

Changing the World one Word at the time

ICF

International Classification of Functioning, Disability and Health



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12th Annual North American Collaborating Center Conference on ICF

**LIVING IN OUR ENVIRONMENT:
The Promise of ICF**

2006
JUNE 5 to 7
Vancouver, British Columbia (Canada)

“Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives” ICF 2001

- The challenges of imitating nature are poorly understood, described and communicated by current parameters and conventional diagnostic systems
- ICF provides a framework for modeling and characterization of the factors that affect, modulate and construct failure and success in rehabilitative dentistry, tissue engineering and organ transplantation.
- Illustrating new technology, new concepts and new parameters helps the evaluation of their performance

Rehabilitation in Dentistry

*Assistive devices & products for personal performance & use in activities of daily living
(ADL) ICF Chapter 1.e 1151*

- Prosthetic devices and dental treatments work differently than Rx, and medications
- There is the human factor for variety in delivery, performance, response and environmental interaction of the same treatment or procedure
- Environments affect the way health care is practiced, measured, and evaluated

“Two persons with same condition, may have different degree of functioning, two persons with the same level of functioning not necessarily have the same condition”

ICF 2001

Operational Definitions & Environmental Factors

- ICF provides elements to construct and methodologically pursue operational definitions
- Operational definitions enable users with powerful descriptors to characterize diversity in biologic, physiologic and environmental response to health care interventions

Operational definitions for

- Edentulism
- Special needs

Factors that affect the way that people live and conduct their life

Natural Environments

ICF e 230

- Natural disasters Katrina

Human –modified Environments

ICF e 235

- Conflicts and war
- Political displacement of people
- Destruction of social infrastructure, homes, dental offices, institutions, lands, buildings (Terrorism)

Access to care

Factors that affect the way that people live and conduct their life

Health professionals education & collective attitude

ICF e 355

- Educational programs & curriculum
- Research activities & innovation
- Institutional resources (human, financial and physical)

Health professionals education & individual attitude

ICF e450

- Practices & philosophies
- Values, norms and parameters (standards)
- Beliefs
- Culture & society

Factors that affect the way that people live and conduct their life

General social support and health services

ICF e 575

- General policies affecting health care practice
- Health care design, regulation and execution of models & policies

Oral health care services and system

ICF e580

- Administrative and clinical mechanisms and parameters for executing services
- Administrative and clinical mechanisms and parameters for monitoring and evaluating services

Research Diagnostic Criteria in Oral & Craniofacial Rehabilitation

An ICF Based Framework for Tissue Engineering, Biomaterials, Implants and Prosthetic Devices Performance Evaluation and Failure Analysis Characterization

Scientific response to a Social problem



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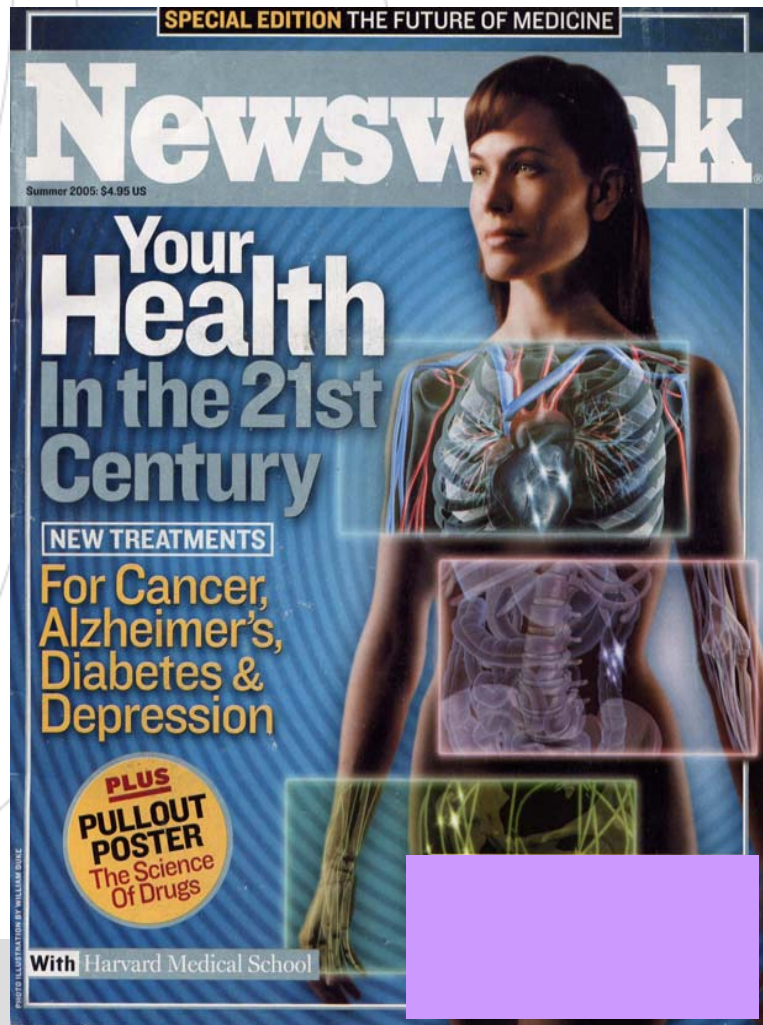
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H S T

