Introduction to Biomaterials
BMS 3100C

Monday: 10:30-12:45
Wednesday: 10:30-12:45

Office hours: M, W: 09:30-10:30
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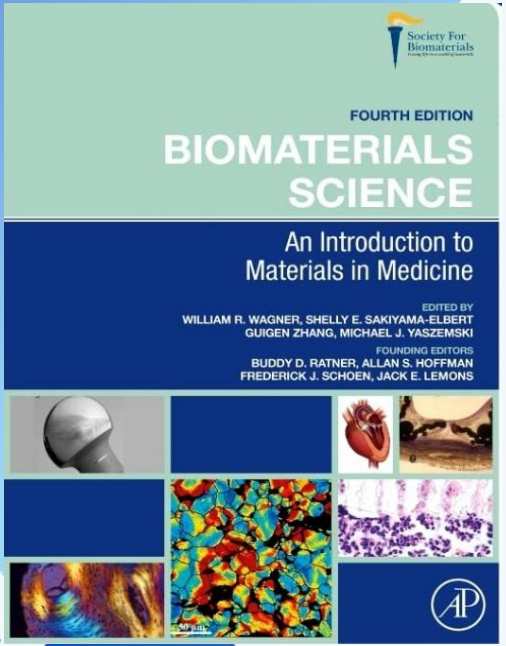


Recommended

Introduction to Biomaterials Science

An Evolving, Multidisciplinary Endeavor

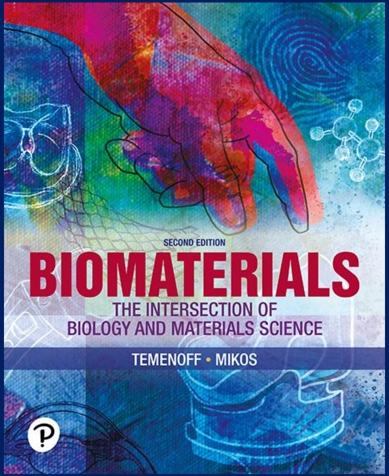
Authored by Buddy D. Ratner, Allan S. Hoffman, Frederick J. Schoen, Jack E. Lemons, William R. Wagner, Shelly E. Sakiyama-Elbert, Guigen Zhang, Michael J. Yaszemski

Affiliations include University of Washington, Brigham and Women's Hospital/Harvard Medical School, University of Alabama at Birmingham, University of Pittsburgh, The University of Texas at Austin, and Mayo Clinic College of Medicine.

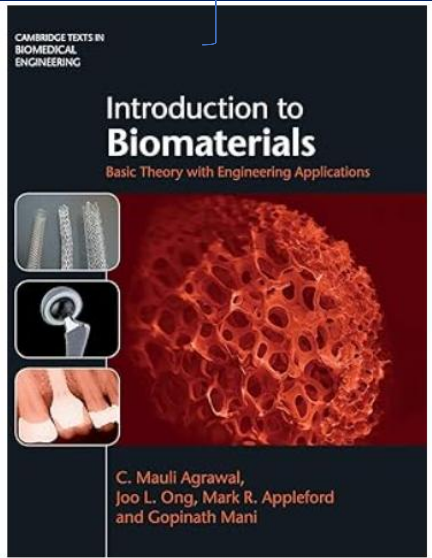
Other Books:

Peer reviewed Scientific Journal articles
-PubMed
-Web of Science
-Scientific Publishers, APS, ACS, AIChE, MRS, BMES

Biomaterials: The Intersection of Biology and Materials Science
Second Edition

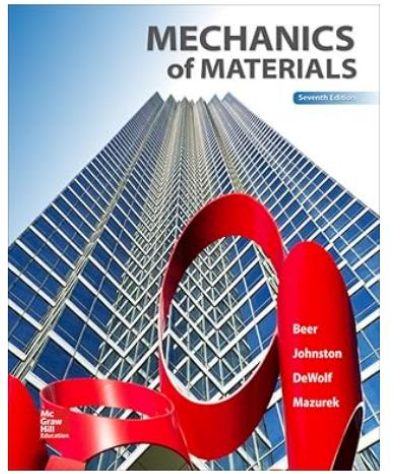


Introduction to Biomaterials: Basic Theory with Engineering Applications (Cambridge Texts in Biomedical Engineering) 1st Edition
by C. Mauli Agrawal (Author), Joo L. Ong (Author), Mark R. Appleford (Author), Gopinath Mani (Author)



Mechanics of Materials
by
Beer, Johnson, DeWolf, Mazurek

- 7^{th} or 8^{th} Edition



GRADING & COURSE ACTIVITIES

Grading for this course is expected to include in-class activities and exercises, quizzes on CANVAS & during class, homework, an individual semester project; 2 midterm exams and final exam. The following weighting of grades will be used, at the instructors' discretion this scale may be expanded (grade thresholds lowered) but will not be tightened.

