8, hardness 76 HRB. Twinning is observed. Original magnification: 100×. Courtesy of Laboratorios Fairchild S.A.

Fig. 3.9 Low-carbon grade austenitic stainless steel 316L transpedicular bone screw, with lateral opening. See also Fig. 6.13.

Vacuum arc remelting is the usual melting method for titanium alloys used in orthopaedics and traumatology. Electron beam cold hearth is an alternative method. Davis and Forbes Jones (Ref 1) give an excellent description of the key processes of titanium alloys for orthopaedic devices.

Titanium is the most biocompatible metallic element of the periodic table. Steinemann (Ref 2) discusses the titanium affinity in the human body. Biocompatibility, high strength–to-density ratio, and excellent corrosion resistance makes titanium the most important element for orthopaedic devices.

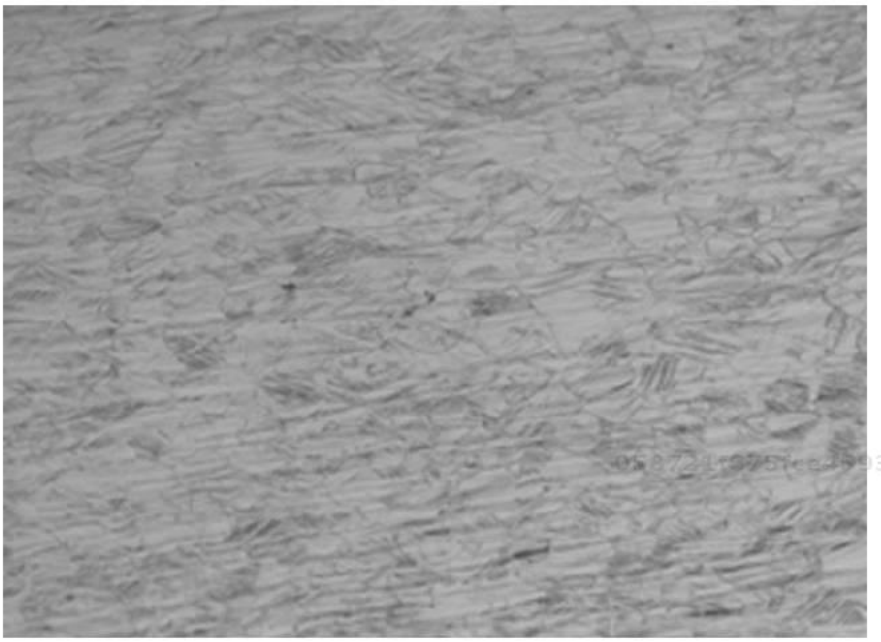


Fig. 3.10 Microstructure of 316L transpedicular bone screw showing deformed austenite grains, martensite, and bands. Hardness: 29 HRC. Original magnification: 100×. Courtesy of Laboratorios Fairchild S.A.

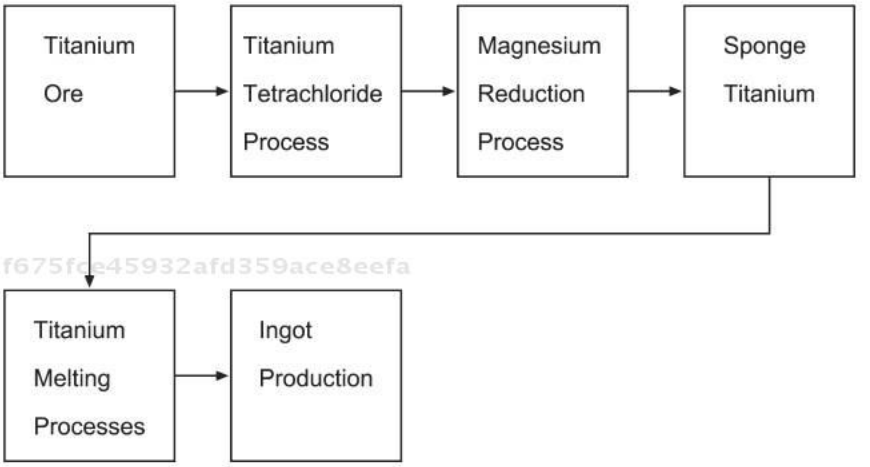


Fig. 3.11 Flow chart of titanium ingot production

Titanium and titanium alloys used for implants can be grouped into the following categories*:

- *Alpha:* CP (commercially pure) titanium
- *Alpha/beta:* Ti-6Al-4V, Ti-6Al-7Nb, Ti-5Al-2.5Fe

*Reprinted with permission from *Medical Applications of Titanium and its Alloys*, ASTM International.

- *Beta:* Ti-13Nb-13Zr, Ti-11.5Mo-6Zr-2Fe, Ti-15Mo-5Zr-3Al, Ti-15Mo-3Nb

Single Alpha Phase Titanium. Pure titanium exhibits allotropy with two different structures: hexagonal close-packed (hcp) α phase from 0 to 883 °C, and body-centered cubic (bcc) β phase from 883 °C up to its melting point 1672 °C.

Unalloyed titanium is a single alpha phase. Four grades of unalloyed titanium are known as CP (commercially pure) titanium. They are described in ASTM F 67, "Standard Specification for Unalloyed Titanium, for Surgical Implant Applications." The chemical requirements (composition %) of the four unalloyed grades of single alpha phase titanium, allow only very small amounts (hundredths) of nitrogen (N), carbon (C), iron (Fe), oxygen (O), and (thousandths) of hydrogen (H). The elements O, N, and C show large solubilities in this single alpha phase. The mechanical property requirements for bar, billets, and forgings for the four grades and quality program requirements are also described in ASTM F 67.

Unalloyed titanium is not hardened by heat treatment because only the alpha phase is present. The CP titanium grades are characterized by relatively low strength and great ductility.

3.1.2.1 Titanium Alloys. The addition of alloying elements to pure titanium improves the mechanical properties of CP titanium.

Near Single Alpha Phase Titanium Alloy. When an element added to a matrix causes an increase in temperature in the existing phase, a stabilizing effect has taken place. This is the case when aluminum is added to titanium. Aluminum becomes an alpha stabilizer for titanium. Figure 3.12 shows the binary Al-Ti phase diagram.

Interstitial elements such as O, N, and C are also alpha stabilizers. The near single alpha phase titanium is not hardened by heat treatment. However, aluminum additions to titanium cause an increase of strength and a decrease in ductility.

Investment casting is a method used to produce titanium-base alloys.

Alpha-Beta Titanium Alloys. Additions of aluminum (Al) as well as the O, N, and C interstitial elements are intended to stabilize the alpha phase at higher temperatures. Aluminum raises the beta transus temperature. The beta transus temperature is the lowest temperature at which a 100% beta phase is present. Aluminum has great solubility in α and β phases in the Ti-Al phase diagram (Fig. 3.12).

Additions of vanadium (V) as well as other elements such as niobium (Nb), tantalum (Ta), and molybdenum (Mo) work as beta stabilizers in the alpha-beta titanium alloys.

The alpha phase is a hexagonal close-packed structure, while the beta phase is a body-centered cubic structure.

Ti-6Al-4V is considered the work horse of the titanium-base alloys, and it is widely used for metallic implants in orthopaedics and traumatology. Ti-6Al-4V is further improved by eliminating interstitial elements, especially

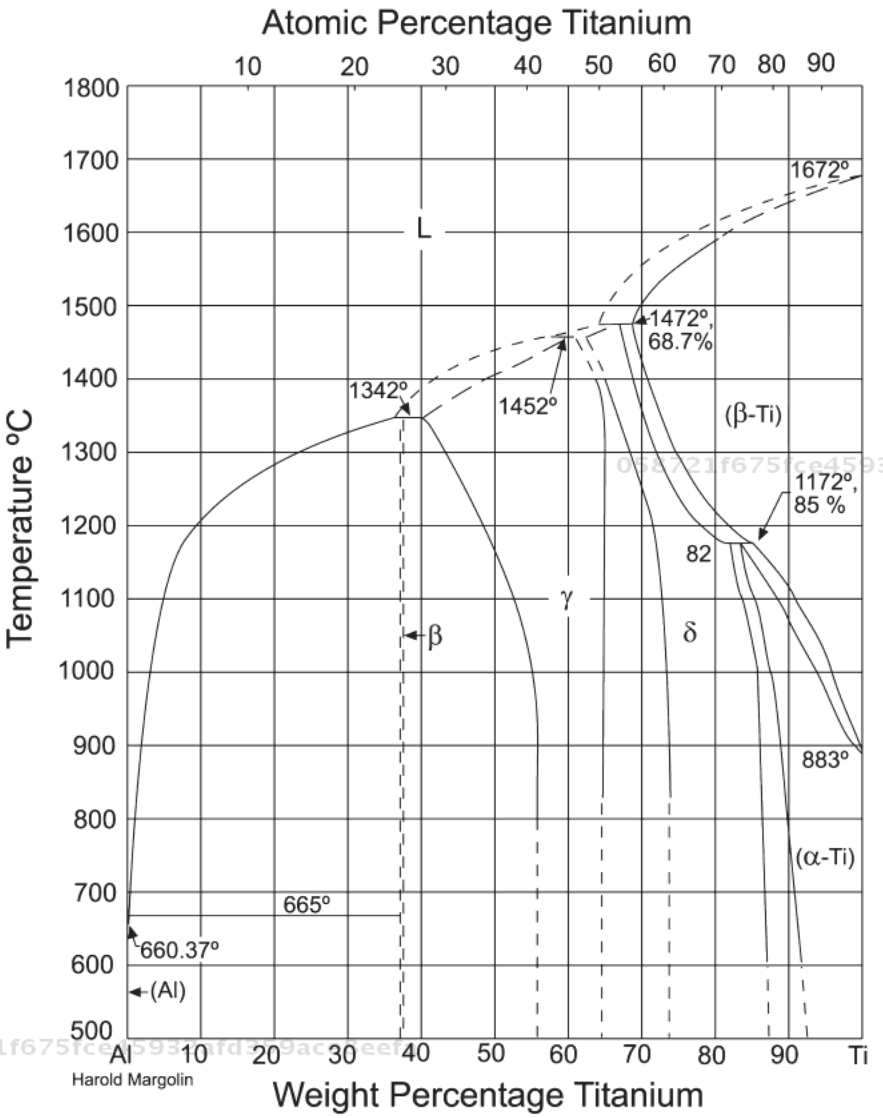


Fig. 3.12 Aluminum-titanium phase diagram

the oxygen content, transforming it to Ti-6Al-4V ELI (extra-low interstitial). This alloy shows better ductility and toughness than Ti-6Al-4V.

These titanium-base alloys are heat treatable. Heat treating processes generally serve to increase strength and lower ductility.

New titanium-base alloys are being considered that would exclude aluminum and vanadium because of their harmful effects in pure form. Okazaki et al. (Ref 3) published a very extensive study of new titanium alloys under consideration for implants. Reference 4 is a review of the use of titanium alloys as implant materials.

Beta Titanium Alloys. The amount and nature of the elements that are alloyed to Ti and the manufacturing processes help us to obtain the

mechanical properties needed for implants. Beta titanium alloys are heat treatable. A high strength and low ductility may be reached. Other beta titanium alloys are described in the literature (Ref 5–7).

3.1.2.2 Microstructures and Grain Size. Figures 3.13 to 3.16 show orthopaedic devices made from Ti-6Al-4V and corresponding microstructures.

3.1.2.3 ASTM Standards for Orthopaedic Devices. Relevant ASTM standards are listed in Table 3.3.

Fig. 3.13 Ti-6Al-4V transpedicular bone screw

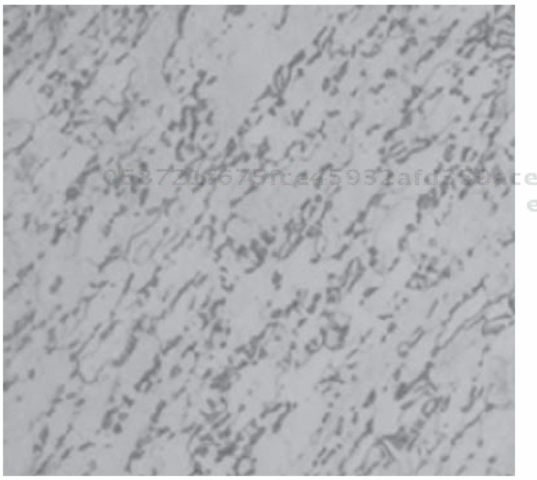


Fig. 3.14 Microstructure of the Ti-6Al-4V transpedicular bone screw (Fig. 3.13), showing very fine slightly elongated grains of alpha structure, mixed with beta phase grains at the border lines of the alpha grains, and in small aisles between grains. Original magnification: 400×. Typical annealed structure. Hardness: 37.5 HRC

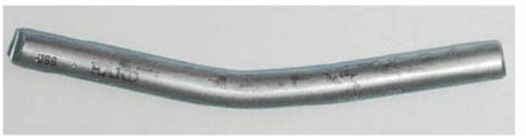


Fig. 3.15 Bar of the system lock for a Ti-6Al-4V alloy transpedicular bone screw

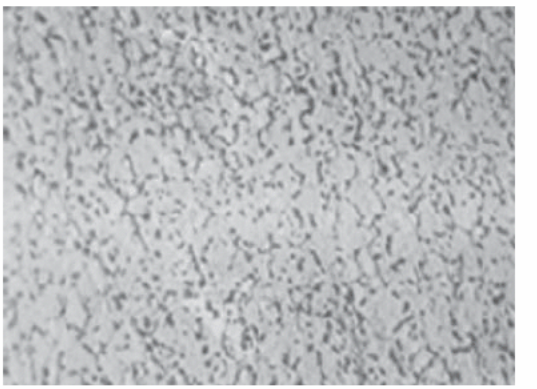


Fig. 3.16 Microstructure of the Ti-6Al-4V bar (Fig. 3.15), showing very fine and slightly elongated grains of alpha structure, mixed with beta phase grains at the border lines of the alpha grains and in small aisles between grains. Original magnification: 400×. Typical annealed structure. Hardness: 38.5 HRC

Table 3.3 ASTM F standards for commercially pure titanium and titanium-base alloys for orthopaedic devices

Titanium-base alloys	Standard specification	Uses in orthopaedics
Four grades of unalloyed Ti	ASTM F 67	Surgical implants
Ti-6Al-4V ELI wrought	ASTM F 136	Surgical implants
Ti-6Al-4V ELI forgings	ASTM F 620	Surgical implants
Ti-6Al-4V casting	ASTM F 1108	Surgical implants
Ti-6Al-7Nb wrought	ASTM F 1295	Surgical implants
Ti-6Al-4V wrought	ASTM F 1472	Surgical implants
Ti-6Al-4V alloy powder	ASTM F 1580	Implant coatings

3.1.2.4 ISO Standards for Orthopaedic Devices. Relevant ISO standards are:

ISO 5832-2:1999	Implants for surgery—Metallic Materials—Part 2: Unalloyed Titanium
ISO 5832-3:1996	Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy
ISO 5832-11:1994	Implants for Surgery— Metallic Materials—Part 11: Wrought Titanium 6-Aluminum 7-Niobium Alloy
ISO 5832-14:2007	Implants for Surgery—Metallic Materials—Part 14: Wrought Titanium 15-Molybdenum 5-Zirconium 3-Aluminum Alloy
ISO 20160: 2006	Implants for Surgery—Metallic Materials—Classification of Microstructures for Alpha + Beta Titanium Alloy Bars

3.1.3 Cobalt-Base Alloys

Cobalt-chromium (Co-Cr) is a solid solution alloy. The role of chromium in these alloys is to inhibit corrosion. The Co-Cr binary phase diagram is shown in Fig. 3.17. Cobalt-chromium alloys are used especially in hip and knee joint replacements because of their compatibility, good mechanical properties, and wear resistance.

The addition of small quantities of other elements such as molybdenum (Mo) and tungsten (W) is used to harden the Co-Cr alloys and increase their corrosion resistance. Molybdenum has a stronger effect than tungsten on a weight percent basis. Stabilizing the γ phase by interstitial elements such as nitrogen will make the Co-Cr-Mo alloy reach a high level of strength and low ductility.

3.1.3.1 Microstructure and Grain Size. The Co-Cr-Mo forged alloys are fine grained. They have higher tensile strength and higher fatigue resistance. Strengthening is provided with solid solution hardening. At the end of the process a very high polish is given to the product. Figure 3.18 shows the microstructure of a wrought Co-Cr-W-Ni alloy. Hot isostatic pressing is used to create Co-Cr implants with fine grain size and homogeneous structure. Examples are shown in Fig. 3.19 and 3.20.

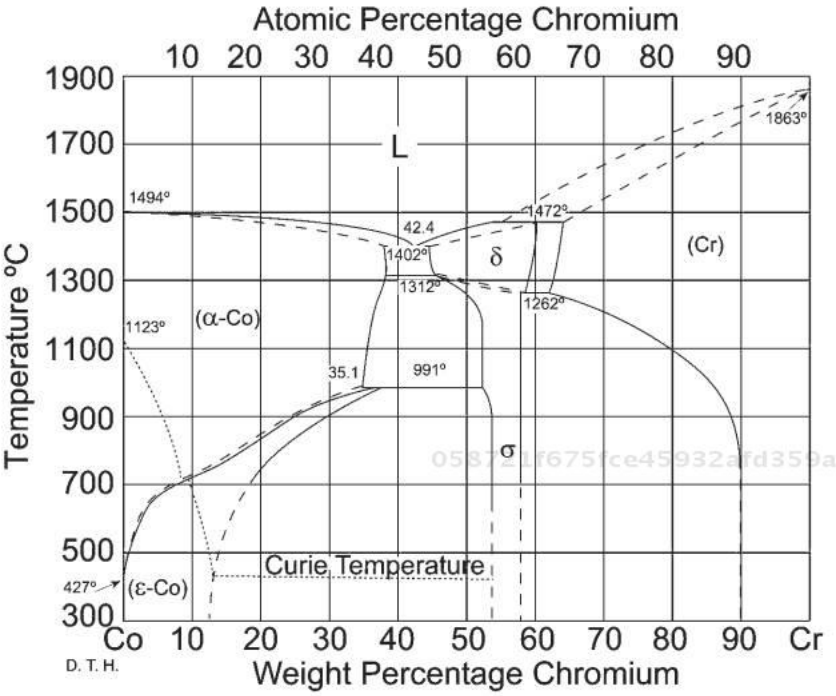


Fig. 3.17 Cobalt-chromium binary phase diagram

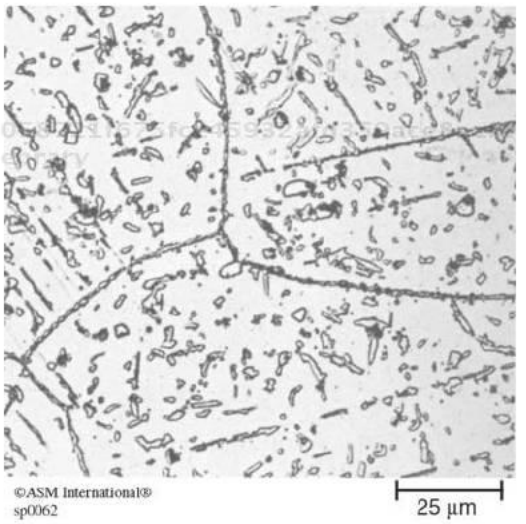


Fig. 3.18 Typical wrought Co-Cr-W-Ni alloy. Structure is precipitates of M_6C and Co_2W intermetallic in a face-centered cubic matrix. Original magnification: 500×

Fig. 3.19 Cobalt-chromium hip prosthesis stems made with the hot isostatic pressing (HIP) process, without the final finish. Courtesy of Industrial Materials Technology, Inc.

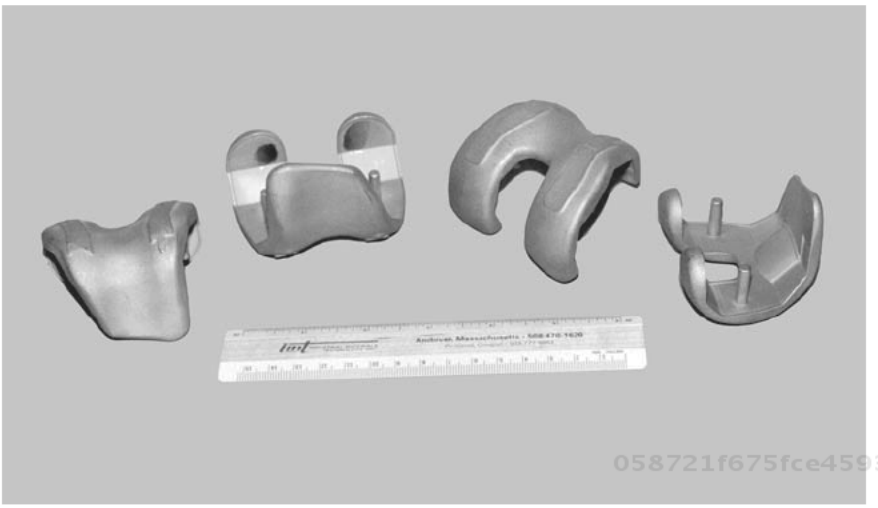


Fig. 3.20 Cobalt-chromium femoral components of total knee joint replacements, made with the hot isostatic pressing (HIP) process, without the final finish. Courtesy of Industrial Materials Technology, Inc.

Table 3.4 ASTM F standards for cobalt base alloys for orthopaedic devices

Cobalt-base alloys	Standard specification	Uses in orthopaedics
Cobalt-chromium		
Co-27Cr-5Mo (shot, bar, casting, or ingot)	ASTM F 75	Surgical implants
Co-Cr-W-Ni (wrought)	ASTM F 90	Surgical implants
Co-28Cr-6Mo (forgings)	ASTM F 799	Surgical implants
Co-Cr-W-Ni (wrought wire)	ASTM F 1091	Surgical fixation wire
Cobalt-nickel		
Co-Ni-Cr-Mo	ASTM F 961	Surgical implants

3.1.3.2 ASTM F Standards for Orthopaedic Devices. Relevant ASTM standards are listed in Table 3.4. ASTM F 75 specification corresponds to cast condition of Co-Cr-Mo alloys and ASTM F 799 specification to forgings.

3.1.3.3 ISO Standards for Orthopaedic Devices. Relevant ISO standards for cobalt alloys are:

ISO 5832-4:1996	Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy
ISO 5832-5:2005	Implants for Surgery—Metallic Materials—Part 5: Wrought Cobalt-Chromium-Tungsten-Nickel Alloy
ISO 5832-6:1997	Implants for Surgery—Metallic Materials—Part 6: Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy
ISO 5832-7:1994	Implants for Surgery—Metallic Materials—Part 7: Forgeable and Cold-Formed Cobalt-Chromium-Nickel-Molybdenum-Iron Alloy

ISO 5832-8:1997	Implants for Surgery—Metallic Materials—Part 8: Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy
ISO 5832-12: 2008	Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy

3.1.4 Definitions of Selected Terms Related to Metallic Materials and Their Manufacturing Methods

The following terms and definitions have been adapted from the *ASM Materials Engineering Dictionary* (J.R. Davis, Ed., ASM International, 1992).

Austenitic steel. Alloy steel whose structure is normally austenitic at room temperature.

Martensitic steel. An interstitial supersaturated solid solution of carbon in iron having a body-centered tetragonal lattice.

Ferrite. A solid solution of one or more elements in a body-centered cubic iron.

Investment casting. Casting metal into a mold produced by surrounding (investing) an expendable pattern with a refractory slurry that sets at room temperature after which the wax, plastic, or frozen mercury is removed through the use of heat. Also called precision casting, or lost wax process.

Hot working. Deforming metal plastically at such a temperature and rate that strain hardening does not occur.

Forging. Plastically deforming metal, usually hot, into desired shapes with compressive force, with or without dies.

Cold work. Permanent strain produced by an external force in a metal below its recrystallization temperature. Recrystallization refers to the formation of a new, strain-free structure from that existing in cold-worked metal, usually accomplished by heating.

Precipitation hardening. Hardening caused by the precipitation of a constituent from a supersaturated solid solution.

3.2 Nonmetallic Biomaterials

3.2.1 Polymers

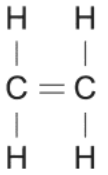
Continuous development and search for improvement of mechanical properties of polymers in prosthetic devices have given rise to a good number of synthetic polymers that have been the object of very extensive research studies in orthopaedic surgery. The process of joining monomers to form polymers is called *polymerization*. The term *polymer* refers to a large molecule or macromolecule. The main characteristic of macromolecules is high molecular weight. The molecular weights of the macromolecules can vary from several thousands to a million or more g/mol; an increase of the molecular weight of polyethylene, for example, corresponds to an improvement in its physical properties.

The monomers that participate in the manufacture of synthetic polymers contain functional groups that are susceptible to chemical reaction. A monomer must be at least bifunctional to undergo a chemical reaction. This means that each monomer has at least two neighbors to build molecules of great size in a repetitive form. For example, ethylene and polymethyl methacrylate monomers are the connecting links of lengthy linear carbon chains.

The two basic types of polymerization reactions are the chain (linear addition) reaction and the stepwise (condensation) reaction. The linear addition reaction is described in the discussion of polyethylene in this section. Two of the most important polymers in orthopaedic surgery are polyethylene and acrylic bone cements.

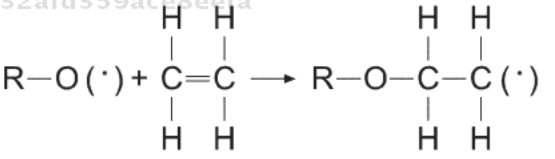
3.2.1.1 Polyethylene. The polyethylene linear addition polymerization chain reaction requires two chemical components, an ethylene monomer and a catalyst.

The Ethylene Monomer C_2H_4. The ethylene structure (monomer) C_2H_4 shows a covalent double bond between carbon atoms and four single covalent bonds between carbon and hydrogen atoms.



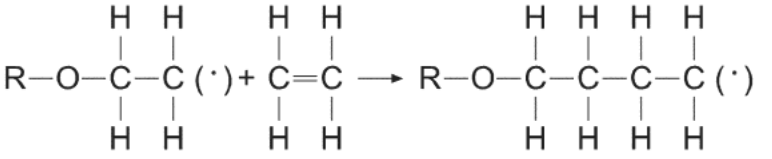
The Catalyst (Free Radicals). Free radicals from the molecule R_2O_2, each with a free electron (•), initiate the polymerization reaction: 2R–O(•)**.** The decomposition of organic peroxide serves as one example of free radicals. The polymerization reaction takes place in three steps.

Step 1 Initiation. The polymerization reaction begins when each monomer (ethylene molecule) reacts with the free radicals in an activation process.



The double bond of the monomer is broken, the free radical is bonded to the starting link of the chain, and the electron from the free radical moves to the carbon atom.

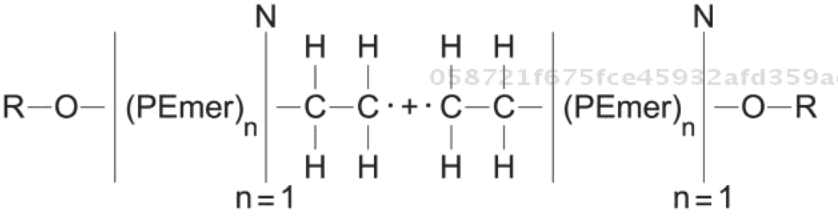
Step 2 Propagation. Once the polymerization reaction has initiated, the reaction propagates giving rise to continuous formation of very large chains.

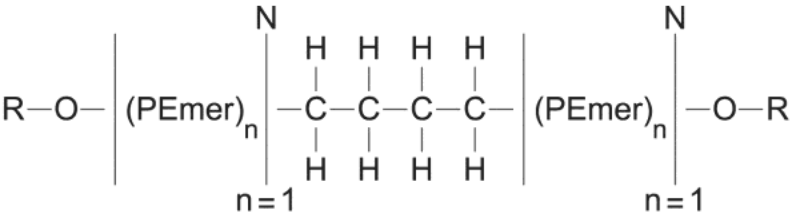


This polymerization reaction will continue to take place; that is, the right-hand side of the preceding reaction will now react with a new available ethylene monomer, decreasing in every reaction the supply of ethylene monomers.

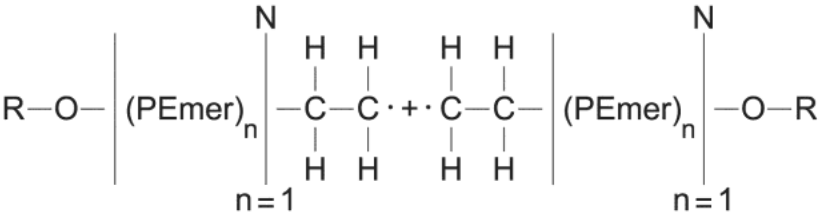
Step 3 Termination. The preceding reaction will continue to take place until the content of ethylene monomers is depleted. Then the termination step takes place either by *radical combination* or by *disproportionation.*

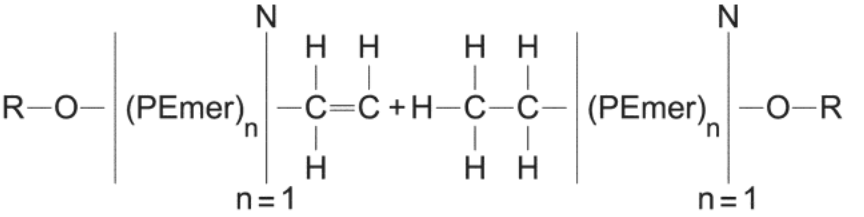
The radical combination mechanism occurs when two free chain radicals combine, forming a single large molecule, as observed in the following reactions:





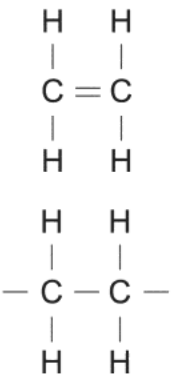
The disproportionation mechanism takes place when two free chain radicals meet but instead of combining, one radical gives away a proton and keeps the electron while the second radical that receives the proton places it on the radical site, as is observed in the following reactions:



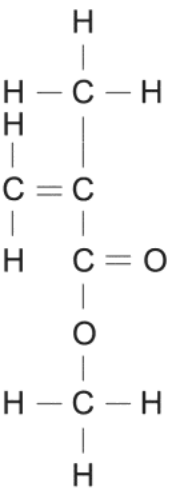


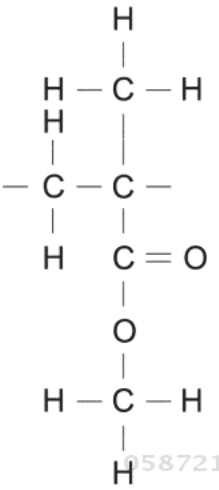
3.2.1.2 Molecular Weight of Polyethylene. Molecular weight is an important consideration for the polyethylene grades used in assemblies of the hip, knee, and shoulder joints replacements. For example, ultra-high molecular weight polyethylene (UHMWPE), with a molecular weight in the millions, is used for bearing surfaces in artificial arthrodic (gliding) joint replacements because of its relatively superior wear resistance.

The ethylene organic structure (monomer) has a molecular weight of 28. The lengths of polyethylene chains depend on the degree of polymerization "n"; the greater the term "n," the greater the molecular weight of polyethylene $(C_2H_4)_n$. In this manner it is possible that polyethylene could reach the molecular weight beyond 1×10^6 g/mol.



3.2.1.3 Acrylic Bone Cements. Acrylic bone cements are copolymers based on mixtures of methacrylate in a powder form, which contain an initiator, and methyl methacrylate, a liquid monomer that contains an activator. When these two substances are mixed, the polymerization reaction takes place.





Acrylic bone cements are used for a number of applications, especially in the fixation of femoral endoprosthetic stems.

3.2.1.4 Homopolymers and Copolymers. The chains of linear addition formed by repeated simple units (molecules of the same type) are called homopolymers. The linear addition chains formed by two or more different molecules are called copolymers. These chemical polymerization reactions produce formations of molecules of greater molecular weight, improving their physical properties. Homopolymers, copolymers, and cross-linking are shown graphically in Fig. 3.21.

3.2.1.5 Cross-linking and Crystallization of Polyethylene. The forces of attraction between hydrogen atoms in the polyethylene polymer chains (van der Waals bonds) are particularly weak. This weakness affects the elastic and plastic properties of the polyethylene, making it necessary to introduce molecules to tie the long chains of polymers to restrict their independent movement.

Cross-links are formed by the union of segments (molecules) bonded covalently between adjacent molecule chains of great length. Increasing the cross-linking in the linear chains will result in a rigid three-dimensional structure, decreasing the possibility of the structure being deformed plastically.

Polyethylene for surgical use must have a given grade of crystallization in order to support bearing weights satisfactorily. A good number of clinical reports concerning the wear of the polyethylene have been published. Many people have directed their research work toward better performance of polyethylene in hip and knee joint replacements. For example, the American Academy of Orthopaedic Surgeons published the book *Implant Wear in Total Joint Replacement* (Ref 8), which compares new cross-linked thermally stabilized polyethylenes from six different manufacturers. Factors compared are radiation type and dose, thermal stabilization, and final sterilization.

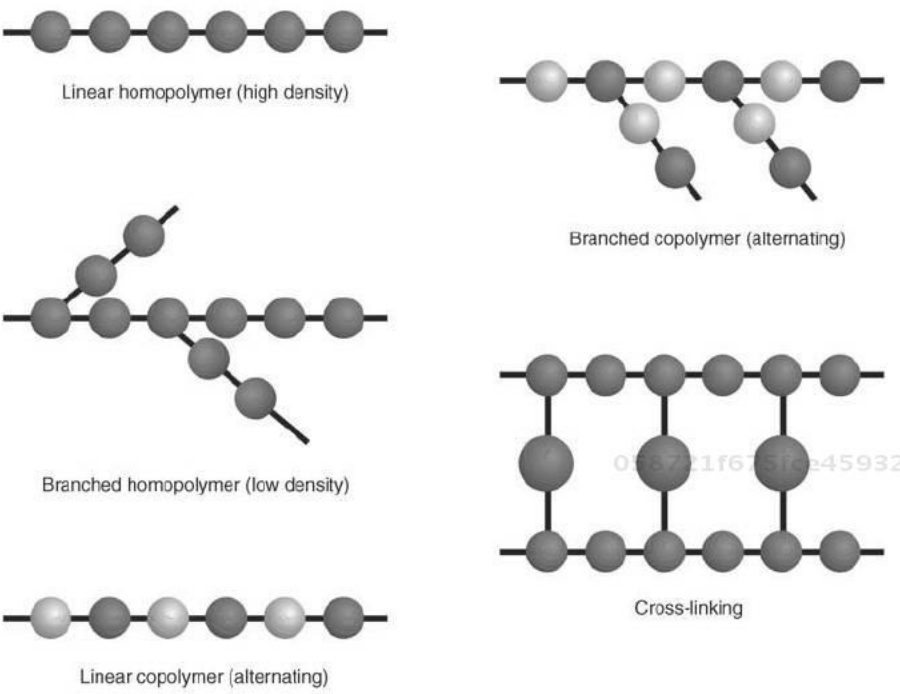


Fig. 3.21 Homopolymers, copolymers, and cross-linking

3.2.1.6 Thermoplastic PEEK Spinal Disc Replacement. The thermoplastic polyether ether ketone (PEEK), also referred to as a polyaryl ether ether ketone, is a linear aromatic polymer. Kurtz and Divine (Ref 9) present an extensive review on the use of PEEK in trauma orthopaedic and spinal implants, as well as basic information about polyaromatic ketones that is important for understanding their mechanical and chemical properties.

In the late 1980s, this polymer started to be widely used for industrial applications (Ref 10) because of its many advantages (high-temperature performance, chemical and wear resistance, and good mechanical properties, among others) compared to metallic materials.

In April 1998 (Ref 9) PEEK started to be offered for implant applications. Continuous research work has been done on this biomaterial. The production of PEEK composites and the use of hydroxyapatite as a surface coating have extended its applications.

Test methods for establishing mechanical properties (such as tensile strength and flexural modulus), creep performance, and tribological properties are specified in the ASTM D standards (Ref 10).

3.2.1.7 Bioabsorbables. In certain applications, bioabsorbable polymers offer advantages over other biomaterials such as metals because the bioabsorbable materials offer the particular advantage of being able to break down harmlessly in the human body environment.

Polyglycolide and polylactide absorbable polymers are hard and crystalline (Ref 11). However, their applications for internal fracture fixation are limited because their mechanical properties are lower compared to their metallic counterparts.

3.2.1.8 ASTM F Polymer Standards for Orthopaedic Devices. The relevant ASTM standards are:

ASTM F 451	Standard Specification for Acrylic Bone Cement
ASTM F 648	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
ASTM F 981	Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone
ASTM F 1635	Standard Test Method for in Vitro Degradation Testing of Poly (L-Lactic Acid) Resin and Fabricated Form for Surgical Implants

3.2.1.9 ISO Polymer Standards for Orthopaedic Devices. The relevant ISO standards are:

ISO 5834-1:2007	Implants for Surgery—Ultra-High-Molecular-Weight Polyethylene—Part 1: Powder Form
ISO 5834-2:2006	Implants for Surgery—Ultra-High-Molecular-Weight Polyethylene—Part 2: Moulded Form
ISO 5834-3:2005	Implants for Surgery—Ultra-High-Molecular-Weight Polyethylene—Part 3: Accelerated Ageing Methods
ISO 5834-4:2005	Implants for Surgery—Ultra-High-Molecular-Weight Polyethylene—Part 4: Oxidation Index Measurement Method
ISO 5834-5:2005	Implants for Surgery—Ultra-High-Molecular-Weight Polyethylene—Part 5: Morphology Assessment Method
ISO 5833:2002	Implants for Surgery—Acrylic Resin Cements
ISO 16402:2008	Implants for Surgery—Acrylic Resin Cement—Flexural Fatigue Testing of Acrylic Resin Cements Used in Orthopaedics
ISO 13781:1997	Poly(L-lactide) Resins and Fabricated Forms for Surgical Implants—In Vitro Degradation Testing
ISO 15814:1999	Implants for Surgery—Copolymers and Blends Based on Polylactide—In Vitro Degradation Testing

3.2.2 Ceramics

Ceramics are polycrystalline materials; the great majority are compounds composed of metallic as well as nonmetallic elements. The main characteristics of ceramic materials are: high melting points, hardness, brittleness, and immunity to corrosion.

3.2.2.1 Bioinert Ceramic. Alumina and zirconia are important bioinert materials; that is, when placed in the human body, they have minimal interaction with surrounding tissue. An ASTM standard was established in 2000 (ASTM F 603, "Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application"), but it was withdrawn in 2009.

3.2.2.2 Bioactives. *Bioactive* refers to a material, which upon being placed within the body, interacts with the surrounding bone and in some cases, even soft tissue. Driskell (Ref 12) presents the early history of calcium phosphate ceramics and the success obtained in the first coating application.

Hydroxyapatite, $Ca_{10}(PO_4)_6(OH)_2$, or HA, a very stable phase of calcium phosphates, is an excellent bioactive and osteoconductive biomaterial with human tissue. It is an important material in orthopaedic surgery because of its chemical and structural similarity with bone tissue.

The fundamental application of hydroxyapatite is for coating of orthopaedic devices such as total hip and total knee joint replacements. The HA coating is also applied to external fixation threads of pins.

The sources of this bioceramic material are: bovine, sea coral, and calcium phosphate mineral.

3.2.2.3 ASTM F Ceramic Standards for Orthopaedic Devices. The relevant standards are:

ASTM F 1185	Standard Specification for Composition of Hydroxylapatite for Surgical Implants
ASTM F 1658	Standard Test Method for Shear Testing of Calcium Phosphate Coatings
ASTM F 1659	Standard Test Method for Bending and Shear Fatigue Testing of Calcium Phosphate Coatings on Solid Metallic Substrates

3.2.2.4 ISO Ceramic Standards for Orthopedic Devices. The relevant ISO standards are:

ISO 13779-1:2008	Implants for Surgery—Hydroxyapatite—Part 1: Ceramic Hydroxyapatite
ISO 13779-2:2008	Implants for Surgery—Hydroxyapatite—Part 2: Coatings of Hydroxyapatite

ISO 13779-3:2008	Implants for Surgery—Hydroxyapatite—Part 3: Chemical Analysis and Characteristics of Crystallinity and Phase Purity
ISO 13779-4:2002	Implants for Surgery—Hydroxyapatite—Part 4: Determination of Coating Adhesion Strength
ISO 6474:1994	Implants for Surgery—Ceramic Materials Based on High Purity Alumina
ISO 13356:2008	Implants for Surgery—Ceramic Materials Based on Yttria-Stabilized Tetragonal Zirconia (Y-TZP)

3.2.3 Composites

Composite materials are composed of two or more nonchemically interacting materials, which are generally of a different nature; for example, metallic, plastic, carbon fibers, and so forth to produce the required physical and/or mechanical properties for a particular function. Bone is a composite biological material. The bone matrix material contains a great amount of collagen fibers that become very resistant as a result of phosphate and calcium salt deposits.

The Bryan Disc Prosthesis used in cervical disc arthroplasty is just one example of a composite biomaterial. It consists of two titanium alloy shells with a polyurethane center. A titanium porous coating is applied to the bone-implant interface of each shell to facilitate bone growth.

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EDUCATIONAL OBJECTIVES

1. What types of stainless steels are extensively used in osteosynthesis and why?
2. What types of stainless steels are extensively used in surgical instruments?
3. Are heat treatments necessary for austenitic stainless steels?
4. Are heat treatments necessary for surgical instruments?
5. What is the role of metallography in metallic biomaterials?
6. What is currently the most biocompatible metallic element used in orthopaedics?
7. Why is the development of new alloys necessary?
8. Where do the metallic biomaterials 316L stainless steel, CP titanium, Ti-6Al-4V, and Co-Cr alloys find their main applications in orthopaedics and traumatology?
9. Name the most important polymers used in orthopaedics, and define their advantages and limitations.
10. In your own words, explain the cross-linking of ultrahigh molecular weight polyethylene (UHMWPE).

11. At present time, what is the most common way to sterilize polyethylene biomaterials?
12. Why are bioabsorbable materials not extensively used in traumatology?
13. In your own words explain the application of bioinert materials.
14. Why is hydroxyapatite (HA) an important biomaterial?
15. Explain in your own words the application and potential future applications of composite biomaterials.

CHAPTER 4

Basic Principles of Biomechanics

The study and application of biomechanics are fundamental to the practice of orthopaedics and traumatology. The main parameters to consider in orthopaedic biomechanics are the site, the position, and the three-dimensional alignment of the devices. Two basic conditions that have to be established in orthopaedic surgery are:

- The implant mechanical stability, which is achieved from applying an understanding of biomechanics
- The biological stability of the bone fracture, which depends on the relation between the metabolic development of the bone tissue and the applied forces

The importance of the study of forces and stresses is clearly demonstrated in osteosynthesis, such as in total and partial joint replacements as well as in spine surgery. It is also well known from Wolff's law (which states that bone in a healthy person will adapt to the loads under which it is placed) that physical laws play an important role in bone modeling and remodeling.

4.1 Force Analysis

4.1.1 Newton's Laws

Mechanics is the oldest of the physical sciences. Galileo (1564–1642) is considered the father of classical mechanics and the most brilliant precursor of Sir Isaac Newton. Newton (1642–1727) established the fundamental natural basis of mechanics in his three laws of motion (defined below) published in 1686 in his *Philosophiae Naturalis Principia Mathematica.* Mechanics is divided into two branches: statics and dynamics.

Statics. The study of the bodies under external forces remain at rest.

Dynamics. The study of bodies in motion considering the external forces that produce such motion. Dynamics is divided into kinematics and kinetics.

Kinematics. Concerned with the motion of the objects without considering the forces that produce such motions.

Kinetics. Concerned with the motion of the objects considering the forces that produce the motion.

Newton's First Law. An object will stay at rest or continue moving at a constant speed in straight line, when the resultant of all forces acting upon the object is zero (Law of Inertia).

Newton's Second Law. The applied force **F** exerted on an object is equal to the mass **m** of the object multiplied by its acceleration **a**; that is, $\mathbf{F} = \mathbf{ma}$.

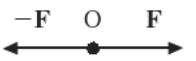
Newton's Third Law. Whenever an object A exerts a force on an object B, the second always exerts on the first an equal force but in the opposite direction (action and reaction). This Law establishes the fundamental understanding of force. (See Appendix III. The International System of Units SI of Force, Area, and Pressure.)

The First and Third Laws of Newton, in which the acceleration is zero, are special cases of the Second Law. It is extremely important that the orthopaedic surgeon carefully analyzes the forces that take place in the internal fracture fixation in order to obtain the mechanical stability that will help the patient recover quickly. It is also important to avoid stress shielding in the implants in order to get rid of bone resorption problems.

4.1.2 Scalars and Vectors

It is important to remember that there are physical quantities such as forces that can be completely specified by a magnitude and a direction; in mechanics, these are known as *vectors*. These vectors have different representations. The most common are: the boldface letters **F** and an arrow positioned over the letter $\vec{F}$. In this book **F** is used.

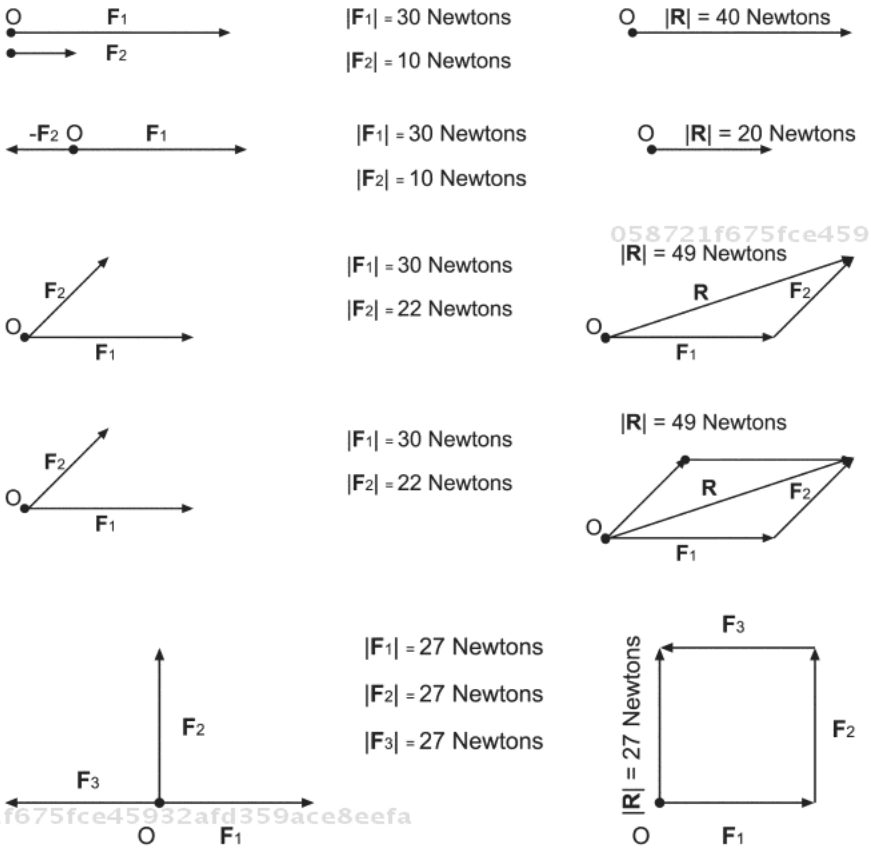
Vectors have *magnitude* and *direction*. Their quantities can be defined in terms of weight, displacement, velocity, acceleration, torque, and so forth. A vector may be represented by means of an arrow having its origin at **O** and the terminal point at **A**. One may write **OA** or simply **A**, the length of the vector **A** is indicated by $|\mathbf{A}|$ and it represents its magnitude; its direction is given by the angle θ. There are no negative vectors; the negative sign preceding the vector represents only the change in direction



If we add these two vectors we get: $\mathbf{F} + (-\mathbf{F}) = \mathbf{0}$. Note that $|\mathbf{0}| = 0$. Scalar quantities such as work, energy, temperature, speed, mass, area, volume, and so forth have magnitude only.

4.1.3 Addition of Vectors (Graphic Method)

Addition of vectors is not an ordinary addition. Let us consider the following examples to illustrate the vector addition by the graphic method. The application of concurrent forces on a block of mass **m** is represented by a black point and the letter **O**.



Vector sum by the graphic method is the resultant vector that goes from the origin O of the first vector to the head of the last vector. In these five examples, the resultant force is different from zero, which implies that the bodies moved with acceleration due to the magnitude of the resultant forces (Newton's Second Law).

For problems in which the head of the last vector corresponds to the origin of the first, the resultant is zero. Therefore, the objects are found to be in static equilibrium, that is, without movement (Newton's First Law).

4.1.4 Vectors in Two Dimensions (Analytical Method)

In many cases, there is a need to determine vectors in one plane or in space coordinate systems.

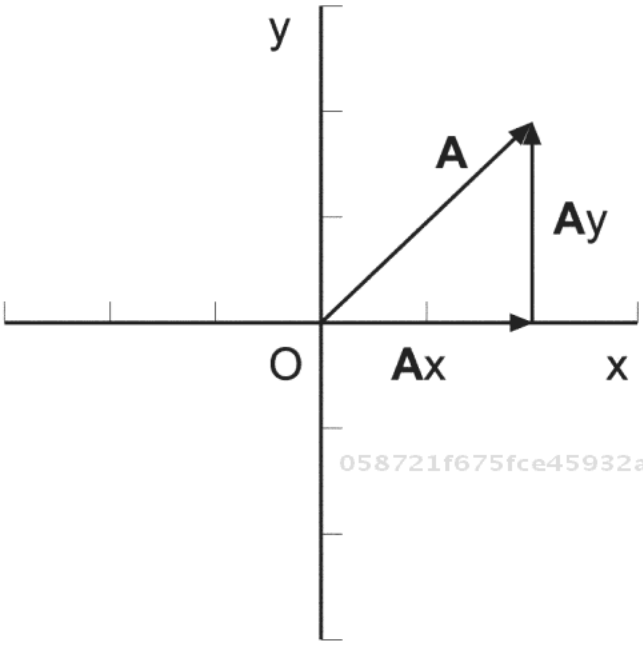


Fig. 4.1 Composition of vector **A** by rectangular resolution

4.1.4.1 The Cartesian Rectangular Coordinates. X-Y plane is used for the composition of forces by rectangular resolution. See Fig. 4.1. In this system the axes are perpendicular lines meeting at the intersection O, which is the origin of the coordinates. The arrows on the X and Y coordinates express the magnitude of the vector components. The coordinates at the point A(x,y) are defined by the distance x (abscissa) and the distance y (ordinate).

Another way of calculating vector replacements in two dimensions is by letting **i** and **j** be unit vectors with directions along Ox and Oy respectively; that is, $\mathbf{A} = \mathbf{i}Ax + \mathbf{j}Ay$.