521 Course Project



Biomaterials and Tissue Engineering in Medical Devices and Artificial Organs

*Dr. Oscar Raul Suarez-Sanchez
DDS., MSD.*

*HSDM- Biomaterials & Restorative
Dentistry*

Prosthodontic Graduate Program

Project Description

1. The need for an RDC in O. Rehabilitation

2. Innovation in Dentistry

3. Problem Description

4. Research Proposal

The need for a RDC

Newsweek

SUMMER 2006
Special Edition

Your Health

In the 21st Century

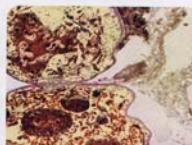
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DATABASED: Medical records go digital

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From the Editor-in-Chief

AT NEWSWEEK, WE have a long and distinguished tradition of reporting on issues about science, medicine and health. Now, as biomedical research enters a new period of discovery, we are proud to offer this special edition (a bonus issue for our subscribers) on the advances that are rapidly changing the face of medicine in the 21st century.

We are pleased that Johnson & Johnson chose to be the exclusive advertiser for this special issue. As I trust NEWSWEEK readers expect, the advertiser had no influence over the editorial content of this

I am especially grateful to the faculty members at Harvard Medical School, led by Dr. Anthony Komaroff, who contributed to this issue. And I want to acknowledge our broadcast partners at NBC and MSNBC, who will produce a full week of related programming. The expertise we have assembled for this special edition reflects our continuing dedication to covering the health concerns so vital to our readers' lives.

Richard M. Smith

RICHARD M. SMITH
Chairman & Editor-in-Chief

Dentistry has failed protecting society, because is unable to communicate its advances in the same language that medicine has done

RDC — Research Diagnostic Criteria

The need for a RDC

Negative aspects

- Outdated oral health care system
- Disarticulated clinical and laboratory work in collision with social, economic and political reality
- Unable to transfer new technology, new science and new standards in to practice

Positive aspects

- Opportunity for innovation
- Evolving perspectives and understanding of biologic & functional emerging concepts (Translational research)

Emerging technology and perspectives in rehabilitation, treatment and management of body parts and body functions at all levels

Molecular-genetic- cellular-tissular-organic-systemic (stomatognathic system)

A RDC is a communication system that facilitates, secure and expedite exchange, analysis and data processing, in a standardized and reliable methodological framework.