Grading Scale:

≥ 95.0 A	≥ 90.0 A-	
≥ 86.6 B+	≥ 83.3 B	≥ 80.0 B-
≥ 75.5 C+	≥ 70.0 C*	
≥ 60.0 D		
≥ 50.0 F		

***C or better is required to advance**

Assignment Weights:

Quizzes	15%
2 Midterms (15% each)	30%
In-Class Activities	10%
Biomaterials Term Project	20%
Final Exam	25%

Late Submissions: Most work will be submitted online through Canvas. Late submissions of either paper or electronic format may not be accepted, or may result in a penalty. Your written work may be electronically tested for plagiarized content.

Do not duplicate another person's work or allow another student to duplicate your work, this will result in a failing grade for the course and other disciplinary actions may be taken.

Midterm & Final Exam:

Exams will focus assessment of learning from assigned readings, homework, and class discussions/exercises. Since the expected learning outcomes are to synthesize, evaluate, and apply the components and tools of product design, exams will typically include variety of question types, from multiple choice to long-format essay responses.

Unless stated otherwise, exams will be closed book and closed notes. The only materials allowed on the desktop during an exam are writing instruments, straight-edges (ruler, etc.), calculators and any materials provided by the instructor. All other materials (cell phones, etc.) must be placed under the desk during the exam.

Once an exam begins, students may not leave the room (i.e. restroom breaks, etc.) without approval of the instructor, until they have completed and submitted the exam.

Quizzes:

Quizzes are designed to be a reminder and encouragement to read the assigned materials prior to each class, as class discussion will be livelier and more meaningful when you are prepared.

Quizzes will be based on the reading assignments from the textbook or any handouts assigned as readings and are meant to highlight the important concepts/topics in each chapter.

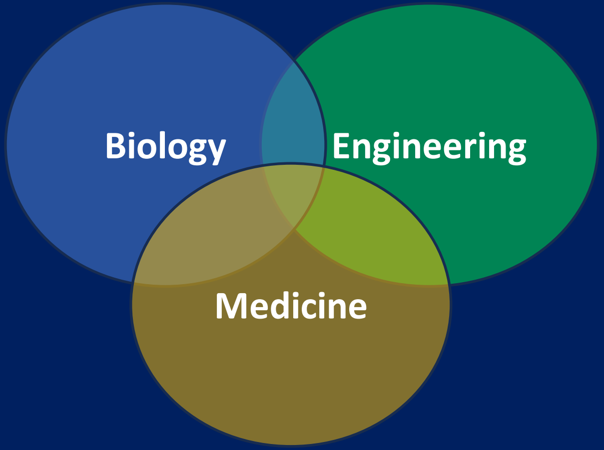
Quizzes will typically be due before class. No makeup quizzes will be given. If a quiz is missed due to a valid medical or family emergency, the overall quiz grade will be based on average of your other quizzes.

Biomaterials Term Project:

Students will select a engineered biomaterial & topic area. Once selected, this is will become the main focus of the term project for the first half of the course. All topics covered in class will be related by students back to their biomaterial , and students will become intimately aware of the process and utilization of the biomaterial.

Students will partner on a biomaterial as they investigate the details and jointly prepare the project portfolio. Students will benefit from classroom discussions about the various biomaterials. The project includes a product ‘portfolio’ detailing the manufacturing process associated with the biomaterial and a final poster presentation will be prepared.

The presentation challenge is intended as a fun and creative activity for learning and applying the biomaterials knowledge and as a friendly competition between student teams.



WHAT IS BIENGINEERING ?

Bioengineering is a multidisciplinary science and engineering that applies these principal to biological systems such as developing products that use biological process e.g., pharmaceuticals, food supplement, biomass-based energy (agriculture), food, environmental protection and so on..

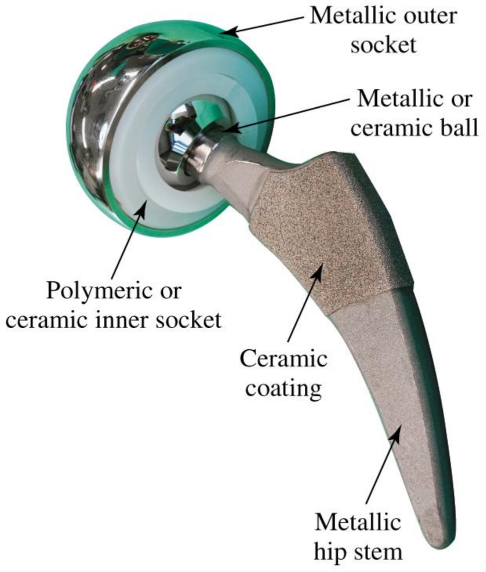
Biomedical engineering on the other hand can be considered as a subset of bioengineering focusing solely on medicine and healthcare by developing medical based devices, diagnostic and therapeutic tools and model physiology System.