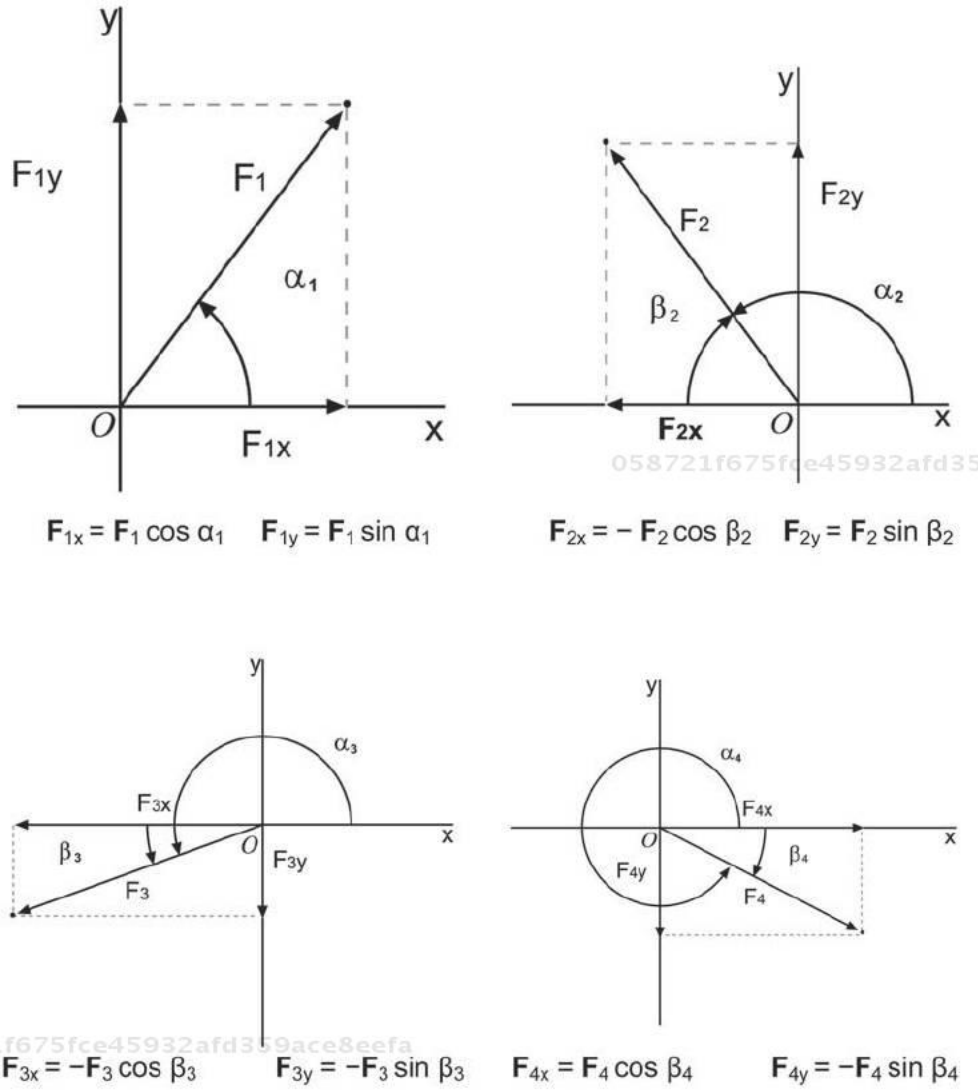
When we have several vectors in a plane X-Y, the sum of those vectors is obtained by replacing each vector in its components corresponding to the axes of X and to the axes of Y.

Figure 4.2 represents the components of a vector in each of the quadrants of the rectangular X-Y coordinate system. Alpha (α) angles are usually measured counterclockwise starting from the positive X axis. The reader may notice it with β angles.

4.1.4.2 The Polar Coordinate System. ($\mathbf{r}$, θ) represents vector **A** in polar coordinates. See Fig. 4.3. The vector **r** is always positive, and the direction is given by the angle θ.

4.1.5 Vectors in Three Dimensions (Analytical Method)

4.1.5.1 The Rectangular Cartesian Coordinates: X-Y-Z Plane. The vector **A** in three dimensions may also be represented by $\mathbf{A} = \mathbf{i}Ax + \mathbf{j}Ay + \mathbf{k}Az$.



$F_{1x} = F_1 \cos \alpha_1$ $F_{1y} = F_1 \sin \alpha_1$ $F_{2x} = -F_2 \cos \beta_2$ $F_{2y} = F_2 \sin \beta_2$

$F_{3x} = -F_3 \cos \beta_3$ $F_{3y} = -F_3 \sin \beta_3$ $F_{4x} = F_4 \cos \beta_4$ $F_{4y} = -F_4 \sin \beta_4$

Fig. 4.2 Vector components of F_1, F_2, F_3, and F_4

4.1.5.2 The Spherical Coordinate System: (F, θ, ϕ). Not all the forces and/or stresses that participate in the body elements (bones, spine discs, ligaments, etc.) are presented in two dimensions (X-Y plane); in many cases, it is necessary to solve the forces and/or stresses in three dimensions.

The vector space representations of displacements, acting forces, and stresses in the study of joint physiology, in spine biomechanics, in kinetics of human motion, and so forth are usually made in the X, Y, Z system and/or in the spherical or polar coordinates system. See Fig. 4.4.

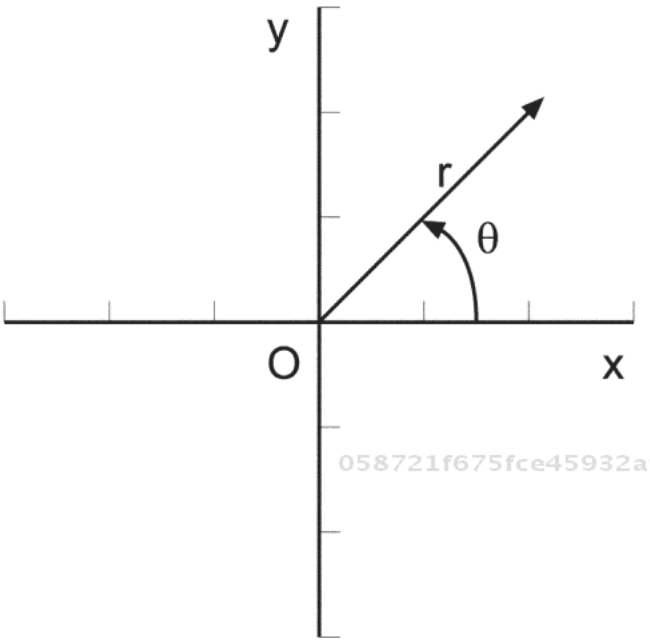


Fig. 4.3 Vector **r** in polar coordinates (**r**, θ)

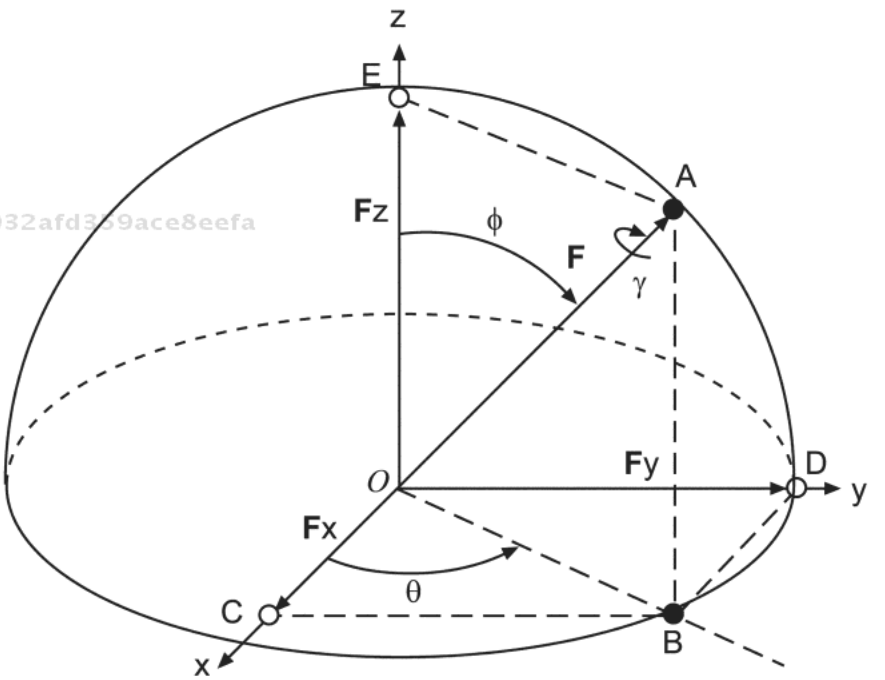


Fig. 4.4 The spherical coordinates system (**F**, θ, ϕ)

Vector **F** is found in the first octant, and it is divided into three components:

$$\mathbf{F}x, \mathbf{F}y, \text{ and } \mathbf{F}z$$

Vector **F** is defined by its angles ϕ and θ, whose values go from 0° to 360°. Angle γ represents the angle that describes vector **F** when rotating on its own axis. This system, then, has six degrees of freedom (x, y, z, θ, ϕ, γ). The planes of the spherical coordinate system are: sagital plane (X-Z). coronal plane (Y-Z), and transversal plane (X-Y). Figure 4.4 clearly shows that the x, y, and z components of **F** are:

$$\mathbf{F}x = \mathbf{F} \sin\phi \cos\theta; \mathbf{F}y = \mathbf{F} \sin\phi \sin\theta; \text{ and } \mathbf{F}z = \mathbf{F} \cos\phi$$

4.1.6 Vector Multiplication

There are two types of vector multiplication: the scalar product, or dot product, and the vector product, or cross product.

4.1.6.1 The Scalar Product, or Dot Product. In this type of multiplication, the product is a real number that represents a scalar quantity.

$$\mathbf{A} \cdot \mathbf{B} = |\mathbf{A}||\mathbf{B}| \cos\alpha, \quad \alpha = \angle(\mathbf{A}, \mathbf{B}) \quad 0 \leq \alpha \leq \pi$$

An example of the scalar product is the work W done by the force component **F** on displacing a body A to a distance **d** in the direction of the force component:

$$W = \mathbf{F} \cdot \mathbf{d} = |\mathbf{F}||\mathbf{d}| \cos\alpha$$

The units of work applied on the body are Newton-meters = Joules.

The commutative and distributive properties of the scalar product are:

- **Commutative Property.** The scalar product between two vectors **A** and **B** satisfies the commutative property:

$$\mathbf{A} \cdot \mathbf{B} = \mathbf{B} \cdot \mathbf{A}$$

- **Distributive Property.** The scalar product between two vectors **A** and **B** satisfies the distributive property:

$$\mathbf{A} \cdot (\mathbf{B} + \mathbf{C}) = \mathbf{A} \cdot \mathbf{B} + \mathbf{A} \cdot \mathbf{C}$$

4.1.6.2 The Vector Product or Cross Product. In this type of multiplication, the product of two vectors is another vector. If two vectors **A** and

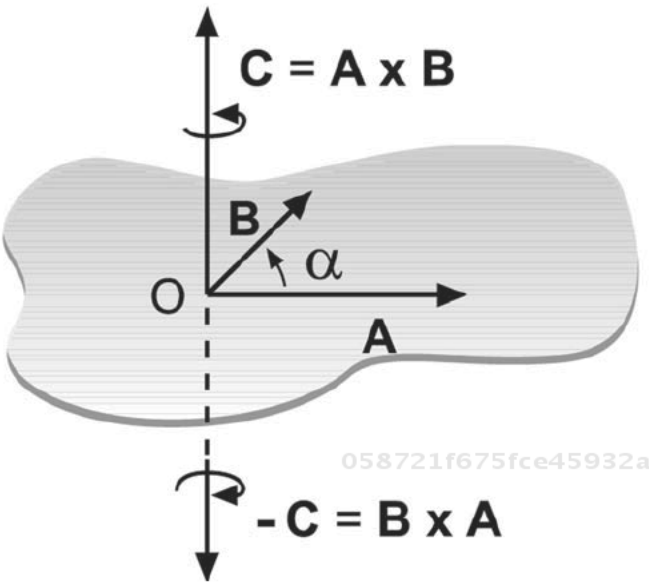


Fig. 4.5 Vector product of **A** and **B**

B meet in a plane, the vector or cross product of **A** and **B** results in a vector **C** that is perpendicular to the **A** and **B** plane, forming a right-handed system. See Fig. 4.5.

The vector product between **A** and **B** is given by: $\mathbf{A} \times \mathbf{B} = \mathbf{C}$. The Magnitude of **C** is given by:

$$|\mathbf{C}| = |\mathbf{A}||\mathbf{B}| \sin \alpha, \quad \alpha = \angle (\mathbf{A}, \mathbf{B}) \quad 0 \leq \alpha \leq \pi$$

$|\mathbf{C}|$ represents the parallelogram area formed by **A** and **B.**

The commutative and distributive properties of cross product are:

- **Commutative Property.** The vector or cross product does not satisfy the commutative property

$$\mathbf{A} \times \mathbf{B} = -\mathbf{B} \times \mathbf{A}$$

  This is known as the anticommutative property.
- **Distributive Property.** The vector or cross product satisfies the distributive property

$$\mathbf{A} \times (\mathbf{B} + \mathbf{C}) = \mathbf{A} \times \mathbf{B} + \mathbf{A} \times \mathbf{C}$$

4.2 Static Equilibrium

Static equilibrium forces may be expressed by two conditions of equilibrium.

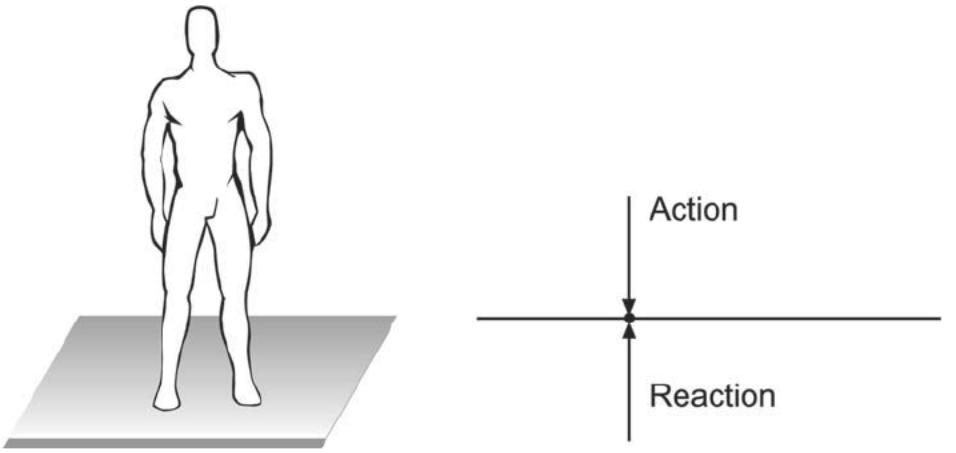


Fig. 4.6 Third Law of Newton (Action and Reaction)

4.2.1 First Condition of Static Equilibrium: $\Sigma F_n = 0$

The vector sum of all the forces that act on a body must be zero. This is equivalent to saying that the resultant of all the forces that interact must be zero.

In mechanics, a body is represented by a black dot when forces acting over such a body are concurrent. The equations corresponding to the first condition of static equilibrium when the forces are in an X-Y plane are:

$$\mathbf{F_{1x} + F_{2x} + F_{3x} + \cdots + F_{nx} = 0; \Sigma F_{nx} = 0}$$
$$\mathbf{F_{1y} + F_{2y} + F_{3y} + \cdots + F_{ny} = 0; \Sigma F_{ny} = 0}$$

For cases of forces in the X-Y-Z plane the following equation is added:

$$\mathbf{F_{1z} + F_{2z} + F_{3z} + \cdots + F_{nz} = 0; \Sigma F_{nz} = 0}$$

Let us consider the following example as a case of concurrent forces; see Fig. 4.6.

4.2.2 Second Condition of Static Equilibrium

The algebraic sum of the moments of all the forces that interact around any rotation axis must be zero.

A torque τ is a vector that measures the tendency of a force $\mathbf{F}$ to rotate an object around an axis. It is defined as the vector product $\tau = \mathbf{r} \times \mathbf{F}$, ($\mathbf{r}$) is the length of the lever arm and is the perpendicular distance from the axis to the force $\mathbf{F}$.

In orthopaedics and traumatology, there are many cases where nonconcurrent forces are applied. An application example of torque $\tau = \mathbf{r} \times \mathbf{F}$ is

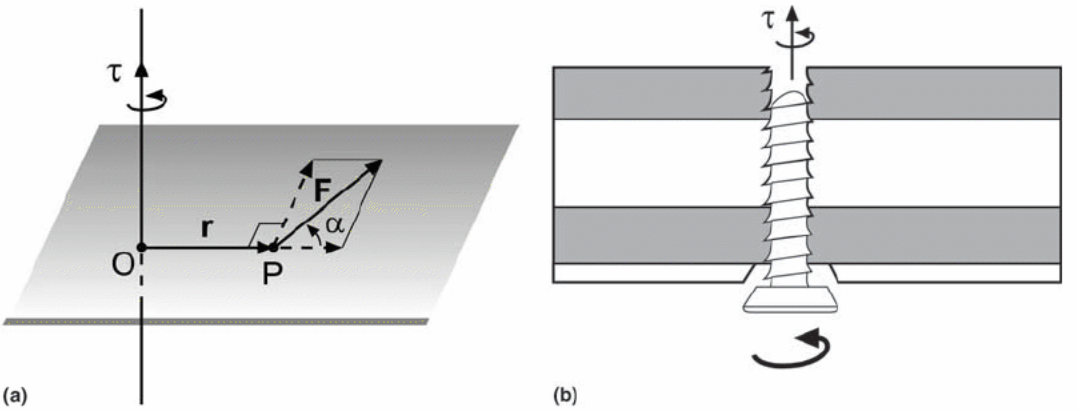


Fig. 4.7 Torque. (a) Torsion torque τ due to a force **F** exerted on a body P around a rotation axis located at O at a distance **r** from the body P. (b) Screw torsion torque

the insertion of screws in the internal fracture fixation with a plate. See Fig. 4.7(a) and (b). The magnitude of τ is given by:

$$|\tau| = |\mathbf{r}|\,|\mathbf{F}| \sin\alpha; \quad \alpha = \angle(\mathbf{r}, \mathbf{F}) \text{ and } |\mathbf{F}| \sin\alpha \text{ is } \perp \text{ to } \mathbf{r}$$

The direction of τ is given by the advance of a right-hand screw thread.

For biomechanical cases in which the forces tend to cause rotation, the second condition of equilibrium establishes that the total sum of torques is equal to zero when the body is in static equilibrium.

$$\mathbf{r}_1 \times \mathbf{F}_1 + \mathbf{r}_2 \times \mathbf{F}_2 + \cdots + \mathbf{r}_n \times \mathbf{F}_n = \Sigma \mathbf{r}_n \times \mathbf{F}_n = \Sigma \tau_0 = \mathbf{0}$$

Moment units are Newton-meters = Joules.

For static equilibrium problems in two dimensions the following equations apply:

$$\Sigma\, \mathbf{F}_x = \mathbf{0}; \quad \Sigma \tau_x = \mathbf{0}$$
$$\Sigma\, \mathbf{F}_y = \mathbf{0}; \quad \Sigma \tau_y = \mathbf{0}$$

For problems in three dimensions, the addition of the following equations is necessary:

$$\Sigma\, \mathbf{F}_z = \mathbf{0}; \quad \Sigma \tau_z = \mathbf{0}$$

4.2.3 Couples—Forces in a Plane

A *couple* is defined as two parallel forces equal in magnitude, not collinear and acting in opposite directions. The resultant of this pair of forces is zero.

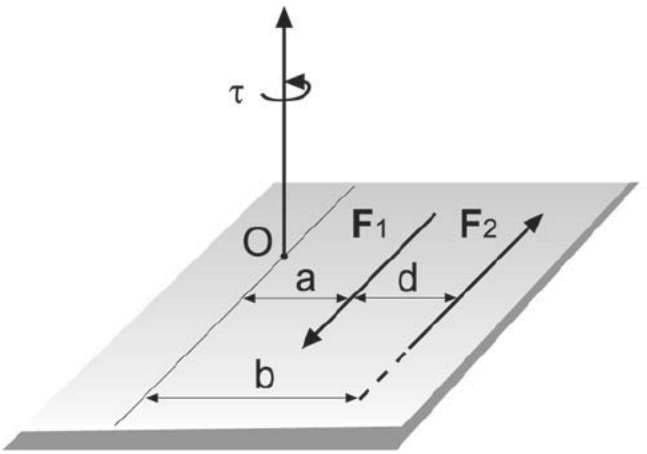


Fig. 4.8 Couple

The couple does not produce translation, but rotation only. See Fig. 4.8. The couple concept is very useful in biomechanics, particularly in studies concerning the loosening of femoral stem components and also in the kinetics of human motion.

Since $|\mathbf{F}_1| = |\mathbf{F}_2| = |\mathbf{F}|$, it can be easily demonstrated that the torque of a couple is given by the following equation where $|\mathbf{d}|$ is the lever arm of the couple

$$\tau = \mathbf{d} \times \mathbf{F}$$

Rotation takes place about an axis that is not physically present but goes through the center of mass even though this center remains at rest.

Special cases of parallel forces are found in different lever arm types that are useful in the muscle-skeletal system such as in hip, knee, shoulder, and ankle joints, among others. Lever arm types are described by the position of the *load*, *fulcrum*, and (*applied*) *force*.

Type 1	Load	Fulcrum	Force
Type 2	Fulcrum	Load	Force
Type 3	Fulcrum	Force	Load

4.3 Friction, Work, and Energy

Friction is a force that opposes movement. It is well known in orthopaedic surgery that sliding friction forces and implant wear constitute a major problem, especially in joint replacement devices in hard-on-soft and hard-on-hard bearing surfaces. An essential consideration is the tribology properties

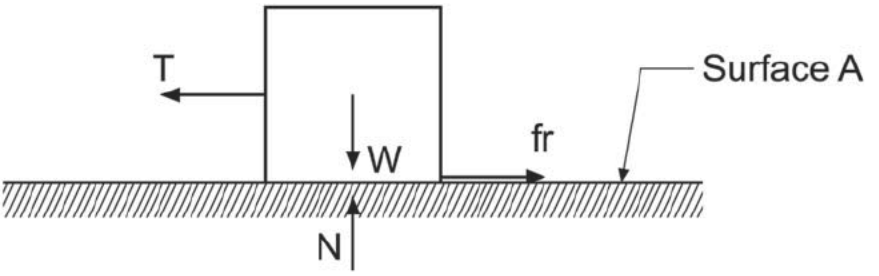


Fig. 4.9 Diagram of forces on a block

of the bearing surfaces of materials. There are two types of tangential friction forces between two solid surfaces, the static friction and the kinetic friction forces. The sliding surfaces are surface A in Fig. 4.9 and the bottom surface (not shown in Fig. 4.9) of the block of weight W. Static friction forces do not permit the sliding of one surface over the other; kinetic friction force permits the sliding of one surface over the other.

Static friction forces are directly proportional to the reaction normal forces.

$$\mathbf{fr}_s \leq \mu_s \mathbf{N}$$

where **N** is the reaction force exerted by surface A on surface B of the block. The equality sign represents the maximum force of friction. Before motion starts, the applied force will be balanced by the friction force opposing the movement.

Kinetic sliding friction forces are also directly proportional to the reaction of normal forces

$$\mathbf{fr}_k = \mu_k \mathbf{N}$$

It is well known that the friction static coefficient μ_s is greater than the friction kinetic coefficient μ_k. Both coefficients are dimensionless.

The direction of friction forces are always parallel to the contacting surfaces but in the opposite direction to the motion of the given objects.

The forces acting on a body (examples 1 and 2 in the next section) are drawn in a free-body diagram as if they were concurrent forces applied on the intersection point of the X-Y axes (sometimes represented as a black dot) that is located in the body's center of gravity. For nonconcurrent forces (examples 3 and 4), body dimensions need to be considered.

Work is a physical scalar quantity and is defined as the force component F exerted on a body of mass m displacing it a distance d in the direction of the force component.

$$W = \int_0^d \mathbf{F} \bullet \mathbf{dx} = \int_0^d F_x dx \quad \text{Newton - meter} = \text{Joules}$$

Fig. 4.10 Horizontal force T applied on a block

Energy is also a physical scalar quantity. In mechanics we have potential and kinetic energy.

Potential Energy. A body of mass m acquires potential energy (PE) when such a mass is lifted from certain level h_1 up to a certain height h_2, then:

$$PE = mg\,(h_2 - h_1)$$

Kinetic Energy. When this body of mass m is released from its height h_2 to h_1, its total potential energy is converted into kinetic energy (KE) at h_1, then:

$$KE = \tfrac{1}{2}\, mv^2$$

There are different ways of producing mechanical work (W) on a body of weight w, such as lifting, pushing, and pulling.

4.3.1 Method for Solving Static Equilibrium Problems

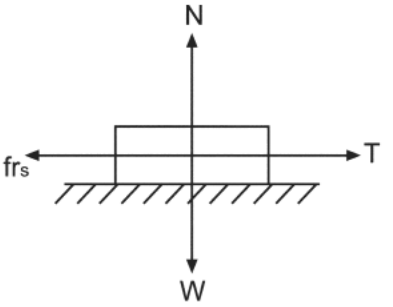
An important factor in the solution of problems is to have a good understanding of them and use deductive reasoning.

1. Write down the data, the question(s) and the equations needed.
2. Draw a free-body diagram to isolate the system. Disclose and identify all forces acting on the body including weight and angles, choose the axes in order to have most vector components on the diagram's axes.
3. Solve the equations algebraically for the unknown variable.

Example 1. A force T of 200 N is trying to pull a block with a weight of 600 N in a horizontal plane; the block is just about to move, see Fig. 4.10.
(a) What is the static friction force fr_s?
(b) What is the static friction coefficient μ_s?

Data		Equations
T = 200 Newtons	(a) fr_s = ?	Σ Fx = 0
W = 600 Newtons	(b) μ_s = ?	Σ Fy = 0

Free-body diagram:



Solution:

$$\Sigma Fx = 0; T - fr_s = 0$$

$$(a)\ fr_s = 200\ N$$

$$\Sigma Fy = 0; N - W = 0$$

$$|N| = 600\ \text{Newtons}; fr_s = \mu_s N = \mu_s\ 600\ \text{Newtons} = 200\ \text{Newtons}$$

$$(b)\ \mu_s = 2 / 6 = 0.66$$

Example 2. A block of 200 N resting on a board is raised until the angle of inclination allows the block to start sliding down the board at a constant speed (Fig. 4.11).

For a kinetic coefficient of 0.30, what is the angle α of inclination?

Data		Equations
W = 200 N	α = ?	Σ Fx = 0
μ_k = 0.30		Σ Fy = 0

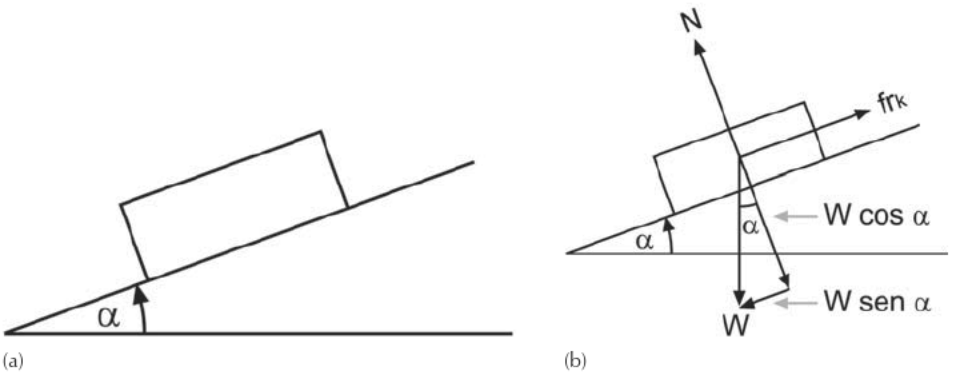


Fig. 4.11 (a) Block in inclined plane. (b) Free-body diagram

Solution:

$$\Sigma Fx = fr_k - W \sin \alpha = 0 \qquad \alpha = 17°$$

$$\Sigma Fy = N - W \cos \alpha = 0$$

$$fr_s = \mu_s N$$

Example 3. Teeterboard (Equilibrium of Forces on a Rigid Body). A homogeneous teeterboard (Fig. 4.12) weighs 250 N and has a length of 4 m. The center of gravity is directly over the point of support.

A man weighing 600 N is sitting at the left end of the board.

a) Calculate the distance x_2 at which another man weighing 800 N must be sitting in order for the teeterboard to remain in static equilibrium.
b) Determine the reaction force of the structure over the board.

Applying the second condition of equilibrium, we take the axis acting at the center of gravity. The total sum of torques of w, w_1, and w_2 should be zero.

Data		Equations
w = 250 N	a) X_2 = ?	$\Sigma\tau_o = 0$
w_1 = 600 N	b) F_{reac} = ?	Σ Fy = 0
w_2 = 800 N		
X_1 = 2.0 m		

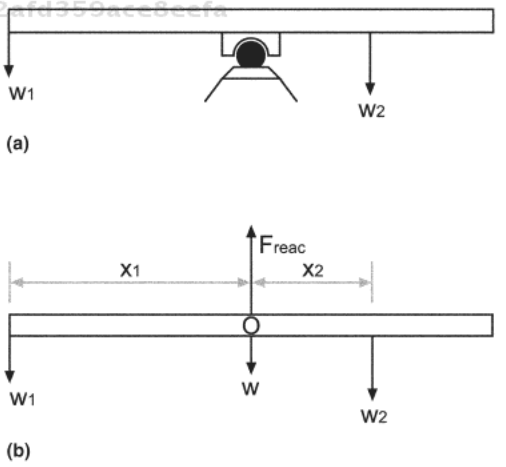


Fig. 4.12 (a) Teeterboard. (b) Free-body diagram

Solution:

$$\Sigma\tau_o = w_2 X_2 - w_1 X_1 = 0$$

$$800\ \text{N}\ X_2 = 600\ \text{N} \times 2\ \text{m}$$

$$\text{a)}\ X_2 = 1.5\ \text{m}$$

$$\Sigma\ \text{Fy} = 0$$

$$F_{reac} - w - w_1 - w_2 = 0$$

$$\text{b)}\ F_{reac} = 1650\ \text{N}$$

Example 4. Beam Supported by a Cable. A 6 meter length uniform beam is shown in Fig. 4.13. It is hinged at O and supported by a cable AB. The angle θ between the beam and the cable is 45°. The weight of the beam is 400 N and carries a load of 1000 N on its edge B.

a) Determine the cable's tension.
b) Determine the reactions Rv and Rh at point O.

Data		Equations
$\theta = 45°$	T = ?	Σ Fx = 0
w = 400 N (beam)	Rv = ?	Σ Fy = 0
W = 1000 N (load)		
ℓ = 6 m	Rh = ?	$\Sigma\tau_o = 0$

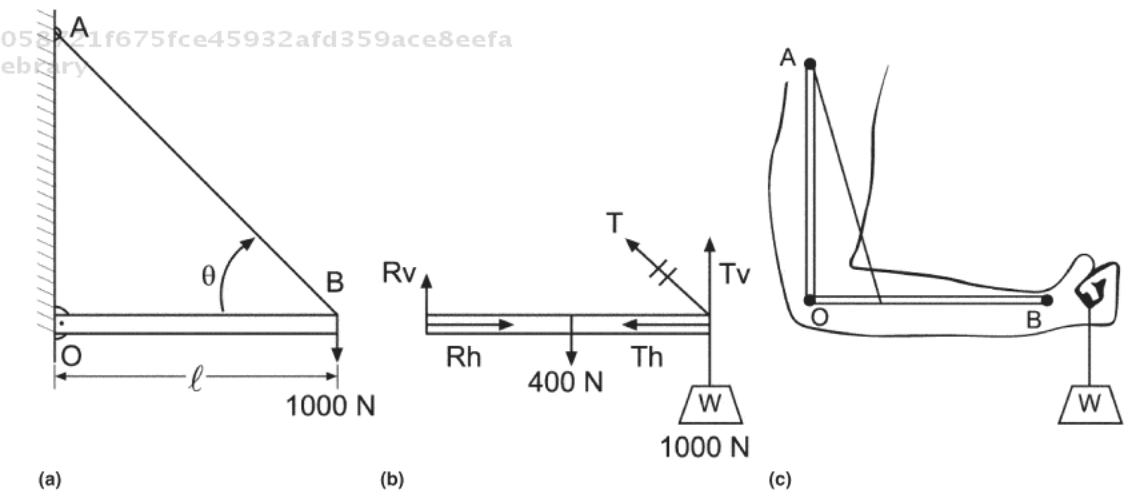


Fig. 4.13 Beam supported by a cable. (a) Schematic. (b) Free-body diagram. (c) Physiological loading

Solution: Solve using the equations of equilibrium conditions:

$$\Sigma Fx = 0, \Sigma Fy = 0, \text{ and } \Sigma \tau_o = 0$$
$$\Sigma Fx = Rh - Th = Rh - T\cos 45° = 0$$
$$\Sigma Fy = Rv + Tv - 400 - 1000 = Rv + T\sin 45° - 1400 = 0$$
$$\Sigma \tau_o = 1000 \times 6 + 400 \times 3 - T\sin 45° \times 6 = 0$$

then:

$$T = 1697 \text{ N}; Rv = 200 \text{ N}; Rh = 1200 \text{ N}$$

4.4 Elastic Behavior of Solids

Elastic materials respond immediately to an applied stress. When such stress is released, its deformation or displacement is recovered instantaneously. This takes place if the deformation or displacement is within the elastic limits of the material.

The physical model of the elastic materials is represented by a spring (Hooke's Law, $\mathbf{F} = kx$), and the response to such ideal elastic materials to alternating cyclic stresses such as tension and compression shows the stresses and displacements in phase. See Fig. 4.14. The spring constant k is given by the slope of the straight line of the Fig. 4.14(b); the steeper the slope the stiffer the constant k.

Metallic implants have an elastic characteristic, and it is important to know they should be working within their elastic limits.

In some of the following figures, the deformations on the bodies caused by the applied stresses are exaggerated for clarity.

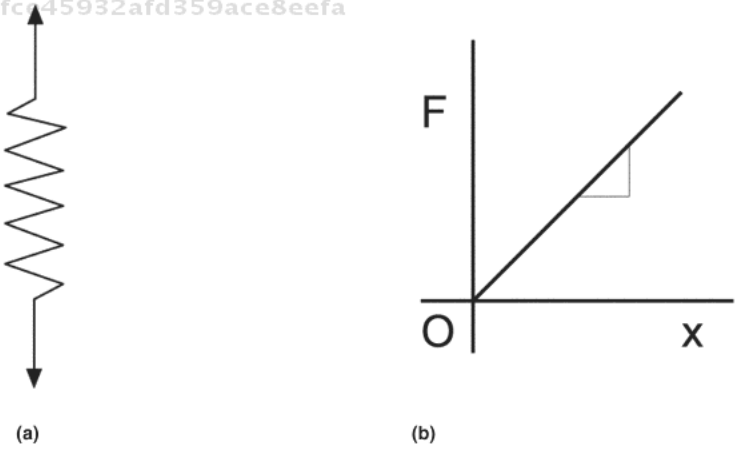


Fig. 4.14 Elastic behavior. (a) A spring in equilibrium position x = 0. (b) Applied force versus displacement x

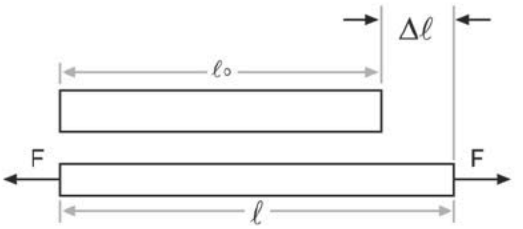


Fig. 4.15 Metallic rod with cross-sectional area A, where tensile forces act along its longitudinal axis causing a change in shape and volume

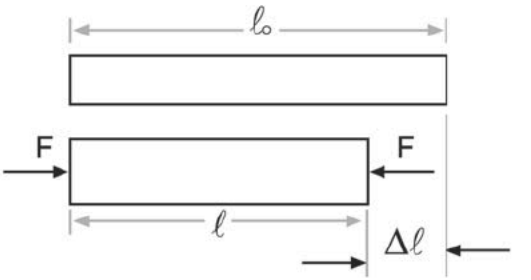


Fig. 4.16 Metallic rod with cross-sectional area A, where compression forces act along its longitudinal axis causing a change in shape and volume

4.4.1 Young's Modulus, E

Young's modulus E of the materials represents the physical quantities that describe their elastic properties as the ratio of stress to strain.

Tensile. A metallic rod with cross-sectional area A is put under two equal tension forces in opposite directions that elongate the rod by its ends. See Fig. 4.15. These tensile stresses are accompanied by a strain along the longitudinal axis and a lateral thinner strain that is perpendicular to the axial stress.

Tensile Stress σ. The axial tensile stresses are given by the longitudinal normal forces **F** per unit of cross-sectional area.

Tensile Strain ϵ. The strain is given by the increase of length $\Delta\ell$ per unit of length ℓ_o.

Compression. A metallic rod with cross-sectional area A is put under compression forces that act along its axis in opposite direction to the tensile. See Fig. 4.16. These compressive stresses are accompanied by a strain along the longitudinal axis and a sidewise swelling perpendicular to the longitudinal axis.

Compression Stress σ. The axial compressive stresses are the longitudinal normal forces **F** per unit cross-sectional area.

Compression Strain ϵ. Compression strain is given by the decrease of length $\Delta\ell$ per unit of length ℓ_o. For tensile and compressive stresses, Young's modulus is the same for isotropic materials, and the units of E are the same as those of stress force per unit of area. The strains are dimensionless. See Table 4.1. Figure 4.17 shows the Young's modulus of five different solid materials; the steeper the slope the higher the modulus.

4.4.2 Shear Modulus, G

Figure 4.18 shows a block whose original rectangular form is given by the dotted line. The block undergoes a strain when applying the shear stresses that are shown in the same figure. The shear stresses in the block act parallel to the surface.

Table 4.1 Young's modulus, shear modulus, and bulk elastic modulus

Force	Stress	Strain	Elastic modulus
Tensile	$\frac{Fn}{A}$	$\frac{\Delta \ell}{\ell_o}$	Young's modulus $E = \frac{\frac{Fn}{A}}{\frac{\Delta \ell}{\ell_o}} = \frac{\sigma}{\varepsilon}$
Compression	$\frac{Fn}{A}$	$\frac{\Delta \ell}{\ell_o}$	Young's modulus $E = \frac{\frac{Fn}{A}}{\frac{\Delta \ell}{\ell_o}} = \frac{\sigma}{\varepsilon}$
Shear	$\frac{F_{shear}}{A}$	$\frac{\Delta x}{\ell} = \tan\phi$	Shear modulus $G = \frac{\frac{F_{shear}}{A}}{\tan\phi} = \frac{\sigma_{shear}}{\varepsilon_{shear}}$
Compression	σ_{hyd}	$\frac{\Delta v}{v_o}$	Bulk modulus $B = -\frac{\sigma_{hyd}}{\frac{\Delta v}{v_o}}$

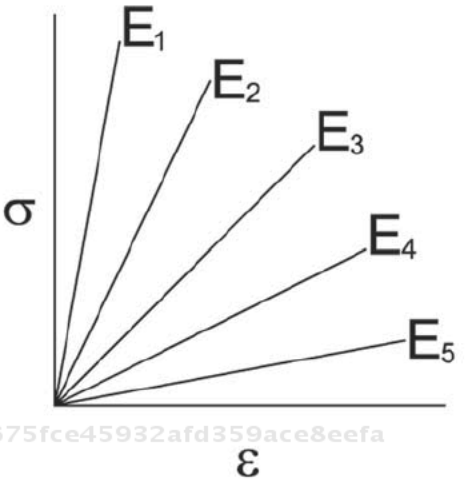


Fig. 4.17 Young's modulus E of five different solid materials, where E1 > E2 > E3 > E4 > E5

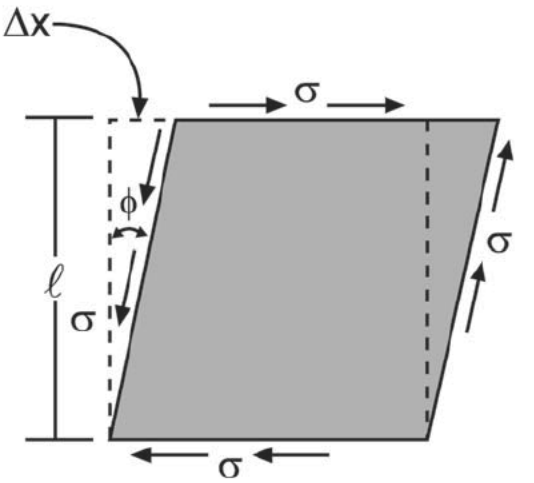


Fig. 4.18 Block deformation resulting from shearing forces, where there is a change in shape but not in volume

Shear Stress σ_{shear}. Shear stresses act parallel to the surfaces and are calculated by the F_{shear} per unit of area.

Shear Strain γ. The shear strain γ is given by Δx per unit length ℓ, which is equal to tan ϕ, for very small angles tan ϕ is $\approx \phi^*$ in radians (see Appendix II).

4.4.3 Bulk Modulus B

The bulk modulus B, as its name indicates, is a compression modulus, in which the hydrostatic stresses act perpendicularly to the body in three

space dimensions. Compression forces cause the body to decrease its volume but not its shape. See Table 4.1.

Compression Stress σ_{hyd}. Hydrostatic stress is set by normal compression stress over the entire body.

Compression Strain $\Delta V/V_o$. The strain $\Delta V/V_o$ is the change of volume per unit of volume. The units of B are the same as those for hydrostatic pressure (force per unit area).

4.4.4 Poisson's ratio ν

A tensile stress in any axial direction produces a strain in the axial direction of the tensile stress. The ratio of the strain $-\epsilon_x$ perpendicular to axial direction strain ϵ_z is named the Poisson's ratio $\nu = -\epsilon_x/\epsilon_z$. See Fig. 4.19. For most metallic materials the Poisson's ratio ν is around 0.33.

The Young's modulus E and the Shear modulus G are independent elastic constants for isotropic materials; G is a function of E. The Poisson's ratio ν is calculated by:

$$G = \frac{E}{2(1+\nu)}$$

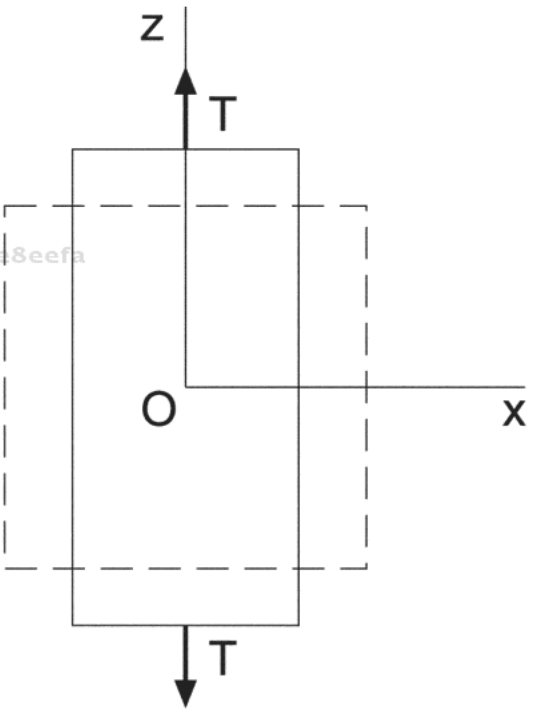


Fig. 4.19 Axial strain

The bulk modulus B as a function of E and the Poisson's ratio ν is:

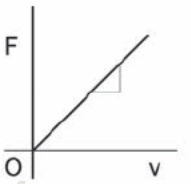
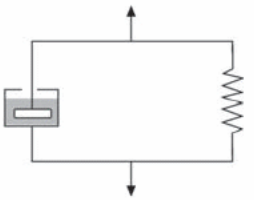
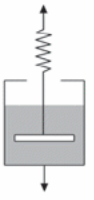
$$B = \frac{E}{3(1-2\nu)}$$

4.5 Anelasticity

Solid materials that are put under stress show a time-dependent behavior when its deformation or displacement is fully recovered after the stress is released. This time-dependent property is called anelasticity.

The Voigt displacement model is used to show the behavior of anelastic materials. These types respond to an applied stress with a time-dependent strain $\epsilon(t)$. These strains are exponentially relaxed. See Table 4.2.

Table 4.2 Schematics of physical models (elastic, viscous, anelastic, viscoelastic) and their displacement recoveries when acting stresses are released in solid materials

Physical model	Material behavior	Displacement recovery
Spring 	Ideal elastic (Hooke's Law) 	Instantaneous
Dashpot 	Viscous (Ideal Newtonian fluid) 	Unrecovered (Not reversible when shear stress is removed)
Voigt 	Anelastic	Recovered with time
Maxwell 	Viscoelastic	Recovered (spring contribution) Unrecovered (viscous contribution)

4.6 Viscoelasticity

Viscoelastic materials exhibit both elastic and viscous properties. The behavior of viscoelastic materials depend on their structure either amorphous or crystalline as well as their temperature. Physical models describe in a simple and objective manner the recovery and/or unrecovered displacements of materials when applied stresses are released. These models represent an approximation of the mechanical behavior of real materials. See Table 4.2

4.7 Biomechanical Behavior of Bones

Cortical and spongy bones are the fundamental components of bones. Their important physical characteristics are specific weight (g/cm^3), mineral content, and water content.

The bone is a nonhomogeneous composite material and has the characteristic of being anisotropic. This means that its mechanical properties depend on the direction in which the stresses are applied, either along its longitudinal axis or in a direction perpendicular to the longitudinal axis. For this reason it is considered a system with different mechanical properties in three orthogonal directions.

4.7.1 Cortical Bone (Compact)

The mechanical behavior of cortical (compact) bone is different when it is put under compression, tension, or shear stress. Given that bones work mainly under compression, bones have the highest resistance to this stress, followed by the tension stress and shear stress.

4.7.2 Trabecular (Spongy) Bone

The ultimate tensile and compression strengths of the trabecular (spongy) bones is equal, and their magnitude is a small fraction of the ultimate compression strength of the femur's cortical bone (Ref 1).

4.8 Biomechanical Behavior of Intervertebral Spine Discs (Physical Model)

Without entering into discussion of the spine disc morphology, which is well described elsewhere, let us consider the recovery time of stresses that act in the spine discs in the daily life of the human being. See the displacement model in Fig. 4.20.

- **Spring.** The elastic strain of the spring in series is recovered immediately.

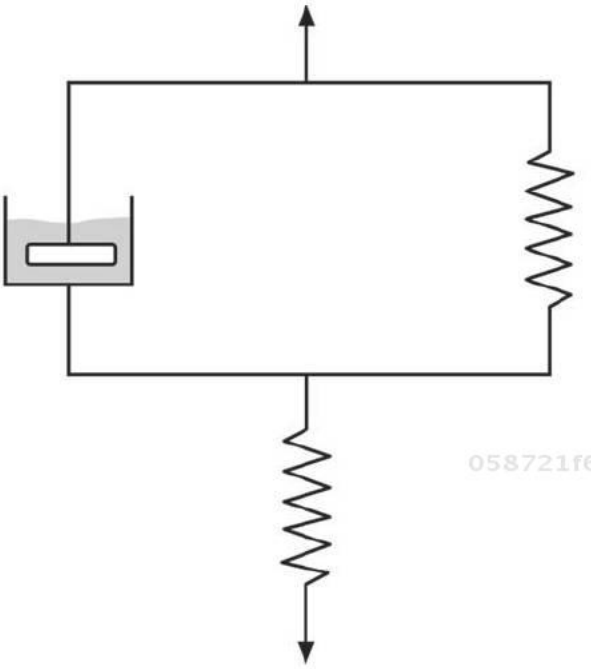


Fig. 4.20 Displacement physical model consisting of two elements: a spring connected in series with a Voigt model, where the spring and the dashpot are connected in parallel

- **Dashpot and a Spring in Parallel.** This element is put under a constant stress σ. It causes an anelastic strain that relaxes exponentially.

For cases like this, and many others, laws of physics are described by mathematical equations in relation to space and time. These types of equations are called differential equations.

The second element is described mathematically:

$$\sigma = E\,\varepsilon + \eta\, d\varepsilon/dt$$

where σ is constant stress applied to the second element (dashpot and a spring in parallel),
E is Young's modulus of the spring,
ε is strain, and
η is viscosity coefficient of the dashpot.

4.9 Torsion in Metallic Biomaterials

4.9.1 Torsion in Solid Cylindrical Materials

Torsion is an important topic specifically in the intramedular nail implants. In some cases fracture failures as well as bending has taken place. Torsion

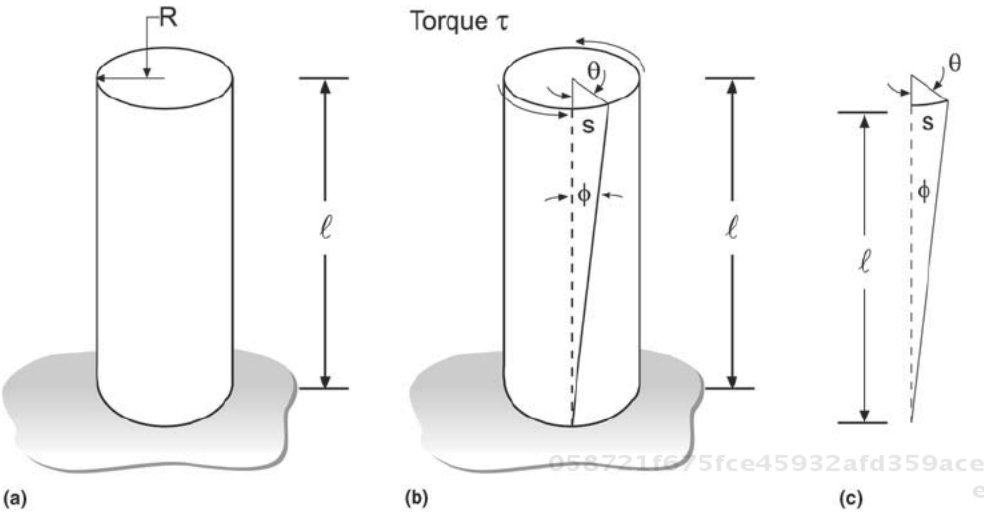


Fig. 4.21 Torsion acting on a solid cylindrical material. (a) The solid cylinder is fixed at the bottom end. (b) The solid cylinder is twisted by applying a counterclockwise torque τ. (c) Relation between the angle of shear ϕ and angle of twist θ

is now to be explained through the analysis of the shear stresses caused by the application of torques and the elastic constants of the materials involved.

For a good understanding of the behavior of metallic materials put under torsion a solid cylindrical rod with radius R and length ℓ is first exemplified. Secondly, a hollow cylinder tube with the same radius and same length ℓ is considered. See Fig. 4.21.

The torsion τ of the rod shown in Fig. 4.21(b) is produced by tangential forces that tend to turn the cylinder on its central axis. The internal shear stress σ resists to this moment of torsion. See Fig. 4.22. This internal shear stress varies linearly with radius. In **σ(r)**, its magnitude goes from zero in the center of the rod to a corresponding maximum σ_{max} of radius R. See Fig. 4.23.

It is assumed that the solid cylindrical material obeys the Hooke's law; that is, the material behaves elastically as the external forces are applied. Therefore, one may establish that the magnitude of the internal shear stresses is a function of the radius of the rod as can be appreciated in Fig. 4.23.

