ASM Intl. *Materials and Processes for Medical Devices* Conference
St. Paul, Minnesota, August 25-27, 2004

Role of Fracture Mechanics in Life Prediction and Quality Control of Medical Implants

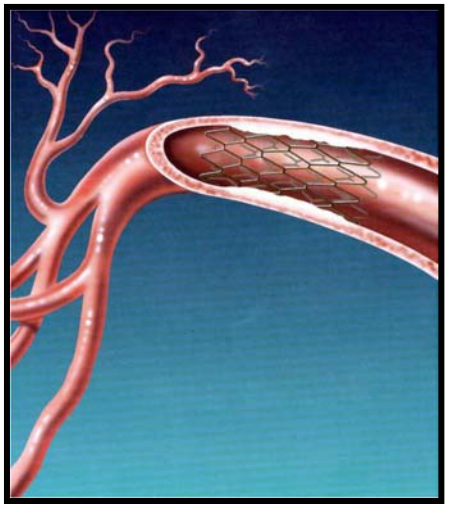
Robert O. Ritchie

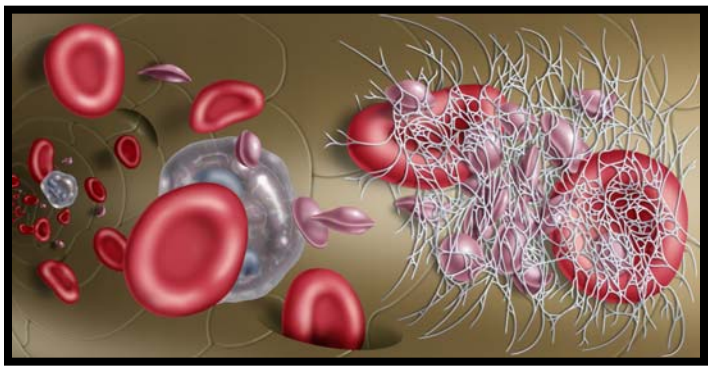
Materials Sciences Division, Lawrence Berkeley National Laboratory
and
Department of Materials Science and Engineering
University of California at Berkeley
email: roritchie@lbl.gov

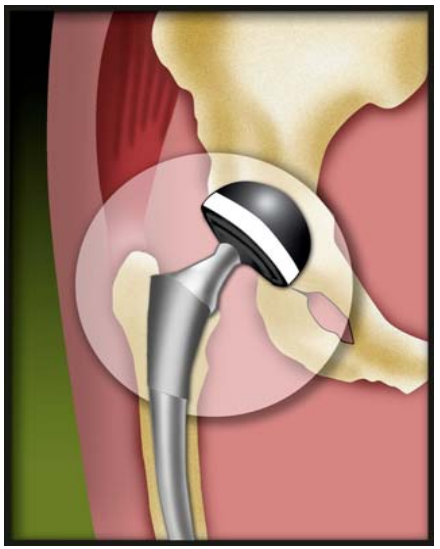
Work supported by ATS Medical, Baxter Healthcare, CV Medical, Inc., Shiley, Sorin, and St. Jude Medical

Substitutive Medicine

- The fundamental tenet of substitutive medicine is that beyond a certain stage of failure, it is more effective to remove and replace a malfunctioning organ than to seek in vain to cure it
- Functional disabilities due to destruction or wear of body parts can be addressed in two ways:
  - implantation of prosthetic devices
  - transplantation of natural organs