Tissue engineering
Neural Implants
Drug delivery devices
DNA expression Arrays

Artificial organs
Pumps
Prosthetics
Artificial veins

Defining Biomaterials Science

Hip implants



Biomaterials Science addresses the design, fabrication, testing, applications, and performance of synthetic and natural materials used in implants, devices, and process equipment that contact biological systems. These materials are called biomaterials.

Millions of lives are saved, and quality of life is improved for millions more through the use of biomaterials.

Defining Biomaterials Science

- Field is 70-80 years old, significantly impacts human health, economy, and various scientific fields.

- Commonly used as prostheses in cardiovascular, orthopedic, dental, ophthalmological, and reconstructive surgery.

- Also used in surgical sutures, bioadhesives, and controlled drug release devices.

Growth is ensured by an aging population, increasing living standards in developing countries, and growing ability to treat untreatable conditions.

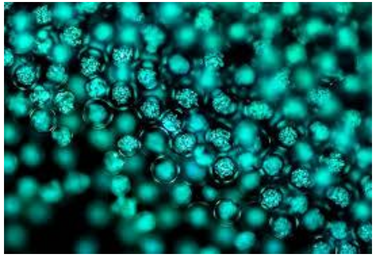
Scope & Objectives of Biomaterials Science

Biomaterials science encompasses basic sciences (biology, chemistry, physics), engineering, and medicine, addressing both therapeutics and diagnostics.

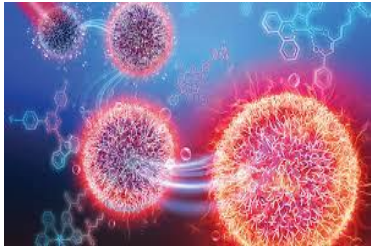
The translation of biomaterials science to clinically important medical devices is dependent on:

- Sound engineering design
- In vitro, animal, and human testing
- Clinical realities
- Industry involvement for product development and commercialization

Scope & Objectives of Biomaterials Science



Modern biomaterials science exemplifies the 'convergence paradigm,' fostering multidisciplinary collaboration and integration.



The aim is to:

(1) focus on scientific and engineering fundamentals;

(2) provide clinical context; and

(3) highlight opportunities and challenges in the field.

Formal Definitions

Biomaterial

"A biomaterial is a nonviable material used in a medical device, intended to interact with biological systems." - Williams (1987)

Removing 'medical' broadens definition; removing 'nonviable' includes tissue engineering and hybrid artificial organs.

Biomaterials Science

The study (from physical and/or biological perspective) of materials with special reference to their interaction with the biological environment.

Biocompatibility

"Biocompatibility is the ability of a material to perform with an appropriate host response in a specific application." - Williams (1987)

- Appropriate host responses: resistance to blood clotting, bacterial colonization, normal healing.
- Specific applications: hemodialysis membrane, urinary catheter, hip joint replacement.

Overview of Definitions

A biomaterial is the substance used in or on the body, such as metals, polymers, or ceramics, to repair, replace, or enhance tissues and organs.

A biomedical device is the complete instrument or system—which may incorporate biomaterials—used to diagnose, treat, or monitor a medical condition, such as a joint implant, heart valve, or cardiac rhythm stimulator.

In essence, biomaterials are the "building blocks," while biomedical devices are the finished "products" or technologies that use those blocks to achieve a medical purpose.

Overview of Applications & Materials

Biomaterials are rarely used in isolation; they are integrated into devices or implants, often using multiple biomaterials from various classes.