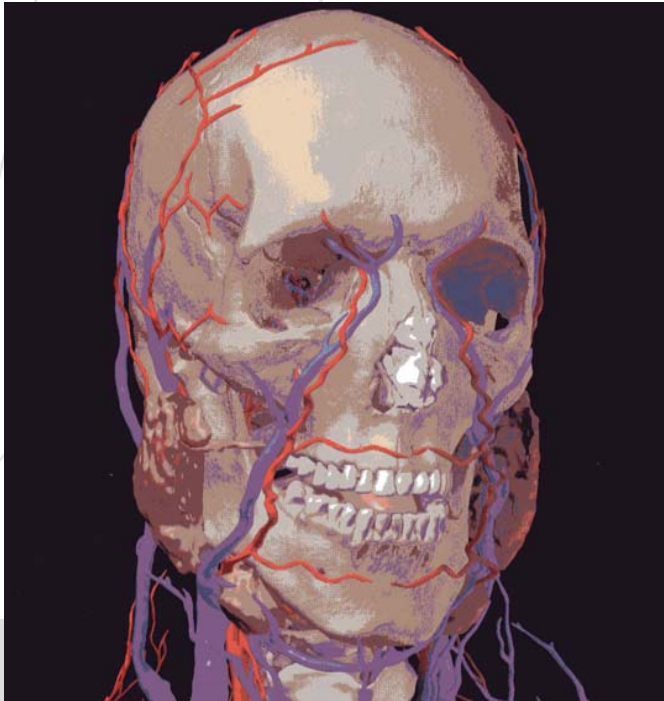
TMD Temporomandibular Disorders RDC

- 1: [John MT, Hirsch C, Reiber T, Dworkin S.Related Articles](#). Translating the research diagnostic criteria for temporomandibular disorders into German: evaluation of content and process. J Orofac Pain. 2006 Winter;20(1):43-52. Review. PMID: 16483020 [PubMed - indexed for MEDLINE]
- 2: [Reiter S, Eli I, Gavish A, Winocur E.Related Articles](#). Links Ethnic differences in temporomandibular disorders between Jewish and Arab populations in Israel according to RDC/TMD evaluation. J Orofac Pain. 2006 Winter;20(1):36-42. PMID: 16483019 [PubMed - indexed for MEDLINE]
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Communication tool across cultures, languages, countries, disciplines, procedures and all domains involved in health care delivering system.

The need for a RDC

The stomatognathic system is composed and sustained by a complex arrangement of micro environments, molecules, cells, tissues, organs and systems



Edentulism (lack of teeth) it is an outdated empiric term that leads to a misconception, by a gross simplification of a wide range of functional compromises.

There are different systemic compromises, in edentulism, depending the body parts and body structures, activities and functions affected for it.

The system is amputated, traumatized an compromised in multiple levels and domains.

Complete edentulism fulfill the WHO definition for impairment and disability.

The need for a RDC

Edentulism is not a health status but a dynamic condition, a complex health process

A social marker?



It compromises biologic, physiologic, psychosocial and essential human functions affecting quality of life in variety of degrees and domains.

The system is amputated, traumatized and compromised in different degrees, body parts & body functions; activities & participation. Capacity & performance

- Bone, tooth, ligament, periodontum, mucosa, muscle, vessel, nerve, glands, joints.
- Mastication, suction, deglutition, phonation, perception, communication, socialization, expression

Problem Description

2. Innovation in Dentistry

- **Salivary gland gene therapy – Gene transfer application.** A. P. Cotrim, F. Mineshiba, T. Sugito, Y. Samuni, and B. Baum
- **Craniofacial bone tissue engineering.** D.C. Wan, R.P. Nacamulli, and M. Longaker
- **The engineering of Craniofacial tissues in the Laboratory- Review of biomaterials & scaffolds.** H. Abukawa, M. Papadaki, M. Abulikemu, J. Leaf, J. Vacanti, L.B. Kaban, and M. Trulis.
- **Bioengineering teeth from tooth bud cells.** P.C. Yelic and J. Vacanti
- **Use of growth factors to modify Osteoconductivity of demineralized bone allografts :Lessons for tissue engineering of bone** B. D. Boyan, D. M. Ranly, and Z. Schwartz
- **The impact of Bioactive Molecules to stimulate tooth repair and regeneration as part of restorative dentistry.** M. Goldberg, S. Lacerda, N. Jegat, N. Six, D. Septier., F. Priam, M. Bonnefoix, K. Tompkins, H. Chardin, P. Denbesten, A. Veis, and A. Poliard.