Expressing the preceding paragraph by the linear function σ(r) = constant f (r), then we may write: $\sigma(r) / r = \sigma_{max} / R$. Now, making the moment of torsion τ equal to the internal shear stresses in the transversal section of the rod one obtains:

$$\tau = \int_A \sigma(r) r \, dA = \frac{\sigma_{max}}{R} \int_A r^2 dA$$

$$I_p = \int_A r^2 dA$$

I_p is the polar moment of inertia for a plane area around an axis.

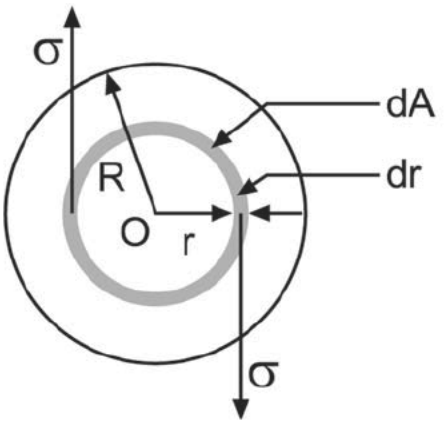


Fig. 4.22 Internal shear stresses in the transversal section of the rod with radius R

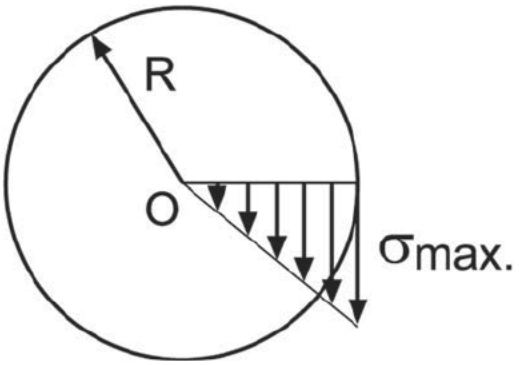


Fig. 4.23 Distribution of the internal stresses of torsion along the radius R

The polar moment of inertia is a mathematical characteristic of the area; it does not have a physical meaning. Then

$$\tau = \frac{\sigma_{max} I_p}{R}$$

The polar moment of inertia I for a circle of radius R equal to:

$$I_p = \int_A r^2 dA = \int_0^R r^2 2\pi r \, dr = \frac{\pi R^4}{2}$$

Then, τ becomes

$$\tau = \frac{\sigma_{max} \pi R^3}{2}$$

4.9.2 Torsion in Hollow Cylindrical Materials

The polar moment of inertia of a hollow cylinder is obtained in the same way as the solid cylinder. See Fig. 4.24. The polar moment of inertia I_p is:

$$I_p = \frac{\pi(R^4 - R_1^4)}{2}$$

Torque τ form previous equation is:

$$\tau = \frac{\sigma_{max} I_p}{R}$$

Then,

$$\tau = \frac{\sigma_{max} \pi(R^4 - R_1^4)}{2R}$$

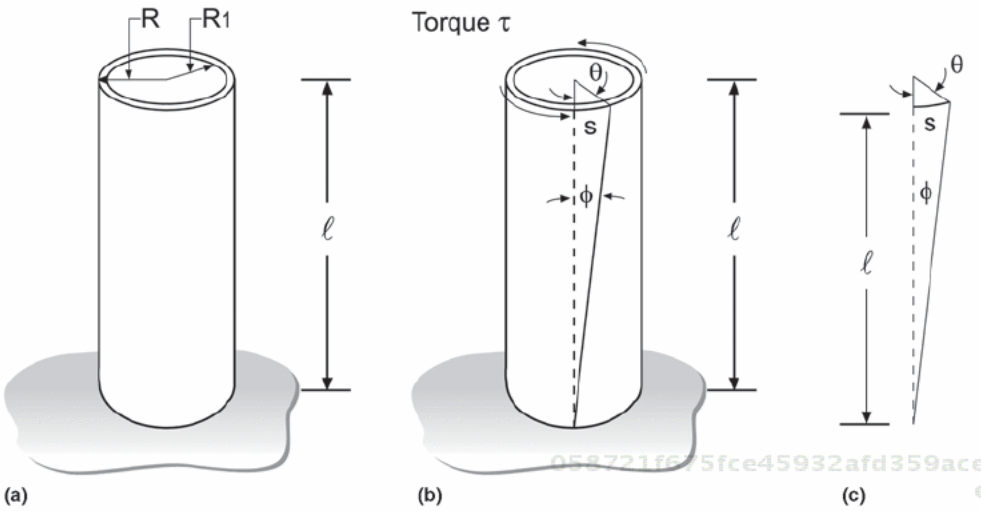


Fig. 4.24 Torsion acting on a hollow solid cylinder. (a) Hollow cylinder fixed at the bottom end. (b) Hollow cylinder is twisted by applying a counterclockwise torque τ. (c) Relation between the shear angle ϕ and angle of twist θ

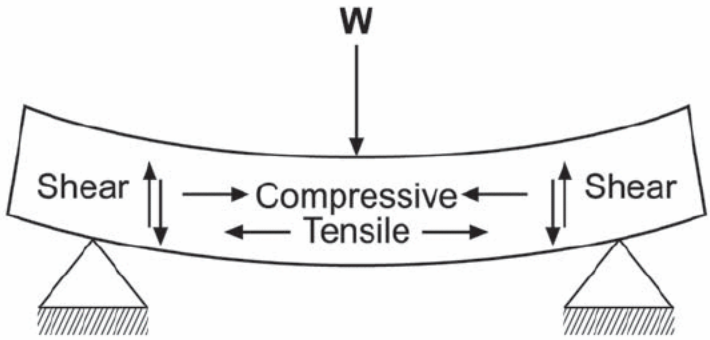


Fig. 4.25 Schema of stresses in a loaded rod

Comparing the solid cylinder rod with the hollow cylinder, it can be seen that the hollow is more efficient because its greater shear stresses supported along the radius reach a maximum (σ_{max}) at radius R. Another advantage is the use of less material as well as the reduction of weight.

In some traumatology applications the intramedular femoral nails are hollow. Therefore, the wall thickness is a very important design parameter as well as the material and manufacturing processes. These considerations are fundamental in order to avoid nail fracture failures and bending.

4.10 Bending in Metallic Biomaterials

The rod shown in Fig. 4.25 is supported near the ends; W is the applied load in the middle of the rod. The stresses produced in the loading rod are

compression, tensile, and shear as shown in the figure. The central axis of the rod not shown in the figure is the dividing line between the upper compressive stresses and the lower tensile stresses.

For detailed information see ASTM F 383, "Standard Practice for Static Bend and Torsion Testing of Intramedullary Rods." This specification describes the determination of bending strength, bending rigidity, and torsional rigidity. For the case of nail plates, ASTM F 384, "Standard Practice for Static Bend Testing of Nail Plates," describes the method for static bend testing of nail plates in order to determine its bending strength, rigidity, and ductility.

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- L.H. Van Vlack, *Materials Science for Engineers*, Addison-Wesley Publishing Co., 1970, p 235–237

EDUCATIONAL OBJECTIVES

1. In your own words, define Newton's Laws.
2. Give a brief definition of vectors, and determine their importance in fracture fixation.
3. Using the graph method draw a force diagram of the pelvis where the force of the abductor muscle is given by $\mathbf{F}_a$, the joint force of the hip by $\mathbf{F}_h$, and the weight of the person by **W**. In this case a person is standing in one leg.
4. Obtain the resultant forces of quadriceps muscle $\mathbf{F}_c$ and patellar ligament $\mathbf{F}_r$.
5. Draw a diagram of the ankle forces during the dorsireflexion.
6. A man is standing up on the floor. See Fig. 4.4. Draw a free body diagram with the action forces and establish the first condition of equilibrium.
7. Calculate the work done by a person who displaces an object to a horizontal distance of 10 meters applying a force **F** of 200 Newtons. Also, calculate the work for different angles (0°, 30°, 45°, and 60°) with the horizontal axis between the force **F** and horizontal displacement **d**.
8. Give an example for each of the three types of levers.
9. In your own words explain the difference between biotribology and tribology.

10. In your own words explain the difference between the friction static coefficient μ_s and the friction kinetic coefficient μ_k.
11. What is the characteristic of material that is described using Young's modulus, and what kind of stresses can it be put under?
12. What is the characteristic of material that is described using shear modulus, and what kind of stresses can it be put under?
13. What is the characteristic of material that is described using bulk modulus, and what kind of stresses can it be put under?
14. What is Poisson's ratio used for?
15. Consider an implant made of stainless steel 316L and one made of Ti-6Al-4V. Which implant would be stiffer and why? How would an implant made of Co-Cr-Mo compare?

CHAPTER 5

Applications of Materials Testing

The properties of metallic biomaterial implants are obtained by various manufacturing processes, starting with the raw material and finishing with the end product. The main role of the materials expert working with a particular metallic alloy is to determine the specific processing required to deliver the necessary properties for the given alloy composition, including any special processes that may be needed to guarantee implant performance in orthopaedics and traumatology applications.

The mechanical properties of metallic biomaterials are determined through testing. It is important to note that laboratory tests are controlled tests; that is, they are carried out in a controlled (laboratory) environment. Most standard tests are conducted at room temperature.

However, implants work inside the human body. Metallic biomaterials are intended to interact with that environment, which includes interaction with intracellular and extracellular liquids, soft and hard tissues, and so forth. One effect of this environment on metals will be a chemical attack, which, combined with cyclic stresses, may lead to corrosion fatigue. Nevertheless, it is necessary to have a starting point that gives the greatest amount of information.

5.1 Mechanical Testing

5.1.1 Tensile Test

For many decades, tensile tests have been used as an important source of information for evaluating the mechanical behavior of metals and alloys. Test samples used in the tensile tests have to be standardized in order to compare the mechanical properties of different materials. Figure 5.1 shows the standard dimensions (not at scale) of the standard threaded tensile test specimen.

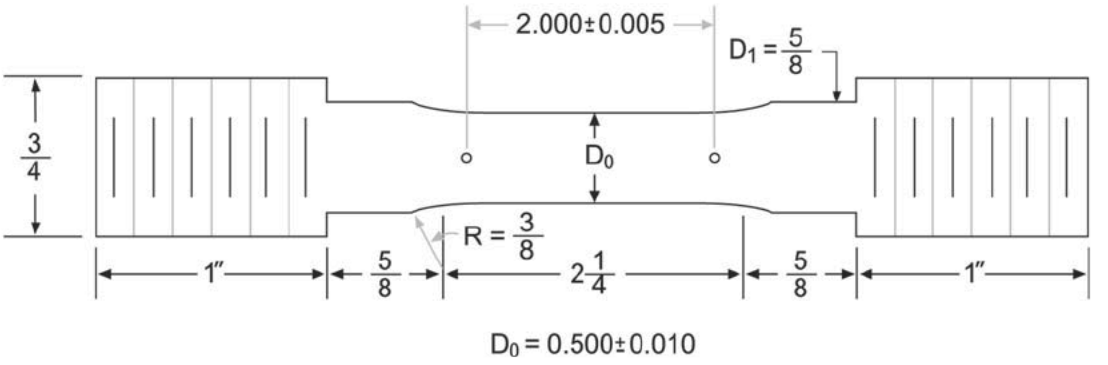


Fig. 5.1 Standard dimensions (not at scale) of standard threaded test specimen for the tension machine. Dimensions in inches. Adapted, with permission, from ASTM E 8-00, "Standard Test Method for Tension Testing of Metallic Materials," ASTM International, copyright ASTM International.

ASTM E 8, "Standard Test Methods for Tension Testing of Metallic Materials" defines test methods for determination of yield strength, yield point elongation, tensile strength, elongation, and reduction of area. ASTM E 8-M defines the tests and specimen dimensions in metric units.

Technological progress has allowed stress and deformation measurements to be precise and exact. Figure 5.2 shows a tensile test machine. In the tensile test, the machine applies an axial tension stress at constant rate to the tensile test sample, causing an elongation $\Delta\ell$ of the sample.

Figure 5.3 shows a typical stress-deformation (stress-strain) curve of commercial steel. In Fig. 5.3 we can observe:

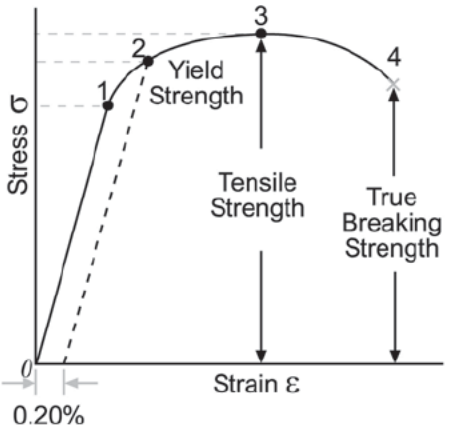
- **Elastic Behavior.** Young's modulus defines the elastic characteristics of the material (see Chapter 4). Young's modulus represents the slope of the elastic part of the stress-strain curve. Resilience is the property of a material to absorb energy when it is elastically deformed; the energy is recovered when the material returns to its original dimension, once the stress is released. The tensile test specimen put under a stress σ elastically extends up to point 1, in such a way that when suppressing the load the test specimen returns to the origin O. Point 1 is called the elastic limit.
- **Plastic Behavior—Yield Point, Yield Strength.** When applying the stress σ on the tensile specimen a second time, it extends again to point 1. If the stress continues to point 2, the test specimen will exceed its elastic limit and the metal will begin to yield, that is, to deform plastically. Point 2 settles down to what is known as the yield point (YP). The corresponding stress at this point is called yield strength. It is the stress at which plastic flow starts. This point is taken by drawing a parallel line to the elastic part, and it is at 0.20% offset from the strain axis.
- **Tensile strength** is defined as the maximum load divided by the original cross-sectional area of the test sample (point 3). Tensile strength is also called ultimate tensile strength (UTS).

Fig. 5.2 Tension, compression, and fatigue testing machine. The machine shown is an integrated machine, designed to obtain mechanical properties data for both materials and components. © 2009 MTS Systems Corporation. MTS and Bionix are registered trademarks of MTS Systems Corporation. Photo courtesy of MTS Systems Corporation.

- **True breaking strength** is the load divided by the cross-sectional area of the test sample at the time of fracture (point 4). Toughness is represented by the total area under the stress-deformation curve, and it indicates the energy required for fracture. Figure 5.4 shows a comparison of two tensile test samples of the same material. The sample on the bottom was put under the tensile test.

Elongation, Reduction of Area—Ductility. Elongation is defined as the increase in length $\Delta\ell$ per unit length ℓ_o, $\Delta\ell/\ell_o$ (%), and it is equal to the plastic strain at fracture.

Reduction of area is the ratio of the reduction of the cross-sectional area ΔA of the test sample at fracture, to the original area A_0, $\Delta A/A_0$ (%). Elongation and reduction of area are indicators of material ductility.



1. Elastic Limit
2. a) Yield Point Y. P.
   b) Yield Strength Y. S.
3. Tensile Strength
4. True Breaking Strength

Fig. 5.3 Tensile stress-strain curve, showing gradual transformation from elastic to plastic behavior until the sample is fractured

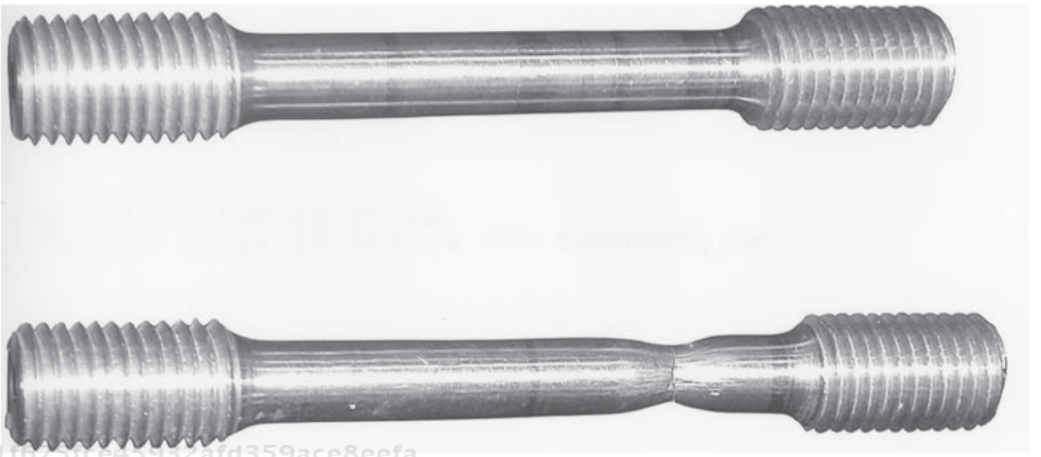


Fig. 5.4 Comparison of two aluminum tensile test specimens. The specimen below was put under the tensile test.

5.1.2 Torsion Test

Torsion is twisting caused by applied torque. Although torsion tests are very important in many applications, they have not been used as much as tensile tests. Torsion tests involve placing materials under shear stresses on a torsion testing machine to find out the properties of materials such as modulus of elasticity in shear, torsion yield strength, and so forth.

As a result of the nature of the stress applied to the materials, torsion tests have a circular transversal section. This can be seen in the torsion testing equipment shown in Fig. 5.5.

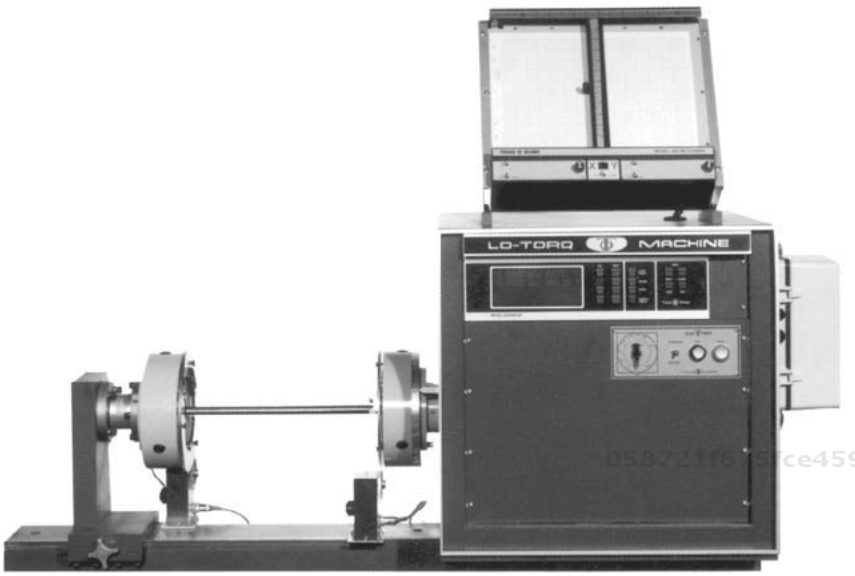


Fig. 5.5 Torsion testing machine. 10,000 in.-lb. Benchtop Lo Torq Model. Courtesy of Tinius Olsen Testing Machines Co., Inc.

Fatigue failures of intramedullary rods occur occasionally. ASTM Standard F 383 "Standard Practice for Static and Torsion Testing of Intramedullary Rods" was developed; however, this standard is not currently active.

5.1.3 Bend Test

Figure 5.6 shows a bend test machine. ASTM F 382, "Standard Specification and Test Method for Metallic Bone Plates" defines test methods for evaluating strength, stiffness, and ductility of metallic plates for bones, including tests for single-cycle bend and bend fatigue characteristics that are related to the in vivo performance of these plates.

The related international standard is ISO 9585:1990, "Implants for Surgery—Determination of Bending Strength and Stiffness of Bone Plates." This test method is not recommended for plates less than 50 mm (Table 5.1) or for those that are part of intramedullary devices.

5.1.4 Hardness Test

Hardness is defined as a material's ability to resist deformation. Hardness testing samples with higher hardness will exhibit smaller deformation in standard tests. There are several methods for measuring metal hardness. The most common methods are indentation tests applied to the surface of a metal. The most frequently used hardness tests are the Rockwell and the Brinell tests.

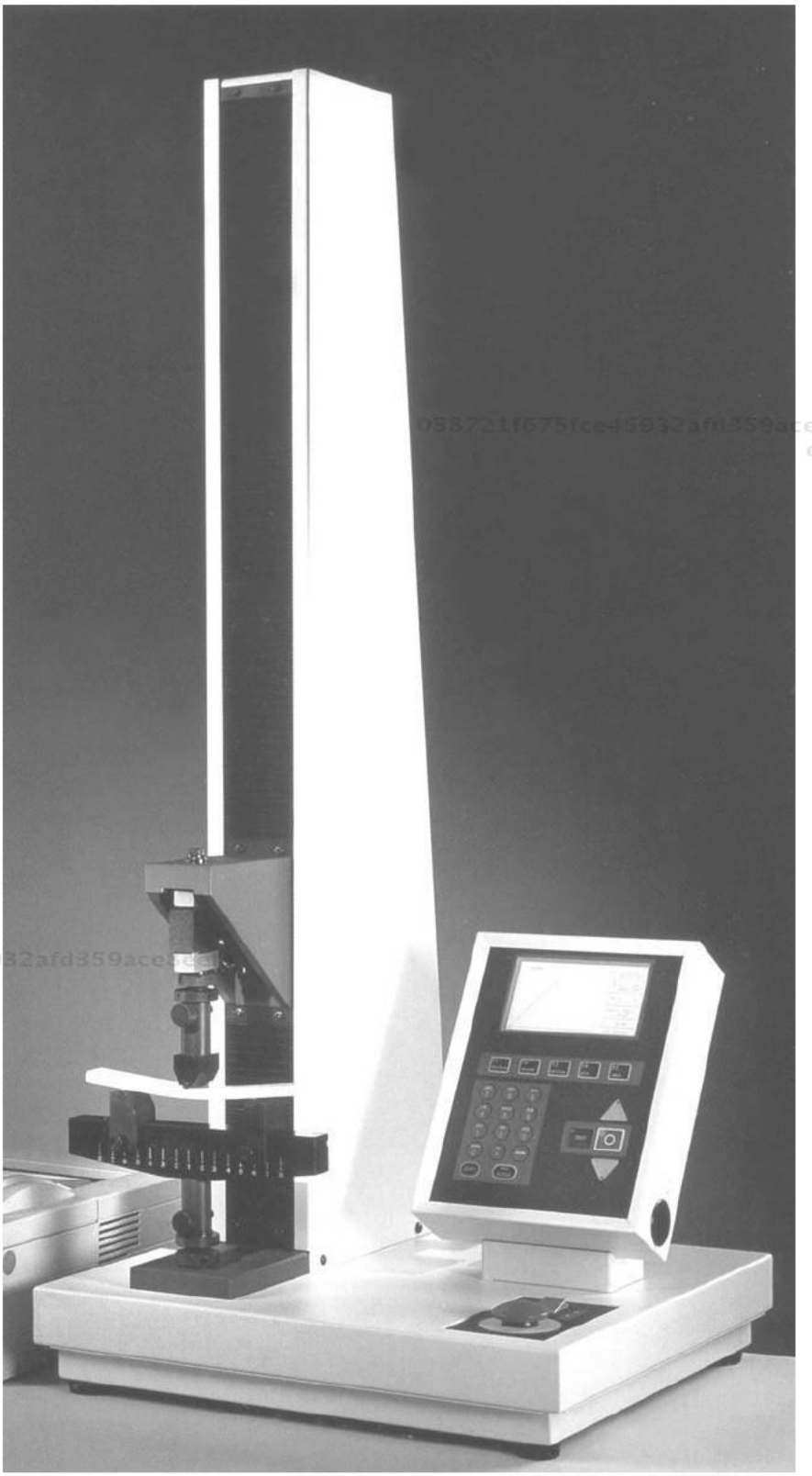


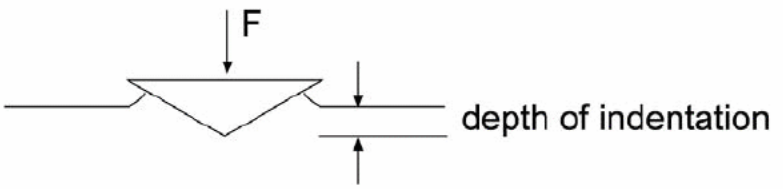
Fig. 5.6 Bend test machine. Bench top Bending Test Machine, Model H5K-S UTM, a 5 kN machine. Courtesy of Tinius Olsen Testing Machine Co., Inc.

Table 5.1 Mechanical property requirements of selected metallic alloys

Alloy	Required minimum: Tensile strength, MPa	Yield strength (0.2% offset), MPa	Elongation, %	Reduction in area, %
Co-Cr-Mo (ASTM F 75, ASTM F 799)				
As cast	655	450	8	8
Forgings	1172	827	12	12
316L stainless steel (ASTM F 139)				
Annealed	485	172	40(a)	. . .
Cold worked	860	690	10(a)	. . .
Ti-6Al-4V (ASTM F 1108, ASTM F 1295)				
As cast	860	758	8	14
Annealed	900	800	10	25
Wrought	930	860	10	25
CP Titanium ASTM F 67				
Grade 1	240	170	24	30
Grade 2	345	275	20	30
Grade 3	450	380	18	30
Grade 4	550	483	15	25

(a) In 50.8 mm. Adapted with permission from the *Annual Book of ASTM Standards*, ASTM International, West Conshohocken, PA

5.1.4.1 Rockwell Hardness. The Rockwell hardness test is widely used for its rapid testing time and error-free measurements. This test uses the depth of indentation under constant load. Below is an illustration showing the measurement of the depth of indentation of the metal surface.



The Rockwell test instrument contains six scales. Each scale has different uses according to the different types of materials. For example, scale C (HRC) with a diamond indenter and a 150 kg load is used for high hardness steels. Given that the Rockwell hardness measurement depends on the load and the indenter, it is necessary to mention the combination for which it is used. To calibrate the Rockwell tester, a comparison to a standard sample is used. Therefore, the Rockwell hardness values are not expressed in terms of absolute units.

5.1.4.2 Brinell Hardness. This test system uses a 10 mm diameter steel ball as the indenter with a load of 3000 kg for hard metals. The Brinell Hardness Number (HB) is given by the load **F** divided by the surface area **A** of the indenter. See Fig. 5.7.

5.1.4.3 Knoop Test. A number of metallurgical cases require microhardness measurements in small surface spaces. It is in these applications where the Knoop test, with results expressed as the Knoop Hardness Number (HK),

Fig. 5.7 Brinell hardness tester. Tinius Olsen Hardness Tester, with diameter readout system, Model DS/AOB. Courtesy of Tinius Olsen Testing Machine Co., Inc.

is useful. The depth of penetration in the Knoop test is very small, and a microscope is needed to measure the dimensions of the marks made by the indenters on the material.

5.1.5 Fatigue Test

Fatigue is the characteristic progressive localized structural damage of metallic materials that are submitted to alternating stresses. The *S-N* graph (stress *S* versus number of cycles *N*) represents laboratory experimental data of many metallic samples put under alternating stresses in a rotating beam machine. The values used to plot *S-N* curves are the results of statistical analyses of a large number of tests, giving the spread value in the *S-N* graph. It is expected that a material will perform indefinitely without fatigue failure when it is under the fatigue limit as defined by the *S-N* graph.

For materials such as austenitic stainless steels and commercially pure titanium, the endurance or fatigue limit of the *S-N* curve is horizontal. See Fig. 5.8. Fatigue limits for 316L austenitic stainless steels vary according to the metallurgical condition of the steel. See Table 5.2.

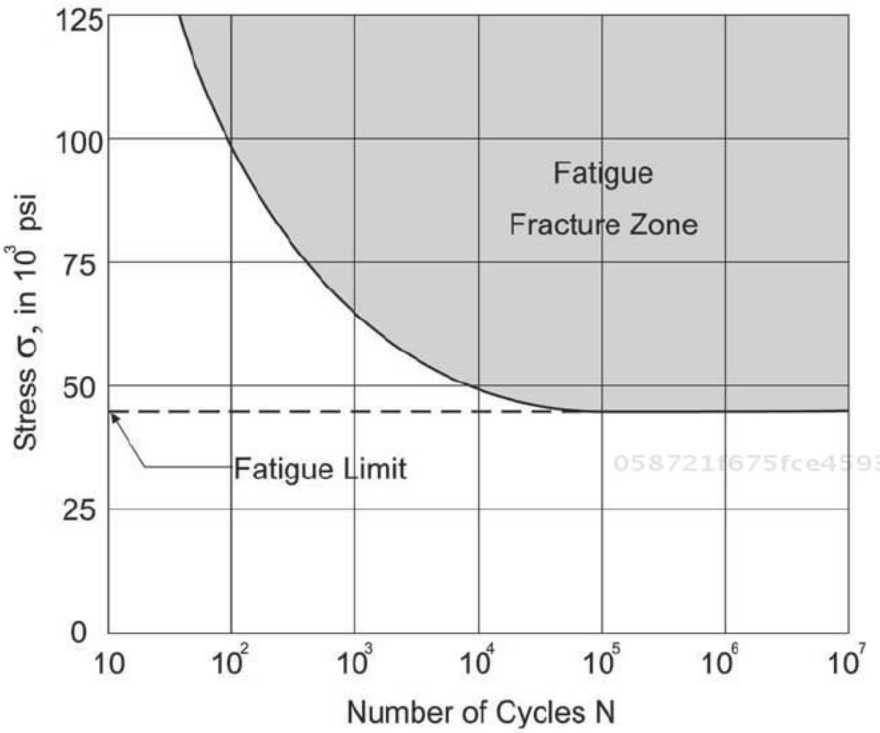


Fig. 5.8 *S-N* graph with hypothetical values for illustrative purposes

Table 5.2 Fatigue limits for 316L low-carbon grade austenitic stainless steel, annealed and cold drawn

Condition	Hardness, HB	Fatigue limit, MPa (ksi)
Annealed	78	262 (38)
Cold drawn	91	275 (40)

For orthopaedic applications, it is necessary to remember the importance of the environment in which these cyclic stresses develop. Metallic biomaterials are chemically attacked by fluids of the human body, amplifying the fatigue damage and increasing the incidence of fatigue failure. Fatigue in such an environment is known as *corrosion fatigue*.

For hip prostheses, ASTM F 1440, "Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion," describes a method for fatigue testing. It is used to evaluate several designs and different biomaterials used for the hip stemmed hip prosthesis. In this method, the stress used is a periodical stress of constant amplitude.

For femoral components put under torsion, the standard practice of tests is described in ASTM F 1612, "Standard Practice for Cyclic Fatigue

Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion."

5.1.6 Creep Test

Creep is plastic deformation that takes place in a material held for extended periods at high temperature. Unlike fatigue tests, where the load is cyclical, creep tests are usually carried out at a constant load and at a constant temperature. The parameter measured is the resulting strain as a function of time.

Considering that the creep rates for metallic implants are rather slow and they have a very small reduction of the cross sections, constant load tests are adequate.

The procedures to follow in a creep test are explained in ASTM E 139, "Standard Tests Methods for Conducting Creep, Creep Rupture, and Stress-Rupture Tests of Metallic Materials." Creep experiments in polyethylene used as inserts in the acetabular hip components as well as the polyethylene used in knee replacements are very important. Parallel studies of wear of joint replacements are also relevant in the performance of the biomaterials used in orthopaedic surgery.

5.1.7 Impact Test

In order to obtain information about the ability of brittle materials to support sudden loads, it is necessary to carry out mechanical tests called impact tests. Several types of impact tests on V-notched specimens of metallic materials are used to determine the brittleness of materials. These tests detect differences among diverse classes of materials that are not observed in a tension test.

The sudden load that is needed for the test is commonly obtained using the equipment shown in Fig. 5.9. These types of tests measure the absorbed energy necessary to fracture the material tested, but do not represent the toughness of the materials (that is, the ability of a material to absorb energy and *deform plastically* before fracturing).

There are two standard types of impact tests using V-notched specimens: the Charpy Test, mainly used in the United States, and the Izod Test, mainly used in England.

5.1.7.1 Charpy notched-bar impact test has a square cross-sectional area and generally contains a V-notch at 45°. See Fig. 5.10.

5.1.7.2 Izod notched-bar impact test may have a circular or square cross-sectional area and a V-notch near one end. See Fig. 5.11. The impact test specimen is positioned and a load F is applied by the impact test equipment shown in Fig. 5.9. For further details, see ASTM E 23, "Standard Test Methods for Notched-Bar Impact Testing of Metallic Materials." The units of the notched-bar impact tests are expressed in units of foot-pounds or energy absorbed per unit cross-sectional area of the sample.

Fig. 5.9 Impact testing machine. Impact Universal Test Equipment Model 84. Courtesy of Tinius Olsen Testing Machine Co. Inc.

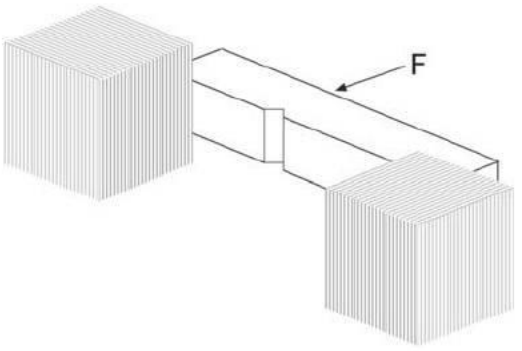


Fig. 5.10 Charpy notched-bar impact test

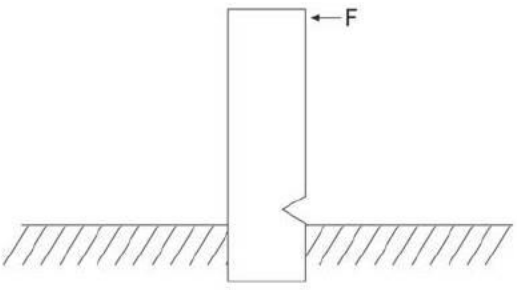


Fig. 5.11 Izod notched-bar impact test

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EDUCATIONAL OBJECTIVES

1. What is the most important part of the tensile test of metallic biomaterials?
2. Where do you apply the knowledge of the preceding question?
3. What implants require testing in the torsion testing machine?
4. What implants require testing in the bending test machine?
5. Why is hardness important? Mention an orthopaedic application that requires high hardness.
6. Why is fatigue testing important? Mention an application.
7. Why is creep testing important?
8. Why is impact testing important?
9. Write down your opinion of the use of the hip and the knee simulators.

CHAPTER 6

Selected Applications of Biomaterials in Orthopaedic Surgery

This chapter addresses the use of biomaterials within the context of the clinical practice of orthopaedics and traumatology.

6.1 Use of Diagnostic Images

Once the patient has been thoroughly examined by a physician, the surgeon then should request the necessary and sufficient diagnostic images. The interpretation of diagnostic images in the specialty of orthopaedics and traumatology is very important, especially x-rays, computerized axial tomography (CAT) scans, and magnetic resonance imaging (MRI).

It is important that a resident knows how to:

- Choose the correct diagnostic test to assess the patient
- Interpret and review the test critically, starting with the technique used to the smallest detail of the image

6.1.1 X-Rays

The German physicist Wilhelm Konrad Roentgen (1845–1923) discovered x-rays in 1895, for which he was awarded the first Nobel Prize in 1901. This exceptional discovery opened the window to orthopaedic surgery.

A simple x-ray represents the basic image that should always be required before any other image study.

To evaluate a structure with an x-ray, it is necessary to require at least two projections taken at 90° angles to one another: the anteroposterior (AP) and lateral view. The first point to assess in an x-ray is its quality. The contrast between white and black should permit one to differentiate cortical

bone from spongy bone, which is not possible if the image is too white (underexposed) or too dark (overexposed).

6.1.2 Computerized Axial Tomography Scan

CAT scanning in its early stages allowed viewing of axial "slices" of the structure being studied. Today, images can be observed in three dimensions as well as in rotation.

Imaging studies are very useful for assessing cavities such as the thorax, the abdomen, and the pelvis; imaging is important to determine the integrity of the cortical bone in the limbs and specifically, for example, stress fractures or tumor lesions. They are also useful for identifying sclerotic lesions, intramedullary calcifications, or intracortical lesions. Additionally, it is possible to determine the density of specific lesions.

6.1.3 Magnetic Resonance Imaging

Magnetic resonance images are used to assess soft tissues. Images are also very useful for the knee because it is possible to evaluate lesions of the meniscus, ligaments, cartilage, and so forth. Shoulder images are useful for evaluating tendon lesions; in the spine, damage of intervertebral discs can be observed.

In general, images are good for identifying intra or extra osseous tumors. In these cases, MRI images are essential for preoperative assessment; they indicate, with precision, the intramedullary extension of the tumor as well as the extramedullary extension. Additionally, these images allow one to determine if the neurovascular bundle is affected.

6.1.4 Bone Fracture Classification

Once the patient has been completely assessed, it is important to classify the bone fracture as well as the implant to be used. The AO *Manual of Internal Fixation* includes classifications ranging from very simple to very complex fractures.

6.2 Surgical Planning Procedure

Surgeries require a careful planning procedure.

6.2.1 Preoperative Planning

Preoperative planning is of paramount importance, and it is based on the patient's profile: gender, age, activity, and so forth, also the information obtained from diagnostic images and laboratory analysis, as well as a thorough appraisal of the patient clinical history.

There are cases where x-ray templates are needed. For primary hip replacement preoperative use of templates is definitely needed in order to

guarantee the use of an adequate prosthetic device as well as to determine the cement thickness for the cemented femoral stems. For cases of tumors where a joint implant replacement is needed, the use of templates is also extremely important in order to have a precise and accurate dimension of the replacement. In cases of bone allografts a careful dimensional measurement of bone is based on MRI images.

6.2.2 Surgical Technique and Navigation Systems

Surgical techniques should be precise and accurate. They call for up-to-date knowledge of the current state of the art in orthopaedic surgery, based mainly on the patients' profile as well as skill and surgical experience.

Navigation systems among other benefits help in the three-dimensional alignment and positioning of joint replacements. They help to decrease the time of the learning curve of the surgeons. These systems are also very useful in spine surgery.

6.2.3 Knowledge of Biomechanics and Biomaterials

Knowing biomechanics and biomaterials ensures that the orthopaedic surgeon is selecting the right type and shape of implant.

6.2.4 Physiotherapeutic Rehabilitation

Postoperative care is also very important. The patient should follow the recommendations given by the surgeon.

6.2.5 Clinical Case Results at Follow-up

Clinical cases should be documented and registered for the surgeon to be able to follow-up the cases through x-ray evaluations. The first postoperative radiographs serve as a reference; they should be compared with posterior imaging studies that help the surgeon identify risk factors for failure leading to unwanted revisions, which are usually complicated.

6.3 Osteosynthesis

6.3.1 Internal Fixation

The surgical treatment of bone fractures has specific indications. The intentions for this type of procedure are primarily the recovery of function and movement, and secondarily, bone fracture consolidation. This as a whole represents a more serious problem regarding the functional prognosis of the patient.

Complete recovery of lost function can be obtained through the use of a fixation system that provides enough stability to suppress pain and to allow the patient to regain movement with a partial load without the risk of jeopardizing fixation.

There is much documentation of the principles of internal fixation involving rigid devices. These devices not only give the necessary stability for their own consolidation, but also interfere with biological processes, as in periostium and vascularization, essential in the healing process. The fundamental system of osteosynthesis involves many different types of screws, plates, and intramedullary nails. Clinical experience and technological development of materials have contributed to the innovation of internal fixation devices. These devices have achieved great feats in the treatment of fractures varying in diversity and complexity.

6.3.1.1 Screws. The first screw and plate types ever used in the internal fixation of bone fractures have provided a great understanding of osteosynthesis. T.E. Sehlinger and D. Seligson (Ref 1) describe the evolution of the design and development of screws. Many distinguished surgeons have made important contributions, including M. Rigard, W. Sherman, A. Lambotte, W. Lyon, L. Peterson, and R. Danis. Danis is considered the father of osteosynthesis.

It is important to mention the role of ASTM International (formerly known as the American Society for Testing and Materials). Section 13 of the *Annual Book of Standards* (Ref 2) covers standards related to screws and other fixation devices among its general coverage of medical devices and materials.

The main applications of bone screws in internal fixation of fractures are:

- Fixation of bone fragments. Torque applied to the screw corresponds to the axial compression force that joins the fragments, giving mechanical stability to the fracture, avoiding micromovements between the fragments, and facilitating fracture consolidation.
- Fixation of bone plates used to maintain the rigidity of the fracture.

Screws help plates give fixation; however, it should be remembered that the compression forces must be uniformly distributed along the entire fracture, regardless of the kind of bone fracture.

Because of the great variety of bone fractures there are many types of screws used in orthopaedics, including the five types described in this section.

Non-self-tapping Cortical Bone Screws. These screws are mainly used in the diaphysis of the bone. The holding power of the screw depends on its thread diameter and the pitch of the thread.

Self-tapping Trabecular Bone Screws. The principal uses of trabecular bone screws are in the epiphysis (the rounded end of a long bone) and the adjacent metaphysis. These screws have a thinner root diameter compared with the non-self-tapping cortical bone screws.

Cannulated Bone Screws (Small and Large). The main reason to use cannulated screws is for its insertion precision.

Transpedicular Screws. These screws are part of universal instrumentation and are used in spine surgery.

Herbert Screws. These screws are headless screws and find applications in, for example, scaphoid wrist fractures.

6.3.1.2 Plates. The orthopaedic technique most commonly used for internal fixation of fractures is made up of plates and screws. They act as a bridge for joining the part(s) of the fracture(s) and absorb stresses at the fracture site.

Awareness of mechanical properties of biomaterials as well as those of bones is important for the success of internal fracture fixation. The different design types each have a specific function in the osteosynthesis. Some of the plate designs are:

- Bridge
- Angled
- Buttress
- Compression
- Dynamic compression plate (DCP)
- Limited contact dynamic compression plate (LC-DCP)
- Low contact plate (LCP)
- Less invasive stabilization system (LISS)
- Reconstruction
- Anatomic plates

A brief description of the functions of selected plates follows.

Buttress Plates. As their name indicates, buttress plates are used to fixate the bone fractures and support stresses. They should be carefully adapted to the bone anatomy considering the procedure of the insertion of the screws. There are different configurations (T-shaped, L-shaped, etc.).

Protection Plates. These plates are used for protecting the lag screw fixation.

Compression Plates. These plates exert static compression on the bone fracture along the axis of the bone.

Limited Contact Plates. The concept of limited contact plates was developed to eliminate disturbance of blood caused by the compression of plates that are flat on the undersurface, such as dynamic compression plates (DCP), and at the same time avoid the formation of temporary porosis on the bone (Ref 3). Figure 6.1 shows the limited contact dynamic compression plate (LC-DCP).

6.3.1.3 Intramedullary Nails. In 1939 Gerhard Küntscher (Ref 4) introduced the use of intramedullary nails. The first intramedullary nail insertion was at the University of Hamburg's Surgery Department.

Intramedullary nails have a clear function—they carry weight through the fracture itself with consequential axial compression between the fracture ends. This type of treatment was very popular in the United States in the 1970s. Since that time intramedullary nail placement has gone through several stages of development.

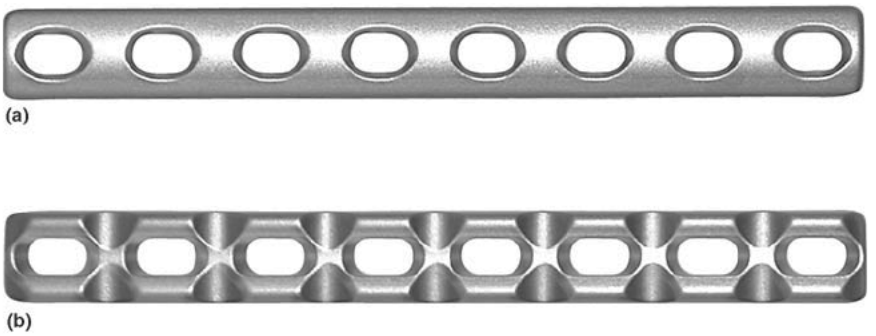


Fig. 6.1 Limited contact dynamic compression plate. (a) Front. (b) Back

Currently, intramedullary nails can be classified as described here.

Nonlocked Nails. These nails allow gliding in the bone along the intramedullar canal, controlling the demands of the fracture focus.

Locked Nails. The purposes of locked intramedullary nails are to bear weight and avoid torsion stresses.

Reconstruction Nails. These are cephalomedullar nails with transfixation screws to control length and rotary alignment.

Flexible Nails. The purpose of prebent flexible intramedullar nails is to fix a fracture. These nails provide stability acting as an internal splint. In other words, a tube is placed inside another tube.

Classification of good number of fractures may be seen in the AO *Manual of Internal Fixation.*

6.3.2 External Fixation

The external fixation system is a very useful, simple, and practical technique for treating pathologies of the musculoskeletal system. It can be an effective tool for highly complex bone fractures with associated damage. The use of the external system has many and clear clinical indications in traumatology and orthopaedics.

The external fixation device permits an ample range of applications using percutaneous screws to obtain consolidation between the bone and the external frame (screw clamps and rods). The first systems were developed for stabilizing open fractures to be able to fix bone fragments and allow healing of the soft tissues. The methods and types of external fixation have evolved so much that they have not only replaced other fixation systems, but their indications have also evolved to different treatment methods in orthopaedics (Ref 5–11). In 1986 the AO (Ref 12) introduced a system of modular fixation for different parts of the body. Its main aim was the stabilization of fractures in the emergency room.

External fixation systems work with a consolidated load and with relative stability resulting in a secondary consolidation.

Looking at the biomechanical characteristics of external fixation, it is important to mention how it differs from other methods of osteosynthesis, especially when extreme rigidity is required. An important consideration in clinical practice is to take into account all the parameters that increase rigidity in a fixation system in order to reduce demands on screws.

6.3.2.1 Basic Principles. While in use, an external fixation system stabilizes the fracture in a way that allows access to the lesion and handling of soft tissues as well as the correction of the bone fracture. Additionally, it fulfills the mechanical requirements of the procedure, while also taking care to provide the most comfortable treatment possible for the patient.

6.3.2.2 Indications for the use of this technique in traumatology are divided in absolute and relative indications.

- The absolute indications are applied for exposed or open fractures, for damage control in polytraumatized patients, for complex fractures without access to internal osteosynthesis, and for fractures associated with burns.
- The relative indications are applied for joint fractures, for fractures related to ipsolateral injury, for unstable joints, and for pelvic fractures.

6.3.2.3 External fixation systems can be divided in two groups: those that use *fixation wires* and those that use *fixation screws*. They also can be divided according to their geometric design as circular, monolateral, and hybrid designs.

Circular External Fixator. This system uses transfixation wires. Circular or ring systems allow for fixation in areas with little healthy bone and joint surfaces. These systems are uncomfortable and very demanding for the patient.

Monolateral External Fixator. This system uses transfixation screws, that is, those that are anchored in both cortical portions of the bone. It is used for one, two, and delta or three planes. See Fig. 6.2.

Monolateral systems have a rod or a dynamic clamp with 90° module to the axis of the diaphysis with the possibility of a 36° to 44° angle depending on the external structure. It allows for three to five screws. The best mounting options come from the prefabricated systems that allow movement.

The external frame of the monolateral fixator consists of screw clamps and rods made of different types of materials. The external frame can be dynamic or static, and it also can have joints that link the device to clamps, also dynamic devices to allow the convenient placement of screws.

This part of the external monolateral fixator is very important; inadequate gripping of the screws by the clamps can considerably reduce the rigidity of the system, changing the prognosis of the treatment.

Hybrid External Fixator. This system uses circular rings with wire fixation and monolateral systems with screws fixation. An external fixation

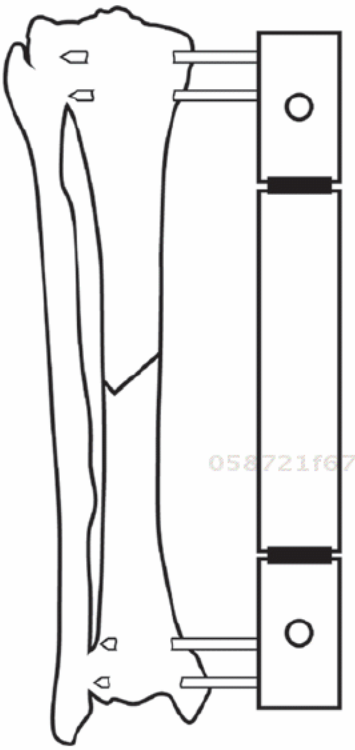


Fig. 6.2 Tibial diaphyseal fracture treated by a monolateral external fixator

device will share daily life with the patient for a relatively long time. The orthopaedist should consider the basic principles described by Behrens (Ref 13) before choosing a fixation device. That is, the device must not damage vital anatomical structures; it should allow access to the injured area, and it should meet the mechanical requirements of the patient and the fracture.

The patient profile and his/her clinical history are considered the departure point for treatment.

6.3.2.4 Assembly Characteristics. Important assembly characteristics of external fixation devices include:

- Maximum versatility with the least amount of possible parts to facilitate application of the device and fracture reduction
- A unique body and screw system that controls demands and allows the device to adequately perform in distraction, compression, and dynamization so that axial loads can act, once the bone callus has formed. (The dynamization concept was introduced by Giovanni De Bastiani and deals with the progressive load transfer to the bone fracture during treatment of the healing process.)

- Maximum rigidity that can be easily accomplished after reduction and maintained during the healing phase of the fracture
- A screw design that maximizes stability, minimizes potential trauma to soft tissues during application and reduces long-term complications such as infection and loosening
- A light and compact assembly to allow the patient to act as normal as possible
- Uncomplicated removal of the assembly and screws when treatment is completed

The monolateral external fixation system is the most widely used method for external bone fracture fixation because of its versatility

6.3.2.5 Biomechanical Principles. There are currently many ways to maneuver modern external fixation systems. These are described in terms of the mechanical fixation functions.

- *Axial compression:* When a compression force is applied from one bone fragment to another in an axial direction
- *Splint:* Keeps the anatomical and mechanical axis relatively stable
- *Neutralization:* When the fixation device fulfills a protection function, changing the loads from the fracture focus or osteotomy toward the fixation body
- *Protection:* When it is alternated with another internal fracture fixation

From a mechanical viewpoint, the most important characteristic is the rigidity of the fixation device.

The fundamental characteristics for external fixation devices are:

- *Resistance to fatigue:* The system must support the patient's weight for a certain amount of time.
- *Adjustability:* The system must be able to correct bone fragment alignment and the stresses at the same time during patient treatment.
- *Rigidity:* It is necessary to neutralize the demands that act on the affected limb.

Rigidity can be defined as the capacity to avoid bone fragment displacement at the fracture focus according to certain demands. The different types of demands are:

- Axial load
- Anteroposterior bending moment
- Lateral bending moment
- Shear
- Torsion

The rigidity of a fixation device usually shows a fluctuating function. At the beginning of its placement the most important deformities are registered; during the consolidation period they progressively stabilize, with the lowest value found between 60 and 90 days of evolution.

Many articles are available that describe different types of fixations. It is very important to keep in mind that no ideal fixation exists for all types of problems: a transverse fracture does not behave like an oblique one, nor does an oblique fracture behave like a comminuted one. The value or ideal amount of rigidity is not known, but the ideal fixation system in the beginning is as rigid as bone and as it consolidates progressively rigidity is reduced.

The properties in a fixation device, presented at the right moment, considerably improve the process of fracture treatment (Ref 14). Using systems that have little rigidity in the treatment of fractures can produce excessive demands on the fracture callus, which will impede its healing. It will also produce an excessive concentration of demands on the screw/bone interface, which can exceed the limits of bone fatigue and cause loosening.