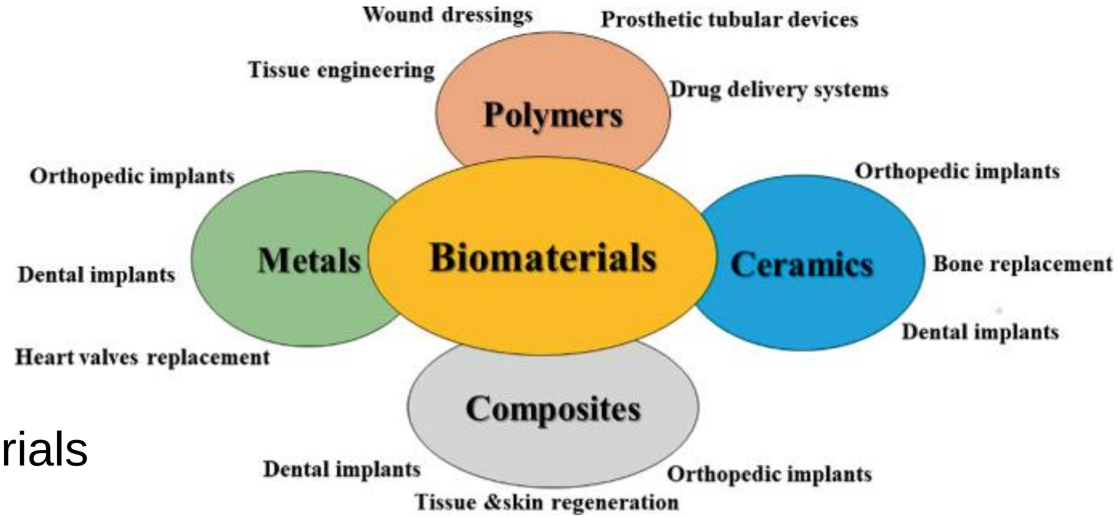
Examples: Chemically pure titanium as a biomaterial, but shaped titanium with polyethylene forms a hip prosthesis.

The subject requires considering biomedical devices and the biological response to them, as material and device impact the patient, and host tissue impacts the device.

Overview of Applications & Materials

Biomaterials must be considered in their final fabricated, sterilized form, as processing can significantly affect performance (e.g., polyurethane casting vs. injection molding).

- Metals
- Ceramics
- Polymers
- Glasses
- Carbons
- Natural and Composite Materials



These materials are used in various forms: molded/machined parts, coatings, fibers, films, membranes, foams, fabrics, and particulates.

Key Applications: Orthopedics & Dentistry

TABLE 1.1.1.1 Key Applications of Synthetic Materials and Modified Natural Materials in Medicine

Application	Biomaterials Used	Number/Year—Global (or Global Market in US$)
Skeletal System		
Joint replacements (hip, knee, and shoulder)	Titanium, CoCr, polyethylene, alumina, zirconia	4,000,000 ($16B)
Trauma fixation devices (plates, screws, pins, and rods)	Titanium, stainless steel, CoCr, polyether ether ketone, poly(lactic acid) (PLA)	1,500,000 ($5.5B)
Spine disks and fusion hardware	Nitinol, titanium, polyether ether ketone, stainless steel	1,100,000 ($8.5B)
Bone defect repair	Calcium phosphates, human bone products	($4.5B)
Bone cement (fixation)	Polymethyl methacrylate (PMMA), glass polyalkenoate (ionomer), calcium phosphate cements	($1.1B)
Cartilage, tendon, or ligament repair and replacement	Decellularized porcine tissue, poly(lactide) and metallic fixation devices, collagen, hyaluronic acid lubricants	($8.6B)
Dental implant-tooth fixation	Titanium, zirconium	10,000,000 ($4B)

Reference: Biomaterials Science;An Introduction to Materials in Medicine. 4th Edition,Wagner, Elbert, Zhang, ISBN: 9780128161388

Key Applications: Cardiovascular & Organ Support

TABLE 1.1.1.1 Key Applications of Synthetic Materials and Modified Natural Materials in Medicine—cont'd

Application	Biomaterials Used	Number/Year—Global (or Global Market in US$)
Cardiovascular System		
Vascular grafts, patches, and endovascular devices (stent grafts)	Dacron, expanded poly(tetrafluoroethylene), Nitinol, CoCr, stainless steel, fixed tissue	($2.5B)
Heart valves: mechanical and bioprosthetic (transcatheter and traditional)	Dacron, carbon, CoCr, fixed bovine and porcine tissue, stainless steel, Nitinol	600,000 ($5.5B)
Pacemakers	Titanium, polyurethane	1,000,000 ($6.5B)
Implantable defibrillators	Titanium, polyurethane	300,000 ($9.0B)
Stents: coronary, peripheral vasculature, and nonvascular	Stainless steel, Nitinol, CoCr, Pt, tantalum, Mg alloys, poly(styrene-*b*-isobutylene-*b*-styrene), poly(*n*-butyl methacrylate), polyethylene-*co*-vinyl acetate, phosphoryl choline containing block copolymers, poly(lactic-*co*-glycolic acid), PLA	5,000,000 ($10.6B)
Catheters: cardiovascular, urologic, and others	Polytetrafluoroethylene (PTFE), poly(vinyl chloride), silicone, polyurethane	($28B)