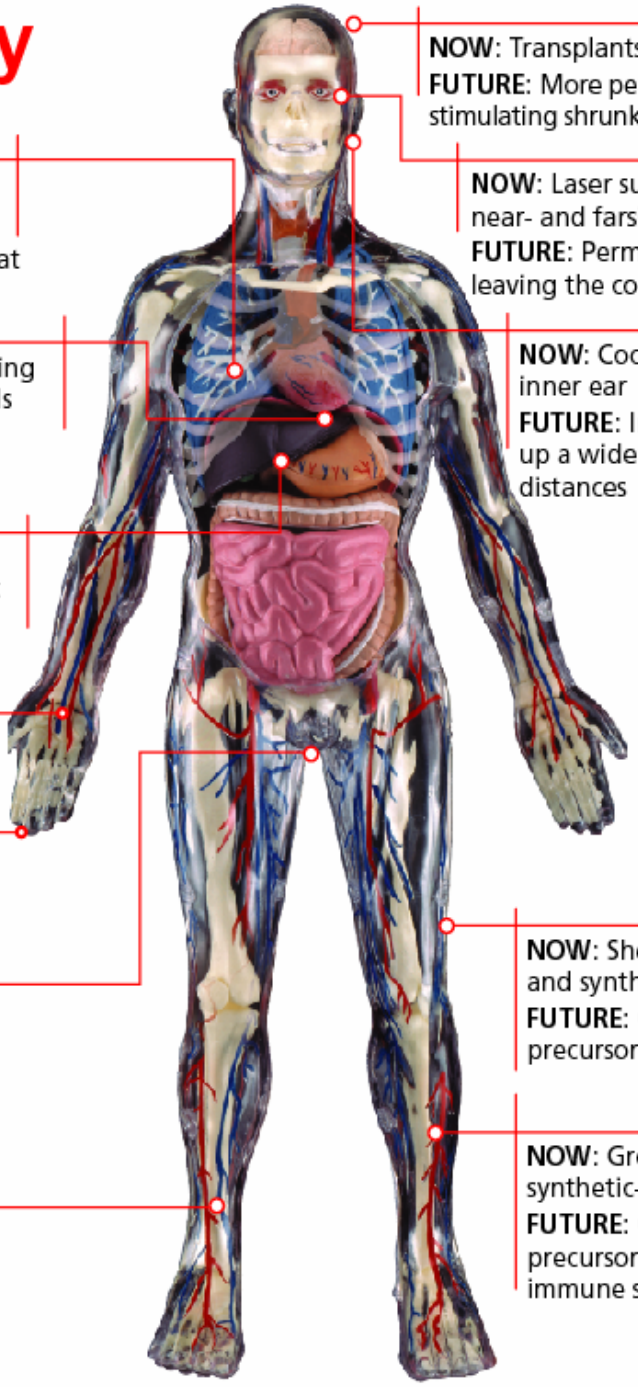


Waiting List for Organs

ORGANS	2001	2002	No. who died (1 yr)
Kidney	47,830	50,885	2,837
Liver	18,047	16,974	1,799
Pancreas	387	408	23
Kidney-Pancreas	2,378	2,425	220
Heart	3,934	3,803	608
Lung	3,708	3,756	497
Heart + Lung	209	198	35
Intestine	170	187	24
TOTALS	76,963	78,636	6,013

www.ustransplant.org

Can I Replace My Body



BREAST

NOW: Breasts are reconstructed with saline sacs or with living tissue, using fat and muscle from the back, buttocks or abdomen

FUTURE: Breasts may be grown in the lab from a patientís own fat cells and infused back through keyhole slits in the chest

HEART

NOW: Bypasses, angioplasty and transplants to keep blood flowing to the heart muscle. Use gene therapy to grow new blood vessels

FUTURE: Growing functional patches of heart muscle or coaxing existing heart-muscle cells to repair themselves

ORGANS

NOW: Small slivers of liver tissue can be grown in the lab from one of the many types of liver cells; not yet ready for transplant

FUTURE: Heart, liver, kidneys grown from stem cells *in vitro* and transplanted into the body

NERVES

NOW: Lab grown from pig cells and synthetic-polymer matrix

FUTURE: Regenerated from stem or precursor cells in the body

LIMBS

NOW: Prosthetics wired to peripheral nervous system

FUTURE: Prosthetics wired directly to motor portions of the brain to improve control and simulate the sensations of touch, pain, etc.

PENIS

NOW: Penile implants and medication to maintain erection. Surgery to reattach a severed penis; skin grafts to recover urinary, but not sexual, function if penis is not recovered

FUTURE: Genetically engineered tissue grown in the lab and attached for final growth to form fully functional penis

BONE AND CARTILAGE

NOW: Injection of bone growth factors into jaw and other fracture areas. Researchers can also grow cartilage in the lab in thin sheets, but it's too weak to be functional in the body

FUTURE: Coaxing the body to grow bone and cartilage on scaffolds infused with a mix of stem cells and growth factors

HAIR

NOW: Transplants, hair plugs and scalp grafts

FUTURE: More permanent approaches, perhaps by stimulating shrunken follicles with growth proteins

EYES

NOW: Laser surgery or implants to correct near- and farsightedness

FUTURE: Permanent lens implants to vision while leaving the cornea intact

EARS

NOW: Cochlear implants to replace damaged inner ear

FUTURE: Implants that can be adjusted to pick up a wider range of frequencies at longer distances

SKIN

NOW: Sheets grown in the lab from human and synthetic-polymer matrix

FUTURE: Grown by the body from stem or precursor cells and growth factors

BLOOD VESSELS

NOW: Grown in the lab from pig cells and synthetic-polymer matrix

FUTURE: Grown in the lab from stem or precursor cells to avoid rejection by the immune system

The Problem!

NIH Statistics

- 20 million people in U.S. have at least one medical implant
- $100 billion spent annually on prostheses and artificial organs
- 20% of all surgeries are to replace failed devices

Three Immediate Problems

- **New implant materials** – e.g., bone-like materials to prevent stress shielding, heart valve materials to prevent thrombosis
- **Improved implant/tissue interfaces** – as vast majority of devices fail due to interface failure
- **Lifetime prediction** for medical devices

Medical Implants Used in the U.S.