The parameters that increase the rigidity of an external fixation system include:

- The diameter of the screws
- The number of screws that protect the screw/bone interface (Ref 15)
- Shortening the distance between the fixation device and the bone axis (bringing the fixation device as close as possible to the skin)
- Avoiding early weight bearing
- Design (conical, cylindrical, threaded with a blunt or sharp end for spongy bone)
- The separation of the screws from each other
- The modulus of elasticity of the biomaterial
- Screws on different planes

The most important parameter is the screw diameter. Figure 6.3 shows several different sizes of screws.

The low-carbon grade 316L austenitic stainless steel screws are the most widely used materials for external fixation.

Surgeons should treat each case individually and consider all needs, as well as the indications and its applications.

6.4 Hip Joint Replacements

A joint can be defined as the union between one or more bones. The most important joints for adequate function and interaction of a living being with his/her environment are those that allow movement. The extremities allow the displacement and movement essential for adequate individual performance.

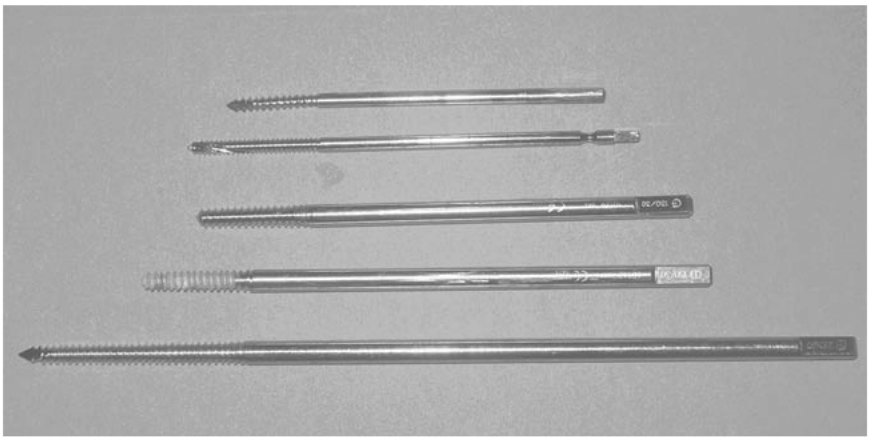


Fig. 6.3 Low-carbon grade 316L austenitic stainless steel screws used for external bone fracture fixation. The second screw from the bottom has threads coated with hydroxyapatite.

In the lower extremities, a number of joints work together to support the body and allow bipedal displacement. The study and understanding of biomechanics is fundamental; for example, the alignment and positioning of the medical device for hip replacements will help avoid leg length discrepancy.

The hip and the knee are the joints that, due to their size and frequency of being affected by traumatic and degenerative processes, have the greatest number of arthroplasties. These joints each support a considerable number of cyclic loads during a given time period.

In the upper extremities, the joint that most frequently has endoprosthetic procedures is the glenohumeral (shoulder) joint.

Medical treatment must be attempted, and alternatives should be considered before deciding to perform a joint replacement. A treatment that could be considered for the reduction of joint activity is physiotherapy or the performance of more conservative surgical procedures. However, if degeneration increases, joint replacement should be considered. The fundamental aim of the orthopaedic surgeon is to relieve pain and maintain or recover mobility.

6.4.1 Total Hip Replacement

Hip replacements are considered multifactorial because of the number of variables involved. The surgeon should consider different approaches, stem designs and materials, head sizes, canal preparations, cementing techniques, cement mantles, cement porosities, stem surfaces, interface bonds (bone/cement and cement/stem), mechanical behaviors, coatings in cementless acetabular and femoral stem components, stress shielding, and

other factors that play an important role in enhancing the longevity of total hip replacements.

The modular components of total hip replacements are the femoral stem, the head (metallic or ceramic), and the different pair of assemblies of the acetabular-femoral components (metal-on-polyethylene, metal-on-metal, ceramic-on-polyethylene, and ceramic-on-ceramic).

Based on many years of clinical results, groups of orthopaedic surgeons and scientists have made efforts to improve the performance of hip joint replacements, either cemented and/or cementless (biological fixation). These improvements are bound to eliminate early failures, revisions, re-revisions, and re-operations as well as enhancing the useful life of implants and avoid stress shielding, thigh pain, aseptic loosening, and osteolysis.

Early failure. Occurs within 4 years of implantation (This definition is reproduced with permission of Douglas E. Padgett, M.D.) (Ref 16).

Revision. Exchange or removal of one or both components (femoral and/or acetabular); exchange of a liner or head component is considered a revision (This definition is reproduced with permission of Henrik Malchau, M.D., Ph.D.) (Ref 17).

Re-operation. Any new hip operation on a patient who previously has undergone total hip replacement (This definition is reproduced with permission of Henrik Malchau, M.D., Ph.D.) (Ref 17).

Totally cemented hip. If the acetabular cup and the femoral stem component both are cemented.

Totally cementless hip. When both the acetabular and femoral stem components are cementless.

Hybrid type. The femoral stem component is the only cemented component.

6.4.2 Fundamentals of Cemented Stem Components in Total Hip Replacements

Clinical problems related to migration, aseptic loosening, osteolysis, and some others are multifactorial. The following considerations in the chain procedure of cemented total hip replacement are intended to familiarize the orthopaedic resident with problems involved in the steps presented in Fig. 6.4. This procedure is based on the results of many clinical cases. Its purpose is intended to enhance in a sensible manner the longevity of the femoral stem component of the hip replacement.

6.4.2.1 Stem Design. It is well known that stem design of the orthopaedic device is of paramount importance in hip joint arthroplasty. Design factors include taper, stem geometry, stem length, neck length, collodiaphyseal (CCD) angles, femoral head diameter, surface finish, coatings of femoral stem components, and mechanical and corrosion-resistant properties. The design provides mechanical stability of the hip joint replacement,

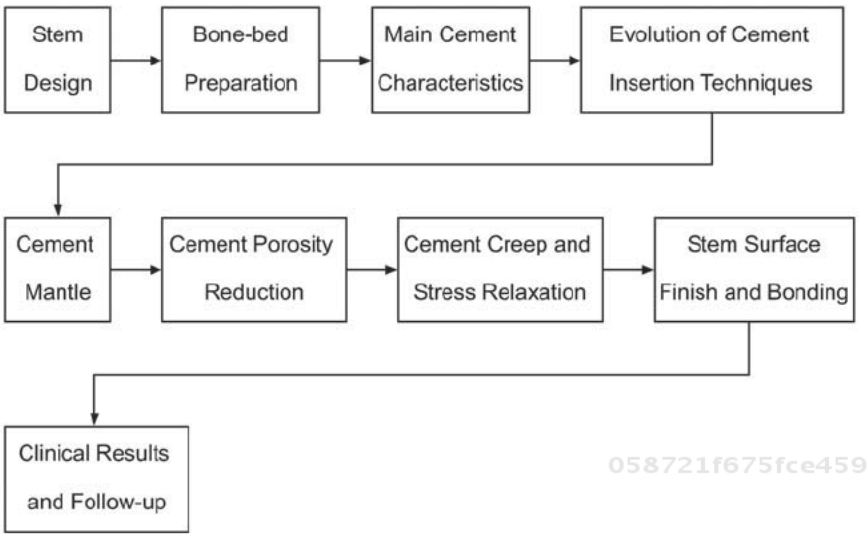


Fig. 6.4 Chain procedure of cemented femoral stem components in total hip replacements

avoiding the stress shielding that causes, among other clinical problems, a localized osteoporosis.

Innovations of Sir John Charnley, M.D. The evolution of cemented femoral stem design femoral components in total hip replacements started in the early 1960s with Sir John Charnley, M.D., in the Wrightington Hospital of Wigan, in England. Charnley's triple tapered flatback design with a small collar produced good clinical results for many years, and, in spite of some cases of stem subsidence (settling), it remains as a model for endurance of cemented stems (Ref 18,19).

In his surgical operations he used the metal-on-polyethylene femoral acetabular assembly for the significant sliding properties of the bearing surfaces, compared at that time to those of the metal-on-metal bearing surfaces. The metallic femoral stem component materials that he very likely used in his surgical operations for prosthetic devices were austenitic stainless steels due to the developments of the medical metallic devices in osteosynthesis at that time.

Innovations of Professor Robin Ling M.D., FRCS. In 1970, Professor Ling (Ref 19) designed the new collarless stem, which was similar to Charnley's flatback design; however, problems of subsidence remained. He also used metal-on-polyethylene as bearing surfaces.

Innovations of William Harris M.D. In the United States, Harris and others introduced cemented stems and other important features to solve remaining problems of subsidence and loosening (Ref 19). Proximal collar and/or tapering of the stem are necessary to prevent subsidence (Ref 17). In his surgical operations he also used metal-on-polyethylene as bearing surfaces.

6.4.2.2 Bone Bed Preparation. Broaching and reaming are processes used in bone bed preparation (Ref 20, 21). Preparation requires use of modern ("third-generation") cementing insertion techniques.

6.4.2.3 Main Cement Characteristics. The following are some of the most relevant cement characteristics that play a very important role in cemented total hip replacements:

- Manufacture
- Preparation
- Monomer density
- Heat of polymerization
- Viscosity and viscoelasticity
- Set times (curing time)
- Shrinkage

6.4.2.4 Evolution of Cement Insertion Techniques. Clinical studies have proved a strong relation between cement insertion technique and clinical results (Ref 17). The following represents the evolution of cement insertion techniques:

- *Finger packing cement:* Sir John Charnley used the finger packing technique for cement insertion starting in the early 1960s.
- *Second-generation technique:* The second-generation technique consists of a distal cement plug and a pressurization gun (Ref 22).
- *Third-generation technique:* Improvements of stem initial fixation are the result of the third-generation cementing technique (Ref 23), which involves pressurized vacuum-mixed cement.

6.4.2.5 Cement Mantle. Even distribution and optimum thickness of cement require a stem centralizer (Ref 22). Documented studies by Maloney et al. (Ref 24) show the relationship between thin cement mantles and cement fractures. It is believed that cement mantle is the weakest link. To obtain a good fatigue resistance of the cement mantle from stresses of the femoral stem, distal and proximal thicknesses are recommended by Noble (Ref 22). Cement material under cyclic loading is put under great shear forces. It is important to consider these stresses in order to avoid revisions resulting from cement failure (Ref 25). Stem designs were investigated (Ref 25) to determine the optimal geometry needed for good stem performance.

6.4.2.6 Cement Porosity Reduction. For cemented stems the interfacial pores at the stem/cement interface, as well as those around the same interface, are of particular interest since these porosities are detrimental for prosthesis fixation.

Pore Sources. There is a difference in the porosity of the cement when it is mixed by hand or in vacuum. In the first case, porosities come from air bubbles and in the second from shrinkage (Ref 26).

Localization of Pores. The pores are located at and around the stem/cement interface. The pores in the cement stem interface were first described by James (Ref 26). After insertion of cement, the direction of polymerization will be from the bone to the stem, creating or forming pores away from the bone due to shrinkage. These pores will be found at and around the stem/cement interface (Ref 26).

Effects of Porosities Leading to Failure. Pores in cement are inversely related to the mechanical properties just mentioned (Ref 26).

To reduce the number of pores, Bishop et al. (Ref 26) and Iesaka et al. (Ref 27) proposed a method preheating the stems to reverse the direction of polymerization.

6.4.2.7 Cement Creep and Stress Relaxation. At this point it is important to mention the effect of mechanical properties of bone cemented stems, in particular on the viscoelasticity of cement creep. The stress relaxation time-dependent properties are also significant. Cemented stems designed by Sir John Charnley were very successful, but had stem subsidence. Professor Ling (19) pointed out the importance of the acrylic cement properties in reconstructive hip surgery, cement creep, and stress relaxation. Shen (Ref 28) mentions the five generations of Dr. Charnley's stem and points out that flat-back first generation is different and considers the possibility that the first design worked as a taper load-slip system as does the Exeter prosthesis developed by Professor Ling.

6.4.2.8 Stem Surface Finish and Bonding. Shen (Ref 28) considers two engineering systems, the composite beam and the taper-slip system. The surface finish as well as cement viscoelastic behavior is also important. Verdonschot and Huiskes (Ref 29) using finite element analysis to simulate the behavior of long-term creep properties found that Exeter polished stems subsided only a few microns (μm) as a result of cement creep, which by itself does not explain the stem subsidence of clinical results. However, it explains the relaxation of cement stresses improving stress distribution at the interface.

It is also possible to coat the surface of the femoral stem component with hydroxyapatite to ensure the bonding between the metallic stem with bone cement.

6.4.3 Hip Resurfacing

Hip resurfacing is a good choice when it gives maximum benefits to the patient. In these cases, the head of the femoral component is reconditioned in order to accommodate a metal cup. This cup and the acetabular cup are usually made of Co-Cr-Mo (ASTM F 75).

6.4.4 Fundamentals of Cementless Stem Components

The fundamental objectives of orthopaedics in hip replacements are:

- Mechanical stability
- Biological stability

- Long-lasting implants
- No thigh pain and no stress shielding
- No implant failures and no revisions

Two very important factors should be considered:

- Patient profile (gender, age, activity, etc.)
- Multifactorial synergy of the hip implant geometry and design, which requires an understanding of the fundamentals of cementless stem components.

6.4.4.1 Stem Design. In 1979, the tapered titanium alloy stem was introduced in Europe by Karl Zweymüller. Later, in 1982, Spotorno presented his design and some modifications have been made (Ref 30). The former design is a tapered stem with a rectangular cross section and rounded corners that has undergone slight modifications from the original design; these modifications were made in order to avoid the problem of stress shielding (Ref 31). Comparative studies have been presented as well as other designs that have been made by Mallory and Head (Ref 30).

6.4.4.2 Acetabular Cup and Femoral Stem Component Coatings. Surface coating of acetabular cup and femoral stem components is an important area of discussion in cementless total hip replacements (Ref 32, 33). The fundamental purpose of surface treatments of these orthopaedic devices is to attain osseointegration through bone apposition on the coated surface. McCutchen et al. (Ref 34) show that osseointegration takes place with the use of smooth, press fit femoral component of titanium-base alloy. Alpha-beta titanium alloys and cobalt-chromium alloys are the substrates currently used in total hip and total knee joint replacements. The usual coating materials are hydroxyapatite and high-purity titanium.

Grit-blasted Surface. This process (Ref 35) involves the use of a pressurized aluminum oxide grit or stainless steel shot. The treated surface presents a rough surface of a few microns in depth caused by the impingement of the grit particles.

Application of this process to Ti-6Al-4V metallic surfaces forms a *nonporous* surface condition. It is expected that with the above surface in contact with the host bone, an osseointegration will take place through bone ongrowth.

Mesh Surface. In this application high-purity titanium is sprayed on the substrate, which is either an alpha-beta titanium alloy or a cobalt-chromium alloy. The purpose of this process is to create a *porous* surface in order to obtain bone apposition by bone ongrowth and by bone ingrowth.

Beaded Surface. In this process very small metallic beads are applied on the metallic surfaces creating a *porous* surface. An ongrowth and ingrowth of the host bone on the beads will help fix the acetabular cup and the femoral stem components. Wolfarth and Ducheyne (Ref 36) propose a novel

porous coating geometry to improve the fatigue strength of Ti-6Al-4V implant alloy.

Hydroxyapatite (HA) Coatings. In the plasma spray process, high-speed calcium phosphate particles collide with the substrate forming the HA coating. A very extensive and thorough explanation of hydroxyapatite coatings in hip and knee joint replacements is given by Dumbleton and Manley (Ref 33). They give the reader very useful information of the characteristics and successful applications of these coatings.

Flohr (Ref 37) mentions the importance of raw material variations, such as composition, impurities, and crystallinity. Tofe et al. (Ref 38) mentions that variations in hydroxyapatite powder affect the coating quality.

6.4.4.3 Femoral Head Component Surface Treatments. A widely used surface treatment in metallic bearing surfaces is the plasma nitrogen ion implantation process. This process takes place under low-pressure nitrogen plasma. The nitrogen ions implanted on the metallic surfaces increase the metallic surface hardness, providing implant wear improvement. In total cemented hip replacements, wear particles lead to local and systemic biological effects as well as to osteolysis. Wear is the most important failure problem in total hip replacements. This process is important for metallic prosthetic devices used in hip and knee joints. The common metallic materials in hip and knee total joint replacements are the Co-Cr-Mo and Ti-6Al-4V alloys. A new technique development described by Ronghua et al. (Ref 39) is high-intensity plasma ion nitriding (HIPIN). Results for this treatment applied to Co-Cr-Mo and Ti-6Al-4V are very promising, especially for the hip and knee joint prosthetic devices.

6.4.5 Cement versus Cementless Fixation in Total Hip Replacements

At this point is important to mention that the performance of both cemented and cementless total hip joint replacements have been proven in several years of clinical experience by many orthopaedic surgeons.

6.4.6 Acetabular Femoral Component Types

The assembly between the head and the acetabulum can vary according to the combination of the different pairs of biomaterials used:

- Metal-on-polyethylene
- Metal-on-metal
- Ceramic-on-polyethylene
- Ceramic-on-ceramic

The most common pair is the metal-polyethylene combination, but recently the metal-on-metal combination has been used frequently. See ASTM F 1636, "Specification for Bores and Cones for Modular Femoral Heads"

(withdrawn in 2001). This specification addresses only the functional dimensions and tolerances for necks of proximal femoral components and the internal dimensions of the corresponding orifices of the metallic and ceramic acetabular heads.

It is highly recommended that the proximal femoral components and the acetabular heads come from the same supplier to ensure their exact and precise dimensions. Commercial manufacturers offer a large variety of designs with an ample range of options to ease selection by the orthopaedic surgeon. In all cases of pairs of assemblies between the head and the acetabulum, the biological response to particles of wear is a determining factor to the longevity of the implant.

6.4.6.1 Metal-on-Polyethylene Assembly. The use of metal-on-polyethylene in hip surgery has been very important, since this combination provides generally good performance. An important problem with the use of this pair, however, is the unavoidable in vivo wear of polyethylene.

Before 1995 (Ref 40) a common practice was sterilization of ultrahigh molecular weight polyethylene in air using gamma rays. A subsequent effect of the radiation is the formation of oxides, which partly contributes to the wear of polyethylene. This oxidation comes from the environment (air), since oxygen acts by diffusion in the reaction with free radicals of the biomaterial, which takes place because of gamma irradiation.

Sterilizing polyethylene liners in air using gamma rays causes wear of polyethylene (Ref 41). The same method of sterilization may be used but in the presence of an inert gas such as argon to avoid oxidation and consequent wear.

The preceding situation brought about the use of alternative methods of sterilization. One of them is ethylene oxide with the intention of eliminating the oxidation index and maintaining mechanical properties.

To improve mechanical properties, as well as resistance to wear, new manufacturing processes are being developed. One method involves irradiation with gamma rays to produce ultrahigh molecular weight polyethylene with a higher cross-link density (Ref 41).

It is very important to have precise information of the manufacturing processes and mechanical properties (such as the yield point, resistance to tension, etc.) of these products, as well as the clinical characteristics of wear and their applications.

6.4.6.2 Metal-on-Metal Assembly. These assemblies originally were abandoned in the 1970s because of an endless number of design problems (Ref 42) that unfortunately led to short-term failure. Recent tests in the hip simulator, however, have demonstrated great viability and confidence in these assemblies, mainly because of wear tests results indicating low wear levels. The alloys of Co-Cr-Mo are mainly used for these applications. Clinical results (Ref 43) displayed by the metal-on-metal assembly show a promising future.

6.4.6.3 Ceramic-on-Polyethylene Assembly. The femoral heads of the ceramic-on-polyethylene assembly are usually of alumina or zirconia. This type of assembly is not susceptible to corrosion.

6.4.6.4 Ceramic-on-Ceramic Assembly. The use of the alumina femoral head component on ceramic acetabular component started in the 1970s (Ref 42). The alumina-alumina pair has demonstrated the lowest wear levels in experimental hip simulators.

It is worth mentioning the well-known properties of ceramic materials: high hardness, brittleness, low friction coefficient, wear resistance, and immunity to electrochemical corrosion. Jacobs (Ref 44) mentions that the systemic effects of ceramic materials are not known; however, possible effects may be attributed to ceramic wear particles.

6.4.7 Partial Hip Replacements

The ASTM F 370 standard covers the materials, functional dimensions, and tolerances of metallic proximal femoral endoprosthesis for partial hip replacement.

6.4.7.1 Femoral Endoprosthesis with Fixed Heads. For this device, it is important to consider the stem cross-sectional area that helps avoid rotation.

Thomson Type. See Fig. 6.5. This type is available with a range of head diameters and with standard and narrow stems. The femoral proximal component head is hardened by nitrogen ions. Biomaterials used are:

- For cemented: Co-Cr-Mo
- For cementless: Ti-6Al-4V ELI

Austin Moore Type. See Fig. 6.6. This type is also available with a wide range of head diameters. Biomaterials used are:

- For cemented: Co-Cr-Mo
- For cementless: Ti-6Al-4V ELI

6.4.7.2 Modular Femoral Endoprosthesis. Figure 6.7 shows an allograft-prosthesis composite, indicating the modularity of the femoral endoprosthesis.

6.4.7.3 Bipolar Endoprosthesis with Removable Heads. See Fig. 6.8. Note the eccentric offset. The components of this device are:

- Femoral component: Ti-6Al-7Nb (ASTM F 1295)
- Head: Co-Cr-Mo (ASTM F 75) or ceramic (zirconia) (ASTM F 603)
- Insert: Highly cross-linked UHMWPE (ASTM F 648)
- Acetabular cup: 316L austenitic stainless steel

Fig. 6.5 Thomson type femoral endoprosthesis with fixed head

Fig. 6.6 Austin Moore type femoral endoprosthesis with fixed head

6.5. Knee Joint Replacements

Total knee replacement is recommended when the knee joint is damaged or diseased. Among the disease causes are:

- Osteoarthritis
- Rheumatoid arthritis
- Osteonecrosis

The orthopaedic surgeon will advise of possible alternative treatment before considering the knee replacement. The main objective of the knee replacement is to eliminate pain as well as to help in restoring full function of the joint. Preoperative planning is similar to that discussed for the total hip replacement (Section 6.2). Additional considerations for knee replacement include:

- Full-length x-rays to obtain, with the proper instruments, the mechanical and anatomical axes with high precision and accuracy
- The implant design and mechanical characteristics of the polyethylene liner and wear performance
- Cement fixation of the bone/cement and cement/prosthesis interfaces

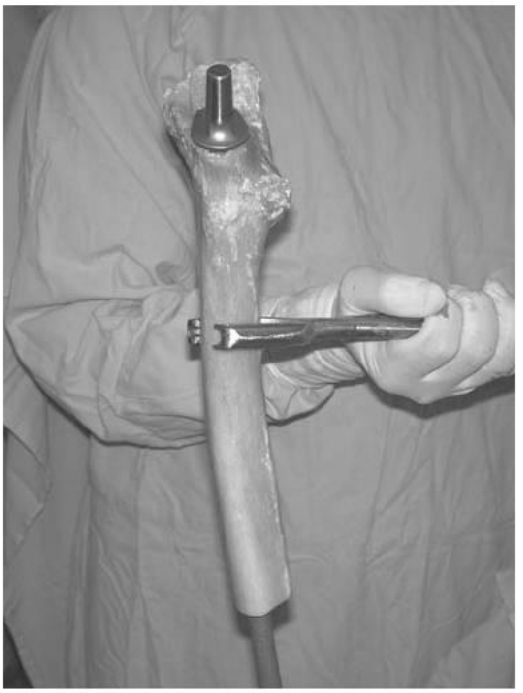


Fig. 6.7 Modular femoral endoprosthesis in place of a proximal femur allograft. Courtesy of Carlos Cuervo-Lozano M.D.

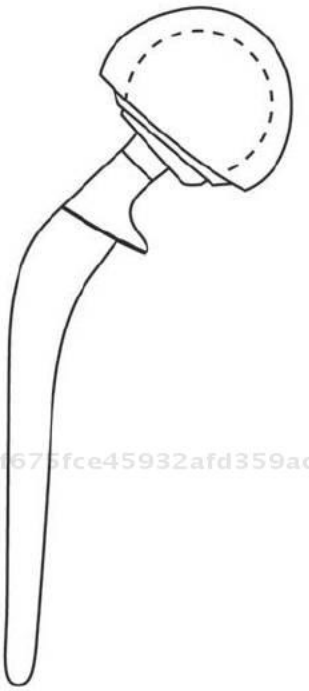


Fig. 6.8 Bipolar endoprosthesis with removable head

In order to eliminate revisions as much as possible, research is being directed to newer and better biomaterials that will enhance the useful life of the prosthetic device.

There are three types of total knee replacements:

- Nonconstrained knee replacements
- Semiconstrained knee replacements
- Constrained knee replacements

ASTM F 1223, "Standard Test Method for Determination of Total Knee Replacement Constraint," specifies a test for quantifying the level of constraint in a particular design.

6.5.1 Nonconstrained Knee Replacements

The stability of this joint replacement will depend on the patient's own ligaments.

6.5.2 Semiconstrained Knee Replacements

This type of knee joint replacement surgery is advised by the orthopaedic surgeon when certain stability is needed from the replacement.

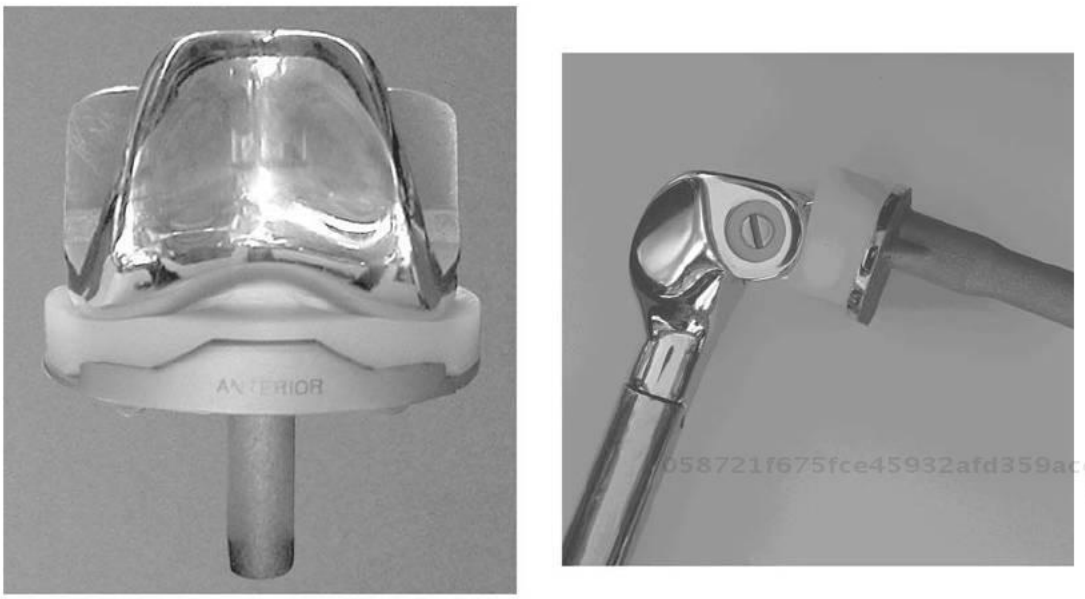


Fig. 6.9 Knee joint implants. (a) Total knee joint replacement. (b) Tumor knee prosthesis with distal femur segment and long tibial stem

6.5.3 Constrained Knee Replacements

The femoral and tibia components are hinged, allowing the patient to have only flexion motion in the knee.

6.5.4 Unicondylar Knee Replacements

This type of replacement is also called half replacement. It is indicated when half of the damaged joint is to be replaced. The knee prosthetic devices are replaced using the same procedures as those of the total hip replacements:

- *Cemented:* The femoral and tibia components are cemented.
- *Cementless:* Neither component is cemented.
- *Hybrid:* Only the femoral component is cemented.

The most widely used metallic biomaterials in total and unicondylar knee replacements are the cobalt-chromium alloys and titanium alloys. Ultrahigh molecular weight polyethylene is mainly used for tibia inserts. See Fig. 6.9. The prosthetic device is expected to last as long as 15 to 18 years. Wear is one of the important failures of joint replacements. Such wear is mainly a function of use, not of time (Ref 45).

6.6 Nonconventional Modular Tumor Implants

A variety of surgical techniques have as their main aim the conservation of the affected limb. This is true for a great diversity of bone problems, particularly those of oncological orthopaedics. For the previously mentioned situation, the use of bone allografts, tumoral modular prostheses, and/or a combination of both should be considered. Technological development of the modular prostheses has greatly improved the application of these systems and has provided solutions to many problems.

The main tumor prosthetic devices are:

- *Tumor knee prosthesis with distal femur body segment:* This is a total knee reconstruction with a segment of the distal part of the femur.
- *Tumor knee prosthesis with a proximal tibia body segment:* This is a total knee and proximal tibial replacement. The instrumentations are designed to obtain high accuracy in the placement of the modular systems.
- *Total femur prosthesis:* The total femur prosthesis is a total hip replacement with femoral body including the total knee joint replacement.

For cases of children with problems such as bone sarcomas in the lower extremities and who are in the growth stage, and where problems of length discrepancy are predicted, the extendible, modular, tumor prosthesis should be considered.

There are two types of extendible modular tumor prosthesis: the invasive and the noninvasive. Both types solve the problems of length discrepancy of the extremities of children that were put under a surgical resection of a distal femur sarcoma. The invasive type needs additional surgical interventions to attain the required stem length for lengthening the limb. The noninvasive does not require additional surgical operation. The stems can be enlarged with the help of an external magnetic field that drives a mechanism within the prosthetic device to lengthen the stem. Figures 6.10 through 6.13 show different modular knee replacement systems.

Humeral Implants. In humeral implants there are proximal, distal, and total replacements Tumor prosthetic devices have certain similar characteristics to those shown in Fig. 6.13, that is, texture on their surfaces in selected parts of the prosthetic device, as well as orifices in order to reinsert and fix the ligaments and tendons that improve function of the limb.

6.7 Spine Implants

Modern surgery of the spine began in 1950, thanks to Paul Harrington M.D., who used instrumentation to correct neuromuscular defects, especially in spine poliomyelitis. Implants placed in the spinal column are permanent. In 1955, Harrington developed the distraction method. This is a dynamic correction system. Later in 1971 he perfected his system with the addition

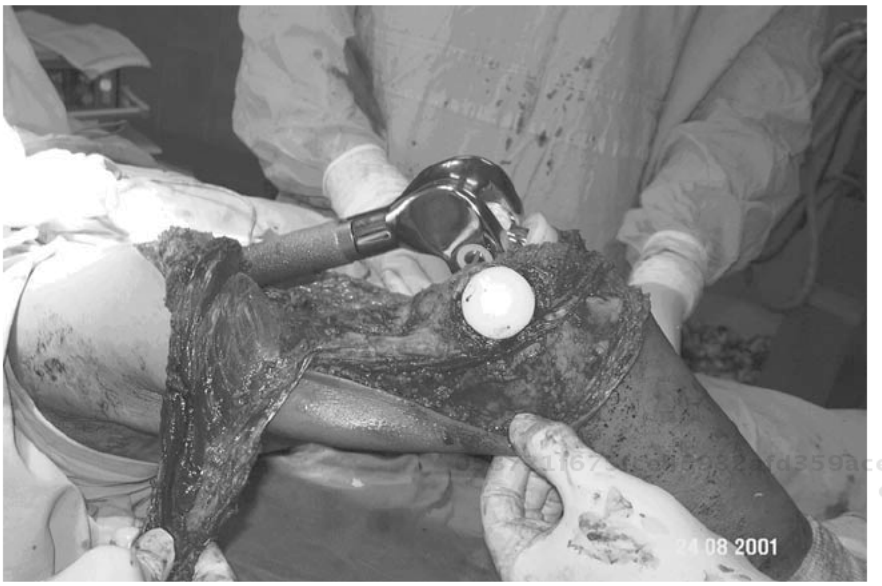


Fig. 6.10 Surgical resection of distal femur sarcoma using constrained knee replacement with distal femur segment. A special texture is observed on the titanium base alloy stem surface of the distal femur. Courtesy of Carlos Cuervo-Lozano M.D.

of a compression system. In 1970, Eduardo Luque, M.D., developed and published the spinal wire system instrumentation with sublaminar wire. The idea of using this kind of the wire system came from Resina and Albes. They used it to hold a bar to the laminar area. In 1974, Cotrel began to develop the segmented instrumentation system, and in 1984 Cotrel and Dobousset started to use pedicular screws.

6.7.1 Spine Implant Types

Following is a quick review of the most important implant replacement types: pedicular screws, hooks, plates, boxes, and cages. Examples are shown in Fig. 6.14 through 6.18.

Pedicular Screws. There are two types of pedicular screw, the monoaxial pedicular screw and the polyaxial pedicular screw systems. See Fig. 6.14 and 6.15. Pedicular screw systems permit a wide range of mechanical manipulation in order to attain the desired mechanical stability of the spine pedicles.

Hooks. The types of hooks are pediculars, transversals, and laminars. Their main uses are for spine deformations and for high thoracic spine fractures.

Plates. The types of plates are cervical (anterior/posterior) and thoracic-lumbar (anterior, lateral, and posterior). Their uses are for degenerative problems, anterior spine fractures, tumors, and infections.

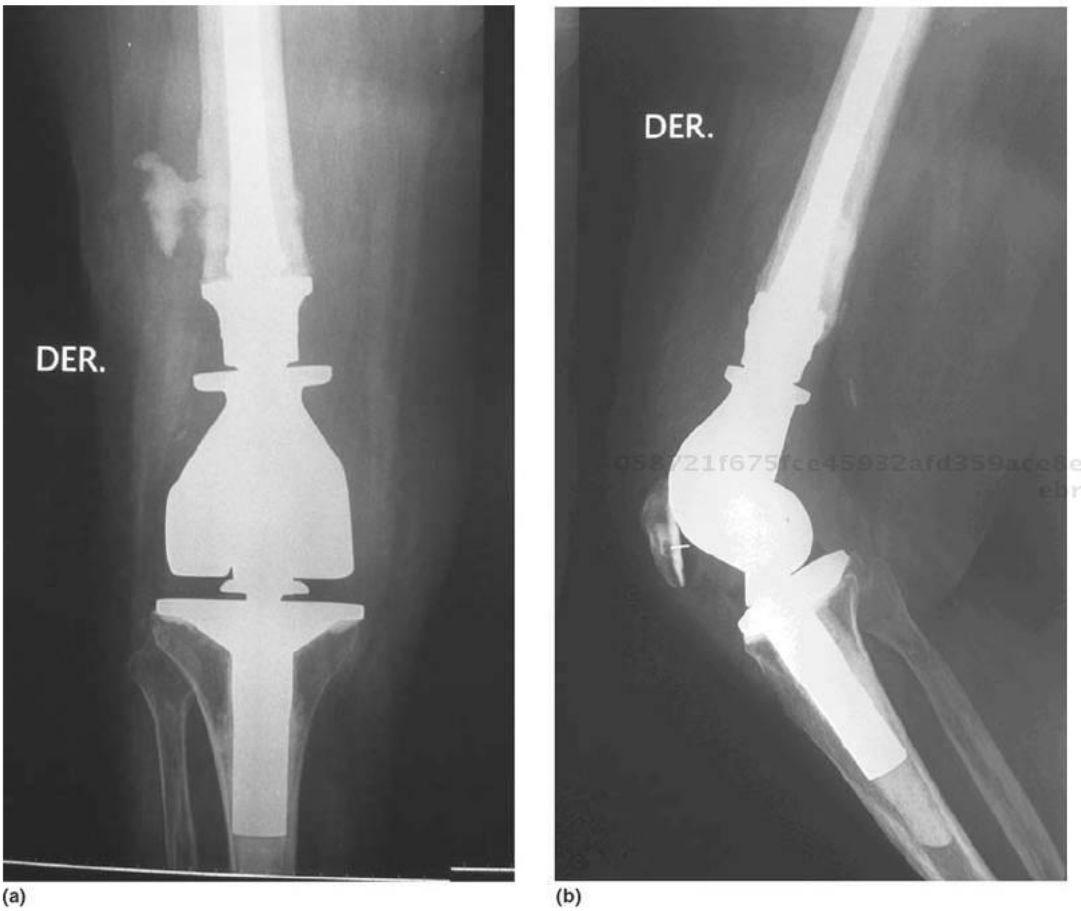


Fig. 6.11 X-rays of a right constrained modular total prosthesis with distal femoral replacement. (a) Anteroposterior (AP) view. (b) Lateral view. Courtesy of Carlos Cuervo-Lozano M.D.

Boxes. The materials used in boxes consist of alpha-beta titanium alloys and/or thermoplastics (PEEK). The main use of the boxes is to:

- Keep the discal space and try to avoid the resorption when bone graft is used either autologous bone or bone allograft
- Hold the alignment
- Secure the segment fixation

The use of thermoplastic materials result the best option since it will keep the space disc, and it will be integrated.

Cages. Low-carbon grade austenitic stainless steel and/or alpha-beta titanium alloys are usually the materials composition of cages. The interior of the cases keep bone grafts, hydroxyapatite materials that are bioactive and osteoconductive in such a way that it will provide osseointegration. The main

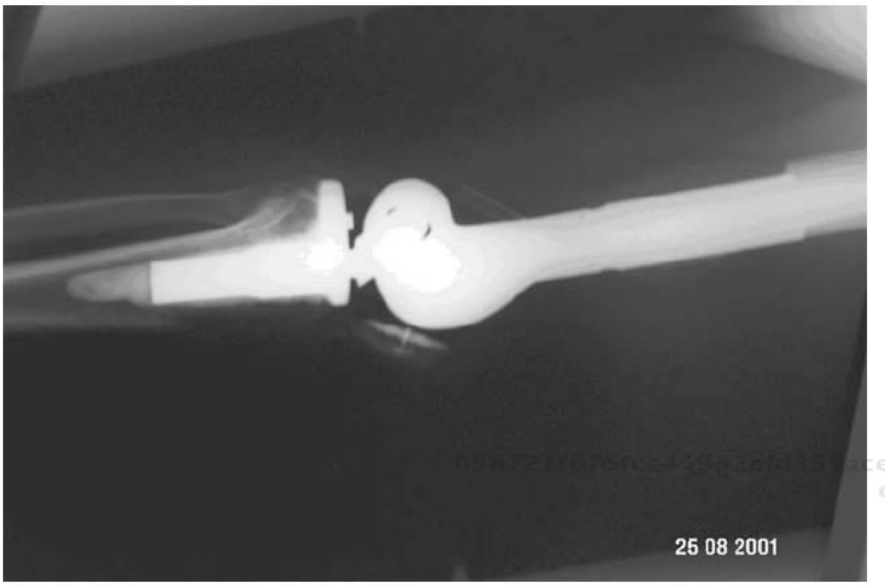


Fig. 6.12 X-ray of a constrained modular knee replacement with distal femur. The distal femoral replacement is longer than that shown in Fig. 6.11. This demonstrates a clear advantage of the modular systems. Courtesy of Carlos Cuervo-Lozano M.D.

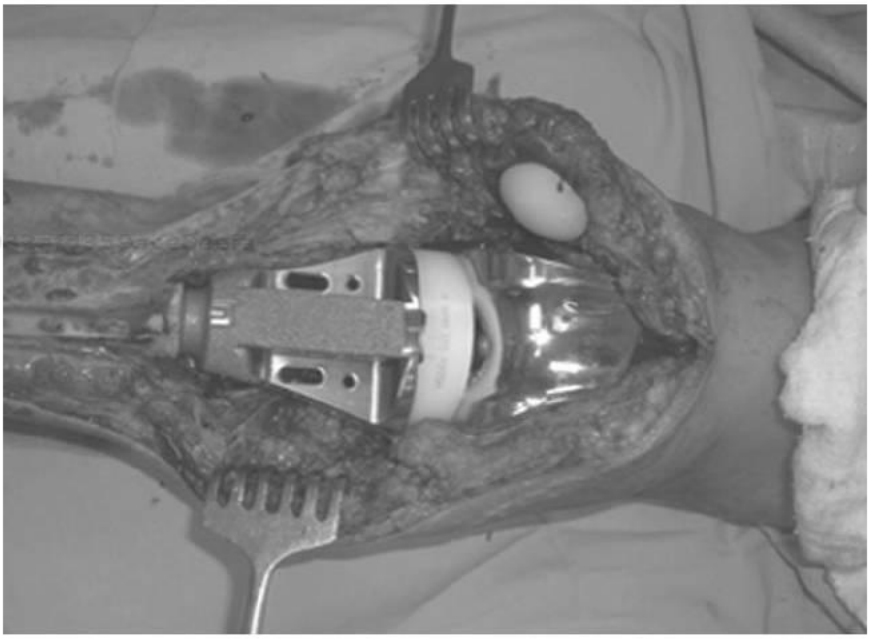
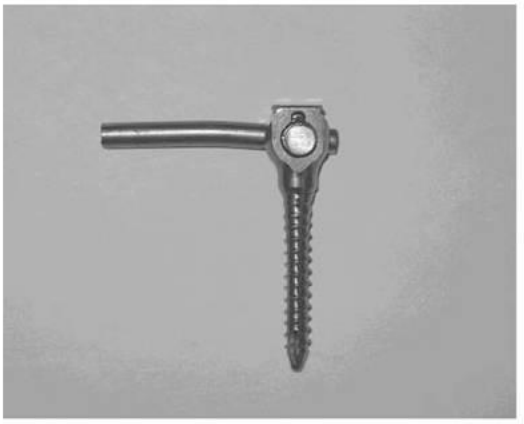


Fig. 6.13 Tumor knee prosthesis with proximal tibia replacement. The orifices shown are made with the purpose of reinserting the ligaments and tendons. The surface texture has the purpose of improving tissue integration on the titanium-based implant. Courtesy of Carlos Cuervo-Lozano M.D.

Fig. 6.14 Pedicular screws. Top line from left to right: a cannulated tap, a transpedicular screw, and the system composed of a lock, a bar, and a transpedicular screw. Bottom line from left to right: there are three different instrumentations that base their design on the locks that join the implants to the bar.

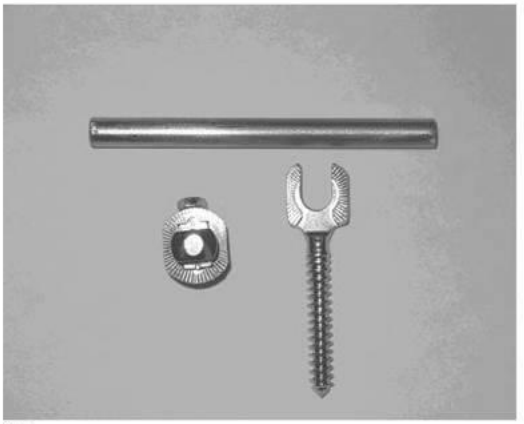
uses are the same as those of boxes. Technology development of biomaterials used in spine surgery has resulted in the following improvements:

- *Fatigue Resistance:* This mechanical property has improved in all the implants.
- *Anatomical Design of Implants:* The most important change that the spinal column implants have experienced is the anatomical design.
- *Metallic Biomaterials:* The use of new alloys in implants is practically continuous, for example, the use of alpha-beta titanium alloys instead of 316L stainless steel. Currently, improvements of titanium alloys are being proposed.
- *Connector Design:* This design is used to distribute loads between the diverse implants of the instrumentation.
- *Implant Distribution by Segments:* This distribution is aimed at treating each segment individually and independently.



(a) (front view)

(b) (back view)



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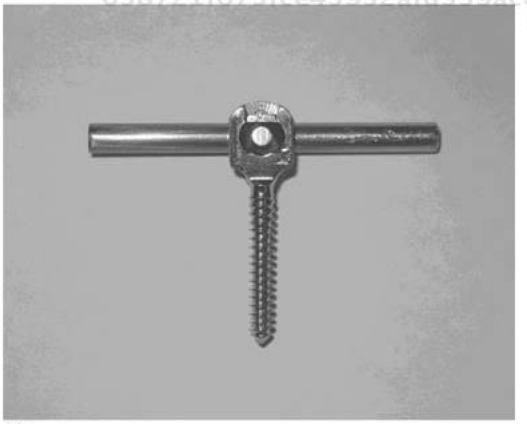
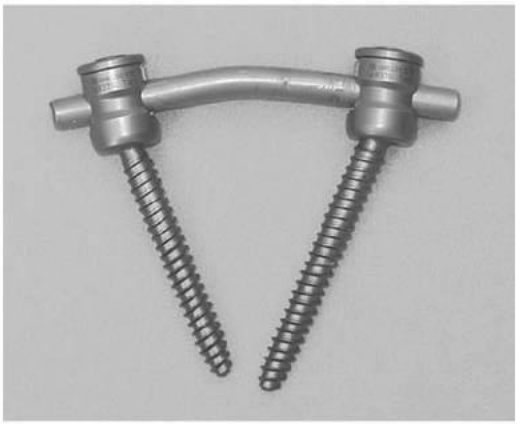


(d)

(e)



(f)

Fig. 6.15 Three pedicular screw systems that can be positioned through rotation at any desired angle in a plane perpendicular to the rod. The middle screw system (c) and (d) can also rotate and be positioned in a plane parallel to the page. The bottom screw pedicle system (e) and (f) can rotate, generating a cone with its vertex on the bottom end of the lock.

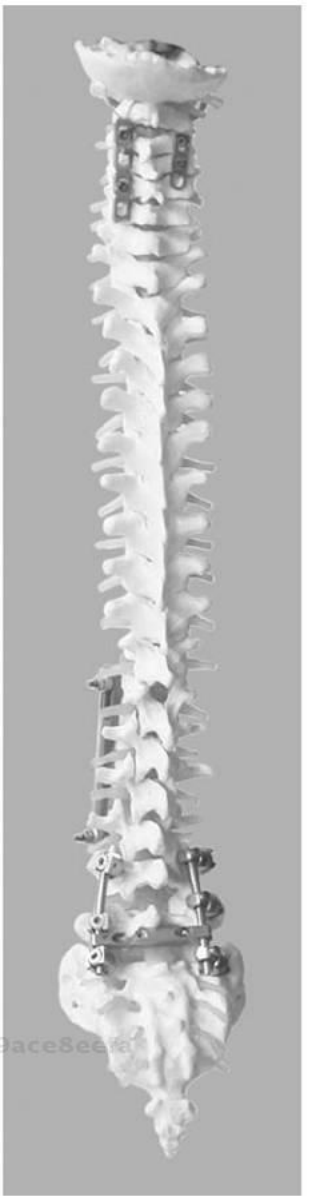


Fig. 6.16 Instrumentations placed on the spine

The above resulted in what is known today as spine stability total systems. This system helps the solution of traumatic, degenerative, congenital, infectious, and tumor problems at the cervical, thoracic, or lumbar level, either by the posterior or anterior approach.

Dynamic Systems (Disc Prosthesis). At the dawn of the 21st century, an increase in the manufacture of very sophisticated implants for solving degenerative pathologies of the spine had taken place. Currently there are

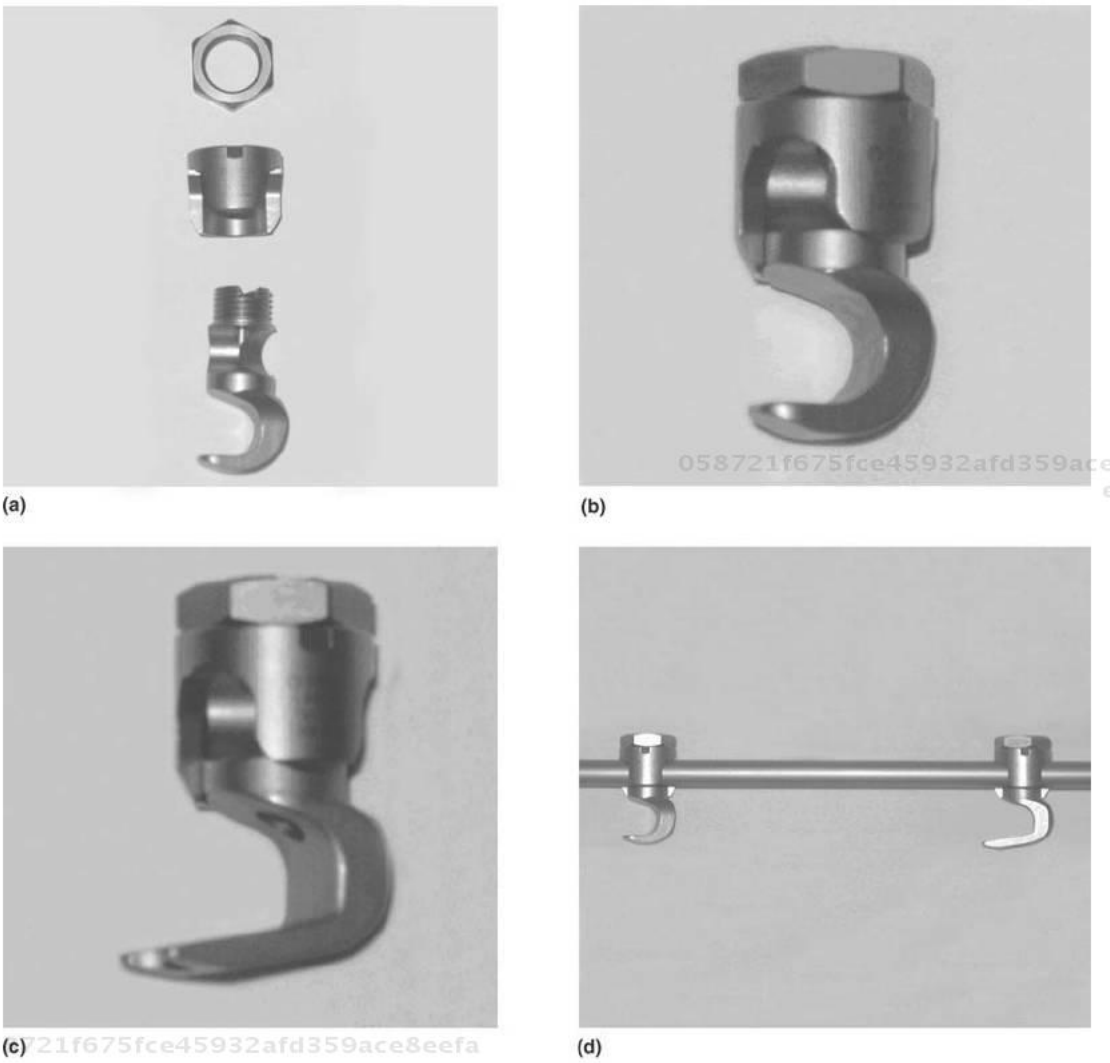


Fig. 6.17 Various screw systems. (a) and (b) Laminar screws. (c) Pedicular screw. (d) Laminar and a pedicular screw mounted in a bar

two disc prosthesis that are used, the cervical and the lumbar prosthesis. Some others are still under study.

The Brian composite cervical prosthesis is a motion-sparing orthopaedic device. It is used mainly for spine disc degeneration, and it adapts very well to spine biomechanical requirements. There are also lumbar prosthetic devices.

Technological development of orthopaedic implants has been very important for the success in many clinical cases. However, there is still much to be done to reach the expectations that have resulted from these successes. This means the continuous search for new and better biomaterials that satisfy the needs that come up day after day in orthopaedic surgery.