Reference: Biomaterials Science;An Introduction to Materials in Medicine. 4th Edition,Wagner, Elbert, Zhang, ISBN: 9780128161388

Key Applications: Other Areas

Organs		
Cardiac assist devices (acute and chronic)	Titanium alloy, polycarbonate, PTFE, poly(ethylene terephthalate), stainless steel	($1.7B)
Hemodialysis	Polysulfone, modified cellulose, polyacrylonitrile, polycarbonate, silicone, polyvinylchloride	2,000,000 patients ($12B)
Blood oxygenator	Polymethylpentene, polypropylene, polysiloxane, poly(vinyl chloride), polycarbonate	($300M)
Skin substitute (chronic wounds, burns)	Collagen, cadaver skin, alginate, polyurethane, carboxymethylcellulose, nylon, silicone	($1.3B)
Ophthalmologic		
Contact lens	PMMA, polyhydroxyethylmethacrylate (PHEMA), polyvinyl alcohol, polyvinyl pyrrolidone, silicone (polydimethyl siloxane [PDMS])	($7.5B)
Intraocular lens	PMMA, PDMS, polyacrylate-PMMA, PHEMA	25,000,000 ($4.5B)
Glaucoma drains	Silicone, polypropylene, cross-linked collagen, stainless steel	($500M)

Reference: Biomaterials Science;An Introduction to Materials in Medicine. 4th Edition,Wagner, Elbert, Zhang,   ISBN: 9780128161388

Key Applications: Other Areas

Other		
Cochlear prostheses	Platinum, platinum–iridium, PDMS, titanium, aluminum oxide	45,000 ($2.7B)
Breast implants	PDMS	3,600,000 ($1.2B)
Hernia and body wall repair meshes	Polypropylene, polyester, expanded PTFE, decellularized porcine/bovine tissue	($4.2B)
Sutures	Silk, nylon, poly(glycolic acid), PLA, polydioxanone, polyester copolymers, polypropylene, PTFE, processed bovine tissue	($3.9B)
Blood bags	Poly(vinyl chloride)	($170M)
Ear tubes (tympanostomy)	Silicone, PTFE	1,500,000 ($70M)
Intrauterine device	Polyethylene, copper, stainless steel, PDMS	168,000,000 ($2.9B)

Data compiled from multiple sources—these numbers should be considered rough estimates that are changing with growing markets and new technologies. Where only US numbers were available, world usage was estimated at approximately 2.5× US. *B*, Billion; *M*, million.

Reference: Biomaterials Science;An Introduction to Materials in Medicine. 4th Edition,Wagner, Elbert, Zhang, ISBN: 9780128161388

Medical Device Market Overview

TABLE 1.1.1.2 The Medical Device Global Market by Segment With Projected Compound Annual Growth Rate (CAGR) ($ Millions)

Segments	2016	2017	2022	CAGR 2017–2022 (%)
Drug delivery devices	200,072	207,814	243,367	3.2
Urology and renal	75,378	82,668	109,003	5.7
In vitro diagnostics	66,143	72,816	99,357	6.4
Orthopedics and spine	65,756	72,086	99,559	6.7
Imaging devices	41,194	45,816	64,282	7.0
Cardiovascular devices	25,384	29,658	45,260	8.8
Endoscopy	9,573	10,372	13,693	5.7
Total	483,500	521,230	674,521	5.3

Source: BCC Research.

Reference: Biomaterials Science;An Introduction to Materials in Medicine. 4th Edition,Wagner, Elbert, Zhang, ISBN: 9780128161388

Biomaterials Evolution: Early Approaches

Biomaterials R&D is stimulated by advances in biology, medicine, chemistry, and engineering, contributing to understanding biointerfaces.

Industrial Material Adaptation & Passive Design

Early applications focused on suitable functional properties and 'tolerable' biocompatibility (minimal host response).

Many widely used medical devices today still utilize industrially repurposed materials like PTFE, stainless steel, and polyurethanes.

These 'first-generation' materials, though empirically selected, continue to be central to new revolutionary devices.

Biomaterials Evolution: Designed & Bioactive

Novel Designed Materials

As needs arose, novel materials were designed or refined for biomedical purposes, such as polyurethanes with improved blood compatibility, hydrogels for soft tissues, and pyrolytic carbon for heart valves.

These materials broadened the palette but were still designed for a 'passive' or 'bioinert' response.

Bioactive Materials (1980s Onward)

Developed to elicit controlled reactions for therapeutic effects: bioactive glasses/ceramics, controlled drug release systems (e.g., Norplant), heparin-coated surfaces, and drug-eluting stents.

Includes resorbable polymeric biomaterials with tailored degradation rates, allowing for transient interfaces and replacement by host tissue.