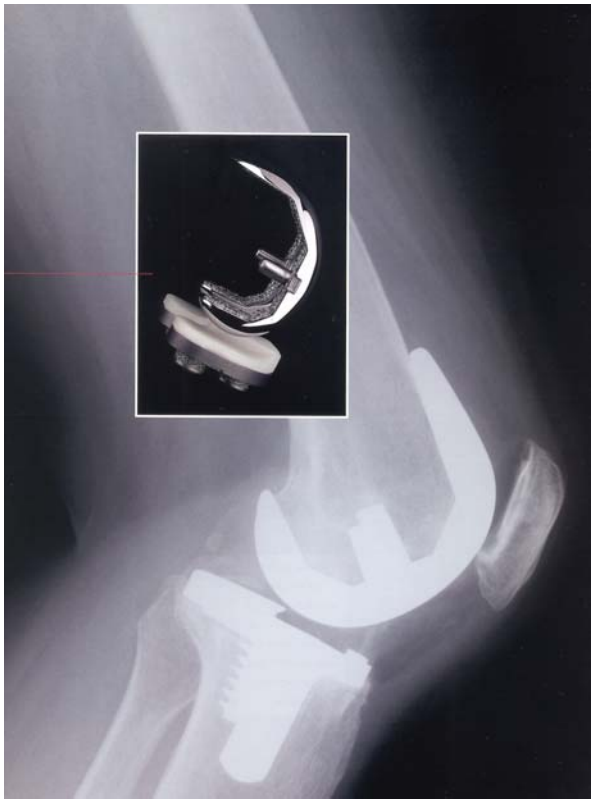
Device	Number/year	Biomaterial
Intraocular lens	2,700,000	PMMA
Contact lens	30,000,000	silicone acrylate
Vascular graft	250,000	PTFE, PET
Hip & knee prosthesis	500,000	titanium, Co-Cr, PE
Catheter	200,000,000	silicone, teflon
Heart valve	200,000	pig valve, PyC, Ti, Co-Cr
Stent (cardiovascular)	>1,000,000	stainless steel, NiTi, Co-Cr
Breast implant	192,000	silicone
Dental implant	300,000	titanium
Pacemaker	430,000	polyurethane
Renal dialyzer	16,000,000	cellulose

Biomaterials

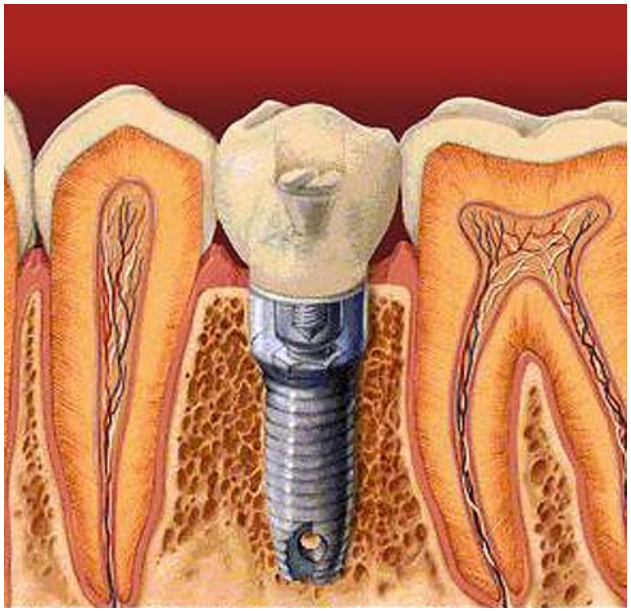
Co-Cr alloys	Hydroxyapatite
Stainless steel	Alumina
Titanium, Nitinol	Bioglasses
Zirconium	Tricalciumphosphate
Niobium	Carbon
Tantalum	Polymers
Gold	

Less than 20 chemical compounds among 1.5 million candidates have been successfully incorporated into clinical devices