Communication & relevance to reality in society. Personal Vs. Social good

Problem Description

3. Problem description

Current management of edentulism and related conditions lacks of:

- Post marketing surveillance programs
- Failure analysis systems with current, relevant, standardized criteria and protocols
- Outcome assessment instruments

There is an opportunity for:

- Translational research & innovation
- monitoring, learning and ensuring the safety, efficacy and reliability of new technology
- Improving the limitations of applications in current interventions and the way they should guide & construct a future in dental practice

Problem Description

4. Proposal



Development of novel (RDC)
Research Diagnostic Criteria for
Oral & Craniofacial rehabilitation
with

tissue engineering, biomaterials,
implants and prosthetic devices

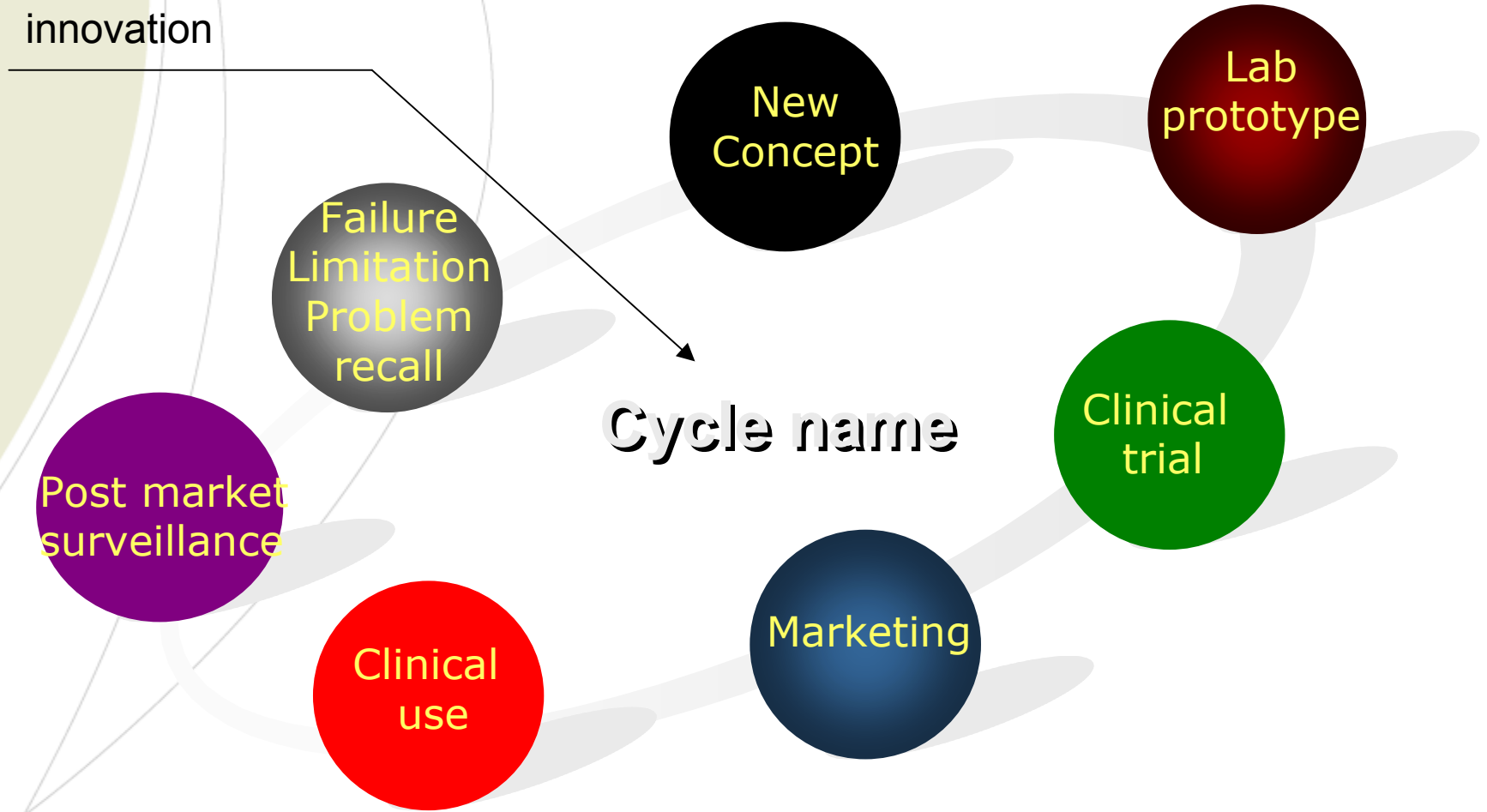
- Performance evaluation
- Failure Analysis
- Outcome assessment
- Decision making