Biomaterials Evolution: Advanced & Remodeling

Engineered Biological Interactions

Leveraging molecular biology, biomaterials scientists engineer specific interactions (e.g., peptide-modified surfaces for cell adhesion, shape-memory polymers, interactive surfaces).

Advanced materials also contribute to fundamental molecular biology understanding (e.g., roles of substrate stiffness, ligand density).

Targeted Systems & Self-Assembly

Innovative particulate systems for targeted drug delivery, gene therapy, and theranostics, often using nano/microscale self-assembling materials.

Self-assembled biomaterials allow nanoscale design for controlled drug release and serve as injectable networks for regenerative medicine, drug delivery, and immunoengineering.

Constructive Remodeling Materials

Designed/processed to facilitate healing with minimal scarring, observed with decellularized animal tissues (e.g., porcine bladder/dermis) that are degraded and replaced by host functional tissue.

Case Study: Heart Valve Prostheses

Heart valve diseases often necessitate replacement; natural valves open/close >40M times/year.

Approximately 4.5 million replacement valves are implanted globally each year.

- Fabricated from carbons, metals, elastomers, plastics, fabrics, and chemically pretreated animal/human tissues.
- Two widely used designs: bileaflet tilting disk mechanical valve and bioprosthetic (porcine xenograft) tissue valve.

While restoring cardiac function, common problems include: blood clots (mechanical valves), degeneration of tissue leaflets, mechanical failure, and infection.

Innovation continues with catheter-based valve designs and tissue-engineering approaches.

Case Study: Total Hip Replacement

Human hip joint endures high mechanical stress, leading to wear out due to cyclic stress or degenerative disease.

- Replacement hip joints are implanted in over 300,000 people annually in the US.
- Materials include titanium, stainless steel, high-strength alloys, ceramics, composites, and ultrahigh molecular weight polyethylene.

Good function is typically restored, sometimes allowing athletic activities (though high-stress activities are not advisable).

Common problems: loosening after 10-15 years (necessitating revision surgery), corrosion and adverse responses to released metal ions with metal-on-metal implants.

Case Studies: Dental Implants & IOLs

Dental Implants

Titanium root form implants revolutionized dental implantology, with 5 million implanted annually in the US.

- Require a tight seal against bacterial invasion where they traverse the gum.
- Attachment is a tight apposition/mechanical fit, not true bonding.
- Problems: loss of tissue support leading to loosening, infection, mechanical issues from cyclic loading.

Intraocular Lenses (IOLs)

Implants replacing clouded eye lenses due to cataracts, fabricated from transparent materials like PMMA, silicone, and acrylics.

Case Study: Ventricular Assist Devices

Nearly 5 million Americans live with congestive heart failure; 50k-100k could benefit from cardiac transplantation or mechanical support.

VADs evolved from experimental concepts to life-prolonging tools, with designs moving from bulky pulsatile pumps to smaller rotary devices.

- Uses: 'bridge' to transplant, permanent support, temporary support.
- Recipients can regain considerable mobility.
- Risks: device-related infection (especially where power line crosses skin), stroke from clots.
- Cost remains a barrier for broad global application despite improved outcomes.

General Insights from Biomaterial Devices

- Widespread implantation with good success, improving quality of life or saving lives.
    - Utilize a broad range of synthetic materials with varied properties.
        - Can interface with nearly all anatomical sites.
    - The body's normal response to foreign bodies is observed.
- Devices commonly encounter problems, concerns, or unintended consequences.
- Most device complications are rooted in biomaterials-tissue interactions.
    - Commercial companies drive manufacturing and bring value to stakeholders.
        - Regulatory agencies assess performance, ensure quality, and protect patients.
            - Each device carries associated ethical and societal issues.

Characteristics: Multidisciplinary & Materials

Multidisciplinary Nature

Biomaterials science brings together researchers from diverse academic and industrial backgrounds, requiring clear communication and integration of complex concepts.

Necessary Steps	Facilitator
Identify a need • Treat a condition • Replace an organ • Cosmetic	• Physician/Dentist • Researcher • Inventor • Entrepreneur
Device Design	• Physician (consults) • Engineer (implements)
Materials Synthesis	• Ceramicist • Metallurgist • Polymer Chemist
Materials testing • Mechanical properties • Toxicology • Bioreaction to the material protein interactions cell activation tissue reaction • Biostability mechanical chemical	• Bioengineer • Mechanical Engineer • Biochemist • Cell biologist • Veterinary surgeon