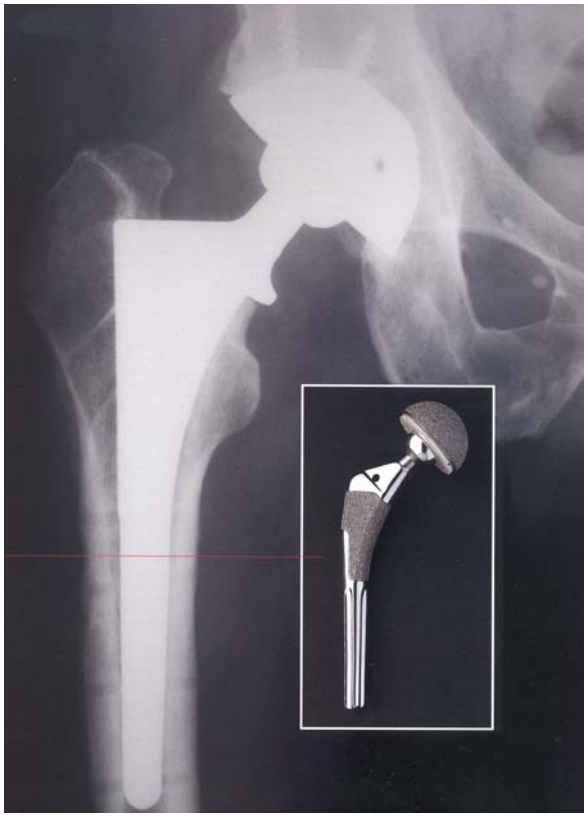
Metallic Implants



Knee prosthesis



Dental implant



Hip stem

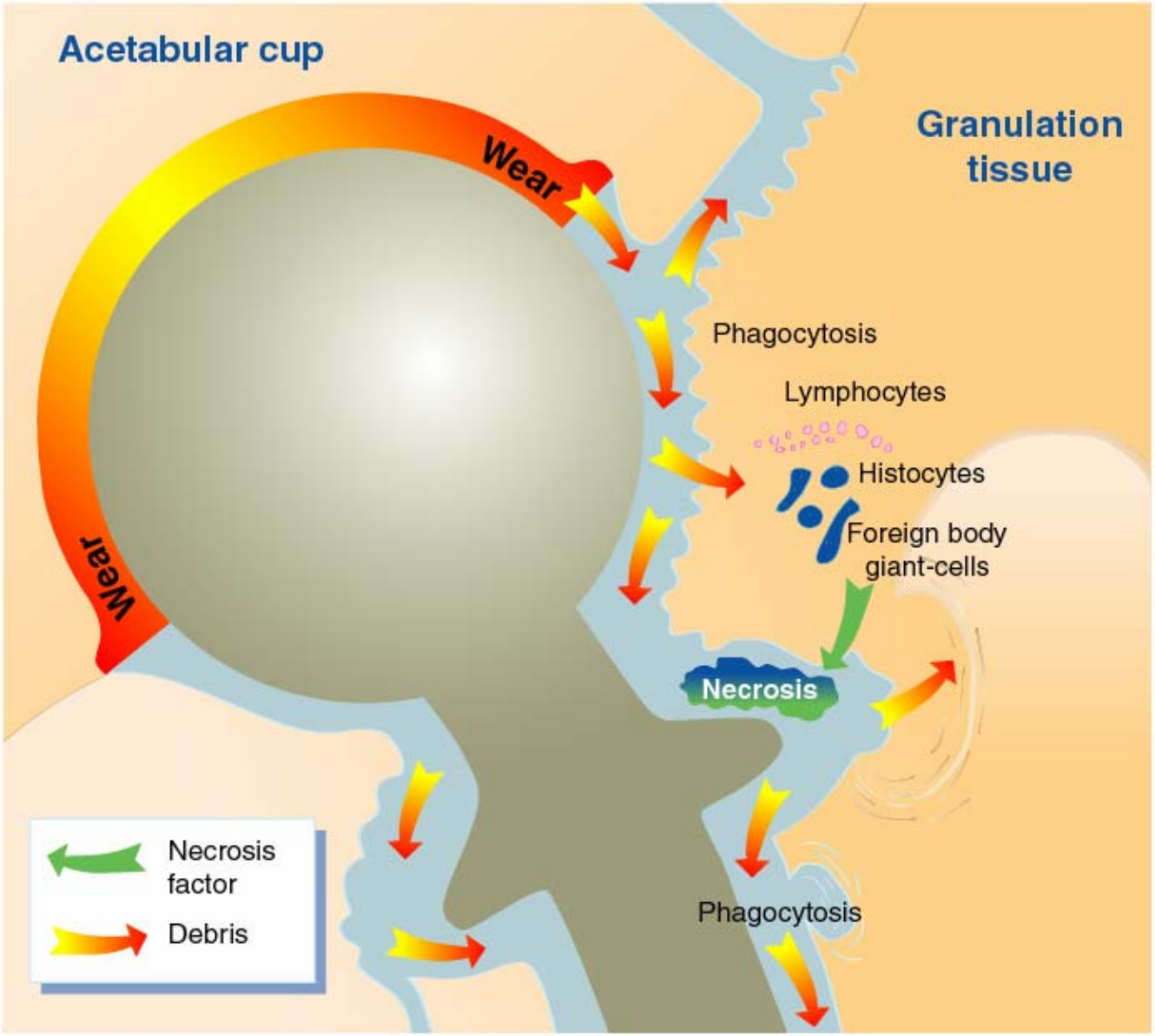
Major problems associated with metallic implants