Hypothesis

There are generic principles and patterns of implant, biomaterials, tissue engineering and prosthesis devices performance and failure mode, studied in medicine that may be usable in dentistry

The interactive (generic) cycle of clinical innovation

innovation



Cycle name

Oral & Craniofacial rehabilitation
should follow this cycle

Generic process

TABLE 2 Important Components and Features of an Implant Retrieval and Evaluation Program

Entire activity is hypothesis-driven
Specimens are appropriately accessioned, cataloged, and identified
Known and potential failure modes are considered
Patient's medical history and laboratory results are reviewed
Data are collected on well-designed, study-specific forms
Careful gross examination, photography, and other basic analyses are always done
Advanced analytical techniques done by specialists are considered
Analytical protocols and techniques for assessing host and implant responses are rigorously followed
Correlations and cause-and-effect relationships among material, design, mechanical, manufacturing, clinical, and biological variables are sought
Quantitative data are collected wherever possible and appropriate
Statistical and multivariate analyses are used

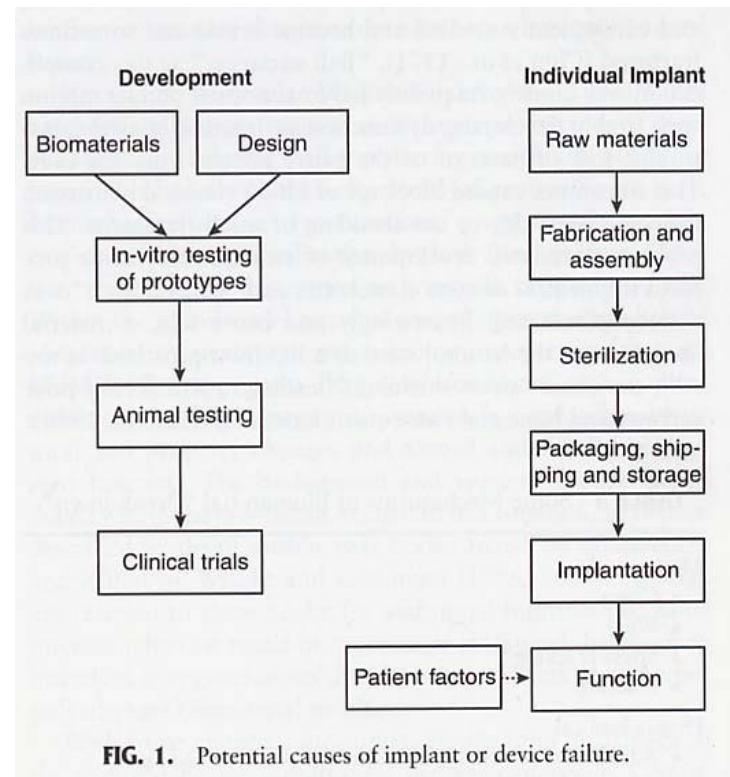


FIG. 1. Potential causes of implant or device failure.