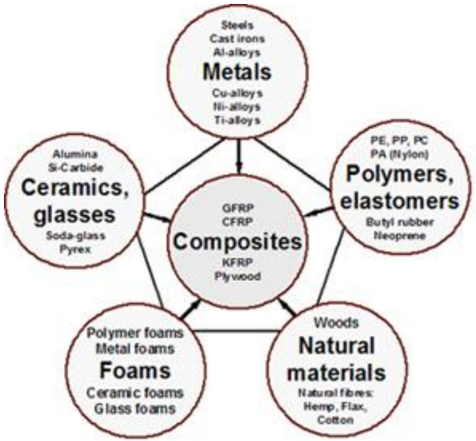
Necessary Steps	Facilitator
Fabrication	• Engineer • Machinist
Sterilization and Packaging	• Bioengineer • Industrial Designer
Device Testing Toxicology In Vitro Biointeraction Animal Testing	• Bioengineer • Veterinary surgeon • Physician/Dentist
Regulatory pre-market approval limited clinical study clinical trials long-term follow-up	• Regulatory Specialist • Regulatory Agency • Legislators
Clinical Use	• Physician • Dentist • Optometrist
Explant Analysis explant registry pathological examination testing to understand failure	• Pathologist • Bioengineer

Reference: Biomaterials Science;An Introduction to Materials in Medicine. 4th Edition,Wagner, Elbert, Zhang,   ISBN: 9780128161388

Characteristics: Multidisciplinary & Materials

Diverse Materials Usage

A biomaterials scientist must appreciate various material classes: polymers, metals, ceramics, glasses, composites, and biological materials.



While specialization is common, a broad understanding of properties and applications across all materials is crucial.

The distinction between 'hard tissue' (metals/ceramics) and 'soft tissue' (polymers) biomaterials is artificial; devices often combine multiple material types (e.g., heart valves, hip joints).

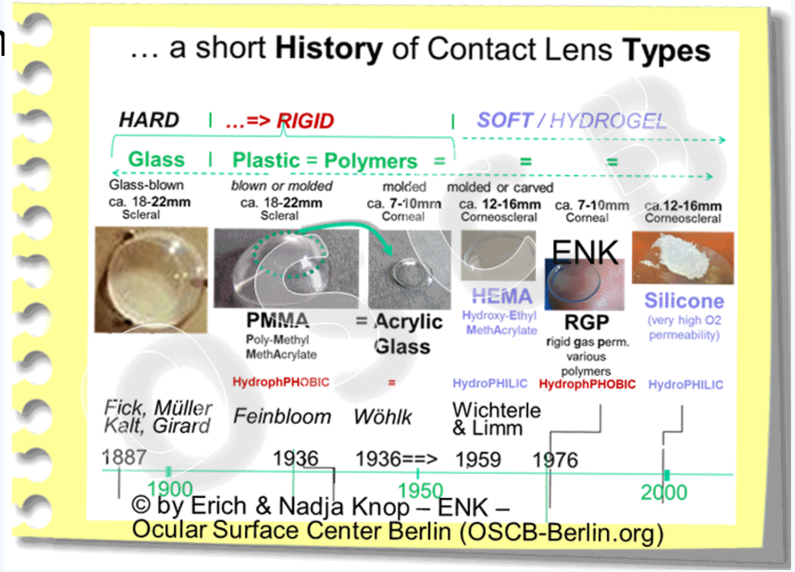
Characteristics: Market & Device Outcomes

Market-Driven Innovation

Biomaterials/medical device innovation is driven by clinical need, with companies playing a crucial role in testing, manufacturing, and commercialization, requiring complex regulatory navigation.

The field's magnitude reflects immense human needs and a sizable, growing commercial market (e.g., hundreds of millions of contact lenses, millions of heart valves/hip prostheses annually).

Devices range from cosmetic (contact lens) to life-saving (heart valve, hydrocephalus shunt), each with varying commercial potential.



Characteristics: Market & Device Outcomes

Success, Failure, and Risk/Benefit

Most biomaterials and devices perform satisfactorily, but all manufactured items have failure rates, influenced by patient variability and physician skill.

- Is the design competent and optimal?
- Who is responsible for inappropriate host responses?
- What are the risk/benefit or cost/benefit ratios?

Despite complications (e.g., heart valve-related issues), the benefit-to-risk ratio is often high, significantly improving patient survival and quality of life.

Core Subjects: Toxicology & Biocompatibility

Toxicology

A biomaterial should generally not be toxic unless specifically designed for therapeutic toxicity (e.g., drug delivery). This involves evaluating substances migrating out or resulting from degradation (e.g., low molecular weight leachables from polymers).

Sophisticated science to ensure design criteria are met during development.

Biocompatibility

Unique to biomaterials science, often defined by performance or success in a specific application rather than precise, universal measurements.