Incompatible tissue/implant properties

Implants loosen with time

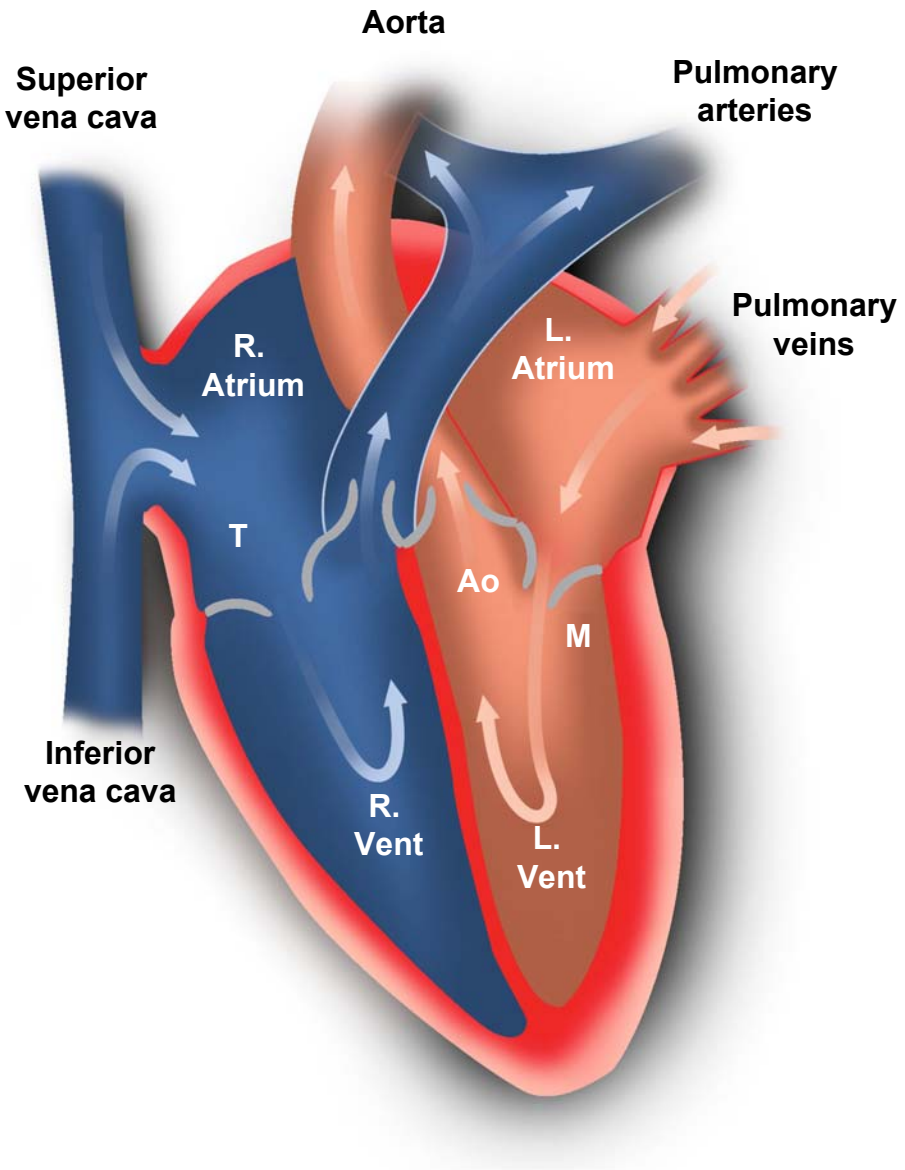
Require revision surgery

Total Hip Replacement – Osteolysis



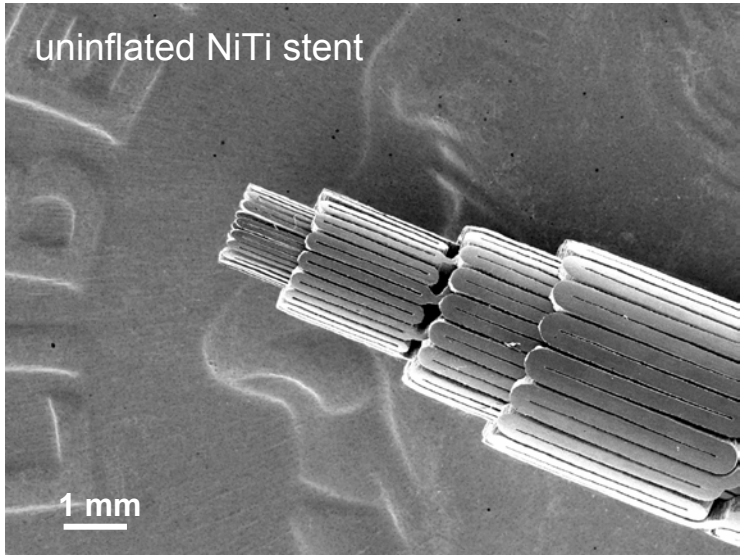
- We take about one million steps a year
- As years pass, strong shock waves caused by walking, running & climbing erode cushioning between ball & socket at top of leg
- Soon, bone grinding on bone causes osteoarthritis, a condition that brings crippling pain and slows everything we do
- What's the answer? For more than 250,000 Americans a year: hip replacement surgery