Generic significance

TABLE 12 Clinical Utility of Retrieval Studies: Hard-Tissue Implants

Implant type	Knowledge gained/lessons learned
Plates, screws, and rods used for fracture fixation	<ul style="list-style-type: none"> • Do not mix metal alloys in same device • Match the hardness (degree of cold work) and stiffness with the application • Metallic implant wear and corrosion may lead to problems associated with allergic reactions
Tooth root implants	<ul style="list-style-type: none"> • Careful surgical technique avoids thermal tissue necrosis of the implant–tissue interface • Implant surface finish is a critical determinant of outcome
Femoral stems of total hip replacements (fracture analysis)	<ul style="list-style-type: none"> • Cobalt alloys require high-quality casting • High-strength superalloys may be advantageous • Welded regions may fail in tensile-loaded locations • Part numbers should not be etched in tensile-loaded locations
Femoral stem, modular interface	<ul style="list-style-type: none"> • Corrosion at an interface is dependent on metallurgical and mechanical design factors
Polymeric component to total joint replacements (excluding one-piece flex hinge joints like finger)	<ul style="list-style-type: none"> • Teflon performs poorly in wear applications • Reinforcement of UHMWPE with chopped carbon fiber is ineffective • Laboratory simulation should be done using clinically realistic implant wear motion and loading patterns • Mechanical designs that produce high localized stresses may cause delamination • Radiation sterilization to produce cross-linking is useful but can lead to molecular-chain scission, oxidation, and aging
Analysis of tissues surrounding total joint replacements	<ul style="list-style-type: none"> • Wear particles derived from breakdown of the implant–bone interface or wear of the articulation (bearing) material cause inflammation and loosening.
Titanium and titanium-alloy implants	<ul style="list-style-type: none"> • A good material in one implant application may not necessarily be good in another • Commercially pure titanium is appropriate for tooth root implant or fracture fixation devices • Titanium alloys may yield severe wear in some total joint applications

Aims

Broad aims

To develop a research diagnostic criteria (RDC) for tissue engineering, biomaterials, implants and prosthetic devices performance evaluation and failure analysis

To propose a conceptual model to operationalize it

Specific Aims

- To I.D. quantify, measure, observe and analyze treatment failures and adverse outcomes using new technology in tissue engineering, biomaterials, implants and prosthetic devices
- To identify, quantify and measure new technology and factors associated to an adverse event significant enough, to be measured in harm or loss to the intended procedure, the patient, the school, or the clinician.

The global concept

Phases

Pilot study
to collect preliminary
data to support
conceptual model

Construct a pilot RDC
model

Test the
RDC
Model

Materials & Methods

Proposal

To I.D. quantify, measure, observe and analyze treatment failures and adverse outcomes using new technology in tissue engineering, biomaterials, implants and prosthetic devices

TTX

clinical procedures performed at HSDM with implants, tissue engineering, biomaterials or prosthetic devices

Outcome

Failures that resulted in a unintended harm, treatment adjustment, change or remake of the first intended treatment.

Fx

Risk Fx for implant (or its components), a biomaterial, a tissue engineered or a prosthetic device failure

Failure Mode Characterization

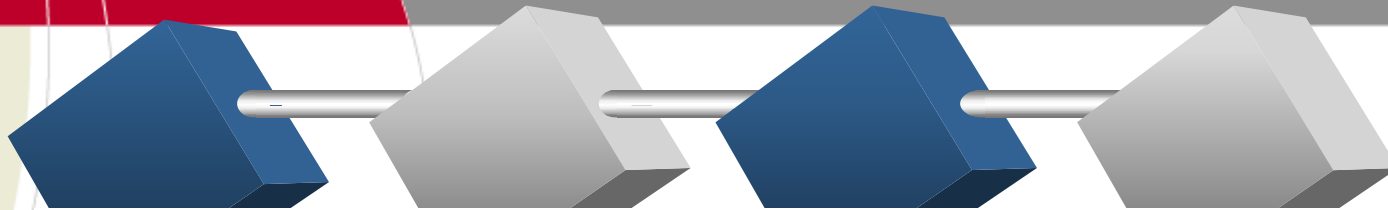


TABLE 11 Complications of Dental Implants

Adverse foreign-body reaction	Loosening
Biocorrosion	Foreign body reaction
Electrochemical galvanic coupling	Corrosion
Fatigue	Particulate formation
Fixation failure	Loosening
Fracture	Loss
Infection	Loss
Interface separation	Wear
Loss of mechanical force transfer	Loosening