The 'operational definition' (patient is doing well) provides little insight for new designs.

Biocompatibility may need to be uniquely defined for each specific application (e.g., soft tissue, hard tissue, blood compatibility).

Core Subjects: Biological Response & Anatomy

Inflammation and Healing

Implantation triggers specialized biological mechanisms: inflammatory reaction sequence leading to normal or pathological healing. The 'foreign-body reaction' occurs when an implant is present.

Understanding how implants shift normal inflammatory reactions and how materials can avoid this response is crucial.

Functional Tissue Structure and Pathobiology

Biomaterials are implanted into diverse tissues/organs (cell composition, organization, vascularization, innervation), each with special physiological consequences.

Biomaterials researchers need to understand normal/abnormal cell, tissue, and organ structures, and mechanisms of disease.

Dependence on Anatomical Site

Each anatomical site (e.g., eye, hip bone, heart muscle, blood vessel) presents unique challenges for device designers regarding anatomy, physiology, geometry, size, mechanical properties, and bioresponses.

Core Subjects: Mechanicals & Industry

Mechanical Requirements and Physical Performance

1. Mechanical performance: devices must match physiological function (e.g., strong/rigid hip prosthesis, strong/flexible tendon).
2. Mechanical durability: devices must function for their intended lifespan (e.g., catheter for days, heart valve for decades).
3. Bulk physical properties: impact overall performance (e.g., membrane permeability, hip joint lubricity, lens transparency).

Design principles are borrowed from physics, chemistry, and various engineering disciplines.

Industrial Involvement

Companies play a vital role, producing implants and generating profits, enabling the widespread availability of devices despite ongoing fundamental research.

Industry excels in specialized technologies like packaging, sterilization, storage, quality control, and contributes significantly to fundamental biomaterials study through in-house research.

Core Subjects: Risk/Benefit

Risk/Benefit and Corporate Realities

Development involves a constant risk/benefit analysis, balancing the alleviation of suffering with scientific innovation, profit motives, and regulatory mandates.

Acceptable risk varies by device type: higher for life-sustaining devices (heart valve) than for pain alleviation (hip joint) or cosmetic applications (breast implants).

Companies face large development and regulatory costs, product liability, and the challenge of introducing improved devices into a complex market.

Core Subjects: Ethics

Ethics

- Animals: Is the animal model relevant and is suffering justified?
- Human Subjects: How to ensure informed consent and minimize negative outcomes?
- Industrial Involvement: Balancing patient needs with financial goals and market availability.
- Researchers: How to minimize bias given potential financial benefits?
- Patients: Trade-off between sustaining life and quality of life with the device.
- Regulatory Agencies: Do they have sufficient information to regulate adequately, and does regulation inflate costs?

Core Subjects: Regulation & Literature

Regulation

Governments (e.g., US FDA) and international bodies (e.g., ISO) regulate medical devices to ensure safety and prevent inadequately tested products from entering the market.

Compliance costs are substantial, raising questions about healthcare costs and access to improved devices.

Regulation highlights the intersection of government, industry, scientists, physicians, and patients.

Biomaterials Literature

The field has developed a rich literature over 70 years, covering basic science, applied science, engineering, medicine, and commercial issues, spanning many disciplines and technical societies.

Biomaterials Professional Societies

The evolution of biomaterials as a profession led to the formation of specialized societies, providing a 'home' for the discipline.

1954 American Society for Artificial Internal Organs (ASAIO) founded.

1969 Clemson University establishes Division of Interdisciplinary Studies, begins International Biomaterials Symposia (IBS).

1973 Canadian Biomaterials Society established.

1974 Society for Biomaterials (SFB) chartered in San Antonio, Texas.

1975 European Society for Biomaterials founded. 7th IBS also recognized a

1978 Japanese Society for Biomaterials formed.

1980 International Liaison Committee (ILC) formed; first World Biomaterials

1986 Society for Biomaterials & Artificial Organs (India) established.

1989 Australasian Society for Biomaterials and Tissue Engineering established.

1996 Korean Society for Biomaterials established.

1997 Chinese Taipei Society for Biomaterials; ILC renamed International Union of Societies for Biomaterials Science and Engineering

1998 Latin American Society for Biomaterials and Artificial Organs established.

Conclusion

Biomaterials science is arguably the most multidisciplinary of all sciences, requiring mastery of diverse fields including science, technology, engineering, and medicine.

Key characteristics include its multidisciplinary nature, utilization of diverse materials, clinical need-driven innovation, significant global market, and inherent risk/benefit considerations.

The field offers an intellectually stimulating endeavor that advances a new basic science of biointeraction and contributes significantly to reducing human suffering.