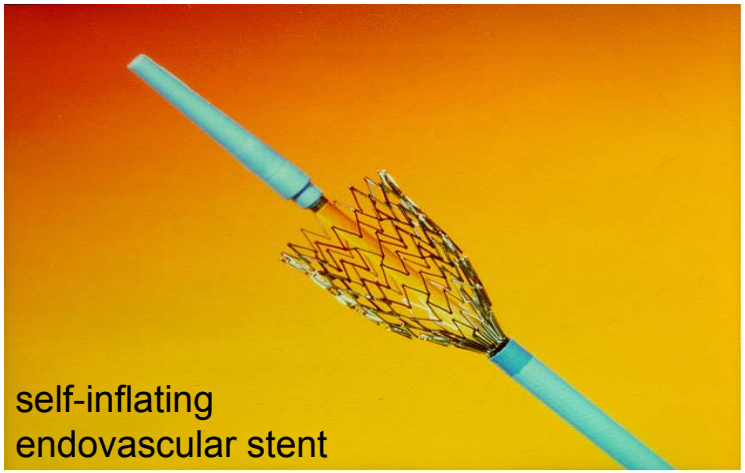
Heart Valve Prostheses and Stents



- 1 million cardiovascular stents and over 200,000 heart valves are implanted in the U.S. each year
- mechanical failure is rare, but with valves has accounted for hundreds of patient deaths in past 20 yrs
- as the human heart beats some 40 million times/yr, fatigue is the prime mechanism of mechanical failure
- design & reliability of mechanical valves and stents must be focused on devices that last in excess of patient lifetimes, ~10^8 - 10^9 cycles
- quality control is thus essential to maintain device components that meet this criteria

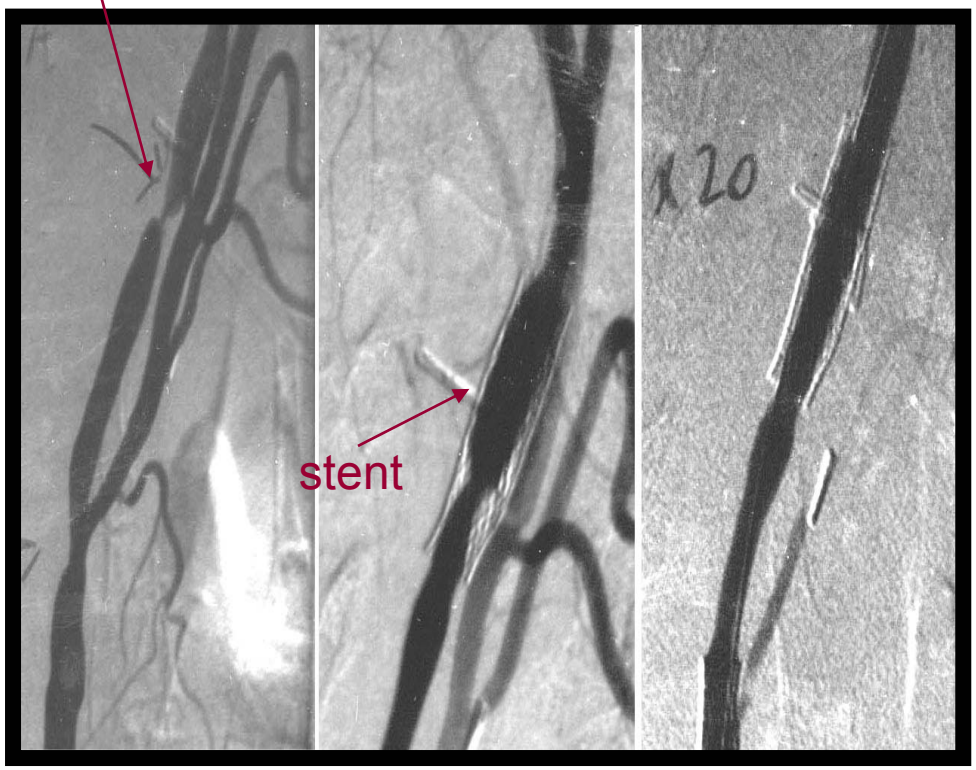
Stenting of Arteries





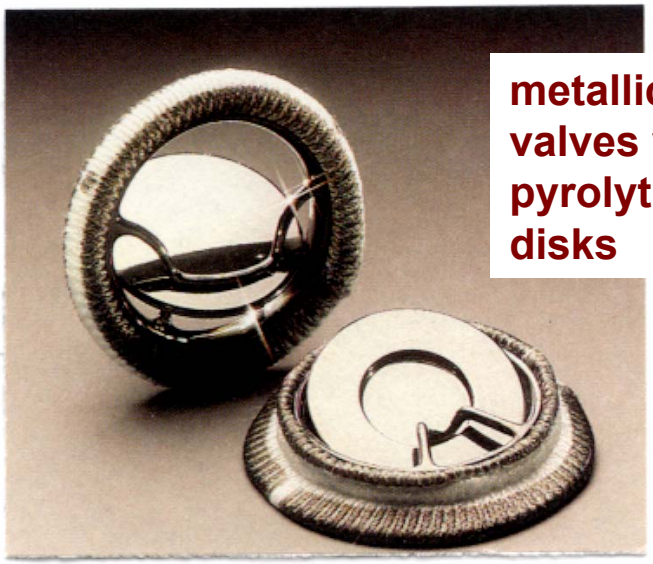
- $3.48 billion market this year
- projected to rise to $7.1 billion by 2006