Multidisciplinary Study

TABLE 6 Study Prioritization

Level I studies

- Gross dissection
- Photographic documentation
- Microbiologic cultures
- Radiography
- Light microscopic histopathology

Level II studies

- Scanning electron microscopy
 - Transmission electron microscopy
 - Energy dispersive X-ray microanalysis (EDXA)
 - Analysis of adsorbed and absorbed proteins
 - Mechanical properties measurement
 - Materials surface analysis
 - Leukocyte immunophenotypic studies
 - Molecular analyses for cellular gene expression
-

Interactive network

1st level

2nd level

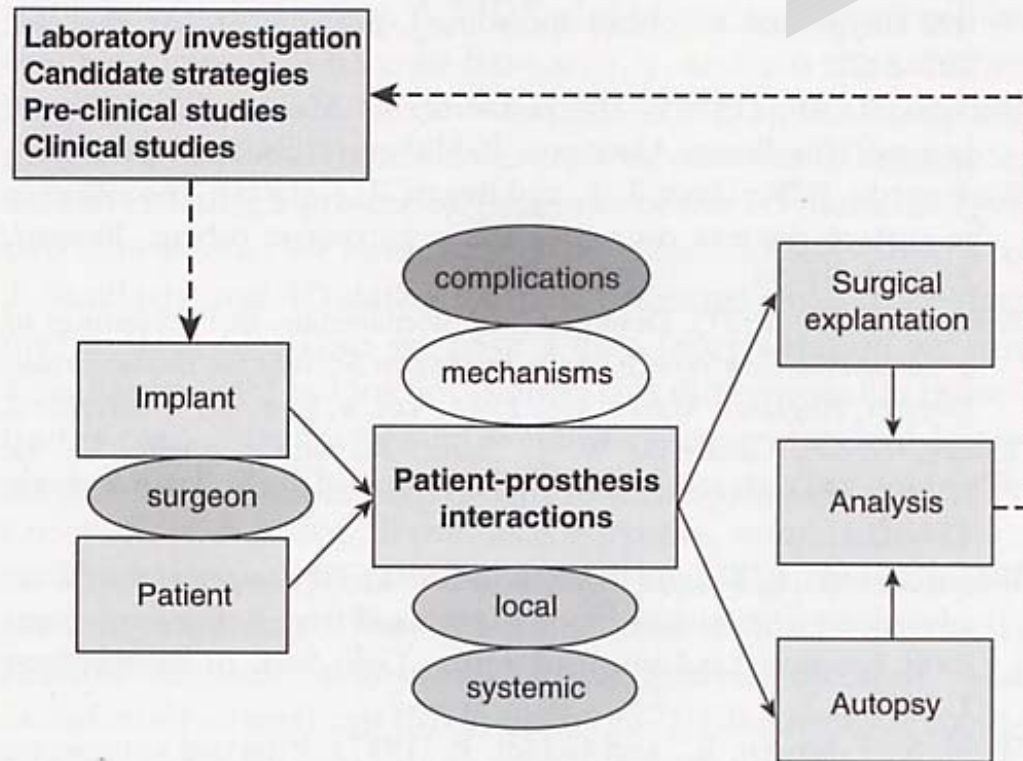


FIG. 1. Role of implant retrieval and evaluation in the development and use of clinical devices.

M. Eng.

Retrieval Program

New roles & Competences

Surgeon

Pathologist

Engineer

Clinician

Retrieval Program

New Standards & Competences

Surgeon

Pathologist

Engineer

Clinician

Retrieval Program

Transfer benefit to society

Post Market
surveillance

safety

efficacy

reliability

Potential Applications of RDC

- Development of relevant animal models & experiments
- Fostering industrial support for research
- Providing elements for decision analysis, regulation and outcome assessment processes
- Research
- Statistics, epidemiology & methodology
- Clinical care
- Social policy making
- Regulatory & marketing process
- Education

Oral Health & the Environment



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