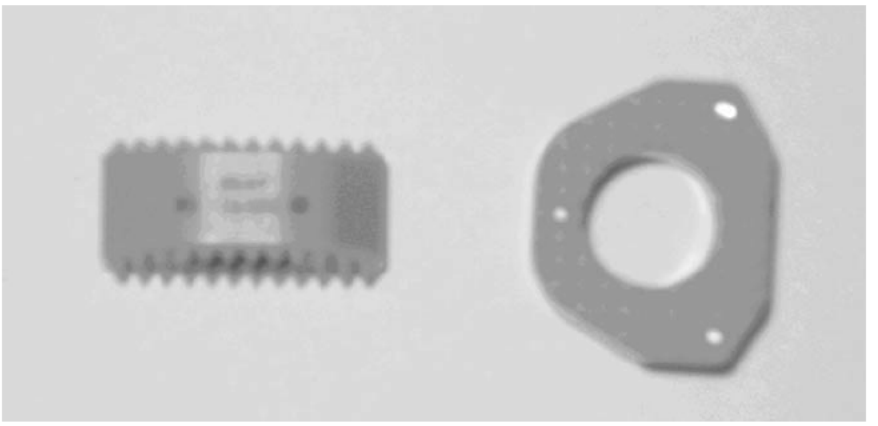


Fig. 6.18 Thermoplastic PEEK cervical spine implant

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EDUCATIONAL OBJECTIVES

1. Name the diagnostic images frequently used in orthopaedics and traumatology.
2. In your own words, explain the usefulness of each type of image.
3. Name and explain each of the themes to be considered in the procedure of surgical planning in orthopaedics and traumatology.
4. Name the most important implants used in osteosynthesis.
5. What are the different external fixation systems? Explain in what cases they are most useful.
6. Name the modular components of total hip replacements.
7. Which are the different acetabular-femoral components? Which are the most widely used?
8. Define the following:
   (a) Early failure
   (b) Revision
   (c) Re-operation
9. What is the main purpose in following the chain procedure of cemented stem components?
10. Who was Sir John Charnley? Describe his main contributions to orthopaedic surgery.
11. What was his main reason for not using the metal-on-metal acetabular assembly in cemented total hip replacements?
12. Is the hip stem component design important in cemented total hip replacements? Is the hip stem surface finish important?
13. Who designed the first cementless stem femoral component?
14. Describe the advantages and disadvantages of the cemented hip prosthesis.
15. Describe the advantages and disadvantages of the cementless hip prosthesis.
16. Before 1995, what was the main concern in using UHMWPE?
17. Is the wear mechanism the same in the metal-on-polyethylene assembly in the hip replacements as in the polyethylene tibial inserts in total knee replacements?
18. What is the main advantage of using ceramic-on-polyethylene assemblies in total hip replacements?

19. What are the possible disadvantages of the ceramic on polyethylene assemblies in total hip replacements?
20. Which implant materials have been used in total hip and total knee replacements?
21. Describe the different modular tumor replacements.
22. Mention the most important spinal column changes and improvements to date.

CHAPTER 7

Bone Allografts

7.1 Introduction

Bone allografting has become a common practice of transplantation in orthopaedic surgery. The demand for bone allografts for surgical use has grown quite rapidly because of the favorable clinical results of allograft surgeries. Bone banking plays a central role in enabling the availability of a large number and many different types of bone allografts, which are preserved and stored using a variety of methods.

Bone allografts have a number of applications in orthopaedic surgery, in bone tumor surgery, and especially in reconstructive surgery. The orthopaedic surgeon should understand the biomechanical behavior of the bone allograft to be transplanted compared to normal bones, in particular the femur and the tibia. Other applications of bone allografts are plastic and dental surgery. The bone allograft literature is very important and extensive (Ref 1–12).

7.2 Bone Autografts

Autografts (bone from the same patient) are considered a gold standard. The iliac crest and fibular are common sources for trabecular and cortical autografts.

7.2.1 Advantages of Bone Autografts

The main advantage of bone autografts is the simultaneous fulfillment of unique properties:

- *Osteogenic:* This intrinsic and fundamental property has the ability of the bone-forming cells to produce new bone.
- *Osteoinductive:* This property implies the process of carrying out the formation of the osteoprogenitor cells with the ability to form new bone.
- *Osteoconductive:* This fundamental property is related to the binding of bone-forming cells for subsequent bone formation.

7.2.2 Disadvantages of Bone Autografts

Some disadvantages of bone autografts are:

- Limited amounts and sizes of osseous tissue available
- Second surgical site and time in operating room
- Donor site pain of harvested bone
- Morbidity

Finkemeier (Ref 3) addresses rates of major and minor complications in autograft procedures.

7.3 Bone Allografts—The Natural Alternative

A bone allograft represents the natural biological alternative to a bone autograft. As of 2009, it is the most common practice of transplantation in medicine. It is ideal for patients who require resection of bone tumors, such as in segments of the femoral or the tibia diaphysis. There are also other very important applications in reconstructive surgery.

7.3.1 Advantages of Bone Allografts

- Well tolerated
- Available in great quantities
- Desired size
- Permanent once integrated

7.3.2 Disadvantages of Bone Allografts

In this book complications are expressed as disadvantages. Dion and Sim (Ref 4) describe nonunion (as a function of time), fracture, and infection complications. The latter two are common; Dion and Sim describe the range of types. Weber (Ref 5) identifies other complications: resorption, instability, and subchondral collapse.

7.4 Standards for Tissue Banking

The American Association of Tissue Banks (AATB) defines standards for bone banking. For example, the bone and tissue bank at the author's university hospital complies with standards issued by AATB.

7.4.1 Processing of Musculoskeletal Tissue

The processing of the musculoskeletal tissues involves retrieval, quarantine, cleaning, packing, and storage of bone allografts. There are several methods for processing the retrieved tissues. Among these methods are:

- *Clean method:* Once processed, the tissues are put under a gamma ray source for sterilization to eliminate pathogens acquired during tissue retrieval.

- *Aseptic method:* Once processed, the tissues are ready for storage and further distribution.

For processing, the clean and aseptic methods use a class 100 or ISO 5 cleanroom (Ref 6). Cleanroom classifications are based on the number and size of particles permitted per volume of air.

7.4.2 Preservation of Bone Allografts

Bone allografts are preserved as follows:

- *Freeze dried/Lyophilized:* Tissue is dehydrated for storage by converting the water content in frozen tissues to a gaseous state in a vacuum that extracts moisture. The main use of this type of bone allograft is for nonstructural purposes, such as filling spaces and/or cavitary defects. These bone allografts are also called fragmented allografts and are stored between 18 to 26 °C.
- *Fresh:* A bone allograft stored for a maximum of 1 week at a temperature of 4 °C is considered fresh. This type of bone allograft is quite special. Its main use is in massive allografts, where preservation of the articular surface is required. Because they keep alive most of the cartilaginous cells, fresh allografts are used as osteoarticular allografts.
- *Frozen:* These bone allografts are stored for up to 5 years at a temperature of −70 or −80 °C. These massive bone allografts are mostly used for structural purposes without the need for the articular surface of the bone allograft.
- *Cryopreserved:* Tissue frozen with the addition of, or kept in a solution containing, a cryoprotectant agent such glycerol or dimethylsulfoxide. This bone allograft is stored for up to 5 years at liquid nitrogen temperature (−196 °C). The purpose of this type of bone allograft is to preserve the viability of the osteoarticular cartilage of the graft.

7.4.3 Demineralization

Demineralized bone matrix is osteoconductive. It is mainly used for filling bone defects and/or cavitary defects. It is not used for structural purposes.

A very general and typical preparation demineralization process is:

1. The allograft tissue is cleaned, crushed into small fragments, and may be also pulverized afterward if required for certain surgical procedures.
2. These fragments are demineralized by the addition of hydrochloric acid.
3. The remaining acid is eliminated by rinsing the particles in sterile water or ethanol.

7.4.4 Quarantine and Storage of Bone Allografts

Quarantine involves the identification of human cells and/or tissue that are not suitable for transplantation or that are not yet recognized as being

suitable for transplantation and then storage of such cells and/or tissue in a clearly identified area. Other procedures can be used, such as automated designation, to prevent the release of nonsuitable cells and/or tissue for transplantation.

Storage is the preservation of cells and/or tissue for future use.

7.5 Sterilization by Gamma Irradiation

7.5.1 Gamma Radiation Source

The production of gamma radiation sources takes place by the interaction of neutrons with matter in very high neutron flux nuclear reactors. The type of interaction that occurs between neutrons and matter depends on the nature of the nucleus and on the energy of the interacting neutron. This energy dependency can result in different reactions with the same nucleus depending on whether the energy of the neutron is thermal, epithermal, or fast.

The most common neutron reaction is radiative capture. It is capable of being produced by almost all nuclides. It occurs predominantly with thermal and epithermal neutrons and proceeds with a very high probability in some nuclides at particular energies. By definition, radiative capture interactions result in the emission of a gamma photon also called prompt gammas.

The Co-60 is the most common source for gamma irradiation. This radioactive nuclide is obtained by means of the interaction of thermal neutrons with $_{27}Co^{59}$ as the target.

The irradiation can be explained by the following neutron nuclear activation reaction

$$_{27}Co^{59} + {}_{0}n^{1} \rightarrow {}_{27}Co^{60} \rightarrow {}_{28}Ni^{60} + {}_{-1}\beta^{0} + \gamma_1 + \gamma_2$$

The half-life of $_{27}Co^{60}$ is 5.2 years.

The $_{27}Co^{60}$ radionuclide decays by emitting $_{-1}\beta^{0}$ and two γ rays in cascade, that is $\gamma_1 + \gamma_2$. The energy of the gammas released per disintegration per second is 2.5 MeV. See the Co-60 nuclear level decay scheme in Fig. 7.1.

The electron volt (eV) is a unit of energy and is equal to 1.602×10^{-19} J; 1 J (Joule) is equal to 10^7 ergs. The high half-life (5.2 years) of the Co-60 radionuclide and the high energy released by its gammas in cascade make the Co-60 very valuable for sterilization purposes.

The strength or activity of the radionuclide sources is measured in Curies (Ci). A Curie is defined as a source that emits 3.7×10^{10} disintegrations/s. Disintegrations per second are also called transformations per second and/or becquerels. The Curie unit has multiples as kilocuries and submultiples as mCi, μCi, and μμCi.

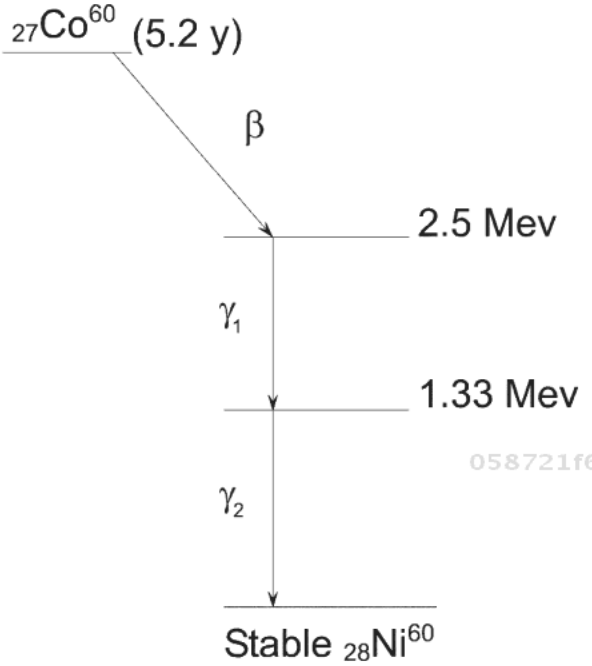

Fig. 7.1 Nuclear level decay scheme of Co-60

X-rays and gamma rays are electromagnetic waves shorter than the visible light. They differ in their origin:

- In x-ray vacuum tube, the source electrons coming out of the cathode collide with the anode (target). The x-rays are generated in the electron shells of the target atom.
- Gamma rays from $_{27}Co^{60}$ radionuclide originate in the atomic nucleus.

7.5.2 Dose Units

The energy absorbed by a given material by the irradiation of the gamma rays is called the absorbed dose. Its unit is the rad. The rad was introduced by the International Commission on Radiological Units at the Seventh International Congress of Radiology, July 1953 (Ref 7). It does not depend on the radiation type or the material being irradiated. The unit of rad is then defined as an absorbed dose of 100 ergs per gram of irradiated matter (1 rad = 100 ergs/g). The SI unit of absorbed dose is the gray (Gy); 1 Gy = 100 rad. The preceding units are usually expressed either in megarad or kGy;1 megarad = 10 kGy.

7.5.3 Standard Gamma Irradiation Dose for Bone Allografts

The typical standard gamma irradiation dose for bone allografts lies between 27 and 30 kGy.

7.6 Biomechanical Effects of Gamma Irradiation on Bone Allografts

When bone allografts of a chosen method of preservation are to replace bones, it is very important to understand the mechanical properties of a normal bone. This is especially true for those bones that carry significant loads, such as the femur and the tibia. Also, if the bone allografts are sterilized by gamma ray irradiation, it is important to consider the effects of this sterilization method.

The following biomechanical properties, in particular, must be considered:

- Compressive and tensile strength
- Modulus of elasticity
- Torsion
- Bending strength
- Breaking strength

Factors that influence the biomechanical effects are:

- Gamma ray irradiation dose (low, standard, high)
- Nonstructural and structural allografts (trabecular, cortical)
- Preservation methods of bone allografts (freeze dried/lyophilized, fresh, frozen, cryopreserved)
- Irradiation temperature (at room temperature, 4, −40, −70, and −196 °C)
- Type of cellular microorganisms, viruses, etc.

We may infer that a good number of combinations can take place, and the results of the mechanical effects may vary considerably based on the particular combination.

7.7 Types and Applications of Bone Allografts

7.7.1 Nonstructural Allografts

Freeze dried/lyophilized bone allografts are not used for structural purposes. Some of the nonstructural applications are in Fig. 7.2 to 7.8.

7.7.2 Structural Allografts

The objective in this section is to get to know the characteristics and evolution of the patients that receive massive allografts transplants in orthopaedic and traumatology surgeries. The main concern is to observe the evolution of the massive allografts integration through radiographic evaluation as defined by the International Society of Limb Salvage (ISOLS). To provide a better understanding of each of the different types of massive allografts, photographs taken from clinical cases are shown in this section.

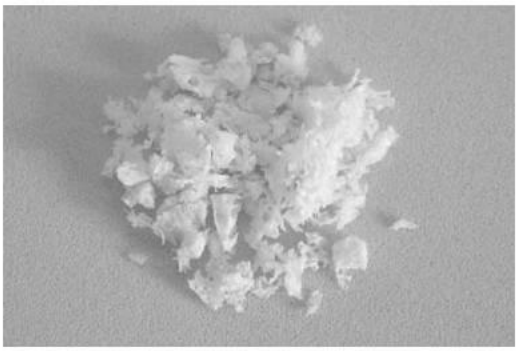

Fig. 7.2 Granulated spongy bone is mainly used for filling small spaces

Fig. 7.3 Chips of spongy bone are used for filling spaces and/or cavitary defects

Fig. 7.4 Spongy monocortical cylinder used for arthrodesis, spine fusions, and other small joint fusions

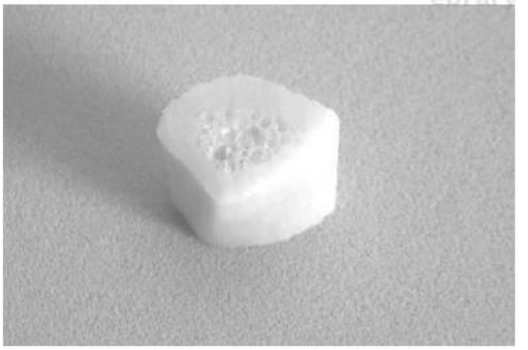

Fig. 7.5 Fibula diaphysis used for cervical spine applications such as corporectomy and discoidectomy for intercorporeal fusion

Fig. 7.6 Fibula diaphysis is used for replacement of bone losses of cubitus, radius, and humerus

Fig. 7.7 Tibia diaphysis is used for thorax, cervical, and lumbar spine applications

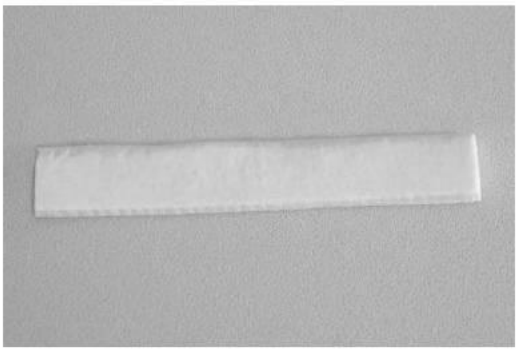

Fig. 7.8 Cortical strut is used for prosthetic revision and to correct and prevent periprosthetic fractures

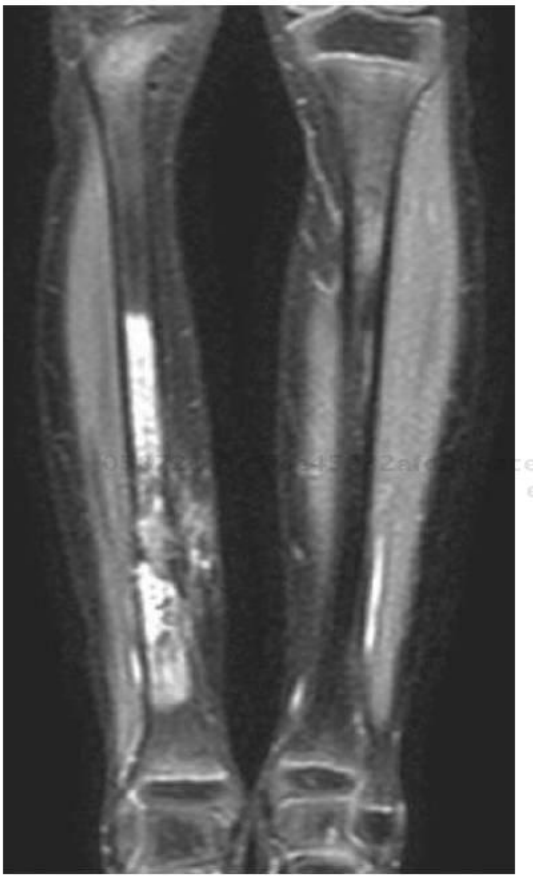

Fig. 7.9 Magnetic resonance image (MRI) of a 7-year-old boy with a right tibia osteosarcoma. Courtesy of Carlos Cuervo-Lozano M.D.

Osteointercalary grafts. This type of massive allograft is mainly used for the diaphysis of long bones. See Fig. 7.9 to 7.13.

Osteoarticular grafts. This type of massive allograft is used to replace a joint. See Fig. 7.14 to 7.18.

Allograft-prosthesis composites. This type of massive allograft is used in connection with a joint prosthetic replacement. See Fig. 7.19 to 7.22.

Alloarthrodesis. This type of massive allograft is recommended for those cases where the joint will remain without flexion and rotation. See Fig. 7.23.

7.8 Definitions of Terms of the American Association of Tissue Banks

The following selected terms are used with permission from the *AATB Standards for Tissue Banking,* 11th edition, 2006, American Association of Tissue Banks, McLean, VA.

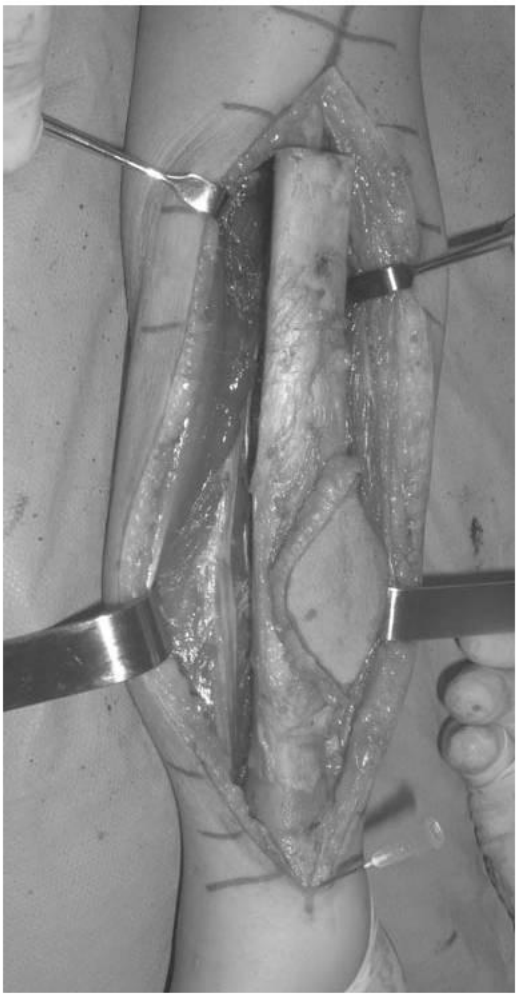

Fig. 7.10 Extensive marginal resection of the right tibia with a resection length of 165 mm. Courtesy of Carlos Cuervo-Lozano M.D.

Fig. 7.11 Segment measure of tibia and the structural allograft for best match. Courtesy of Carlos Cuervo-Lozano M.D.

Allograft. Cell and/or tissue intended for transplantation into another individual of the same species.

Aseptic processing. The processing of cells and/or tissue using methods to prevent, restrict, or minimize contamination with microorganisms from the environment, processing personnel, and/or equipment.

Aseptic retrieval. The retrieval of cells and/or tissue using methods that restrict or minimize contamination with microorganisms from the donor, environment, retrieval personnel, and/or equipment.

Clean room. A room in which the concentration of airborne particles is monitored and controlled to define specification limits.

Cryopreserved. Tissue frozen with the addition of, or in a solution containing, a cryoprotectant agent such as glycerol or dimethyl sulfoxide.

Fig. 7.12 Allograft fixation with plate, screws, and muscular flap to protect the plate and allograft in order to diminish the probability of infection. Courtesy of Carlos Cuervo-Lozano M.D.

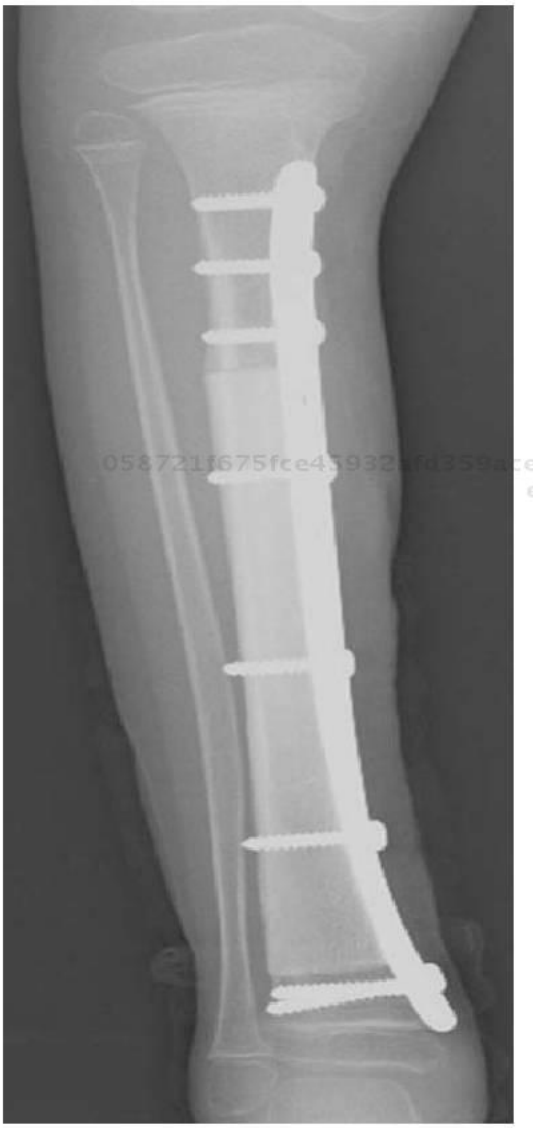

Fig. 7.13 Intercalary allograft placed between two segments of the host bone of the patient. Courtesy of Carlos Cuervo-Lozano M.D.

Cryoprotectant. An additive that serves to minimize osmotic imbalances that occur with the progression of freezing fronts through a substance and is intended to limit the amount of cell damage caused by cell shrinkage and intracellular ice formation.

Dehydration. The removal of water from cells and/or tissue.

Distribution. A process that includes receipt of a request for cells and/or tissue, selection and inspection of appropriate cells and/or tissue, and

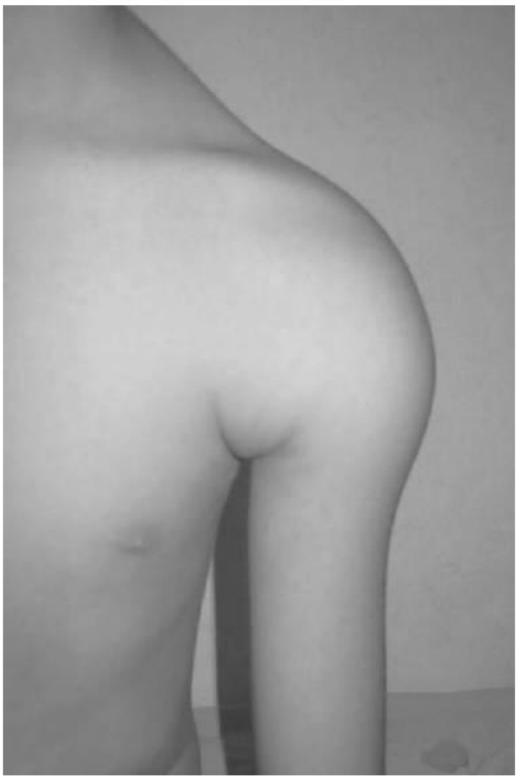

Fig. 7.14 Clinical photograph of an 8-year-old boy with a sarcoma diagnostic of the left proximal humerus. Courtesy of Carlos Cuervo-Lozano M.D.

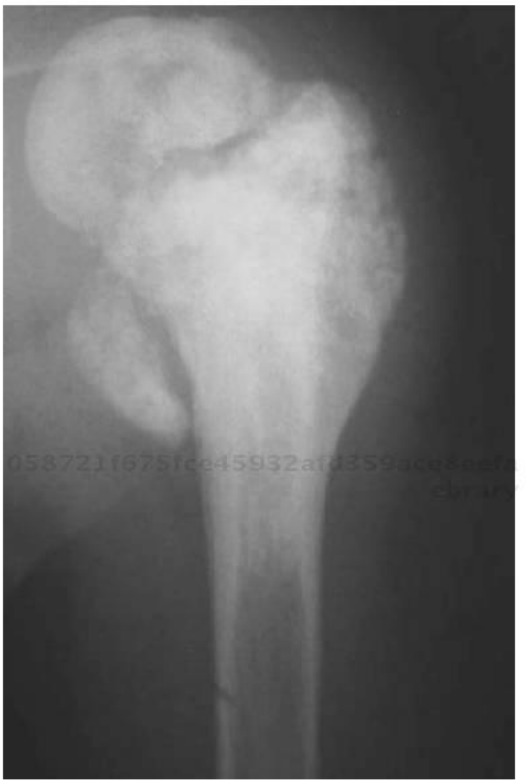

Fig. 7.15 Anteroposterior (AP) radiography of the left proximal humerus, which includes the proximal metaphysis as well as the epiphysis of the humerus. Courtesy of Carlos Cuervo-Lozano M.D.

inspection and subsequent shipment and delivery of cells and/or tissue to another tissue bank, tissue distribution intermediary, or tissue dispensing service.

Donor. A living or deceased individual who is the source of cells and/or tissue for transplantation in accordance with established medical criteria and procedures.

Donor referral sources. Entities such as hospitals, medical examiners, coroners, and individual allied health care professional who identify potential cells and/or tissue donors and refer them, or their next of kin, to tissue banks.

Donor suitability assessment. The evaluation of all available information about a potential donor to determine whether the donor meets qualifications specified to the Standard Operating Procedure Manual and standards; this includes, but is not limited to: medical, social, and sexual histories; laboratory test results; physical assessment or physical examination; and autopsy findings (if performed).

Finished tissue. Cells and/or tissue that have been fully processed, enclosed in its final container, labeled, and released to distribution inventory.

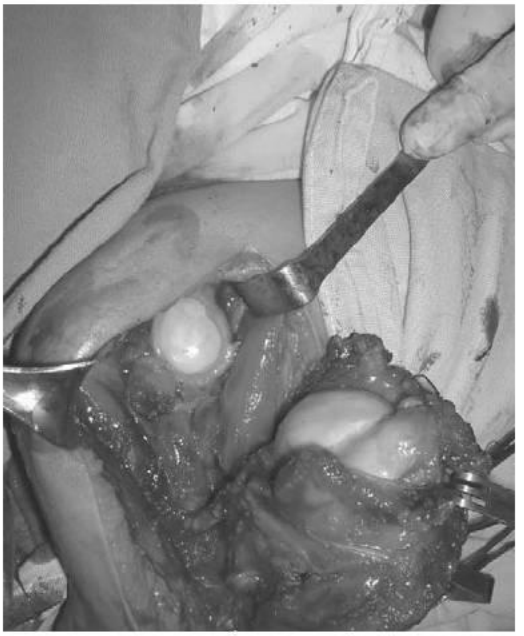

Fig. 7.16 Transoperative photograph of an intrarticular proximal humerus tumor resection together with a shoulder muscle (extensive resection). Courtesy of Carlos Cuervo-Lozano M.D.

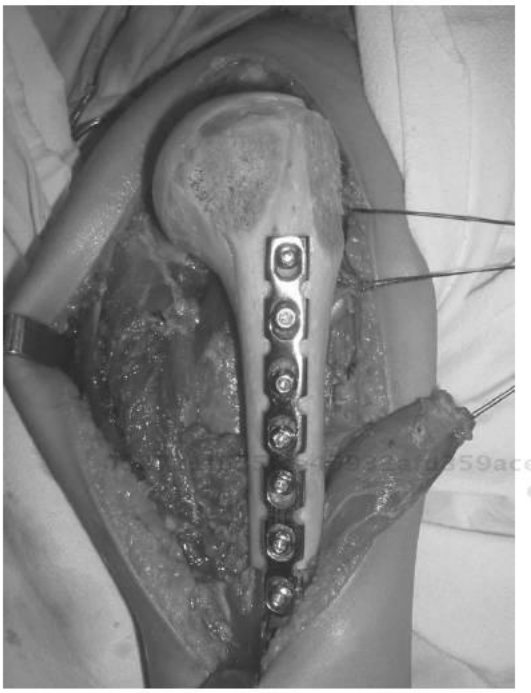

Fig. 7.17 Osteoarticular proximal humerus allograft with tuborosities caused by shaping, with muscular reference to reinsert the allograft. Courtesy of Carlos Cuervo-Lozano M.D.

Freeze dried/lyophilized. Tissue dehydrated for storage by conversion of the water content of frozen tissue to a gaseous state under vacuum that extracts moisture.

Informed consent. A procedure whereby information concerning the donation process is presented to the donor or donor's next of kin for an opportunity for them to ask questions, after which specific approval is documented.

Lot. Cells and/or tissue produced from one donor at one time using one set of instruments and supplies. Also refers to a quantity of reagents, supplies, or containers that is processed or manufactured at one time and identified by a unique identification number.

Osteoarticular graft. A large weight-bearing allograft with intact articular surfaces, consisting of a joint with associated soft tissue and bone.

Physical examination. A recent documented evaluation of a living donor's body to determine whether there is evidence of high-risk behavior and that determines overall general health of the donor. After a donor risk assessment interview is completed and if any history is suspect, the physical examination should also encompass a directed examination (of a body part or region).

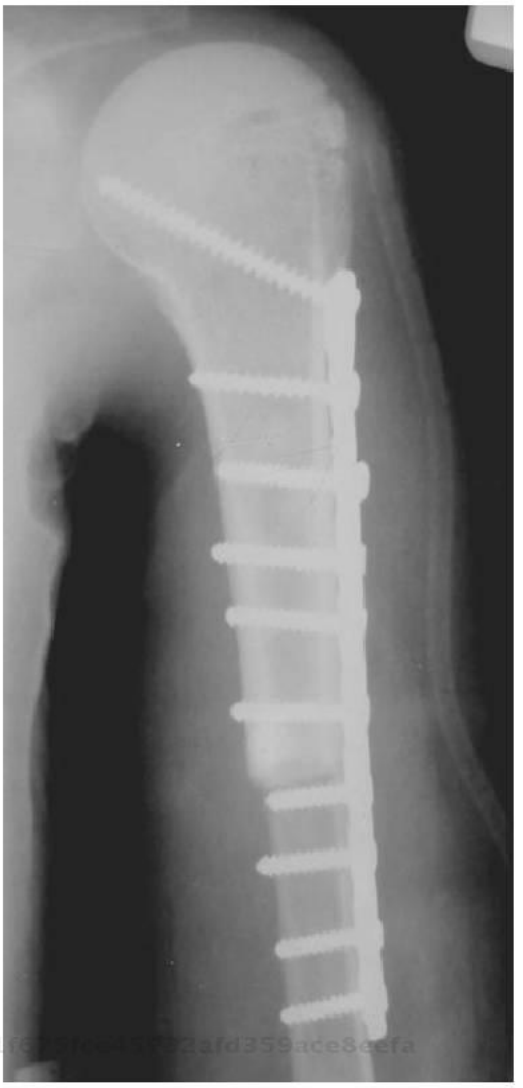

Fig. 7.18 Postoperative radiograph of a plate that covers a great portion of a bone allograft for splinting purposes. Courtesy of Carlos Cuervo-Lozano M.D.

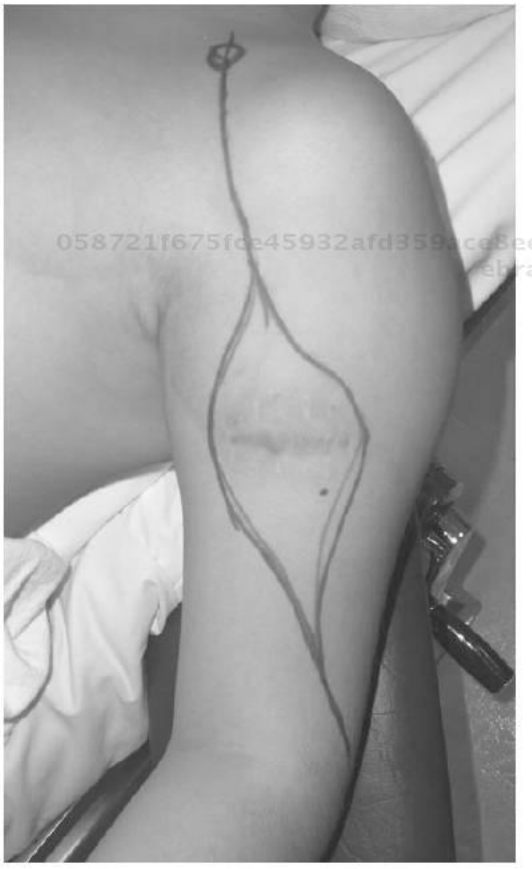

Fig. 7.19 Preoperative clinical photograph of an 11-year-old boy with a proximal humerus osteosarcoma. Courtesy of Carlos Cuervo-Lozano M.D.

Preservation. The use of chemical agents, alterations in environmental conditions, or other means during processing to prevent or retard biological or physical deterioration of cells and/or tissue.

Processing. Any activity performed on cells and/or tissue, other than cells and/or tissue recovery, including preparation, preservation for storage, and/or removal from storage, to ensure the quality and/or sterility of human cells and/or tissue. Processing includes steps to inactivate and remove adventitious agents.

Fig. 7.20 Transoperative clinical photograph used to compare and measure a bone allograft with a resection tumor segment. Courtesy of Carlos Cuervo-Lozano M.D.

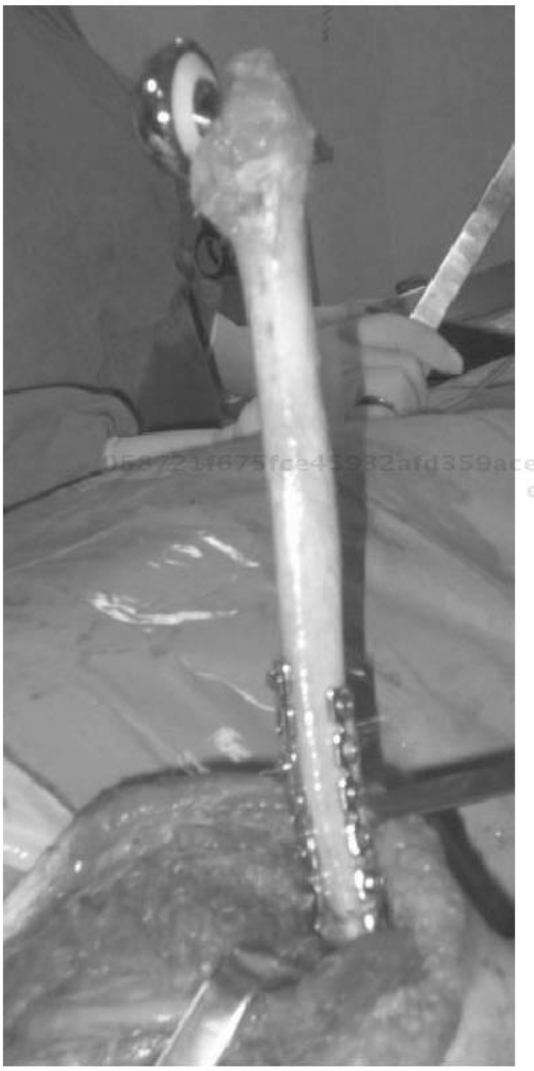

Fig. 7.21 An allograft-prosthesis composite formed with a proximal allograft of the humerus and a bipolar prosthesis that is distally fixed with two reconstruction plates. Courtesy of Carlos Cuervo-Lozano M.D.

Procurement. see *Retrieval.*

Quality. The conformance of cells and/or tissue or a process with preestablished specifications or standards.

Quality assurance (QA) program. A program that defines the policies and environments that are required to meet standards of quality and safety and that provides confidence that the process and cells and/or tissue consistently conform to requirements for quality. Dimensions of QA

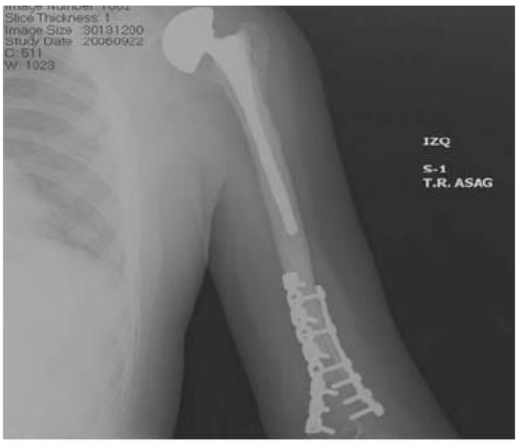

Fig. 7.22 Postoperative radiograph with a non-splinting zone located between the tip of the prosthetic stem and the upper end of the plate (weak zone). Courtesy of Carlos Cuervo-Lozano M.D.

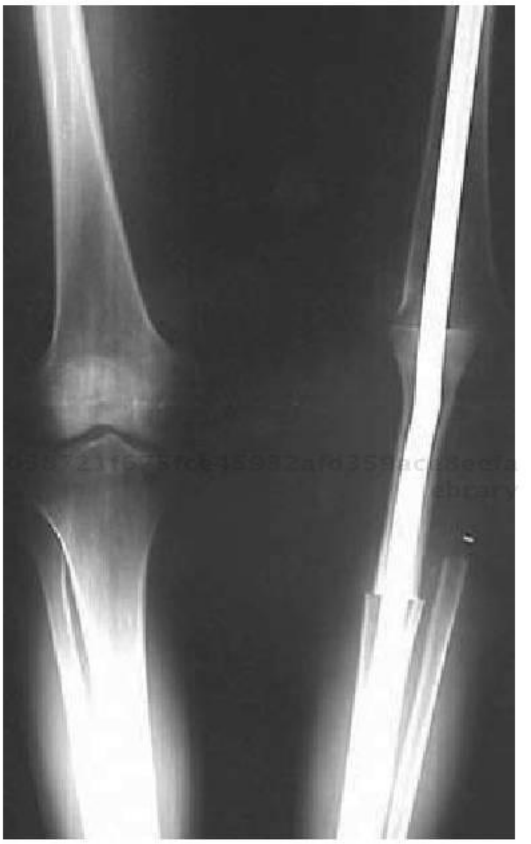

Fig. 7.23 Postoperative radiograph showing a proximal tibia allograft with an intra medullar nail going through the tibia and the femoral host bone in order to substitute the knee joint. Courtesy of Carlos Cuervo-Lozano M.D.

may include quality control, auditing and process control, standards for personnel, facilities, procedures, equipment, testing, and record-keeping activities.

Quality control (QC). Specific tests defined by the QA program to be performed to monitor retrieval, processing, preservation and storage, cells and/or tissue quality, and test accuracy. These may include, but are not limited to, performance evaluations, inspection, testing, and controls used to determine the accuracy and reliability of the tissue bank's equipment and operational procedures, as well as the monitoring of supplies, reagents, equipment, and facilities.

Quarantine. The identification of human cells and/or tissue as not suitable for transplantation, including human cells and/or tissue that have not yet been characterized as being suitable for transplantation. Quarantine includes the storage of such cells and/or tissue in an area clearly identified

for such use, or other procedures, such as automated designation, to prevent the release of such cells and/or tissue for transplantation.

Recipient. An individual into whom cells and/or tissue is transplanted.

Recovery. Obtaining cells and/or tissue from a donor that is intended to use for transplantation.

Retrieval. The removal, acquisition, recovery, harvesting, or collection of donor cells and/or tissue.

Standard operating procedure manual (SOPM). A group of standard operating procedures (SOPs) detailing the specific policies of a tissue bank and the procedures used by the staff/personnel. This includes, but is not limited to, procedure to assess donor suitability, retrieval, processing, quarantine, release to inventory, labeling, storage, distribution, and recalling cells and/or tissue.

Standards. AATB Standards for Tissue Banking.

Sterile. The absence of detectable, viable microorganisms (refer to ANSI/AAMI ST67:2003, "Sterilization of Health Care Products—Requirements for Products Labeled "Sterile").

Sterility assurance level (SAL). The probability of a single viable microorganism occurring on a product after *Sterilization* (refer to ANSI/AAMI ST67:2003).

Sterilization. A validated process used to render tissue free from viable microorganisms (refer to ANSI/AAMI ST67:2003) including spores.

Storage. The maintenance of cells and/or tissue for future use.

Structural support. Those tissue grafts that contribute biomechanical strength to a surgical construct.

Terminal sterilization. A validated process whereby tissue within its primary package is sterilized (refer to ANSI/AAMI ST67:2003).

Tissue. A functional group of cells. The term is used collectively in *Standards* to indicate both cells and tissue.

Tissue bank. An entity that provides or engages in one or more services involving cells and/or tissue from living or deceased individuals for transplantation purposes. These services include donor suitability, recovery, processing storage, labeling, and distribution of cells and/or tissue.

Tissue identification number. Any unique combination of letters, numbers, and/or symbols assigned to cells and/or tissue and linked to a donor, from which the complete history of collection, processing, packing, quarantine, labeling, storage, and distribution of cells and/or tissue can be traced. Identical cells and/or tissue processed under the criteria defined in "lot" may be assigned the same tissue identification number.

Transplantation. The transfer of allograft cells and/or tissue to a recipient. This includes musculoskeletal, skin, cardiovascular, and fetal cells and/or tissue, as well as reproductive cells and/or tissue used in assisted reproductive procedures.

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EDUCATIONAL OBJECTIVES

1. Define in your own words the following. Compare your definitions with the given definitions by the AATB.
   (a) Bone allograft
   (b) Donor

(c) Aseptic retrieval
(d) Aseptic processing
(e) Tissue

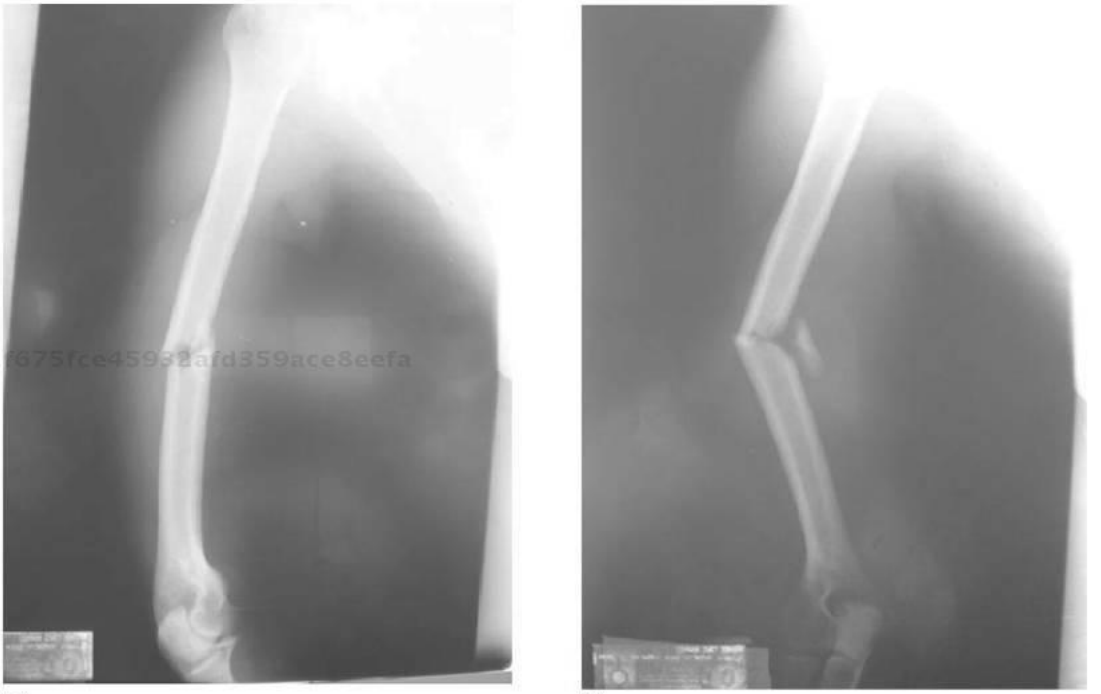
2. List the advantages and disadvantages of bone autografts.
3. List the advantages and disadvantages of bone allografts.
4. List the processing steps of the musculoskeletal tissues.
5. List and explain the classification of preserved bone allografts.
6. What are the main applications of massive bone allografts?
7. Are the biomechanical properties of bone allografts important? Why?
8. What is the usual range of the standard sterilization dose in megarad and kGy?

CHAPTER **8**

Clinical Cases

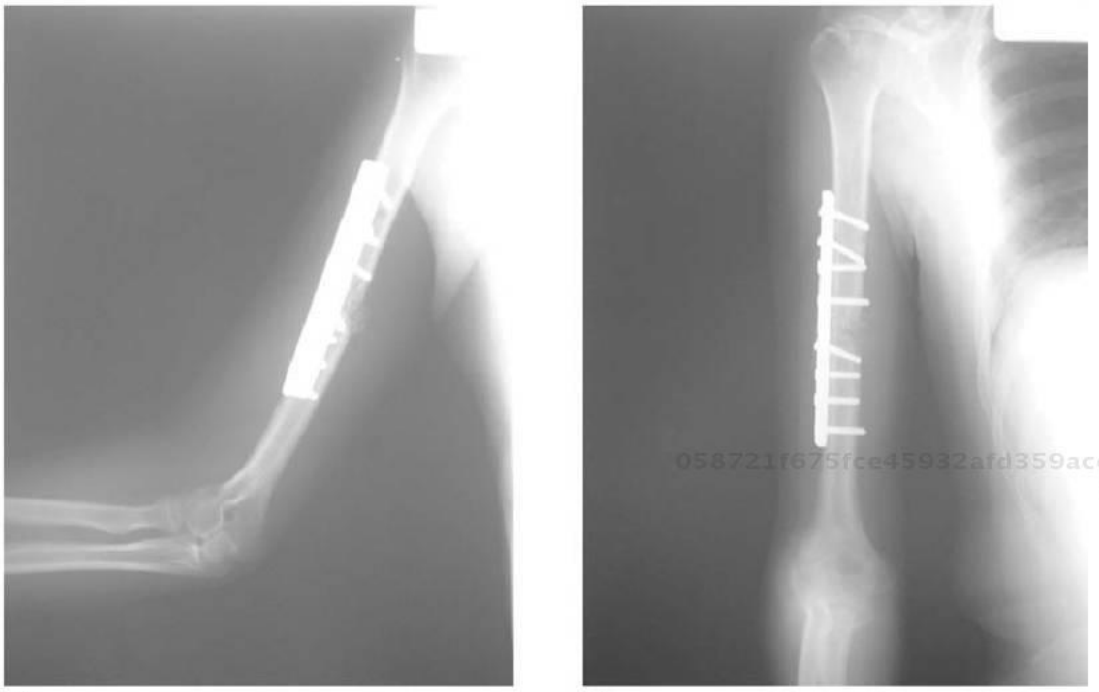
8.1 Right Humeral Fracture

Patient is a 38-year-old female with a right humeral fracture with a butterfly-shaped fragment.



(a) (b)

Fig. 8.1 X-rays showing the fracture and surgical treatment. (a) and (b) Anteroposterior and lateral x-rays of the fracture. (c) and (d) Surgical treatment, a wide straight plate with nine orifices of 4.5 mm. Courtesy of Carlos de la Garza-Páez, M.D.



(c) (d)

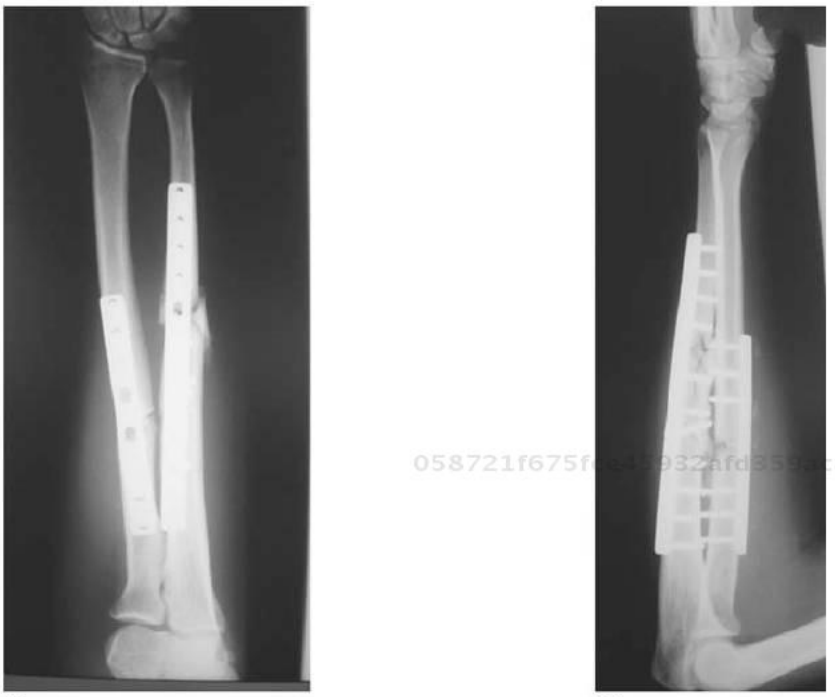
Fig. 8.1 (continued) X-rays showing the fracture and surgical treatment. (a) and (b) Anteroposterior and lateral x-rays of the fracture. (c) and (d) Surgical treatment, a wide straight plate with nine orifices of 4.5 mm. Courtesy of Carlos de la Garza-Páez, M.D.