- Stents manufactured with:
  - AISI 316 stainless steel
  - Nitinol (Ni-Ti alloy)
  - Co-Cr (Haynes 25) alloy

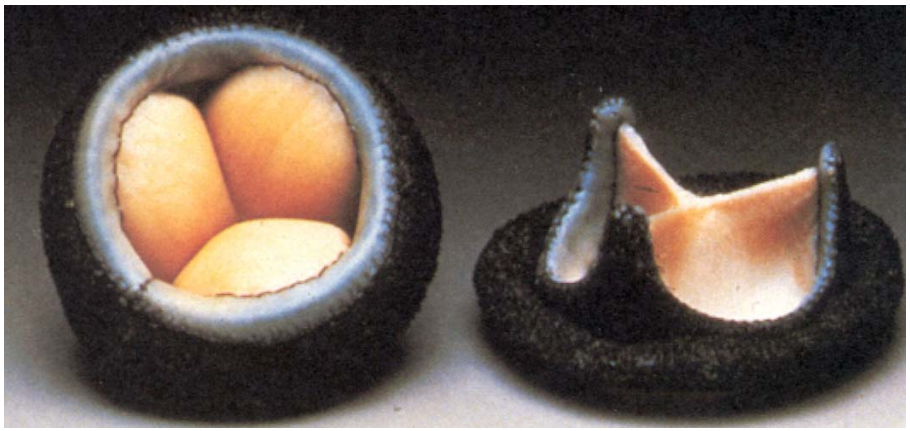


made by NDC, a J&J Company, Fremont, CA

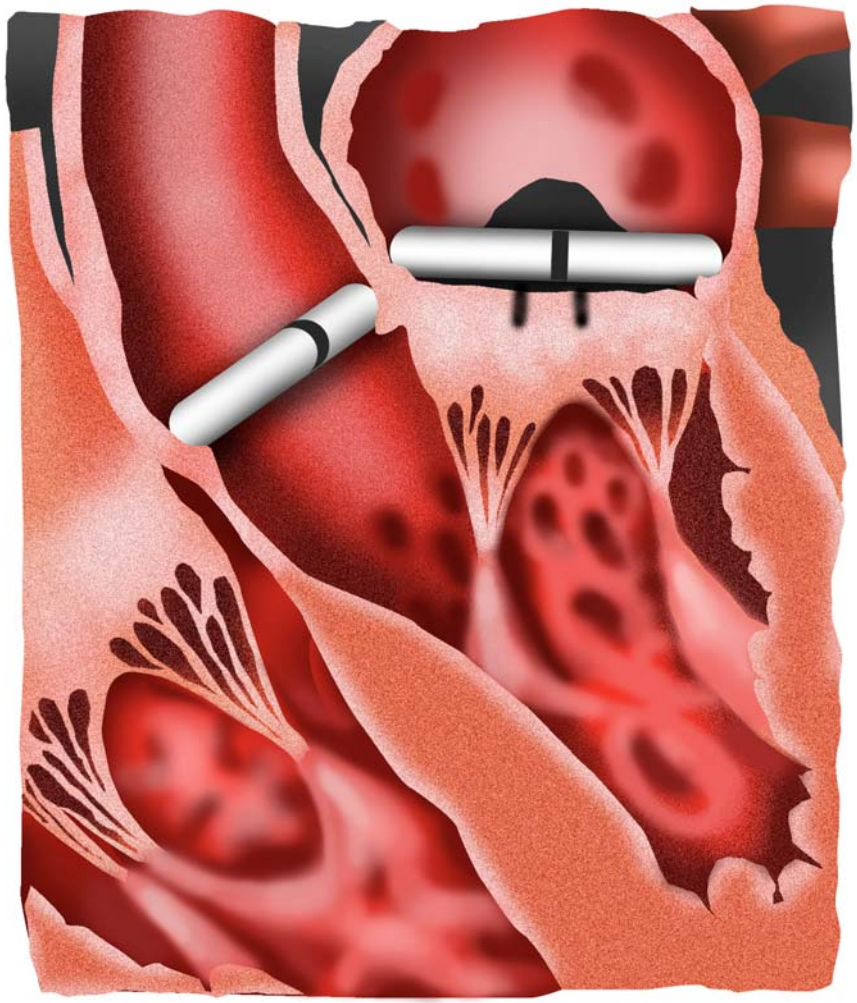
Heart Valve Prostheses



metallic Co-Cr valves with pyrolytic carbon disks



aortic valves from pigs or made from bovine pericardium

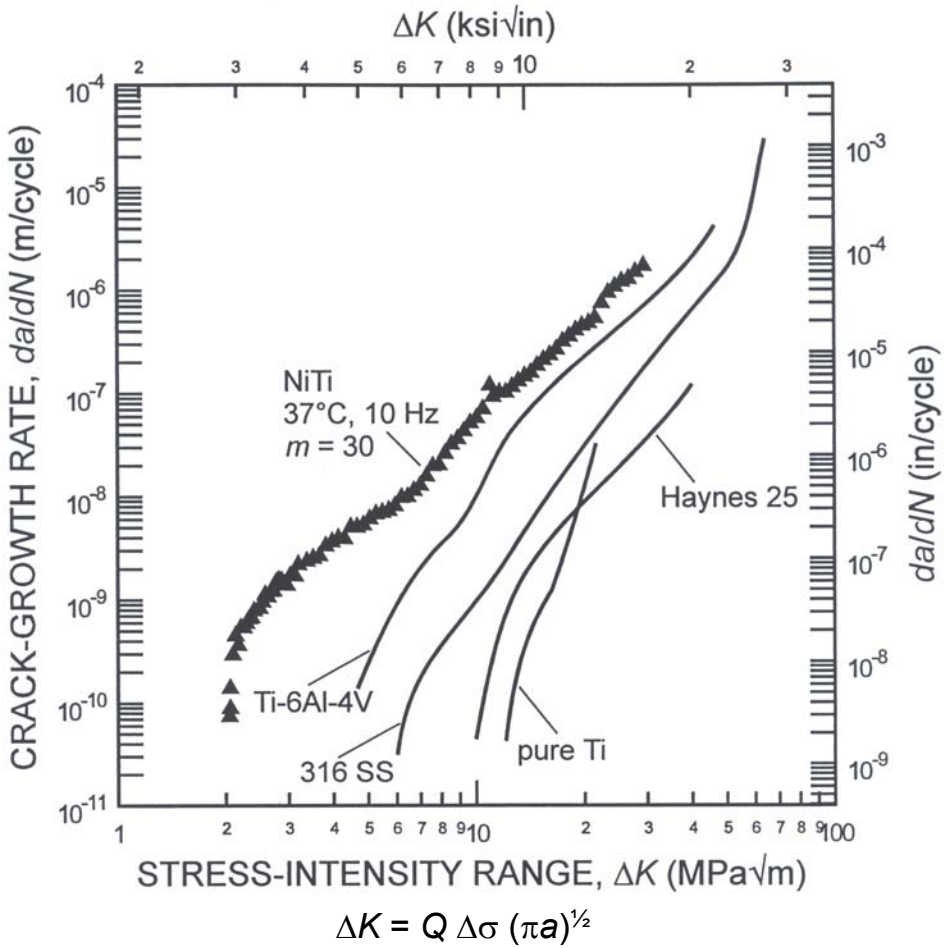


Mechanical Heart Valve Prostheses

- In the aftermath of the Shiley valve problems, the trend has been away from metallic valves towards pyrolytic carbon valves
- with respect to fracture toughness, pyrolytic carbon is more than an order of magnitude more brittle than Ti or Co-Cr alloys