8.2 Fracture of the Right Radius and Ulna

Patient is a 25-year-old-male with diaphyseal fracture of the right radius and ulna.

(a) (b)

Fig. 8.2 X-rays showing the fracture and surgical treatment. (a) and (b) Views showing diaphyseal fracture of the right radius and ulna. (c) and (d) Treatment with two 3.5 mm dynamic compression plates (DCP). Courtesy of Carlos de la Garza-Páez, M.D.



(c) (d)

Fig. 8.2 (continued) X-rays showing the fracture and surgical treatment. (a) and (b) Views showing diaphyseal fracture of the right radius and ulna. (c) and (d) Treatment with two 3.5 mm dynamic compression plates (DCP). Courtesy of Carlos de la Garza-Páez, M.D.

8.3 Fracture of the Radius and Ulna

Patient is a 25-year-old female with a diaphyseal fracture of the radius and ulna.

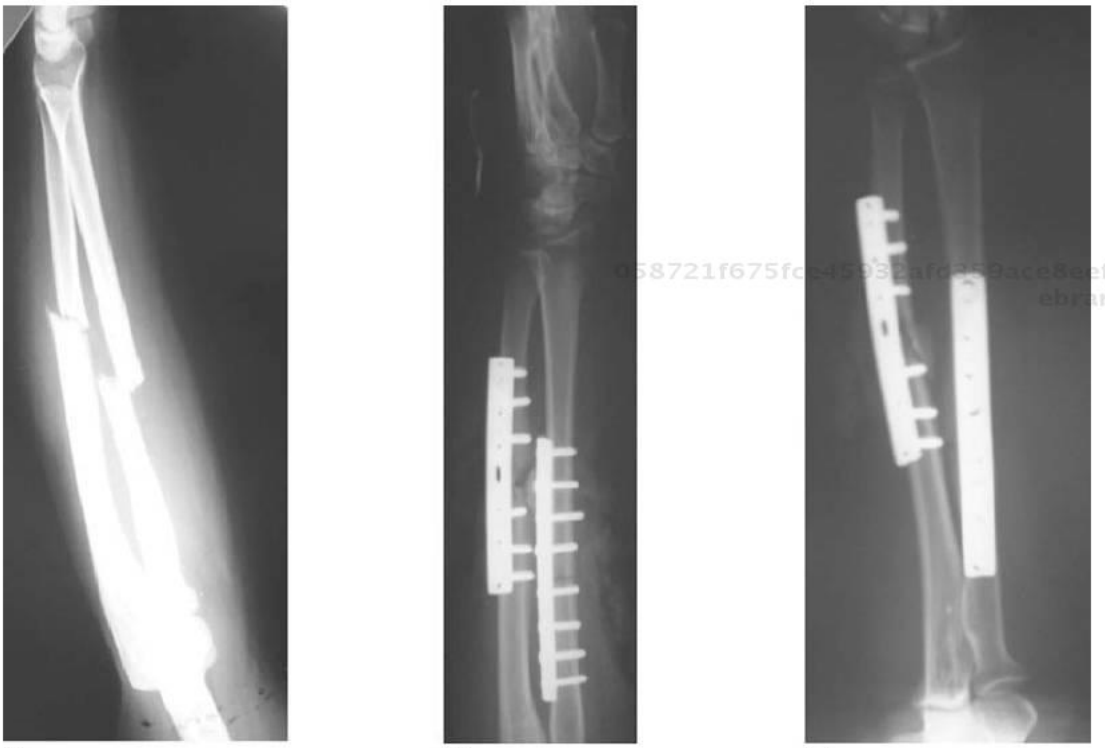


Fig. 8.3 X-rays showing the fracture and surgical treatment. (a) Diaphyseal fracture of the radius and ulna. (b) and (c) Treatment with two 3.5 mm dynamic compression plates (DCP). Courtesy of Carlos de la Garza-Páez, M.D.

8.4 Fracture of the Radius

Patient is a 32-year-old male with a diaphyseal fracture of the radius.

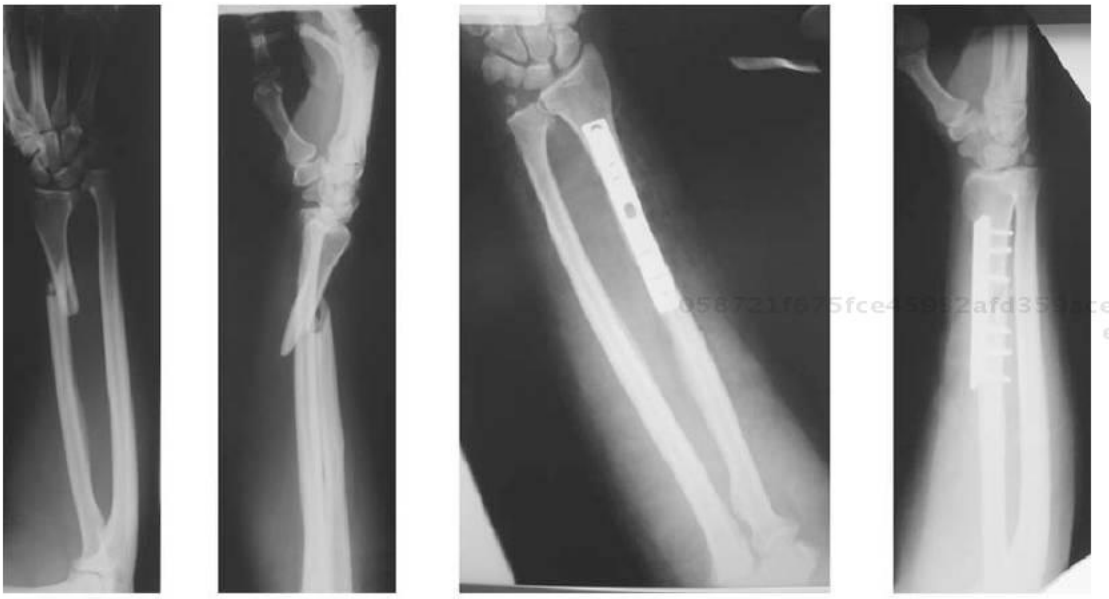
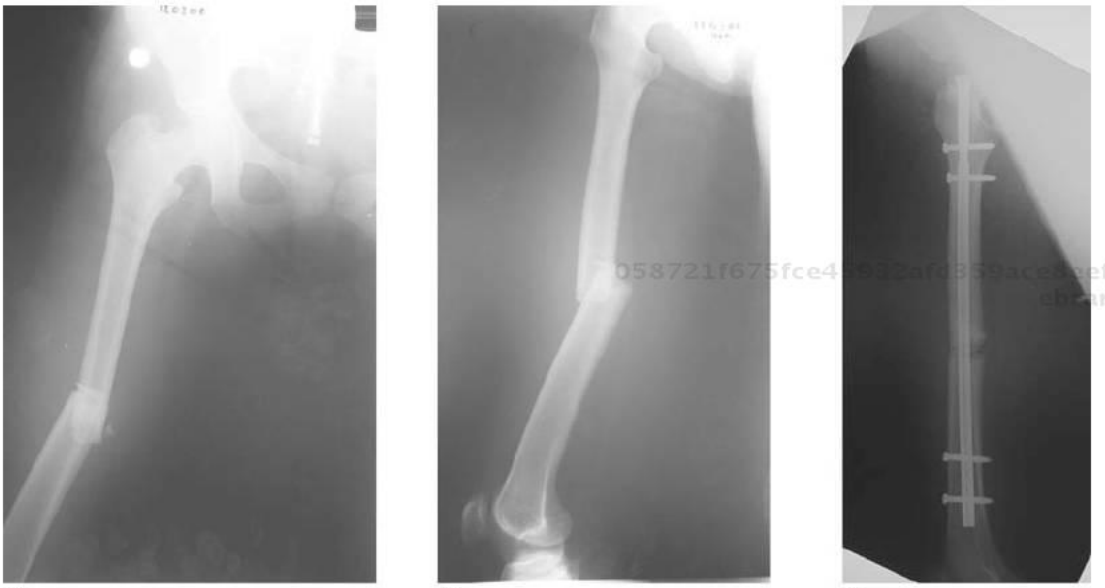


Fig. 8.4 X-rays showing the fracture and surgical treatment. (a) and (b) Views showing diaphyseal fracture of the radius. (c) and (d) Treatment with a 3.5 mm dynamic compression plate (DCP). Courtesy of Carlos de la Garza-Páez, M.D.

8.5 Closed Diaphyseal Fracture of the Right Femur

Patient is a 35-year-old male with a closed diaphyseal fracture of the middle third of the right femur.



(a) (b) (c)

Fig. 8.5 X-rays showing the fracture and surgical treatment. (a) and (b) Views showing closed diaphyseal fracture of the middle third of the right femur. (c) Treatment with a locking intramedullary nail. Courtesy of Carlos de la Garza-Páez, M.D.

8.6 Exposed Tibia and Fibula Fractures

Patient is a 21-year-old male with exposed tibia and fibula fractures in the left leg from a motorcycle accident.

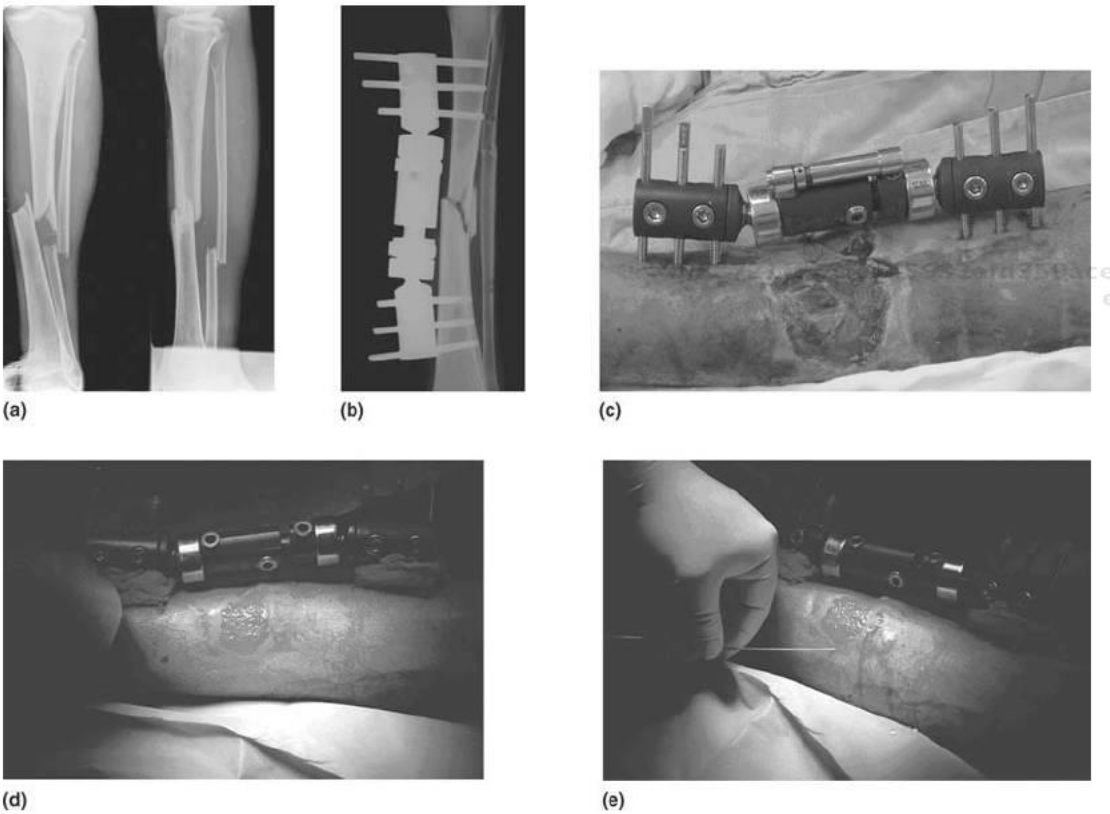
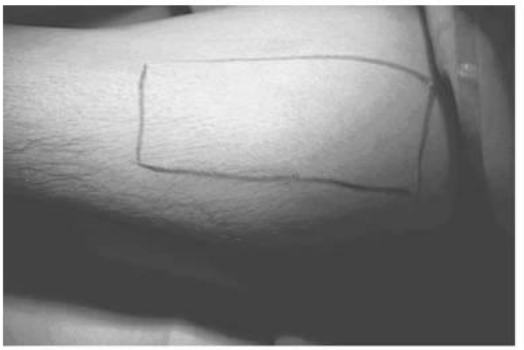


Fig. 8.6 Fractures and surgical treatment. (a) Lateral x-ray of the tibia and fibula fractures. (b) X-ray and (c) photograph showing surgical treatment with placement of monolateral external fixator and coverage of soft tissues. (d) Appearance of the wound after 1 month of wet dressing. (e) Preparation of the implementation of autologous skin. (f) Donor site. (g) Placement of the skin graft taken with dermatome. (h) Graft placed in receptor's site. (i) Final result 2 months after the accident. Courtesy of Eduardo Alvarez, M.D., Ph.D.



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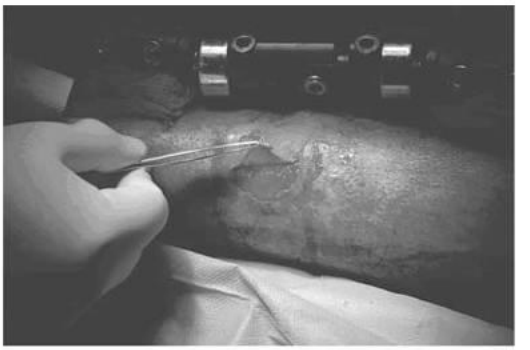

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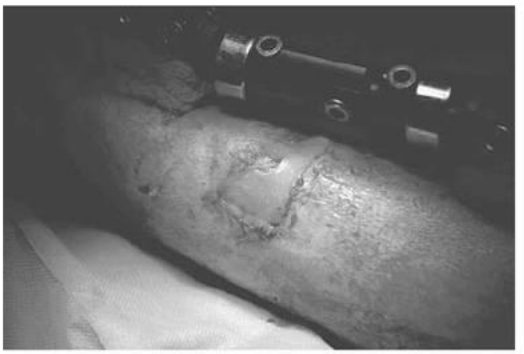


(h)

(i)

Fig. 8.6 (continued) (f) Donor site. (g) Placement of the skin graft taken with dermatome. (h) Graft placed in receptor's site. (i) Final result 2 months after the accident. Courtesy of Eduardo Alvarez, M.D., Ph.D.

8.7 Exposed High-Energy Tibia and Ulna Fracture and Compromised Soft Tissue

Patient is a 14-year-old male who suffered, as the result of an automobile accident, an exposed high-energy tibia and ulna fracture in his left leg and also compromised soft tissue.

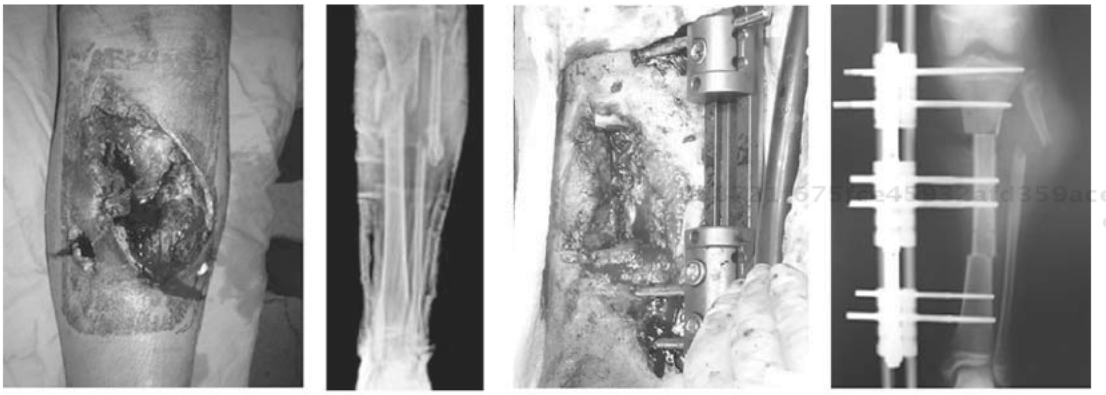


Fig. 8.7 Fractures and surgical treatment. (a) Photograph of injury. (b) X-ray of the fracture. (c) Square osteotomy in the defect area and subperiostic distal corticotomy in order to carry out the bone elongation. (d) Acute shortening of the limb due to a square osteotomy in the defect area. (e) Soft tissues handling and primary closure. (f) Through (i) Sequence showing elongation of bone by 12 cm (0.25 mm every 6 hours) and healing of the soft tissue. (j) Soft tissue cicatrization and restored tibia length. (k) and (l) Treatment evolution at 24 weeks after withdrawal of the external fixation device. The patient reported no pain and exhibited complete mobility. Courtesy of Victor Manuel Peña-Martínez, M.D.

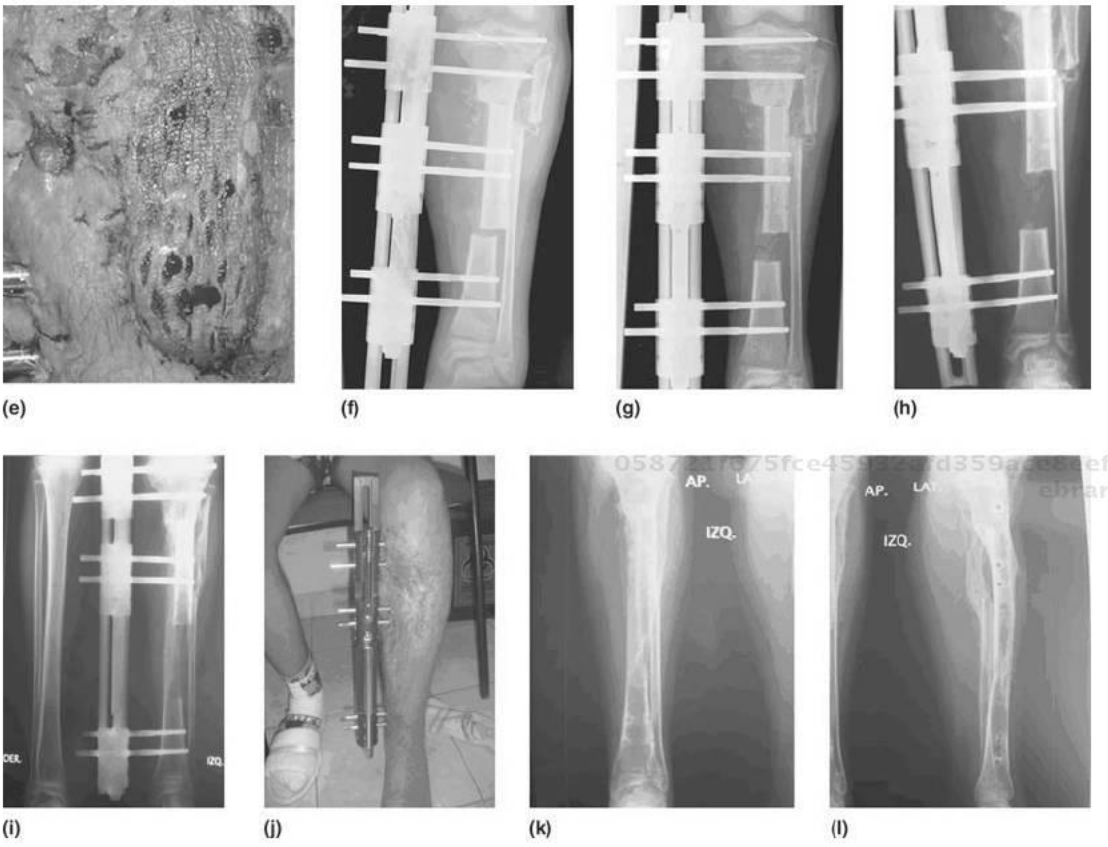
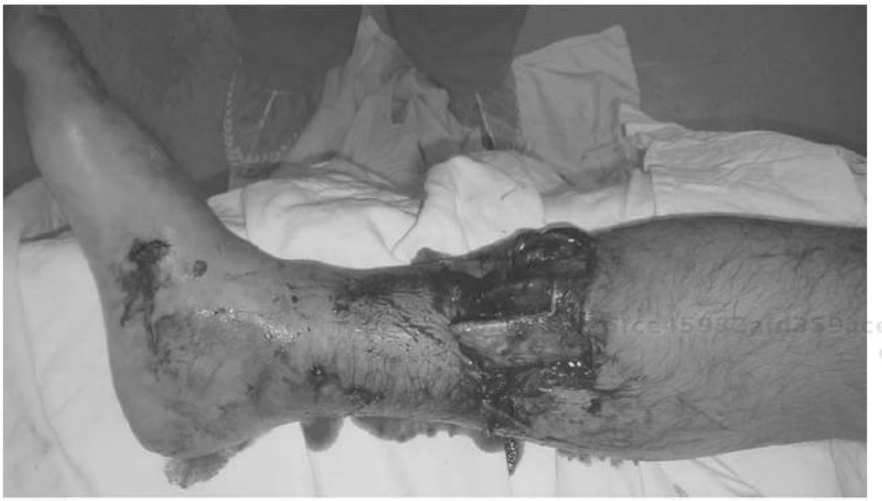


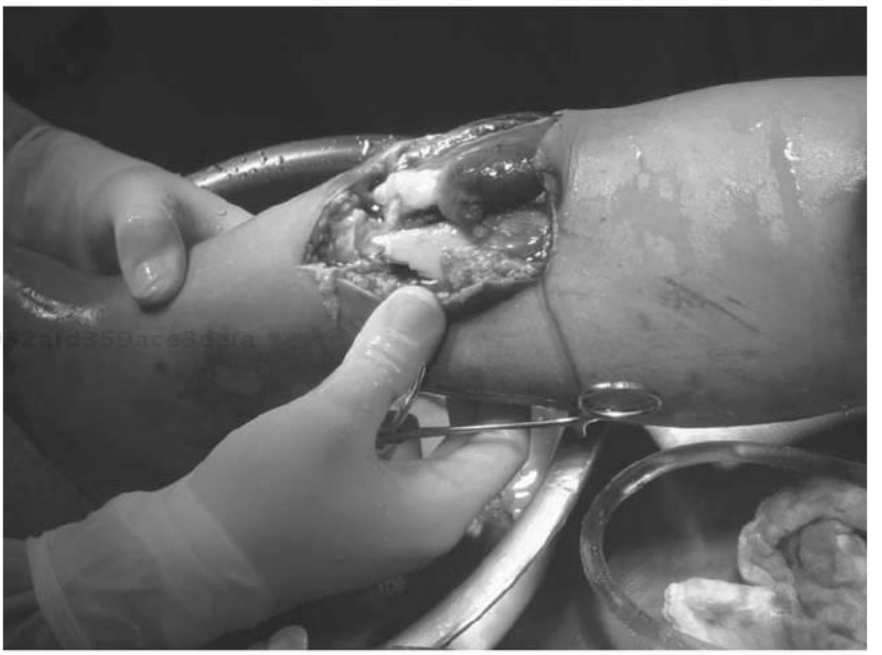
Fig. 8.7 (continued) (e) Soft tissues handling and primary closure. (f) Through (i) Sequence showing elongation of bone by 12 cm (0.25 mm every 6 hours) and healing of the soft tissue. (j) Soft tissue cicatrization and restored tibia length. (k) and (l) Treatment evolution at 24 weeks after withdrawal of the external fixation device. The patient reported no pain and exhibited complete mobility. Courtesy of Victor Manuel Peña-Martínez, M.D.

8.8 Exposed Tibia Fracture

Patient is a 30-year-old male with an exposed tibia fracture.

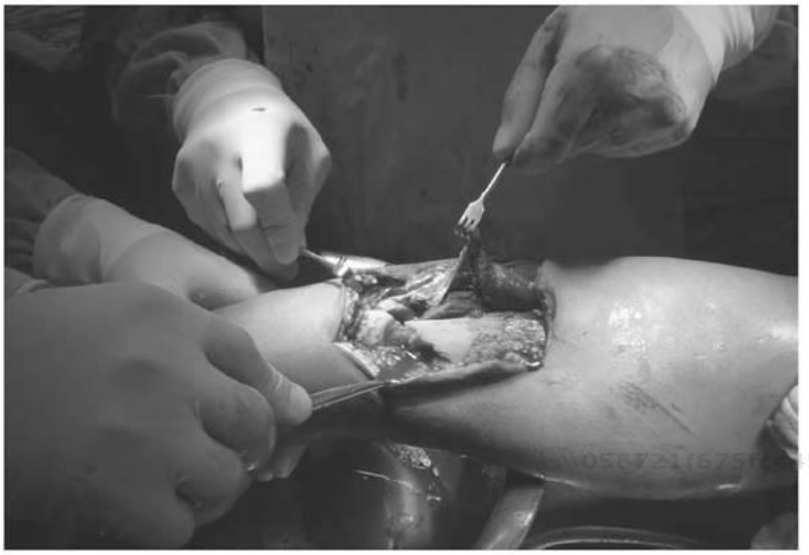


(a)

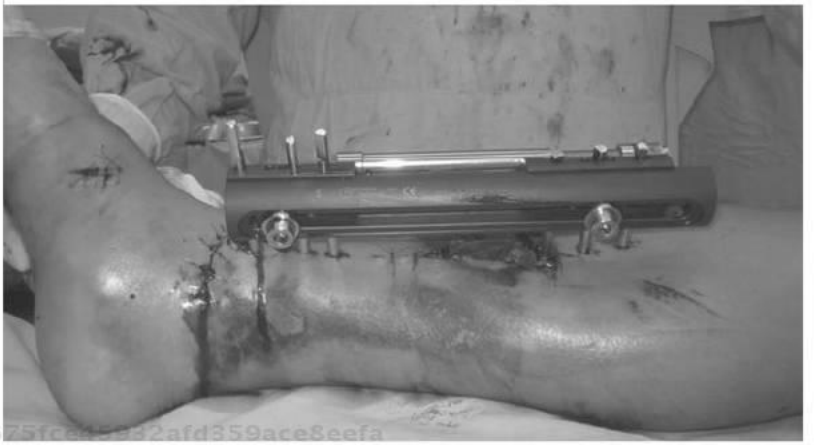


(b)

Fig. 8.8 Photographs showing fracture and treatment. (a) Exposed tibia fracture. (b) Comminuted fracture being irrigated and debrided during surgery. (c) Surgical postdebridement and irrigation. (d) Lateral view of postsurgical external fixation device in place. (e) Anteroposterior view of the external fixation device with cutaneous defect and partial closure of the wound. Courtesy of Carlos Cuervo-Lozano, M.D.



(c)



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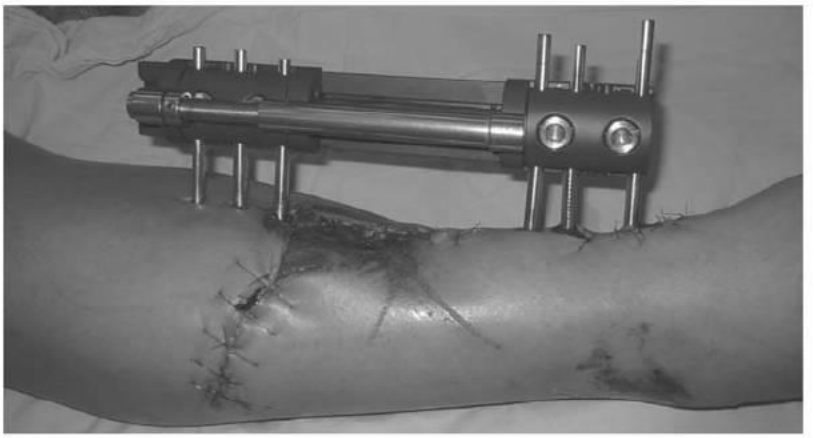


(e)

Fig. 8.8 (continued) (c) Surgical postdebridement and irrigation. (d) Lateral view of postsurgical external fixation device in place. (e) Anteroposterior view of the external fixation device with cutaneous defect and partial closure of the wound. Courtesy of Carlos Cuervo-Lozano, M.D.

8.9 Periprosthetic Fracture in the Right Femur

Patient is a male with a previous total hip arthoplasty, presenting a periprosthetic fracture in the right femur, with poor bone quality in the proximal femur and metallosis.

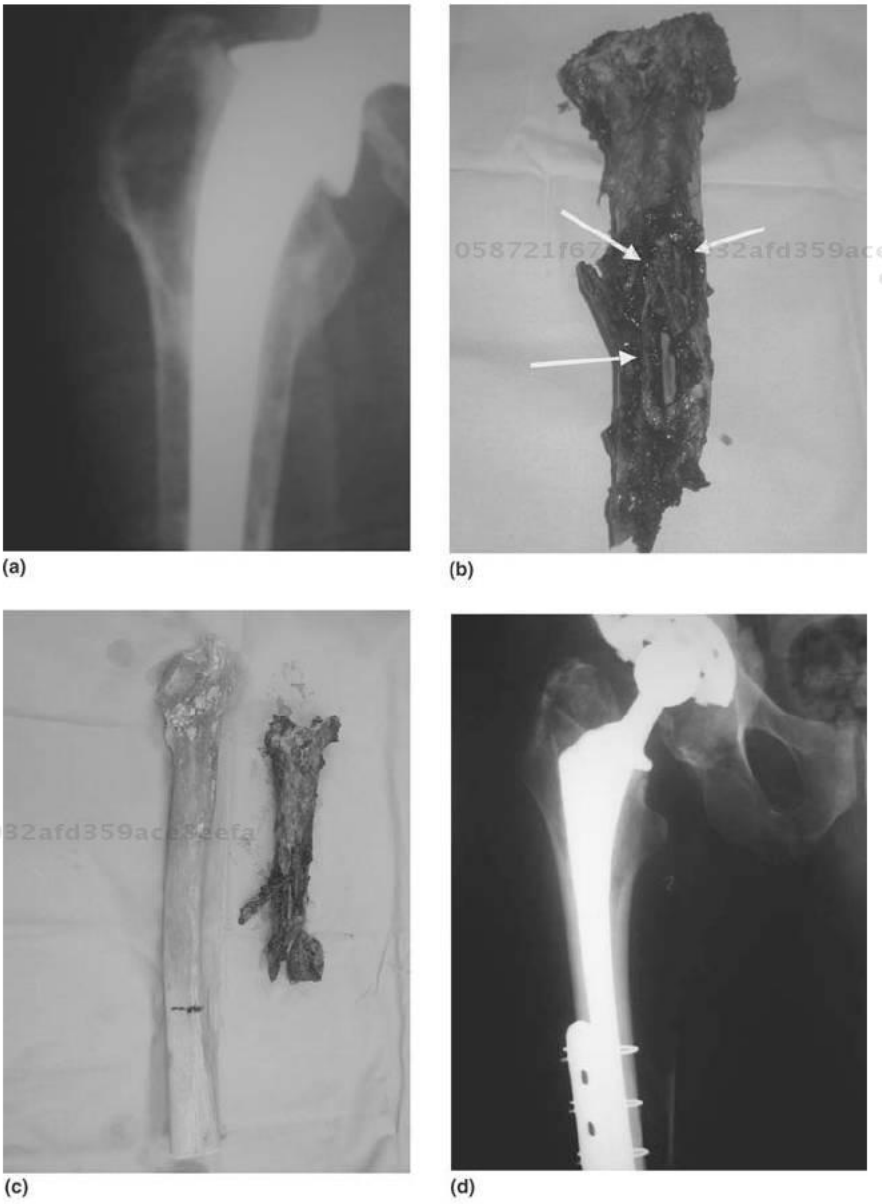
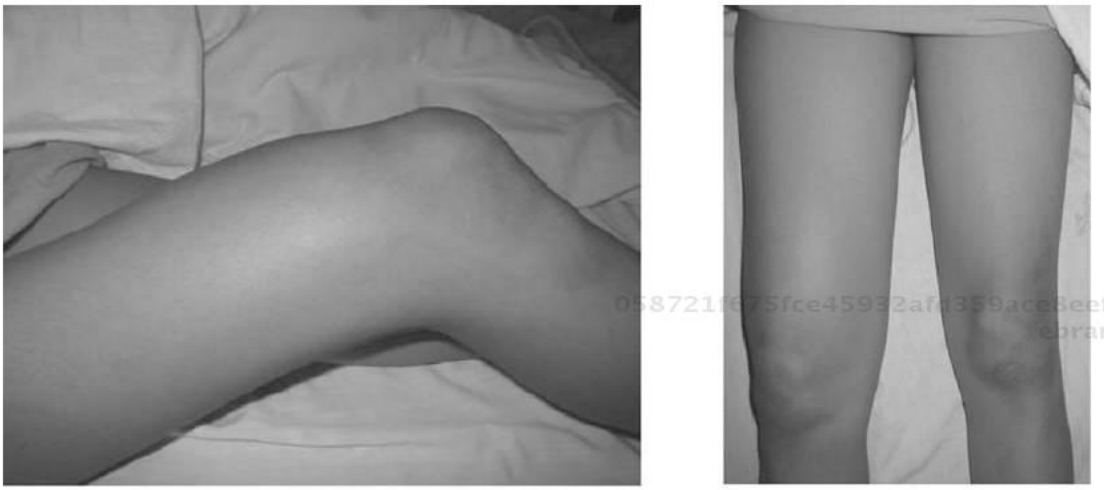


Fig. 8.9 X-rays and photographs showing fracture and treatment. (a) X-ray of hip arthroplasty. (b) Resection of a proximal femur showing several metallosis areas. (c) Massive proximal femur replacement allograft. (d) Postsurgical radiography with a wired plate to reinforce the union between the proximal femur allograft and the patient's femur. Courtesy of Carlos Cuervo-Lozano, M.D., and José Fernando de la Garza-Salazar, M.D.

8.10 Distal Right Femoral Osteosarcoma

Patient is a 9-year-old female with a distal right femoral osteosarcoma.



(a) (b)

Fig. 8.10 Photographs and x-rays showing the tumor and treatment. (a) and (b) Two views of the volume increase of the distal third of the right thigh by osteosarcoma. (c) Postchemotherapy x-ray. Ossification of the extraosseal portion of the tumor is observed, an indicator of good response to chemotherapy. An x-ray with a marker was taken to see the magnification and be able to manufacture the prosthesis according to size. (d) Postchemotherapy magnetic resonance image. In this MRI, the intramedullary extension of the tumor can be measured exactly to determine the resection level during surgery. (e) and (f) Prosthesis template. The x-rays show the template superimposed to verify measurements before manufacture. (g) Treatment of an anteromedial approach is performed. (h) Medial and lateral fasciocutaneous flaps are made. (i) The femoral vessels are identified and isolated. (j) The distal femur is completely isolated with part of the quadriceps muscle surrounding the tumor. (k) Modular tumor extendible prosthesis: the tibial ream or bur specially designed for the tibial portion of the prosthesis. (l) Modular tumor extendible prosthesis: three of the four femoral parts of the prosthesis. From left to right: the tibial stem, the femoral stem with locking holes, and the body of the prosthesis with the extension system (telescope). (m) and (n) Assembled femoral portion of the prosthesis (four parts). (o) Prosthesis in its place articulated at the knee by an ultrahigh-molecular-weight polyethylene hinge system (surrounded by muscles). (p) Lateral view of the prosthesis with the fixed knee. (q) Proximal blocking of a femoral stem. (r) Placement of a cemented tibial stem. Courtesy of Carlos Cuervo-Lozano, M.D.

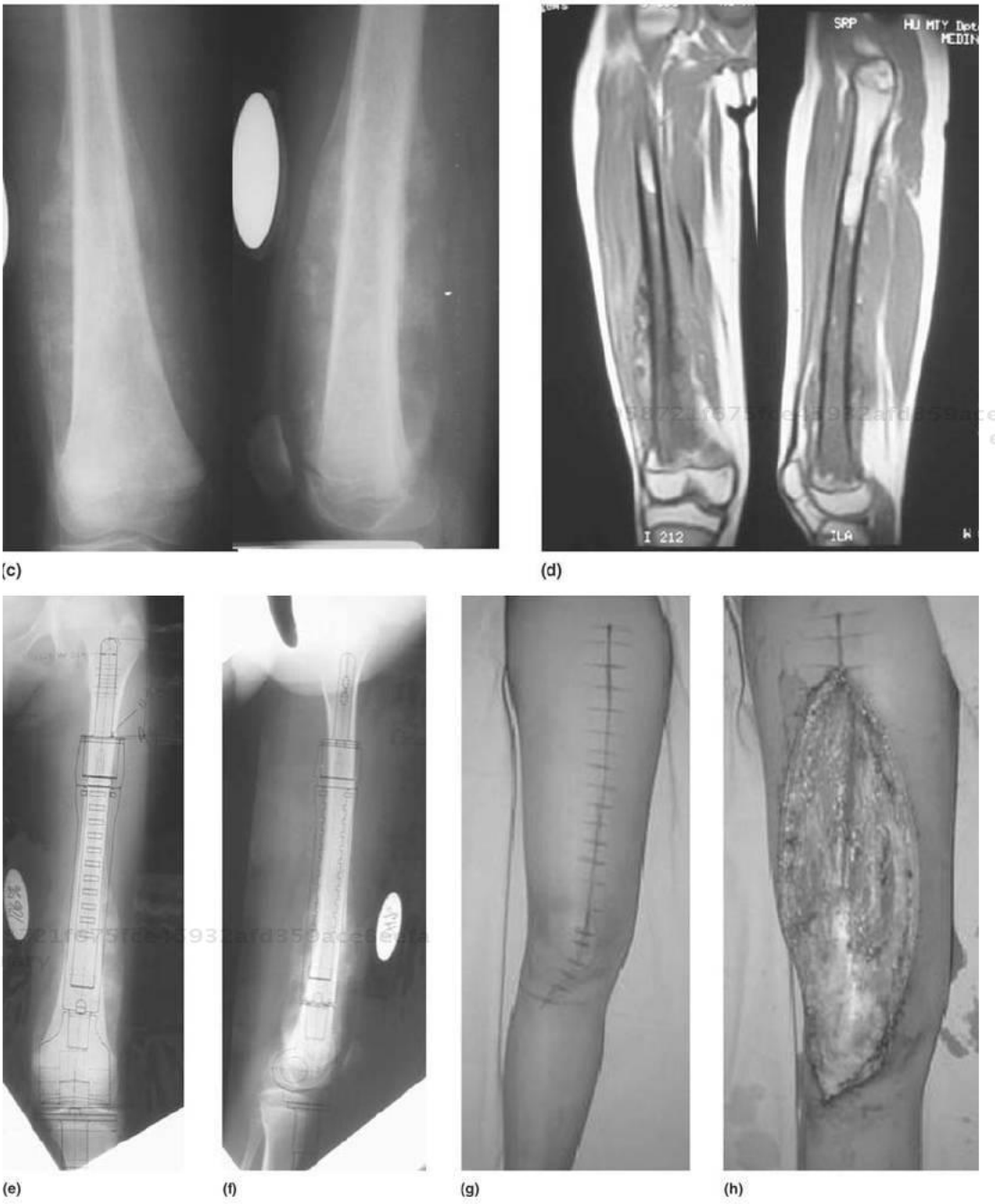
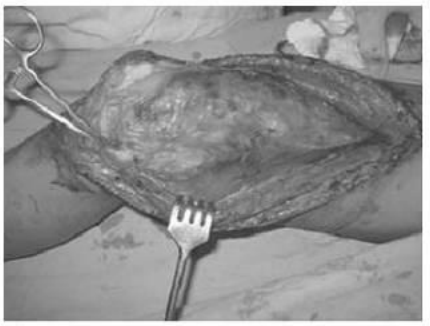
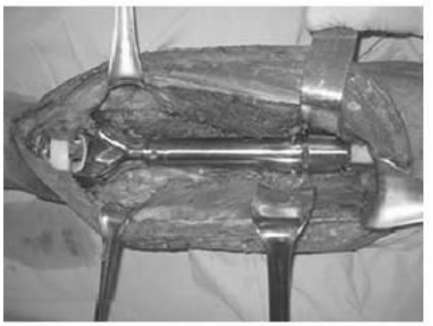


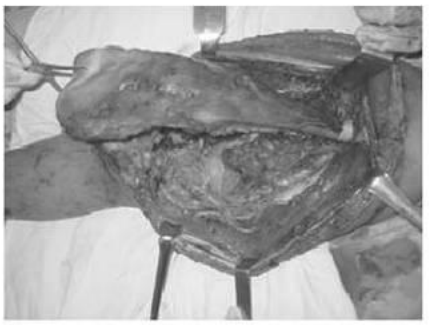
Fig. 8.10 (continued) (c) Postchemotherapy x-ray. Ossification of the extraosseal portion of the tumor is observed, an indicator of good response to chemotherapy. An x-ray with a marker was taken to see the magnification and be able to manufacture the prosthesis according to size. (d) Postchemotherapy magnetic resonance image. In this MRI, the intramedullary extension of the tumor can be measured exactly to determine the resection level during surgery. (e) and (f) Prosthesis template. The x-rays show the template superimposed to verify measurements before manufacture. (g) Treatment of an anteromedial approach is performed. (h) Medial and lateral fasciocutaneous flaps are made. Courtesy of Carlos Cuervo-Lozano, M.D.



(i)



(o)



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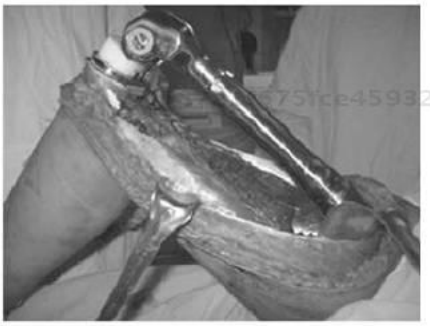


(p)

(k) (l)

(q) (r)

(m) (n)

Fig. 8.10 (continued) (i) The femoral vessels are identified and isolated. (j) The distal femur is completely isolated with part of the quadriceps muscle surrounding the tumor. (k) Modular tumor extendible prosthesis: the tibial ream or bur specially designed for the tibial portion of the prosthesis. (l) Modular tumor extendible prosthesis: three of the four femoral parts of the prosthesis. From left to right: the tibial stem, the femoral stem with locking holes, and the body of the prosthesis with the extension system (telescope). (m) and (n) Assembled femoral portion of the prosthesis (four parts). (o) Prosthesis in its place articulated at the knee by an ultrahigh-molecular-weight polyethylene hinge system (surrounded by muscles). (p) Lateral view of the prosthesis with the fixed knee. (q) Proximal blocking of a femoral stem. (r) Placement of a cemented tibial stem. Courtesy of Carlos Cuervo-Lozano, M.D.

8.11 Deformity Caused by Collapsed Massive Bone Allograft and Tumor Relapse

Patient is a 35-year-old female with previous resection of a giant cell tumor involving allograft placement and cobalt-60 γ irradiation. The patient exhibits a deformity caused by collapsed massive bone allograft and tumor relapse.

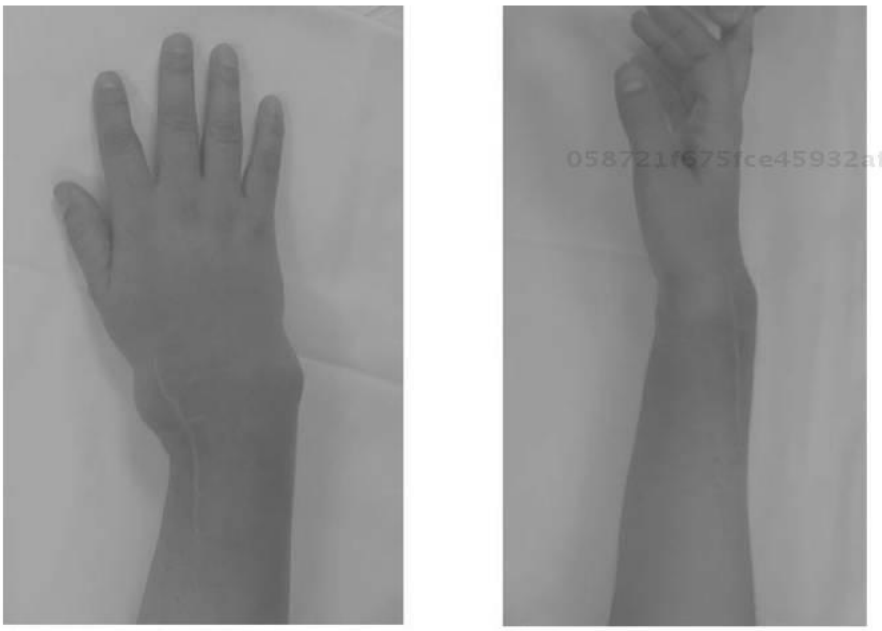
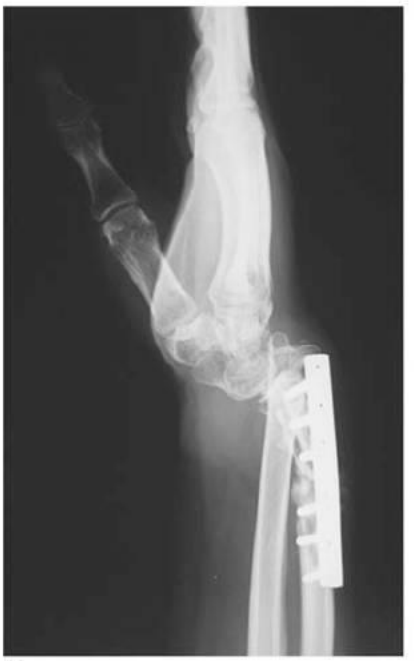


Fig. 8.11 Treatment of a deformity from a massive collapsed bone allograft and tumor relapse. (a) View showing deformity. (b) Side view of deformity also showing radiodermatitis around the surgical scar. (c) Lateral radiograph showing the postirradiated fractured massive bone allograft; wrist deformation with subluxation. (d) Lateral radiograph showing the postirradiated fractured massive bone allograft; wrist deformation with subluxation metallic artifact is shown. (e) MRI shows the relapsed tumor. The massive collapse bone allograft is underneath the DCP plate. (f) MRI of an axial slice showing relapsed tumor with a hyper intense area and a hypo intense area due to a metallic artifact. (g) Distal radius massive bone allograft with a reconstruction LCP plate for fusion of the wrist used to replace the fractured bone allograft. (h) Placement of a massive radius bone allograft aligned with the third metacarpal. The extensor tendons and the radial artery are observed. The relapsed tumor and collapsed bone allograft were previously withdrawn. (i) Postoperative radiograph of the massive radius bone allograft placed at the proximal end of the radius and fixed on the distal end to the big carpal bone and the third metacarpal fixed to the LCP plate. Courtesy of Carlos Cuervo-Lozano, M.D.



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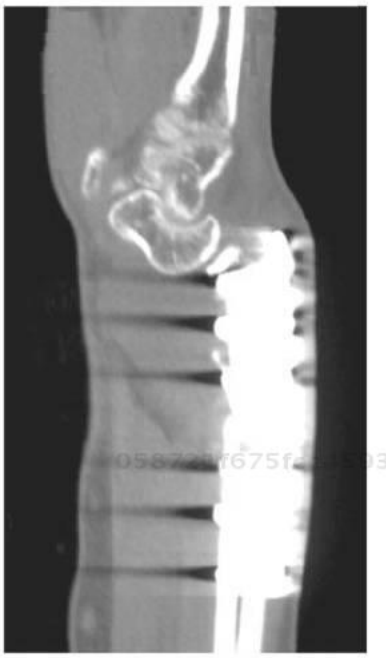

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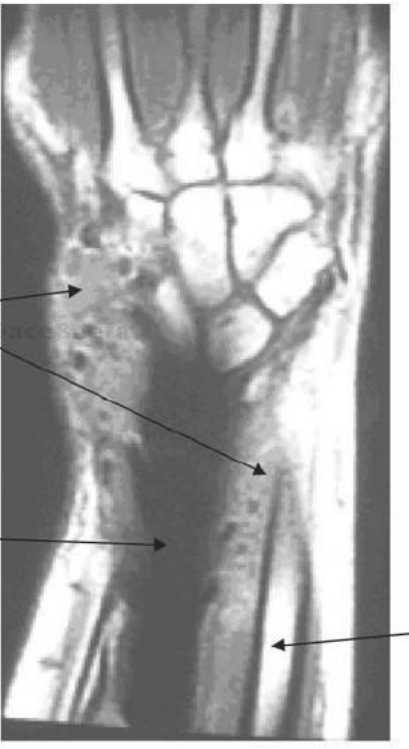
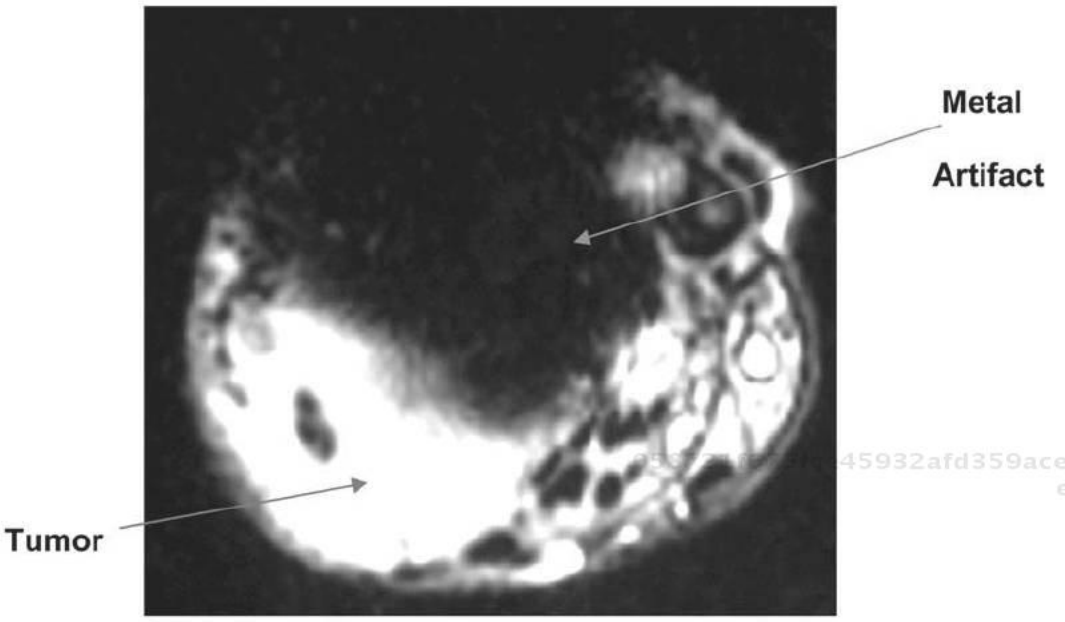


(e)

Fig. 8.11 (continued) (c) Lateral radiograph showing the postirradiated fractured massive bone allograft; wrist deformation with subluxation. (d) Lateral radiograph showing the postirradiated fractured massive bone allograft; wrist deformation with subluxation metallic artifact is shown. (e) MRI shows the relapsed tumor. The massive collapse bone allograft is underneath the DCP plate. Courtesy of Carlos Cuervo-Lozano, M.D.



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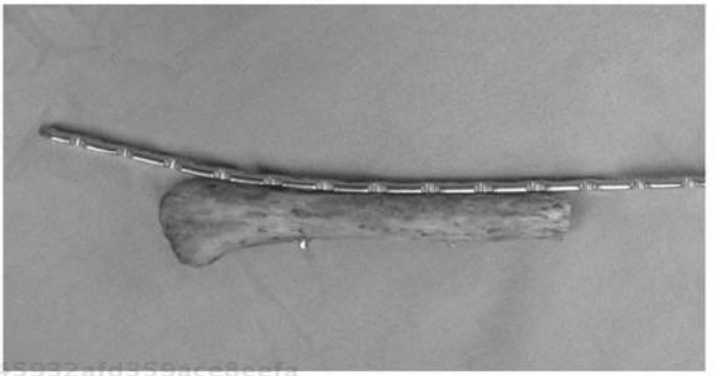
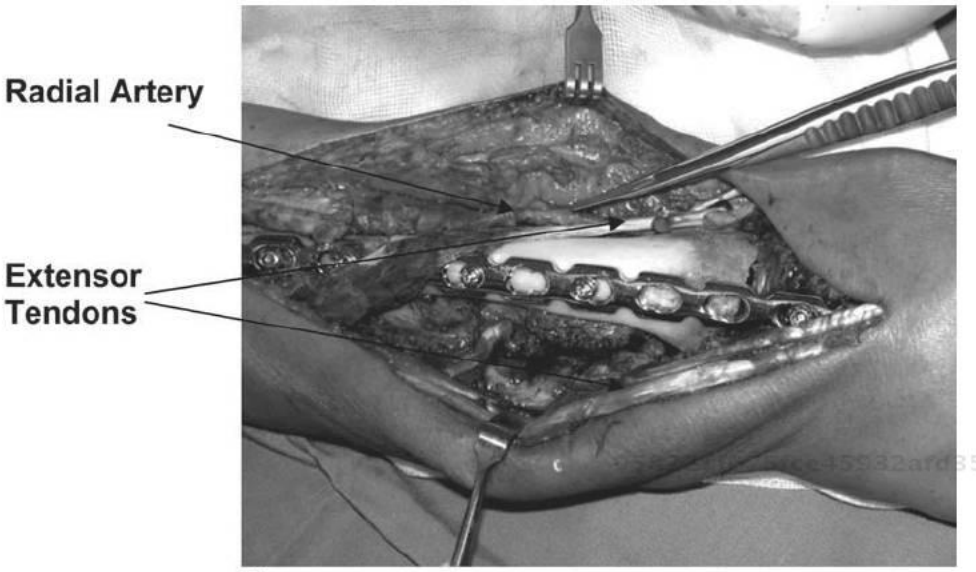


(g)

Fig. 8.11 (continued) Treatment of a deformity from a massive collapsed bone allograft and tumor relapse. (a) View showing deformity. (b) Side view of deformity also showing radiodermatitis around the surgical scar. (c) Lateral radiograph showing the postirradiated fractured massive bone allograft; wrist deformation with subluxation. (d) Lateral radiograph showing the postirradiated fractured massive bone allograft; wrist deformation with subluxation metallic artifact is shown. (e) MRI shows the relapsed tumor. The massive collapse bone allograft is underneath the DCP plate. (f) MRI of an axial slice showing relapsed tumor with a hyper intense area and a hypo intense area due to a metallic artifact. (g) Distal radius massive bone allograft with a reconstruction LCP plate for fusion of the wrist used to replace the fractured bone allograft. Courtesy of Carlos Cuervo-Lozano, M.D.



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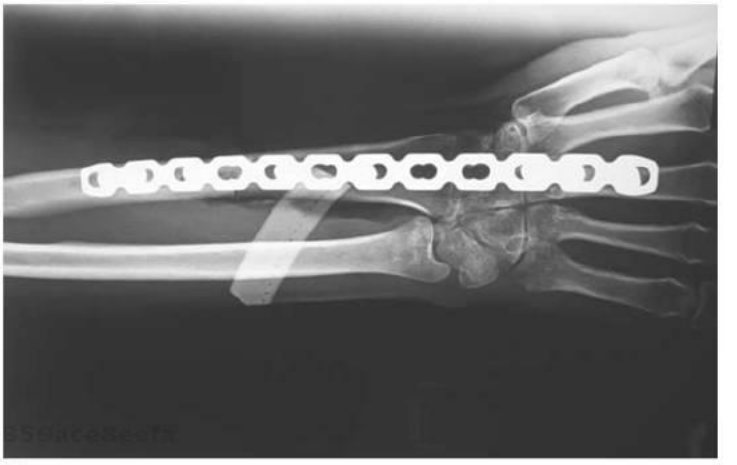
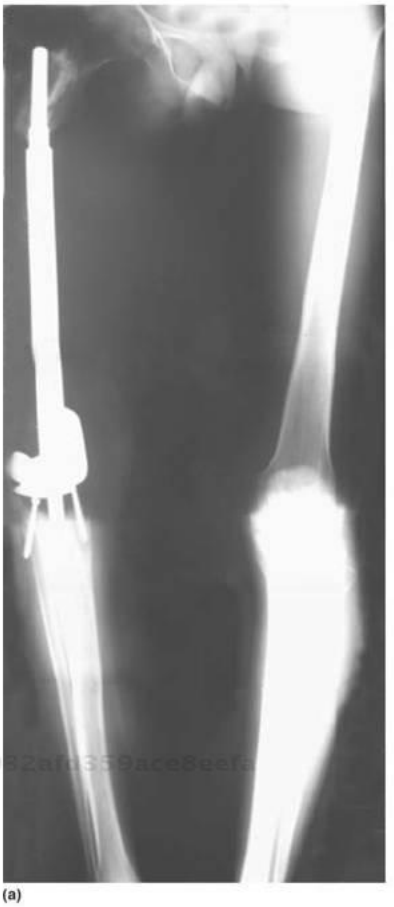


(i)

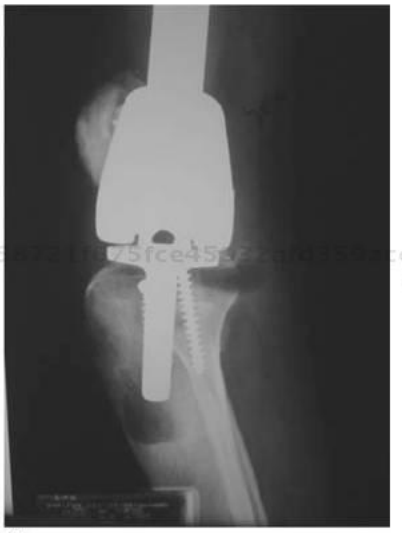
Fig. 8.11 (continued) (h) Placement of a massive radius bone allograft aligned with the third metacarpal. The extensor tendons and the radial artery are observed. The relapsed tumor and collapsed bone allograft were previously withdrawn. (i) Postoperative radiograph of the massive radius bone allograft placed at the proximal end of the radius and fixed on the distal end to the big carpal bone and the third metacarpal fixed to the LCP plate. Courtesy of Carlos Cuervo-Lozano, M.D.

8.12 Proximal and Distal Loosening of a Prosthetic Knee Replacement as a Result of Infection

Patient is a 21-year-old male with previous resection of a distal femur osteosarcoma with a tumoral knee prosthetic replacement. Investigation shows proximal and distal loosening of the prosthetic replacement as a result of infection.



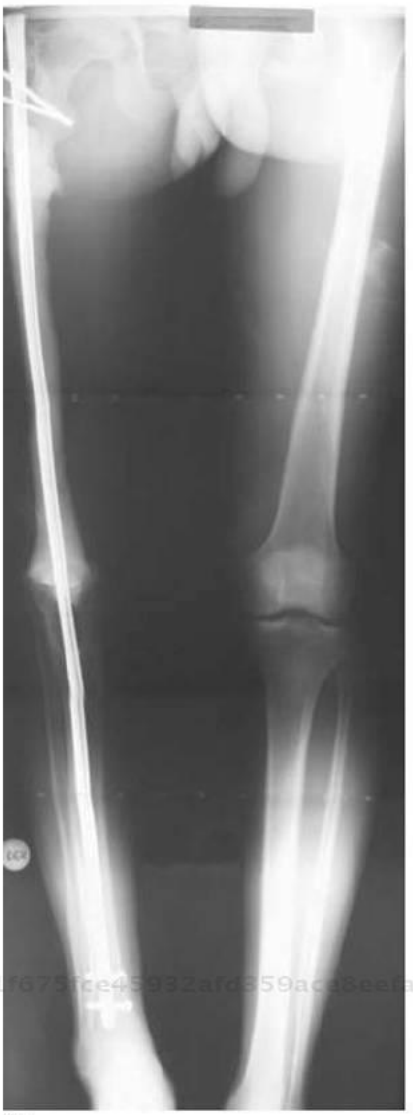
(a)



(b)

(c)

Fig. 8.12 Treatment of proximal and distal loosening of a prosthetic knee replacement due to infection. (a) X-ray showing proximal and distal loosening of the prosthetic replacement due to infection. (b) X-ray showing zones of osteolysis in the proximal tibia and prosthetic loosening. (c) X-ray showing septic loosening of the femoral stem component with bone resorption. (d) Previous treatment: x-ray showing the result of provisional treatment after the prosthesis removal and cleaning. Treatment consisted of placing a long intramedullar nail for fusion with bone cement used as a spacer and antibiotic to eradicate infection. (e) X-ray showing the expected fracture of the intramedullar nail and bone cement 2 years after placement. (f) Clinical photograph showing the expected nail and cement failure before the withdrawal of the nail and bone cement. (g) Clinical photograph of the intramedullar nail and bone cement after withdrawal. Corrosion is observed at the proximal end. (h) Thigh area previously occupied by the bone cement spacer prepared for final treatment. Clean tissue as well as the proximal femur and tibia are observed. (i) Massive bone allograft, with a length of approximately 400 mm, prepared with a proximal step cut. (j) The bone allograft is reinforced with wires in order to prevent fracture while being reamed or during placement of the intramedullar nail. (k) Placement of the massive bone allograft in the thigh previously occupied by bone cement. (l) Postoperative x-ray showing the distal tibia with the blocked intramedullar nail. (m) Postoperative x-ray showing the union of the bone allograft-bone with a stair cut in the blocked proximal femur. (n) X-ray of the proximal femur 3 years later. Complete consolidation of the bone allograft and bone is observed. (o) X-ray of the proximal tibia 3 years later. Complete consolidation of the bone allograft and bone is observed. Courtesy of Carlos Cuervo-Lozano, M.D.



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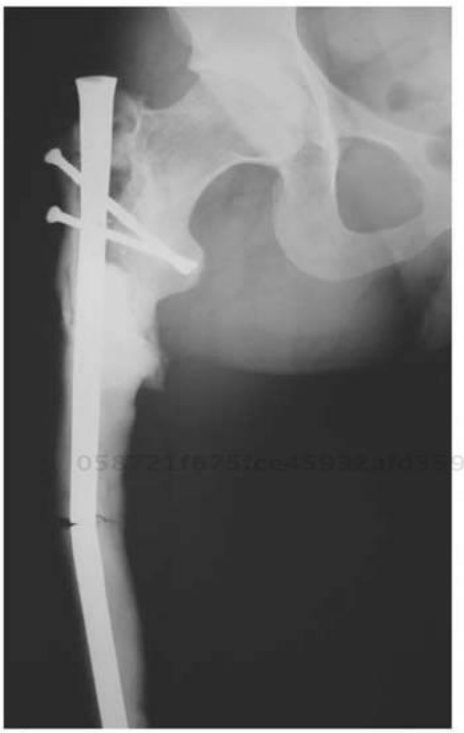

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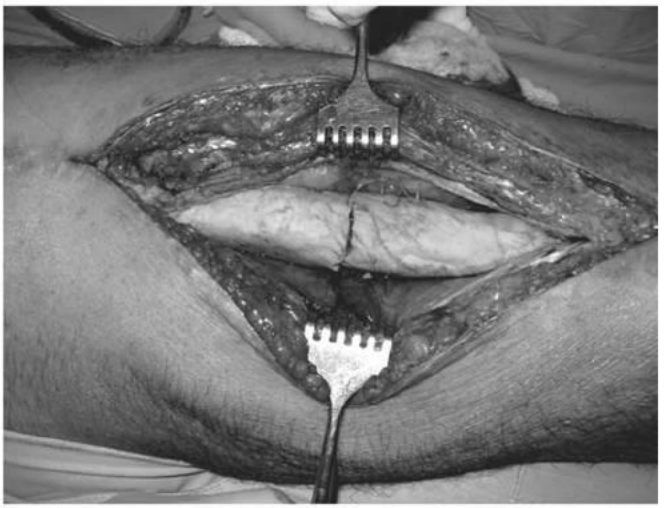
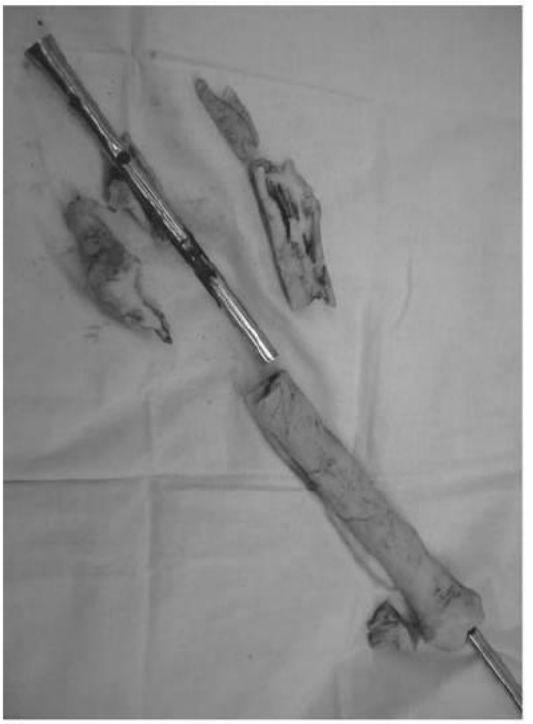


(f)

Fig. 8.12 (continued) (d) Previous treatment: x-ray showing the result of provisional treatment after the prosthesis removal and cleaning. Treatment consisted of placing a long intramedullar nail for fusion with bone cement used as a spacer and antibiotic to eradicate infection. (e) X-ray showing the expected fracture of the intramedullar nail and bone cement 2 years after placement. (f) Clinical photograph showing the expected nail and cement failure before the withdrawal of the nail and bone cement. Courtesy of Carlos Cuervo-Lozano, M.D.



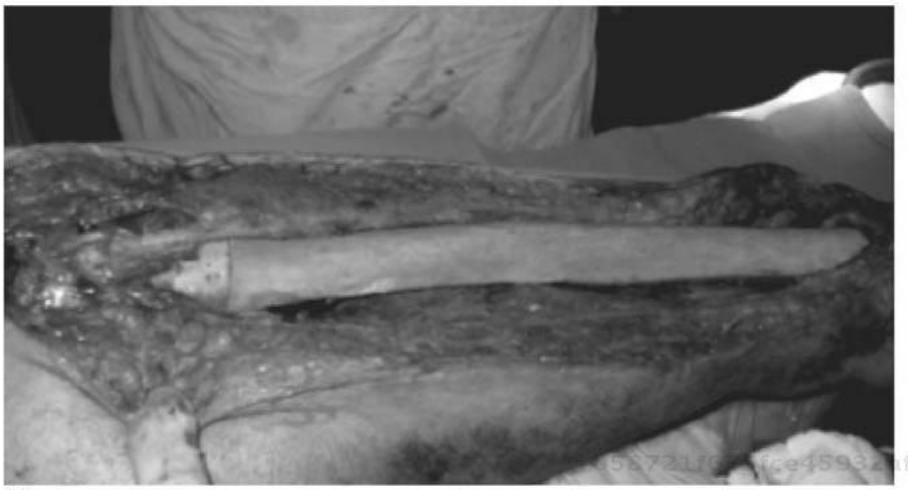
(g)

(i)

(h)

(j)

Fig. 8.12 (continued) (g) Clinical photograph of the intramedullar nail and bone cement after withdrawal. Corrosion is observed at the proximal end. (h) Thigh area previously occupied by the bone cement spacer prepared for final treatment. Clean tissue as well as the proximal femur and tibia are observed. (i) Massive bone allograft, with a length of approximately 400 mm, prepared with a proximal step cut. (j) The bone allograft is reinforced with wires in order to prevent fracture while being reamed or during placement of the intramedullar nail. Courtesy of Carlos Cuervo-Lozano, M.D.



(k)

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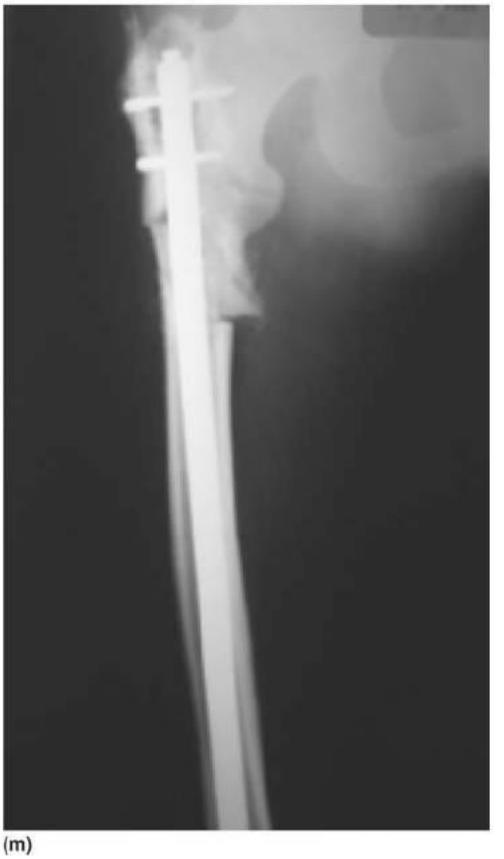
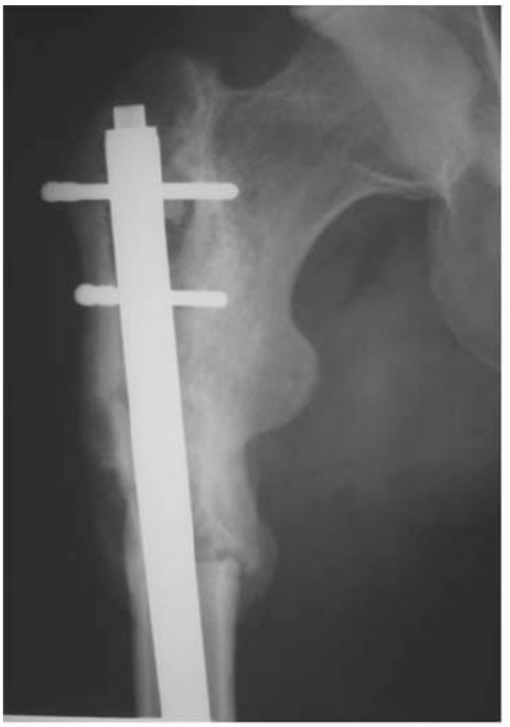


(m)

Fig. 8.12 (continued) (k) Placement of the massive bone allograft in the thigh previously occupied by bone cement. (l) Postoperative x-ray showing the distal tibia with the blocked intramedullar nail. (m) Postoperative x-ray showing the union of the bone allograft-bone with a stair cut in the blocked proximal femur. Courtesy of Carlos Cuervo-Lozano, M.D.



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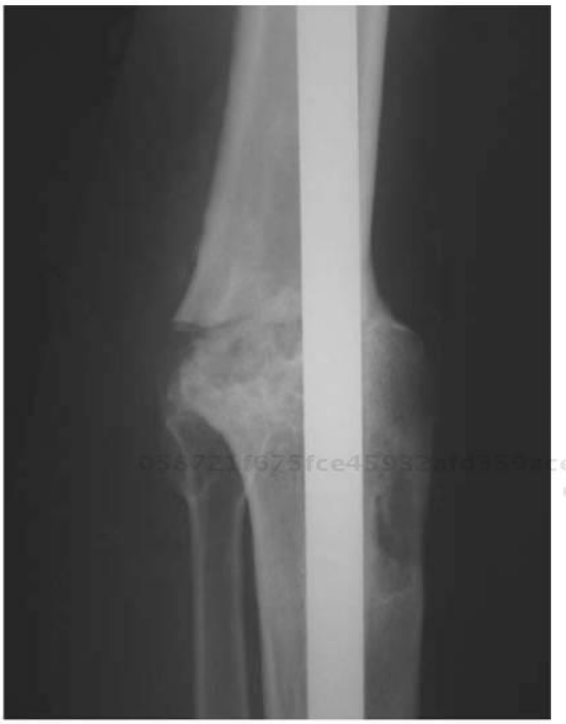


(o)

Fig. 8.12 (continued) (n) X-ray of the proximal femur 3 years later. Complete consolidation of the bone allograft and bone is observed. (o) X-ray of the proximal tibia 3 years later. Complete consolidation of the bone allograft and bone is observed. Courtesy of Carlos Cuervo-Lozano, M.D.

8.13 Hernia in a Cervical Disc

Patient is a 50-year-old male with cervical pain and pain in his left arm.

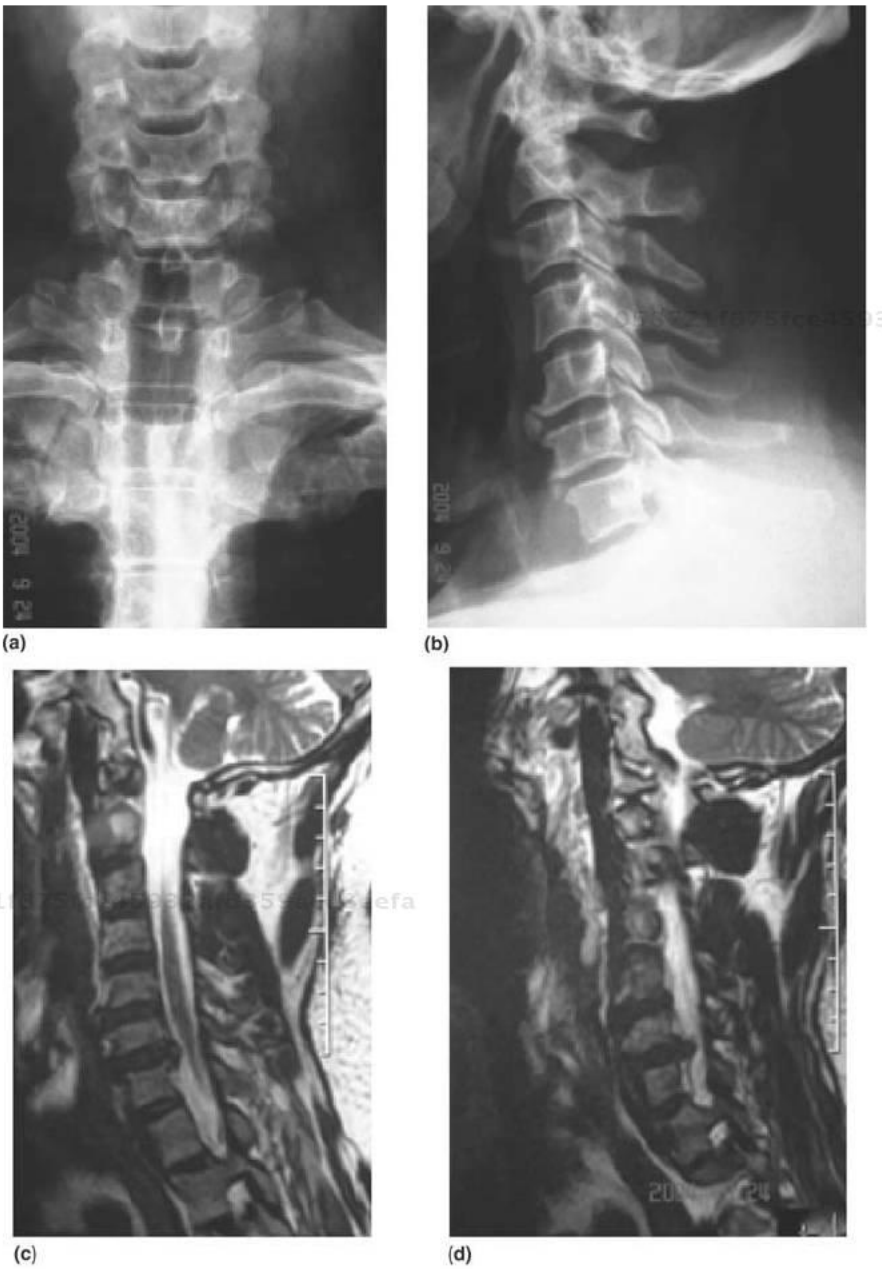


Fig. 8.13 Treatment of hernia in a cervical disc with cervical disc arthroplasty in C6–C7. (a) and (b) X-rays showing degenerative cervical changes in C5–C6 and C6–C7. (c) and (d) MRI sagital projection shows hernia in cervical disc that contacts medullar cordon. (e) and (f) MRI in axial projections shows hernia in C6–C7 cervical disc posterolateral in left side that impinges C6–C7 cervical root. (g) and (h) Postoperative x-rays of a C6–C7 cervical discectomy via anterior. Brian disc prosthesis was used in disc arthroplasty. Courtesy of Oscar Armando Martínez-Gutiérrez, M.D.

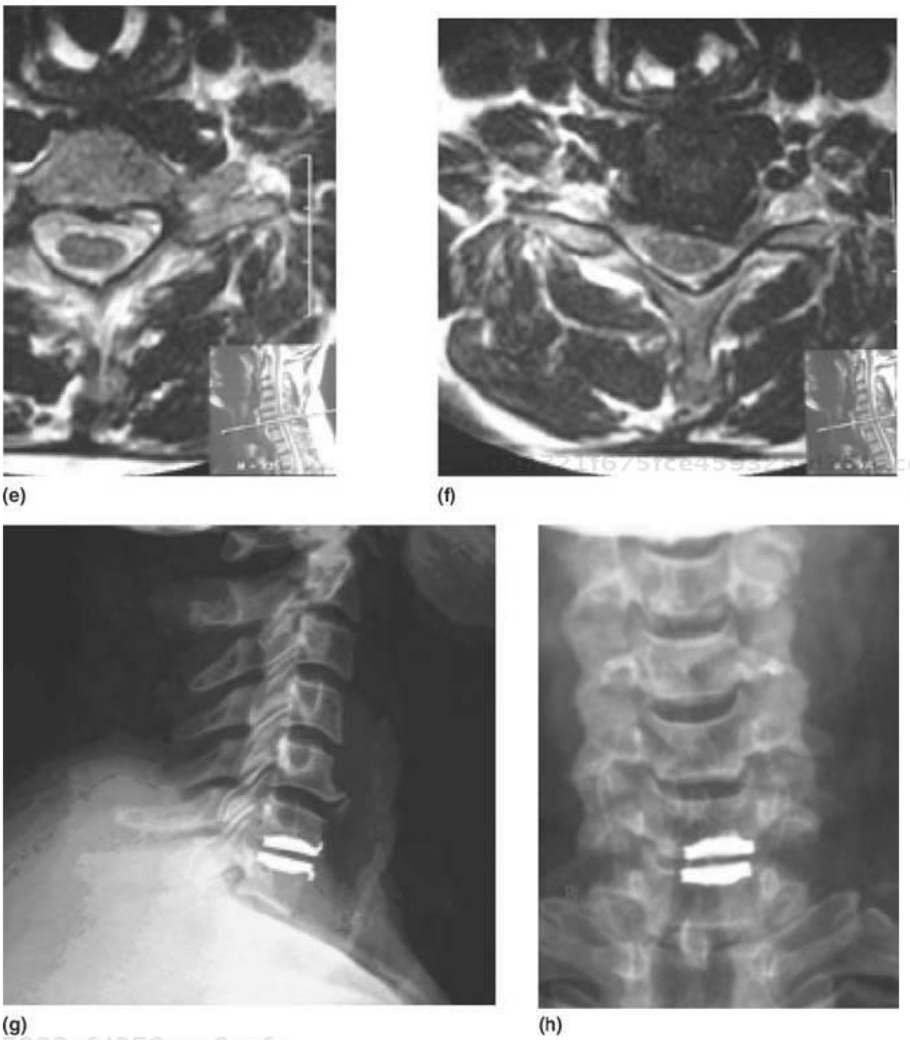


Fig. 8.13 (continued) (e) and (f) MRI in axial projections shows hernia in C6–C7 cervical disc posterolateral in left side that impinges C6–C7 cervical root. (g) and (h) Postoperative x-rays of a C6–C7 cervical discectomy via anterior. Brian disc prosthesis was used in disc arthroplasty. Courtesy of Oscar Armando Martínez-Gutiérrez, M.D.

8.14 Isthmic Lytic Spondylolisthesis

Patient is a 35-year-old female with a 3-year history of continuous and disabling pain. Investigation results in the diagnosis of isthmic lytic spondylolisthesis of L5–S1 with a grade II 50%. For treatment, a posterior lumbar approach is performed + transpedicular instrumentation of L4–L6–S1 + laminectomy + posterior lumbar interbody fusion (PLIF). An interbody cage is placed and filled with granulated bone graft form the Bone and Tissue Bank of the Dr. José E. González University Hospital. Two months later the patient was asymptomatic, moving with external support to protect the surgical procedure, which is found with adequate reduction. The osteosynthesis biomaterial is in its place; a slight mass of posterolateral fusion is observed.

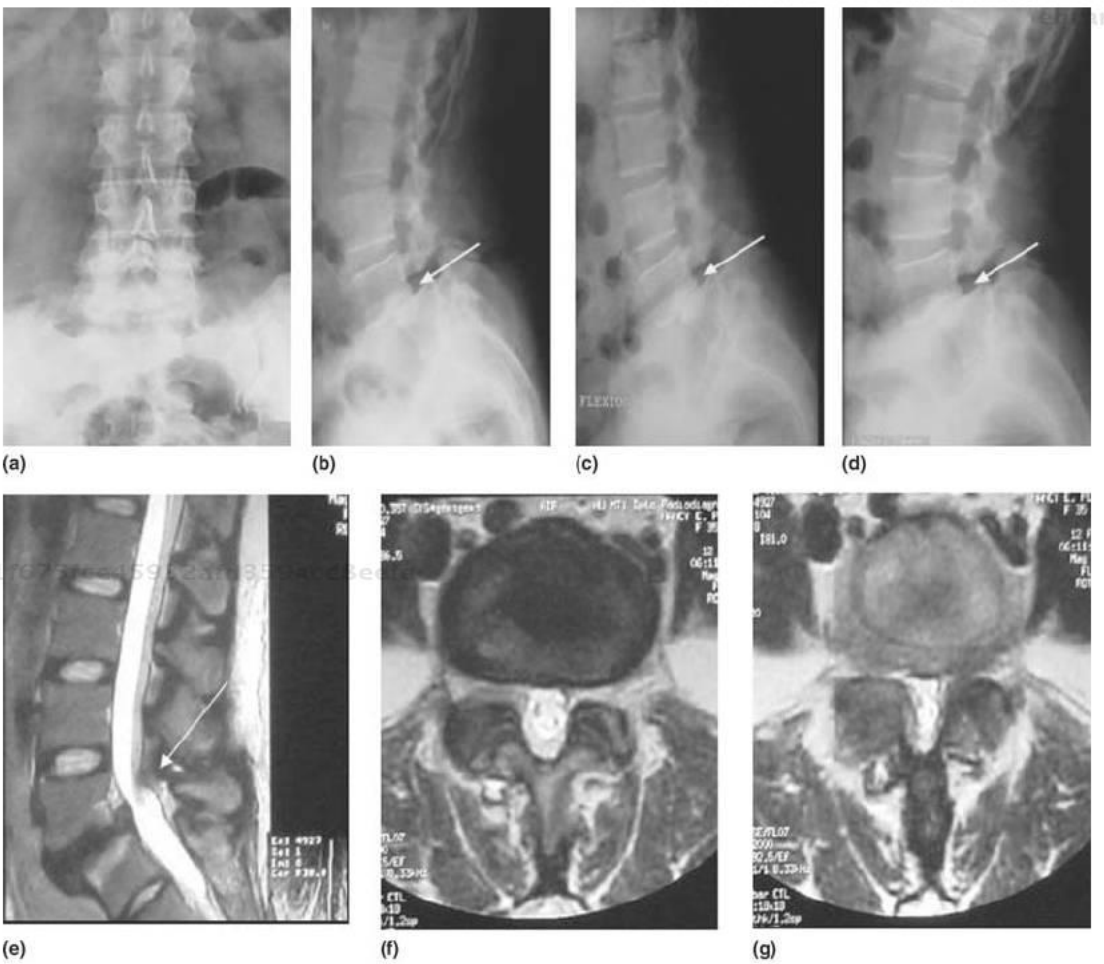
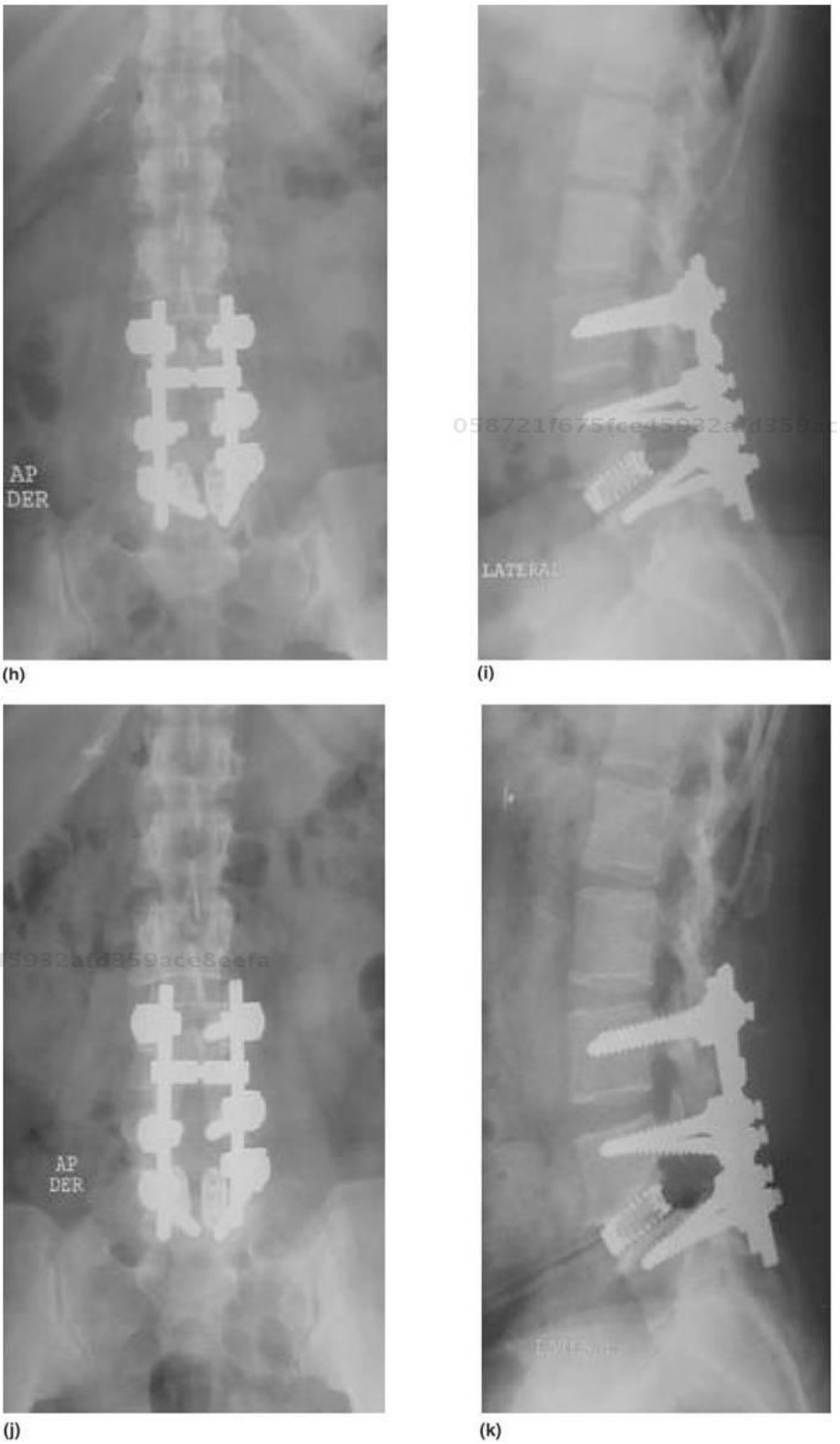


Fig. 8.14 Diagnosis and treatment of isthmic lytic spondylolisthesis. (a) through (d) Presurgical x-rays. Dynamic x-rays in flexion (a) and (c) and extension (b) and (d) show signs of instability with translation of L5 over S1. (e) Sagital T1-weighted magnetic resonance image that shows a narrow spinal canal at the levels of L5–S1. (f) T1-weighted magnetic resonance image that shows a narrow lumbar canal. (g) T2-weighted magnetic resonance image that shows a narrow lumbar canal. (h) and (i) Postoperative x-rays. (j) and (k) Postsurgical x-rays at 2 months. Courtesy of Pedro Martín Reyes-Fernández, M.D.

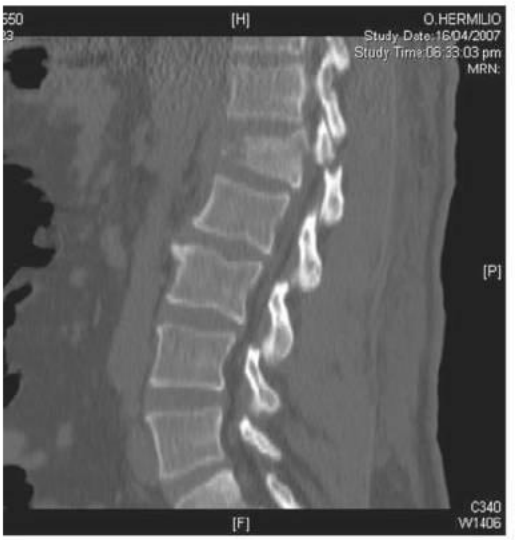


(h) (i) (j) (k)

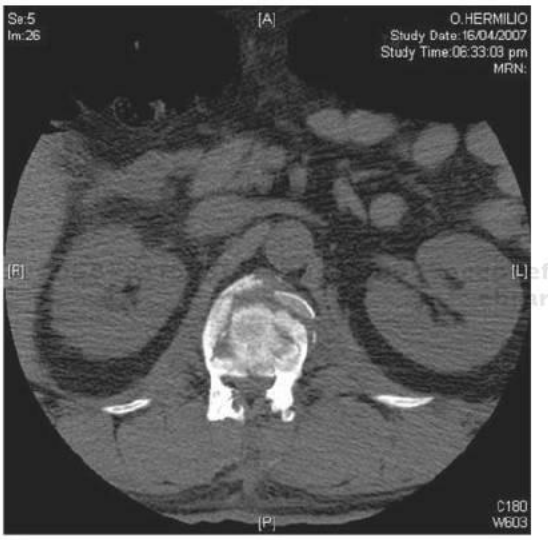
Fig. 8.14 (continued) (h) and (i) Postoperative x-rays. (j) and (k) Postsurgical x-rays at 2 months. Courtesy of Pedro Martín Reyes-Fernández, M.D.

8.15 Spinal Fracture at L1

Patient is 45 years old and experienced an automobile accident. The patient is diagnosed with an L1 fracture classified as Magerl B1 flexion-distraction.



(a)



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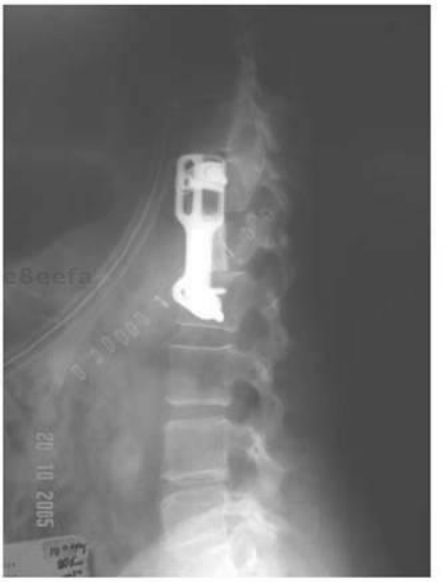


(c)

Fig. 8.15 Treatment of a spinal fracture. (a) L1 fracture classified as Magerl B1 flexion distraction. (b) Cross-sectional slice where comminution of the body of L1 is observed with a 50% invasion of the canal. (c) Anterior decompression, application of bone graft and plate stabilization was performed. Courtesy of Oscar F Mendoza-Lemus, M.D.

CHAPTER 9

Failures Modes of Implants

Orthopaedic devices within the human body interact with several intrinsic body agents, such as soft and hard tissues, intracellular and extracellular body fluids, blood, and so forth. The interactions of these agents with different types of implant materials (metal, plastic, ceramic, and bone cement among others) have a direct influence on the implant failures and different local and systemic biological effects.

This chapter considers some of the more common failure modes of implants, such as implant wear, aseptic loosening, fatigue, and corrosion. The main characteristics of an orthopaedic device include biocompatibility, mechanical properties, wear resistance, and corrosion resistance. Equally important are design, surface treatments, and processing. A great deal of research goes into the evaluation of implant designs and the manufacturing processes.

9.1 Biomaterial Interactions

9.1.1 Fatigue

For implants used in orthopaedic surgery that are continually put under alternating stresses, it is important to determine the experimental strength of fatigue in order to understand the magnitude of this failure on implants.

In fatigue type of failure, there is usually a time competition between the time it takes for the bone fracture to consolidate versus the time it takes the implant to fail by fatigue. See Fig. 9.1.

Fatigue failures of the metallic implants begin as a small crack that increases continuously as a result of the repeated applications of alternating stresses. As the crack increases, the cross-sectional area that supports the load decreases; therefore, the supported stresses increase until the remaining cross-sectional area no longer supports the stresses and the fracture takes place.

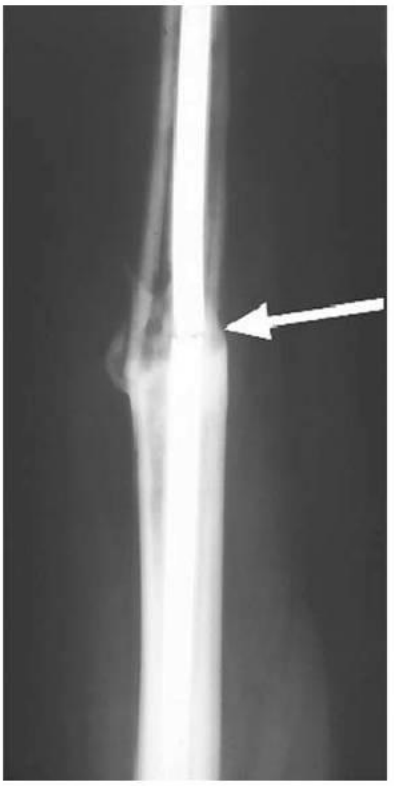


Fig. 9.1 Arthrodesis of the knee after resection of a giant cells tumor in a 32-year-old male with good bone consolidation and subsequent failure of a long intramedullary nail. Courtesy of Rafael Briseño-Navarro M.D.

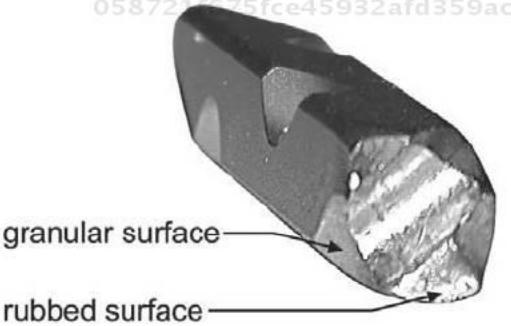


Fig. 9.2 Fatigue fracture of an intramedullary nail

Fatigue failure does not send a warning signal. This failure is a brittle fracture that may be recognized in two regions:

- *Rubbed Surface*. The shining effect is caused by the constant rubbing between surfaces before the fracture; as the fracture extends, the rest of the cross-sectional area cannot support the load and the metallic biomaterial fails by fatigue. The shining area usually indicates brittle fracture. The fatigue cracks spread in a stop-and-go mode, manifested by fatigue arrest lines, observable under a microscope as a result. The fracture surface resulting from fatigue appears rough.
- *Granular Surface*. The rubbed and granular surfaces at the failure area are observed in Fig. 9.2.

9.1.2 Corrosion

Corrosion is an important factor in application of metallic biomaterials. Corrosion is an electrochemical process equivalent to an electron exchange (such as that which occurs in a galvanic cell). Ceramic and polymer materials are

not susceptible to electrochemical corrosion. In the human body there are ionic compounds of extracellular fluids (plasma and interstitial fluids) and intracellular fluids (Ref 1). Weisman (Ref 2) published that the medium (the human body) essentially contains isotonic sodium chloride solution at a concentration of 0.9% of the weight of the medium.

In some cases, orthopaedic devices are protected from body fluids:

- The system of plate and screws used in osteosynthesis, where the parts of the set that are in contact correspond to the low concentration of oxygen and therefore are anodic.
- The modular design of the total hip replacements particularly in the metal-on-metal conical taper connection (Ref 3).

Test methods include:

ASTM F Standards for Corrosion of Metallic Surgical Implant Materials

- ASTM F 746 "Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials"
- ASTM F 897 "Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws"
- ASTM F 1089 "Standard Test Method for Corrosion of Surgical Instruments"

ISO Standards for Corrosion of Metallic Surgical Implant Materials

- ISO 16428:2005 "Implants for Surgery—Test Solutions and Environmental Conditions for Static and Dynamic Corrosion Tests on Implantable Materials and Medical Devices"
- ISO 16429:2004 "Implants for Surgery—Measurement of Open-Circuit Potential to Assess Corrosion Behavior of Metallic Implantable Materials and Medical Devices over Extended Time Periods"

Classic Galvanic Cell. Electrochemical reactions cause electron movement. They are the main origin of corrosion. In electrochemical reactions, the energy of a chemical reaction is converted into electrical energy. These energy conversions occur in what is known as galvanic or voltaic cells, named after Luigi Galvani (1737–1798) and Alessandro Volta (1745–1827), who established the fundamental principles of the galvanic cells. The physical quantity, electrical potential, can be measured in joules/coulomb and is called volt in honor of the Italian scientist Alessandro Volta.

Electrochemical reactions occur between metallic solids and liquids (aqueous solutions called electrolytic solutions, containing ions). The best known are aqueous saline solutions. In a galvanic cell, two different types of reactions occur on the electrodes: oxidation (anodic) and reduction (cathodic). See Fig. 9.3. This type of cell involves two unlike electrodes where one electrode is the cathode and the other electrode is the anode.

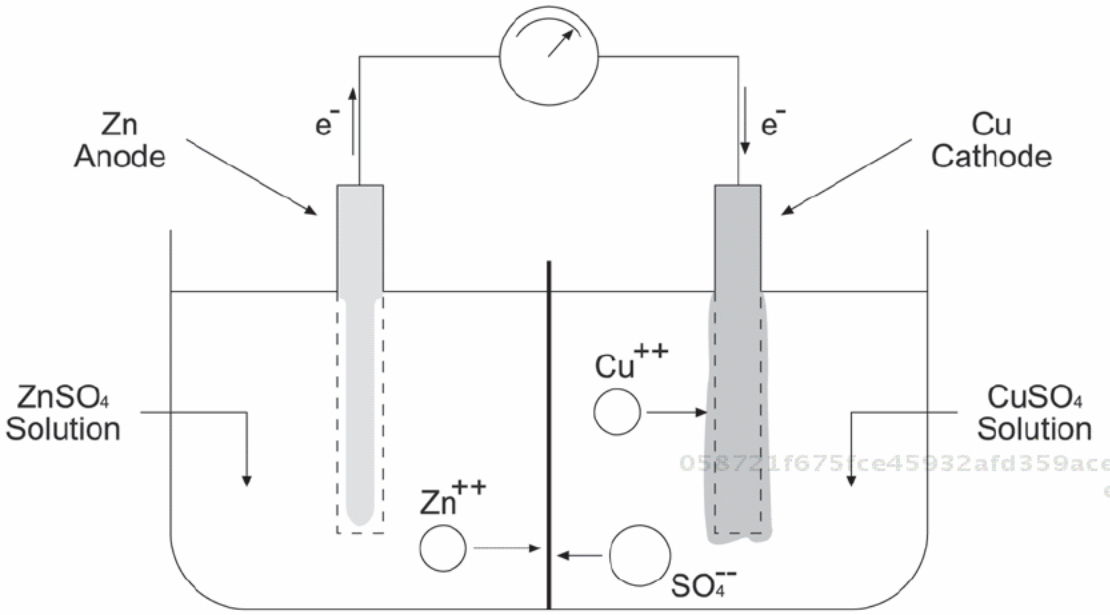


Fig. 9.3 Classic galvanic cell

Consider the following oxidation-reduction reactions as noted in Fig. 9.3. The oxidation (anodic) reaction is:

$$Zn(s) \rightarrow Zn^{2+} + 2e^{-}$$

The Zn^{2+} ions leave out the zinc electrode (anode) in the solution and the electrons travel through the conductor that connects the electrodes. For the reduction (cathodic) reaction, the chemical balance is:

$$Cu^{2+} + 2e^{-} \rightarrow Cu\ (s)$$

The Cu^{2+} ions in the solution are depleted and move toward the copper electrode where the electrons that come from the zinc electrode complete the reaction. The SO_4^{-} anions move toward the anode.

The basis of galvanic corrosion lies in the electric potentials (voltages) of the electrodes. This classification represents an order of the tendencies of dissolution of the chemical elements. According to data of the electrode potentials [25 °C; molar solutions (number of moles of solute per 1000 cm^3 of solution)]:

- $Cu\ (s) \rightarrow Cu^{2+} + 2e^{-}$ yields an oxidation potential of +0.34 V.
- $Zn(s) \rightarrow Zn^{2+} + 2e^{-}$ yields an oxidation potential of −0.76 V.

The voltage between two electrodes (anode and cathode) of any cell is obtained from the algebraic sum of the electrical potentials of the former

elements. The voltage between copper (Cu) and zinc (Zn) as the cathode and anode, respectively, is 1.1 V.

The voltage produced between different electrodes of a galvanic cell depends on the concentration of the electrolyte, the composition of the material (metal and/or alloys) of the electrodes, as well as the ratio of anodic to cathodic areas of the electrodes. The speed at which galvanic corrosion takes place depends on the potential difference between the two metals. The larger the potential difference between the two metallic elements, the greater the speed of the corrosion process.

9.1.2.1 Types of Electrochemical Corrosion Within the Human Body. As an example, consider the case of an internal fracture fixation where a low-carbon grade austenitic stainless steel (316L) plate is fastened to the bone with titanium screws with body fluids acting as the electrochemical solution. The titanium plays the role of a cathode and the 316L austenitic stainless steel the role of an anode. Another case may be when an austenitic stainless steel wire is in contact with any metallic alloy implant other than the austenitic stainless steel. Other corrosion types also take place.

9.1.2.2 Pitting Corrosion Case of a 316L Stainless Steel Plate. This type of corrosion is observed as a localized attack on various parts of a metallic surface. This process is autocatalytic since the oxygen content in the area where the corrosive process takes place decreases, causing an increase in the corrosion ratio. This localized attack results in small pits that in many cases are easily identifiable. The intensity of the propagation of corrosion is increased because the pits act as sacrificial anodes. See Fig. 9.4(a) to (d).

Decreasing the oxygen content in the pit causes potential differences between the pit, which is the anode, and outside surface, which is the cathode. The area ratio of large cathode and small anode further accelerate the corrosion process.

9.1.2.3 Intergranular Corrosion. The 316L austenitic stainless steels used mainly for implants in traumatology require low carbon content (0.03% max). When the carbon content is exceeded, then chromium carbides $M_{23}C_6$ (black dots) precipitate at the grain boundaries. The narrow band formed at the grain boundary represents chrome depletion, leaving a sensitization area along the grain boundary that is susceptible to intergranular corrosion. See Fig. 9.5.

In cobalt base alloys, intergranular corrosion has been observed (Ref 3). Proper heat treatment can eliminate grain-boundary precipitation and hence intergranular corrosion.

9.1.2.4 Stress Corrosion. An example of this type of corrosion is when cold-worked metallic implants are not homogeneous. The distortion zones act as anodes, and the zones that are free of stress act as cathodes. Stress corrosion also happens when the implants are scratched or are exceeded in bending, creating zones of distortion. See Fig. 9.6(a) and (b).

9.1.2.5 Uniform Chemical Attack. From an electrochemical viewpoint, oxidation and reduction reactions can occur at random on the entire

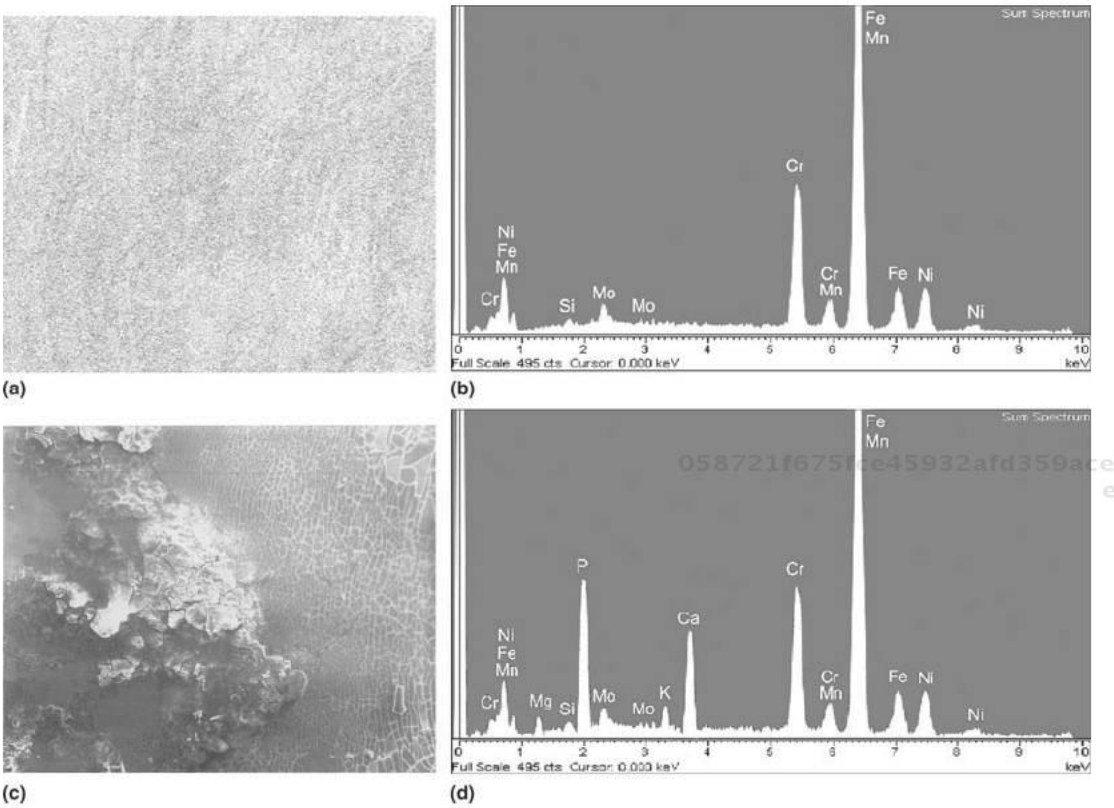


Fig. 9.4 (a) Micrograph from a scanning electron microscope of an implant (plate) of austenitic 316L stainless steel. Original magnification: 100×. (b) Spectrum from the analysis of the elements of the implant (plate) of 316L austenitic stainless steel, iron (Fe), chrome (Cr), nickel (Ni), molybdenum (Mo), manganese (Mn), and silicon (Si). An energy-dispersive x-ray analyzer (EDXA) was used. (c) Micrograph from a scanning electron microscope that shows pitting corrosion in an implant (plate) of 316L austenitic stainless steel, in the micrograph a cracked surface ("mud cracks") are observed. Original magnification: 100×. (d) Spectrum analysis of pitting corrosion shows the following elements: phosphorous (P), calcium (Ca), potassium (K), magnesium (Mg), and the elements of the 316L austenitic stainless steel implant (plate). An energy-dispersive x-ray analyzer (EDXA) was used.

surface of a metallic biomaterial when it has a heterogeneous structure, whether the metallic biomaterial is a pure metal or an alloy.

9.1.2.6 Fretting Corrosion. This mechanical process of corrosion occurs when two metallic surfaces in contact slide repeatedly under stress. The nullification of this corrosion type is obtained by ensuring the static conditions of the interacting metallic surfaces.

One case is the use of the plate and screw system used in internal fracture fixations. Another case is the taper connections of the modular femoral joint replacements; it seems that the main factor is the angular mismatch between the orifice of the head of the femoral component and the taper of the femoral stem component (Ref 3).

9.1.2.7 Crevice Corrosion. This type of galvanic cell is an oxygen cell. Corrosion takes place when different concentrations of oxygen are

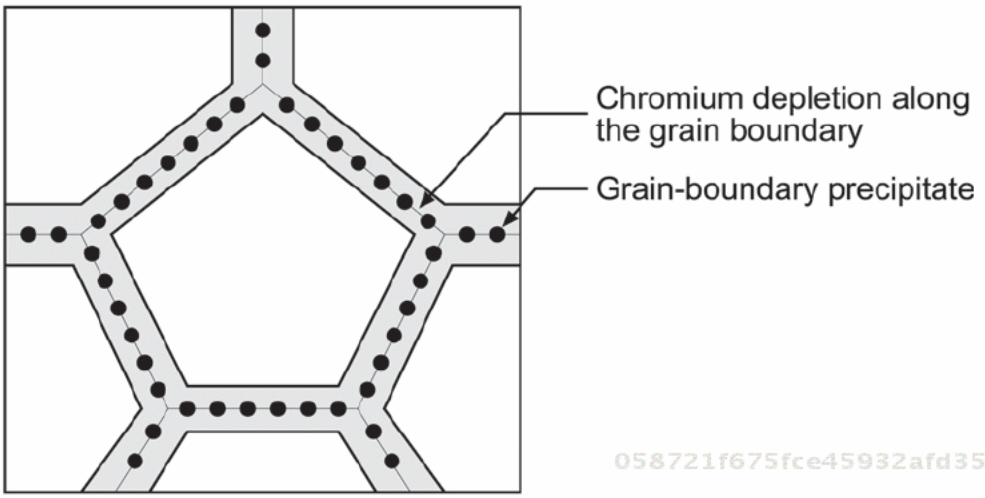


Fig. 9.5 Intergranular corrosion

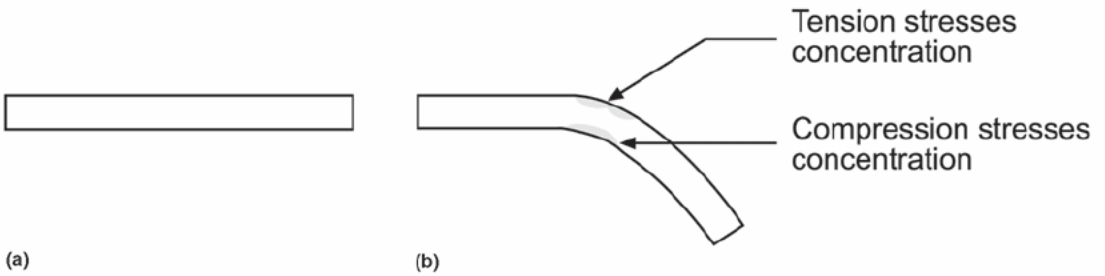


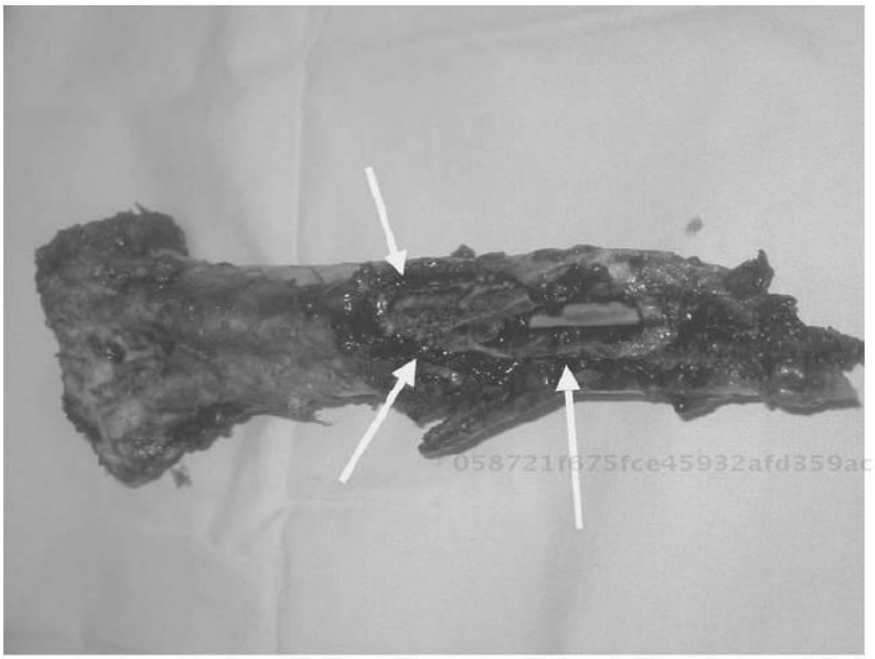
Fig. 9.6 Fixation plate. (a) Plate before bending. Plate after bending

present. Corrosion is produced in lower concentrations of oxygen because this anodic area is not accessible to oxygen.

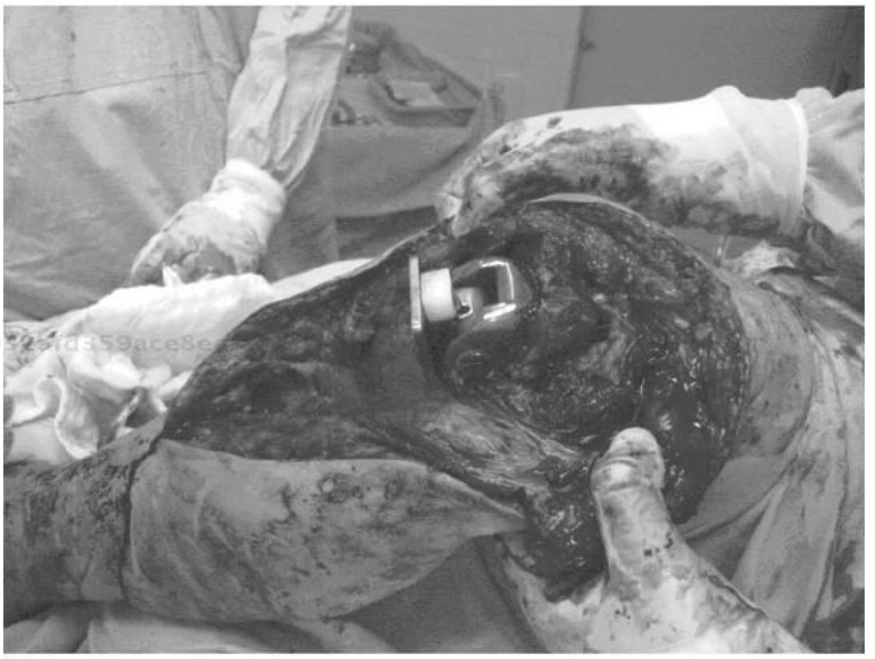
9.1.2.8 Passivation. Some metals and alloys are put under a passive treatment to increase their resistance to corrosion. The process of passivity of metallic materials is carried out when they are exposed to oxidizing agents. The passivity in some active metals that function as alloying elements in orthopaedic devices causes the formation of an oxide film that protects the metallic surface from further anodic reaction. For surface treatment of implants, see ASTM Specification F 86 "Surface Preparation and Marking of Metallic Surgical Implants."

9.1.3 Metallosis

The release of particles and metal ions can originate from orthopaedic devices, and these releases may have local and systemic biologic effects. For example, localized necrosis in areas of the resected proximal femur are observed in Fig. 9.7(a). In Fig. 9.7(b) an extensive periprosthetic necrosis surrounds the prosthetic device.



(a)



(b)

Fig. 9.7 (a) Resection of a proximal femur showing several metallosis areas. (b) Metallosis of a Co-Cr-Mo. Total hip replacement. Courtesy of Carlos Cuervo-Lozano M.D.

Metallosis is defined by Black et al. (Ref 4). See Fig. 9.7. Toxicology data from the elements that composed the metal devices correspond to such elements in soluble forms (Ref 3), which is not the case of the released metallic products coming from the prosthetic devices.

9.1.3.1 Low-Carbon Grade Austenitic Stainless Steel 316L. It was mentioned in Chapter 3 that austenitic structure is also achieved by the addition of manganese/low-nickel to the iron chromium composition to reduce the probability of having nickel ion released.

9.1.3.2 Titanium-Aluminum-Vanadium Alloy: Ti-6Al-4V. The main purpose of using newer titanium base alloys is to replace aluminum (Al) and vanadium (V) in alpha-beta Ti-6Al-4V, because the Al and V elements may be detrimental to the human body (Ref 5). Newer titanium-base alloys are described in Chapter 3.

9.1.3.3 Cobalt-Chromium-Molybdenum Alloy: Co-Cr-Mo. The Co-Cr-Mo alloy is used mainly for the modular total and partial hip replacements. Jacobs et al. (Ref 3) analyzed the solid corrosion debris of a good number of these modular types of implants and found as the main product a cobalt-orthophosphate hydrate-rich material.

9.1.4 Quality and Mechanical Handling of Implants

Metallic screws, plates, and nails are currently used for osteosynthesis as well as for joint replacement and spine surgery. Quality and adequate mechanical handling of the implants are two conditions that help prevent implant failures.

In Fig. 9.8 through 9.10 a series of screws failed for several reasons. One failure was the torque applied when the screws were inserted into the bones. To prevent most of these failures, it is necessary to consider the metallic alloy quality and the applied torque to the screw. Figure 9.11 shows a failed nail.

9.1.4.1 Plates. Two cases of plate failure caused by improper preparation of the material are shown in Fig. 9.12 and 9.13. In Fig. 9.12, severe blows are observed on the plate. The plates have hammer blows; they were done with the idea of adapting them to the anatomical shape of the bone. In Fig. 9.13, a semitubular plate was beaten to flatten it. The result shows that the plate was partially fractured before it was used in a surgical intervention. This plate ended up fracturing before consolidation of the bone fracture.

In both cases, the plates were partially fractured before being used in surgical interventions. The plates in both cases ended up fracturing during the patients' recovery period, without achieving fracture consolidation; for this reason the patient had to be operated on again. An austenitic stainless steel 316L plate that is placed with different screw size can be seen in Fig. 9.14. It is important to point out that the three preceding cases (Figs. 9.12, 9.13 and 9.14) of failed plates arrived from out of state hospitals.

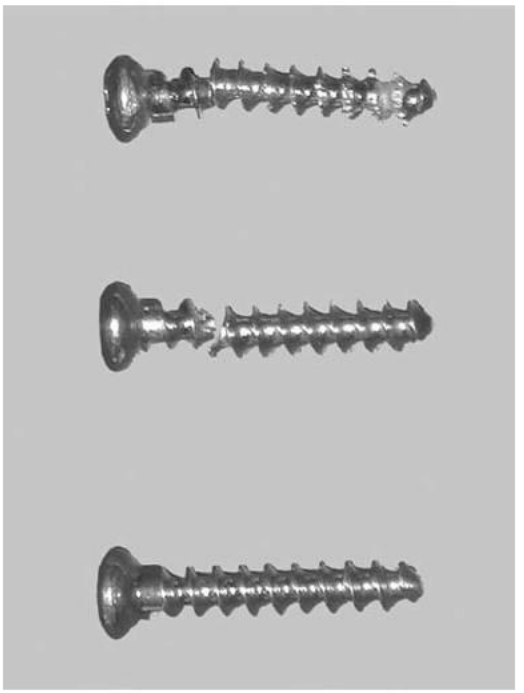


Fig. 9.8 Cortical screw failures

Fig. 9.9 Failure of transpedicular screws

9.2 Some Clinical Results in Follow-up after Total Hip Joint Replacements

9.2.1 Stress Shielding of the Femoral Stem Component

An investigation made by Jacobs and Huggler (Ref 6) indicates the importance of the studies of biomechanics. This is supported by extensive bibliographic literature.

Finite element analysis models have helped in new designs of femoral hip replacements, contributing also to the understanding of the biomechanical role of the orthopaedic device in joint replacement, specifically the hip joint. The prevention of stress shielding is one of the many results of such model studies.

Stress shielding is a purely biomechanical effect because the implant takes part of the mechanical load that should be taken by the bone element. This stress shielding effect causes the bone to diminish its density and consequently shows an increase of the bone porosity around the implant area. Proximal stress shielding may present as localized proximal osteoporosis and bone calcar resorption. Observe the femoral Gruen zones 1 and 7 in Fig. 9.15.

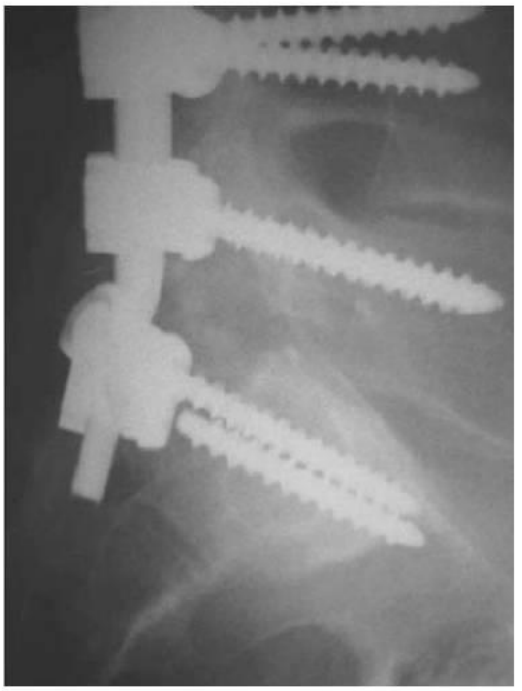


Fig. 9.10 Failure of a transpedicular screw

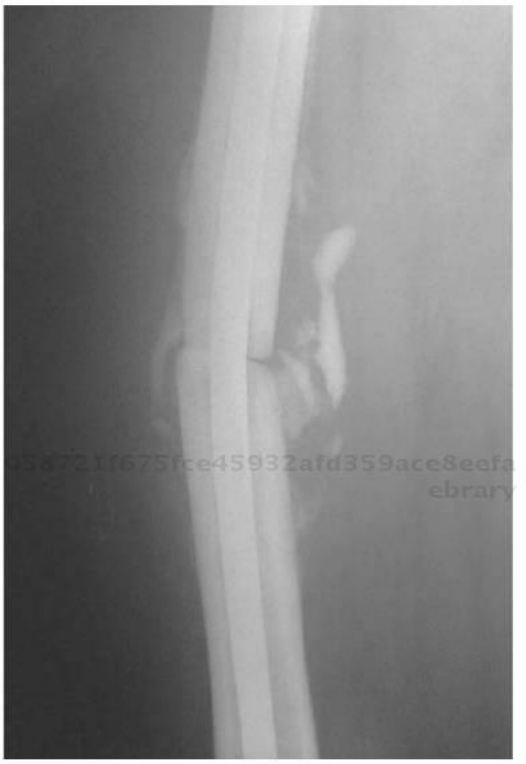


Fig. 9.11 Failure of an intramedullary femoral nail, 32 year-old male, diaphyseal comminuted fracture in the middle third of the right femur

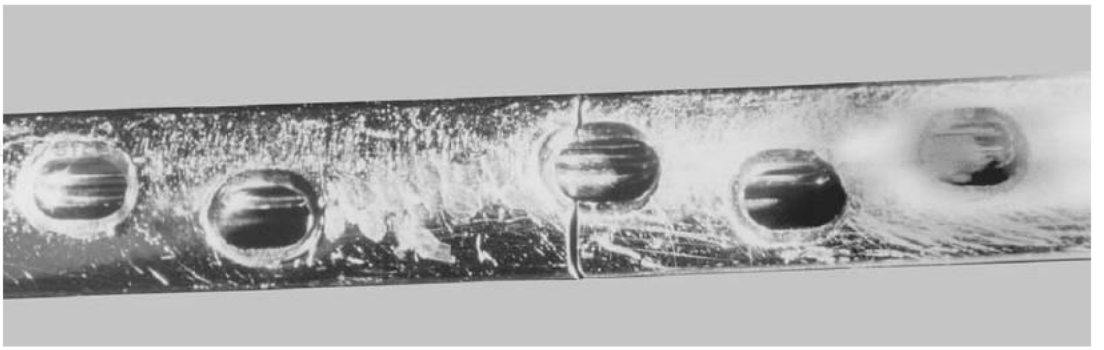


Fig. 9.12 Austenitic stainless steel 316L plate, visibly fractured

Fig. 9.13 Austenitic stainless steel 316L plate with inadequate mechanical handling

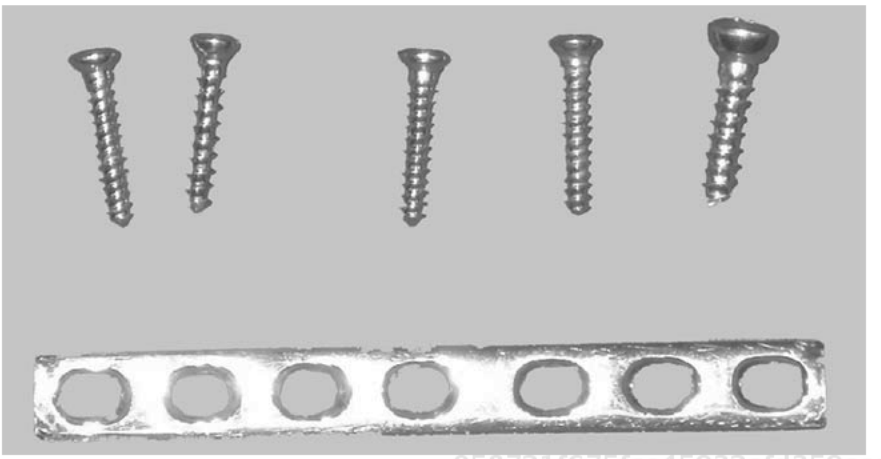


Fig. 9.14 Austenitic stainless steel 316L plate with different size screws

9.2.2 Femoral Stem and Acetabular Femoral Components Loosening

The scientific evolution of cemented stem total hip replacements began with Charnley-type implants. However, because of persistent stem subsidence problems and stem loosening attention was focused on the biological fixation of the stem femoral components mentioned in Chapter 6. This type of cementless femoral component is also prone to stem loosening. Therefore, it is quite obvious to expect different stem-loosening behaviors between the cemented and the cementless femoral stem components.

9.2.2.1 Radiolucency Lines in Cemented Femoral Stem Components. Radiolucency lines along the metal/cement interface describe the loosening of the femoral stem component.

9.2.2.2 Radiolucency Lines in Cementless Femoral Stem Components. Iain Watt et al. (Ref 7) mention the presence of thin radiolucent lines (fibrous tissue) in cementless femoral stem components along the bone/metal interface. The radiolucencies found by radiographies (not shown) can be depicted in the femoral Gruen zones in Fig. 9.15.

9.2.2.3 Mechanical and Aseptic Loosening of the Femoral Stem Components. Mechanical loosening takes place when the femoral component starts to be debonded. An early failure could be one possible cause. Aseptic loosening of cemented femoral component is a major cause of failure because of the presence of wear debris.

9.2.2.4 Variables Affecting Femoral Component Loosening. The failure of the femoral component loosening is multifactorial. The participating variables may come from the following sources:

- *Patient profile:* Gender, age, weight, height, diagnosis, etc.
- *Orthopaedic surgeon:* Surgical technique, bone bed preparation, cement preparation, heat of the polymerization reaction, cement insertion

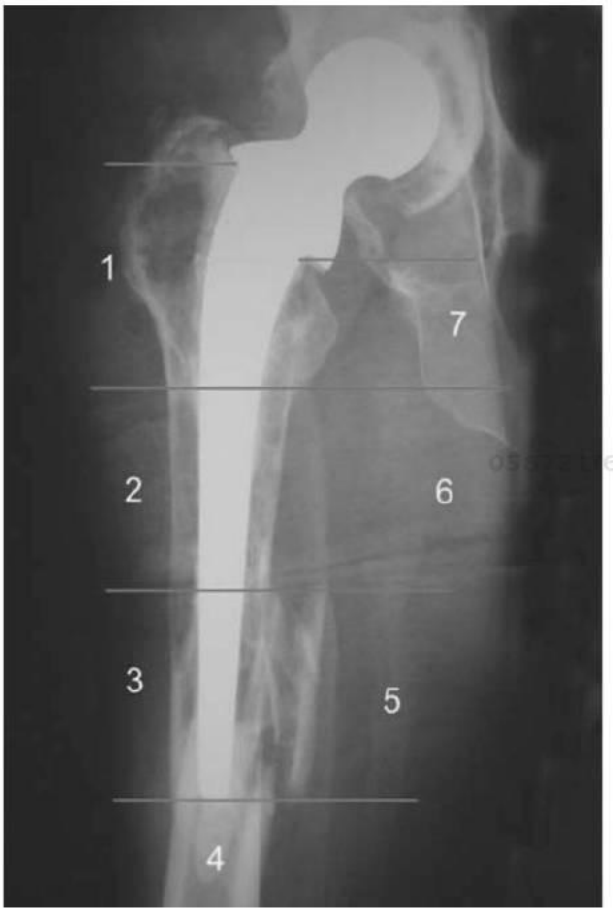


Fig. 9.15 Periprosthetic fracture. Femoral zones according to Gruen. Courtesy of Carlos Cuervo-Lozano M.D.

technique, cement thickness, implant alignment and positioning, initial fixation, etc.

- *Orthopaedic device:* Implant wear, design (tapered, stem geometry, stem length, neck length, CCD angles, etc.) femoral head diameter, surface finish, coatings, hydroxyapatite, fatigue and corrosion resistance, etc.

9.2.2.5 Early Migration Measurements of Femoral Stem Components. There are two methods to measure the migration of the femoral stems:

- *Vertical migration measurements based on standards radiographs:* Freeman and Plante-Borderneuve (Ref 8) measured the vertical migration on standard radiographs of four groups of proximal femoral prosthesis followed up for 9 years.

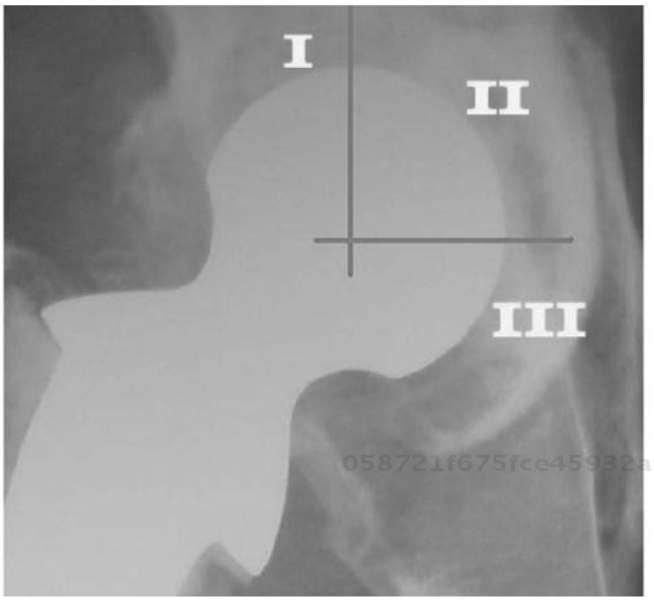


Fig. 9.16 Femoral acetabular zones according to De Lee and Charnley. Loosening of the femoral acetabular component

- *Einsel-Bild-Roentgen-Analyse-Femoral-Component-Analysis:* Krismer et al. (Ref 9) presented the results of a 10-year study for three designs of femoral stems in 240 total hip replacements. They measured the subsidence on standard radiographs and used the EBRA-FCA method to accurately measure the migration patterns. Their results (Ref 9) will help evaluate the current orthopaedic device designs.

9.2.2.6 Acetabular Femoral Component Loosening. The radiolucent zones in acetabular femoral components are defined by De Lee and Charnley. It is quite common to find radiolucencies in zone I (not shown in Fig. 9.16) but not in zones II and III (Ref 7). See Fig. 9.16.

9.2.2.7 Femoral Osteolysis. Periprosthetic osteolysis is the end result of a complicated biological process originated by the presence of wear particles, causing bone loss and thus producing further loosening. It is a progressive disease that needs to be continuously monitored by x-ray evaluation (as required in some cases, every 6 months or annually). The treatment of femoral osteolysis for cemented and cementless stem femoral components is well discussed (Ref 10).

9.2.2.8 Acetabular Osteolysis. One classification system for the acetabular osteolysis is given by Paprosky (Ref 10). This system considers the cemented and the cementless cups. For the cemented cup, the loose and stable conditions are the initial considerations. For the cementless cup the initial considerations are the three different stable and unstable defect types. The treatment of acetabular osteolysis is also discussed thoroughly in (Ref 10).

9.3 Implant Wear in Hip and Knee Joint Replacements

Tribology is the study of friction, wear, and lubrication of interacting surfaces in motion. In orthopaedic surgery, wear of the bearing surfaces of orthopaedic devices is a topic of considerable study and research, because it is a prominent cause of failure of implants in total joint replacements. Good wear resistance characteristics are achieved with cross-linked polyethylene (Ref 11), where gamma radiation or electron beam radiation induce cross linking along with different processes for thermal stabilization and final sterilization.

9.3.1 Bearing Surface Combinations in Total Hip Replacement

There are four types of hip acetabular femoral component that are used as replacements for bearing surface combinations.

9.3.1.1 Metal-on-Polyethylene. Before the 1990s, ultrahigh molecular weight polyethylene was sterilized in the presence of air using gamma rays from Co-60. It took a number of years to find out that this practice causes deleterious effects and prompt wear of particles of the polyethylene caused by oxidation problems (Ref 12).

The UHMWPE that is air-irradiated with Co-60 gamma rays produce wear particles. At the time of publication of this book, the sterilization using the Co-60 source of gammas is made in the presence of an argon or nitrogen atmosphere.

9.3.1.2 Metal-on-Metal. Problems presented in the preceding method assembly encouraged the use of the metal-on-metal as a bearing surface combination. However, this assembly is prone to corrosion and the release of wearing particles.

9.3.1.3 Ceramic-on-Polyethylene. The advantage of this bearing surface combination is that it is free of corrosion problems, but not free of problems caused by wearing particles.

9.3.1.4 Ceramic-on-Ceramic. This type of bearing surface combination has the same characteristic as the previous assembly; that is, it is not prone to corrosion, but it cannot avoid particle problems induced by wear. However, great achievements have been made in ceramic manufacturing of alumina for prosthetic devices.

9.3.2 Bearing Surface Combinations in Total Knee Replacement

Biomaterials used for knee prosthesis are usually cobalt-chromium alloys or titanium-base alloys. Ultrahigh molecular weight polyethylene (UHMWPE) is used as the bearing surface combination.

9.3.3 Polyethylene Wear in Hip and Knee Joint Replacements

Process modifications have been made to increase the cross-linking of polyethylene, resulting in lower wear rates. The wear rate of the acetabular cup liners is different from the liners on the tibia base plates.

9.3.4 Hip and Knee Simulators

This section describes how research employs MTS servohydraulic-based test systems for wear testing of biomaterials of hip and knee implants.

It is important to direct present and future research to all those areas that affect the working life of the implants. However, new materials and improved manufacturing processes as well as total quality control of implant biomaterials have also made significant contributions enhancing the lifetime of femoral hip replacements. The ideal goal is to provide an implant material for the hip and knee replacements with an ad infinitum working life with no pain, no failures, no revisions, and with complete recovery of the joints.

9.4 Artifacts of Metallic Implants in Magnetic Resonance Imaging (MRI)

Magnetic resonance imaging provides images with good definition of anatomical structures. It is used to depict soft tissues, bone, vascular structures, and lymphatic systems. Magnetic resonance studies are performed without having to invade the patients. There are also interventional procedures that take place with MRI guidance.

For the orthopaedic surgeon, it is very important to know how the patient with a metallic implant may be given MRI studies since metallic implants produce artifacts because of the distortion of the magnetic field gradients.

Patients that are examined by traditional MRI are exposed to three different types of magnetic fields.

- *Static Uniform Magnetic Field:* Typically, the scanner's magnetic field starts from 0.5 up to 3.0 Tesla (1 Tesla = 10,000 Gauss).
- *Radiofrequency Electromagnetic Field:* This field is used to obtain radiofrequency signals coming from the energy release of the protons; these signals are detected by the scanner.
- *Gradient Magnetic Field:* While the scanner is in operation, the application of three orthogonal magnetic gradients allows many images of the anatomical structure.

A widely used magnet type of MRI scanner is the superconductive magnet. Recent developments in high-temperature superconducting (HTS)

coils into low-field MRI scanners result in very high quality images among other advantages.

9.4.1 Magnetic Induction Flux B Related to Magnetic Field Intensity H

Static uniform magnetic field creates a strong magnetic field intensity H on a movable bed that is in the tunnel of the MRI scanner. Consider that the relation between B and H is given by

$$B = \mu_o H \quad \text{(Eq 1)}$$

where B is the magnetic induction field (1 weber/m^2 = 10,000 Gauss = 1 Tesla), H is the magnetic field intensity (ampere per meter), and μ_o is the permeability of free space = $4\pi \times 10^{-7}$ weber/ampere-meter.

Equation 1 is valid for free space (vacuum), that is, in the tunnel of the scanner when there is no material inside the scanner. When material is inside the tunnel of the MRI scanner, Eq 1 becomes

$$B = \mu H \quad \text{(Eq 2)}$$

where μ is the magnetic permeability of the material (weber/amp-m).

9.4.2 Magnetization and Magnetic Susceptibility of Metallic Elements

Metallic orthopaedic devices that are exposed to external magnetic fields show a tendency to align their atomic magnetic dipoles in the direction of the magnetic induction field.

9.4.2.1 Magnetization of Metallic Elements. The degree of alignment of all the magnetic moments per unit volume of the metallic material represents the magnetization vector **M** of such metallic material.

When there is a metallic orthopaedic device within the tunnel of the scanner we may write Eq 1 as:

$$\mathbf{B} = \mu_o (\mathbf{H} + \mathbf{M}) \quad \text{(Eq 3)}$$

The second term in Eq 3 is the contribution of the magnetization vector **M** of the metallic material. The magnetization vector **M** is in direct function of the magnetic field intensity **H**, and the magnetic susceptibility (χ_m) is the constant of proportionality; that is

$$\mathbf{M} = \chi_m \mathbf{H} \quad \text{(Eq 4)}$$

9.4.2.2 Magnetic Susceptibility of Metallic Elements. Magnetic susceptibility (χ_m) as defined here is a pure number since **M** and **H** have

the same units. Magnetic Susceptibility (χ_m) represents a quantitative measure of the magnetization **M** for a given metallic material.

From Eq 3 and 4, we obtain:

$$\mathbf{B} = \mu_o (1 + \chi_m) \mathbf{H} \quad \text{(Eq 5)}$$

From Eq 2 and 5 we obtain:

$$\mu = \mu_o (1 + \chi_m) \quad \text{(Eq 6)}$$

9.4.3 Classification of Magnetic Materials

According to theoretical and experimental data, the application of an external magnetic field in metals and/or alloys can be classified as diamagnetic, paramagnetic, and ferromagnetic.

9.4.3.1 Diamagnetic magnetic materials have very small *negative* magnetic susceptibilities. This means that when these materials are put under an external magnetic field, the magnetic induction is weakened, causing the materials to become barely magnetized and in a direction that is opposite to the direction of the external magnetic field; in addition, these susceptibilities are constant and temperature independent. Among the diamagnetic elements are: gold (Au), silver (Ag), zinc (Zn), copper (Cu), and the values of χ_m go from -10^{-6} to -10^{-8}.

9.4.3.2 Paramagnetic materials are characterized by having an unpaired electron spin and are randomly oriented as a result of thermal vibrations. When an external magnetic field is applied to these types of materials, their electron magnetic moments align with the field showing very small *positive* magnetic susceptibilities, resulting in an enhancement of the magnetic induction.

MRI studies are carried out at human body temperature of 37 °C (with ±0.5 °C). The magnetic susceptibilities of these paramagnetic materials decrease as temperature increases, which means that χ_m is not constant.

Among the paramagnetic elements we have: titanium (Ti), aluminum (Al), vanadium (V), chromium (Cr), manganese (Mn), and the values of χ_m go from $+10^{-3}$ to $+10^{-7}$.

Cold working during fabrication of the austenitic stainless steels adds substantial strength to the stainless steel. However, cold working may cause some structural changes from face-centered cubic (fcc) (γ phase) to body-centered cubic (bcc) (α phase), which is ferromagnetic, and thus increase its magnetic susceptibility. In case of an MRI scan, the change of crystal structure from fcc to bcc may enhance the metallic artifact.

9.4.3.3 Ferromagnetic Materials. The phenomenon of ferromagnetism occurs in a unique form of interaction called "exchange coupling." The nature of this interaction is quantum mechanical. It occurs between neighboring atoms of small regions called dominions. In these dominions, their magnetic moments join in such a way that they are parallel aligned.

When an external magnetic field is applied, all the domains are aligned in the same direction as the field; this is called ferromagnetism. The transition elements iron (Fe), cobalt (Co), and nickel (Ni) are ferromagnetic. Gadolinium (Gd) and dysprosium (Dy) are also ferromagnetic.

Gadolinium is toxic in its free state; however when it is chemically linked to diethylene triamine penta-acetic acid (DTPA) it is innocuous and paramagnetic. It is applied intravenously to humans. It was the first contrast material used in magnetic resonance studies in order to increase the accuracy of the images.

The magnetic susceptibility (χ_m) for ferromagnetic materials is *positive, very large,* and *not constant,* showing great variation with the applied magnetic fields. There is not a mathematical function between the magnetic induction B and the magnetic intensity H. However, magnetic susceptibilities may be presented in tables or graphs, meaning that for every value of B and H there is a correspondent value for the magnetic susceptibility (χ_m).

9.4.4 Summary of Magnetic Materials

Let us summarize the magnetic susceptibilities of the different materials:

- For diamagnetic materials χ_m is constant, negative, and very small (-10^{-6} to -10^{-8}).
- For paramagnetic materials χ_m is temperature dependent, positive, and very small ($+10^{-3}$ to $+10^{-7}$).
- For ferromagnetic materials χ_m is not constant; it is positive, and it depends on the strength of the applied magnetic field, which may reach very high values (around 10^4).

Therefore, we understand that very small quantities of ferromagnetic materials produce an effect that is equivalent to a material with a "very large mass" whether it has a diamagnetic or paramagnetic nature.

In general, metallic implants, whether diamagnetic or paramagnetic, do not present problems of artifacts on magnetic resonance images; however, the mass, the form, the orientation, and the location of the metallic implant in the body, whether diamagnetic or paramagnetic, should be considered. In most cases these can be adjusted on the MRI system.

Additionally, it is important to mention that metallic implants experience a small increase in temperature when patients are under MRI studies. Temperature increase in the metallic implants is caused by eddy currents induced by magnetic fields in the system that vary with time.

Recent technological development of software and hardware for the magnetic resonance systems has been very relevant. Images obtained from this new generation of systems such as the MR-3T have sensitively improved their definition, reducing the times of acquisition, providing clear,

high-resolution images for the orthopaedic surgeon, thus allowing for a better follow-up of the patients' evolution.

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EDUCATIONAL OBJECTIVES

1. What are the two most important causes of failures?
2. Are wear problems a function of time or a function of use?
3. Name and explain the main wear modes.
4. How many and what are the bearing surface combinations in THR?
5. Is fatigue an important cause of failure? Explain.
6. What are the different corrosion types?
7. In your own words, explain the artifacts that take place in the MRI studies. Are the metallic artifacts the only ones?
8. Why ferromagnetic materials unacceptable in an MRI scan?

APPENDIX 1

Determination of Composition at a Point in the Iron-Chromium-Nickel Ternary Phase Diagram at 650 °C

The iron-chromium-nickel ternary phase diagram is discussed in Chapter 3 (Fig. 3.1). To read the element compositions at point A as shown in the diagram (Fig. A1.1) let us consider the following procedure:

1. Start at any desired vertex of diagram, where the element composition (chromium, iron, or nickel) is equal to 100%. In this example, we will start with the 100% Cr vertex.
2. Draw a line from 100% Cr down to the center of the Fe-Ni bottom line, perpendicular to the Fe-Ni line. This line represents the range of composition from 100% Cr at the top down to 0% Cr at the bottom.
3. Ten equally spaced parallel lines starting from the bottom line (Fe-Ni), to the Cr vertex cross the perpendicular line. Each line indicates a 10% increment of element composition.
4. This process is repeated from the Fe and Ni vertices to indicate the compositional increments for iron and nickel.
5. Three lines intersect at point A. The line that crosses point A and that is parallel to the bottom (Fe-Ni) line indicates the chromium composition, indicated by the number shown to the right on the Cr-Ni axis. The reading is 10% Cr.
6. By repeating the procedure, it is possible to obtain the compositions of iron and nickel, which are, respectively, 70% Fe and 20% Ni.

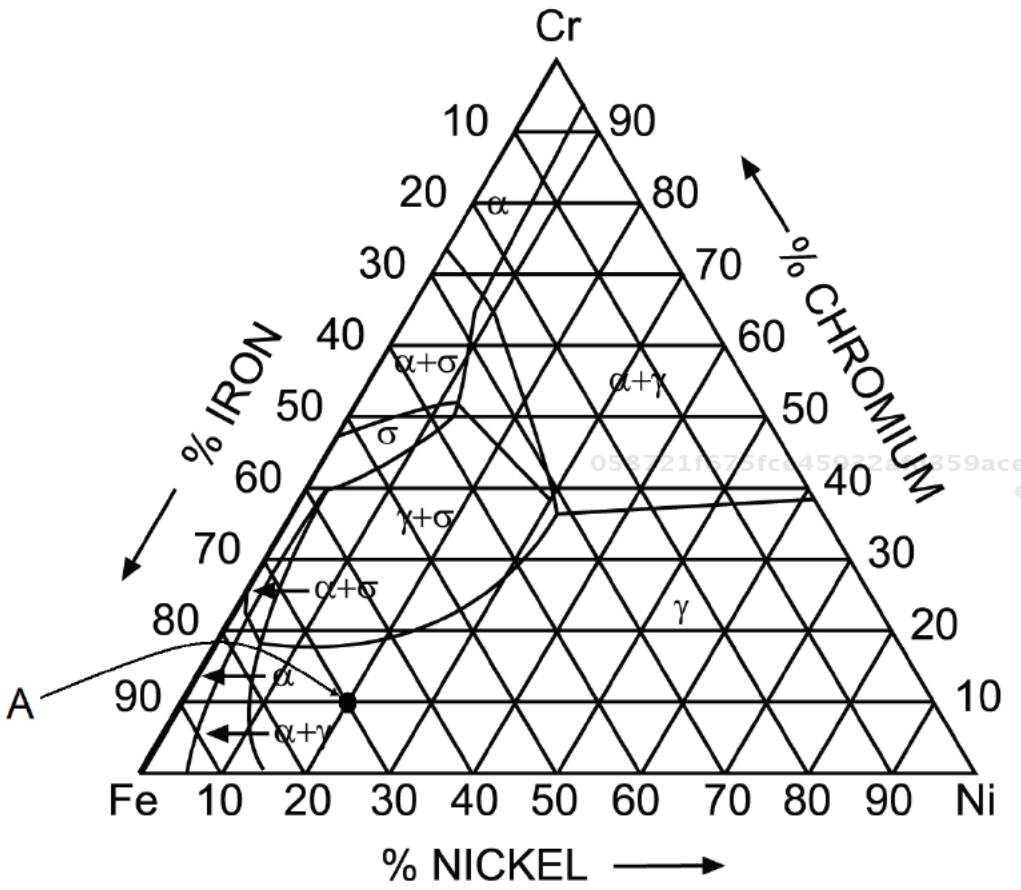

Fig. A1.1 Iron-chromium-nickel ternary alloy phase diagram showing the isothermal section at 650 °C. Source: *Metals Handbook,* 8th ed., Vol 8, *Metallography, Structures, and Phase Diagrams,* American Society for Metals, 1973, p 425

7. Thus the composition at point A in the diagram is 10% Cr, 70% Fe, and 20% Ni.

APPENDIX **2**

The Pythagorean Theorem and Natural Trigonometric Functions

Trigonometric functions help us transform vectors into rectangular components in one plane (x, y) or in space (x, y, z). The right triangle is the fundamental geometric figure to obtain the rectangular components of vectors.

In our daily life, we frequently use inductive reasoning (reasoning based on experience or observation). However, in certain cases, such as problems of geometry, it may be necessary to use deductive reasoning (reasoning that develops a logical consequence from a premise). The truth of the conclusions obtained deductively will depend on the validity of the premises established in the syllogism.

The following examples are quite easy to understand so a simple treatment would be good enough.

The Pythagorean Theorem (Theorem of Pythagoras) addresses the relation among the three sides of a right triangle (Fig. A2.1). It states:

In any right triangle, the area of the square whose side is the hypotenuse (the side opposite the right angle or h) is equal to the sum of the areas of the squares whose sides are the two legs (the two sides that meet at a right angle, a and b). Stated in an equation:

$$a^2 + b^2 = h^2$$

Another important characteristic of all triangles is that the sum of the interior angles equal 180°. So for a right triangle, the sum the right internal angle (90°) plus the sum of internal angles is equal to180°:

$$\alpha + \beta + 90° = 180°$$

$$\alpha + \beta = 90°$$

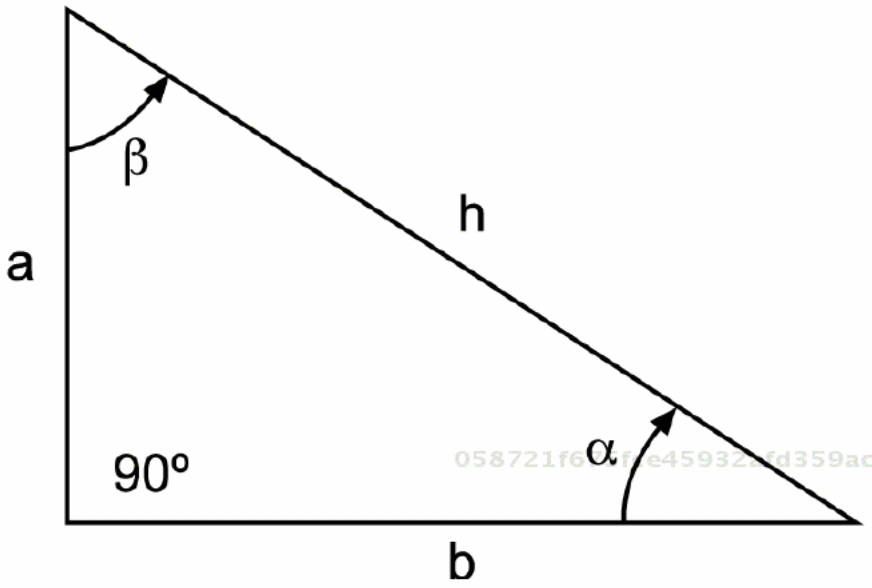

Fig. A2.1 Right triangle

Table A2.1 Trigonometric functions of selected angles

	Angle (α), degrees				
Function	**0°**	**30°**	**45°**	**60°**	**90°**
Sin α	0	½	0.707	0.866	1
Cos α	1	0.866	0.707	1/2	0
Tan α	0	0.577	1	1.73	∞
Cot α	∞	1.73	1	0.577	0
Sec α	1	1.15	1.414	2	∞
Csc α	∞	2	1.414	1.15	1

Trigonometric Functions. The value of the ratio of the sides of a right triangle depends upon the size of the angle and each ratio is named:

Sine α = sin α = side a / hypotenuse = a / h
Cosine α = cos α = side b / hypotenuse = b / h
Tangent α = tan α = side a / side b = a / b
Cotangent α = cot α = side b / side a = b / a
Secant a = sec a = hypotenuse / side b = h / b
Cosecant α = csc α = hypotenuse / side a = h / a

There are some useful right triangles whose trig functions are easy to remember or calculate from the Pythagorean Theorem, such as the 30° −60°−90° triangle and the 45° right triangle. Then if you can imagine the extreme cases of angle α being as small as it can be (0°), or growing to 90°; the values of the trig functions are as given in Table A2.1.

Angle measure. The size of angles can be express in degrees or in radians. Their relation is:

1 radian = 360° / 2π
360° = 2π radians = 6.28 radians
I80° = π radians = 3.14 radians
90° = π / 2 radians = 1.57 radians

APPENDIX **3**

International (SI) Units for Force, Area, and Stress

Stress can be defined as the intensity of the internally distributed forces or components of forces that resist a change in the volume or shape of a material that is or has been subjected to external forces. Stress is expressed in force per unit area and is calculated on the basis of the original dimensions of the cross section of the specimen.

This appendix is a brief guide (Table A3.1) to units for force, area, and stress as defined by the Système International d'Unités (SI). The purpose of SI units, developed and maintained by the General Conference of Weights and Measures, is to provide a basis for worldwide standardization of units and measure. The General Conference of Weights and Measures is a formal diplomatic organization. One may still find data expressed in customary (English) units, so these are included. The equivalence of the units is given in Table A3.2

Some conventions call for expressing units of force in kilograms (kgf). The following approximation can be made between the kilogram force and the Newton:

$$1 \text{ kgf} \approx 10 \text{ N}$$

A more precise conversion is 1 kgf = 9.80665 N at sea level.

Table A3.1 Units of stress

System	Force (*F*)	Area (*A*)	Stress (*F*/*A*)
SI units	Newton (N)	Square meter (m^2)	1 N/m^2 = 1 Pascal (Pa)
Customary (English) units	Pound (lb)	Square inch ($in.^2$)	1 $lb/in.^2$ = 1 psi

Table A3.2 Relation of units of stress

Equivalence between the two systems	Multiples
$1\ Pa = 0.145 \times 10^{-3}$ psi	1 Megapascal (MPa) = 10^6 Pa
	1 Gigapascal (GPa) = 10^9 Pa
$1\ psi = 6.895 \times 10^3$ Pa	1 ksi = 1000 psi

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