- hence special care must be taken in design and life-prediction procedures to prevent *in vivo* fractures

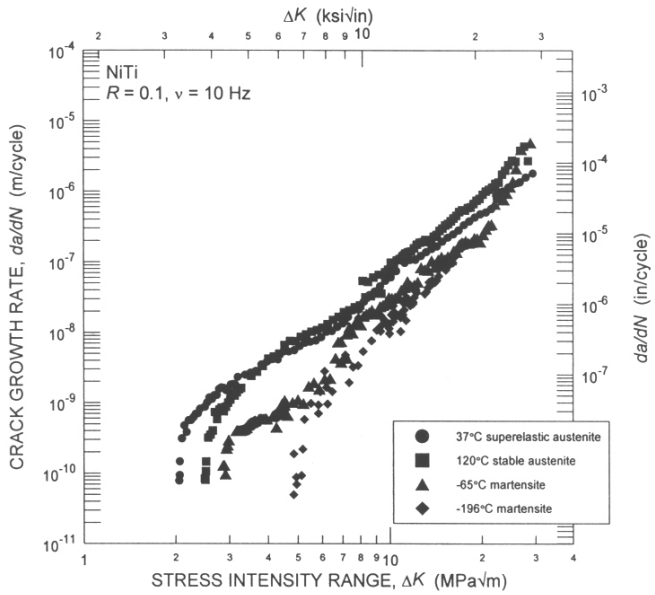
Prosthetic material	*Young's modulus*	*Strength*	*Fracture toughness*	*Fatigue threshold*
	(GPa)	*(MPa)*	*(MPa √m)*	*(MPa √m)*
Pyrolytic carbon	27 - 31	350 - 530	1 - 2	~0.7 - 2
Co-Cr (Haynes 25) alloy	209	450 - 1000	~60	4.5 - 10
Ti-6Al-4V alloy	115	925 - 1000	60 - 80	~3 - 4
Stainless steel (316L)	210	250 - 560	>100	~6 - 8
Nitinol (Ni-Ti) alloy	55 - 90	200 - 1200	35 - 50	~2

Comparison of Metallic Implant Materials



$\Delta K = Q\,\Delta\sigma\,(\pi a)^{1/2}$

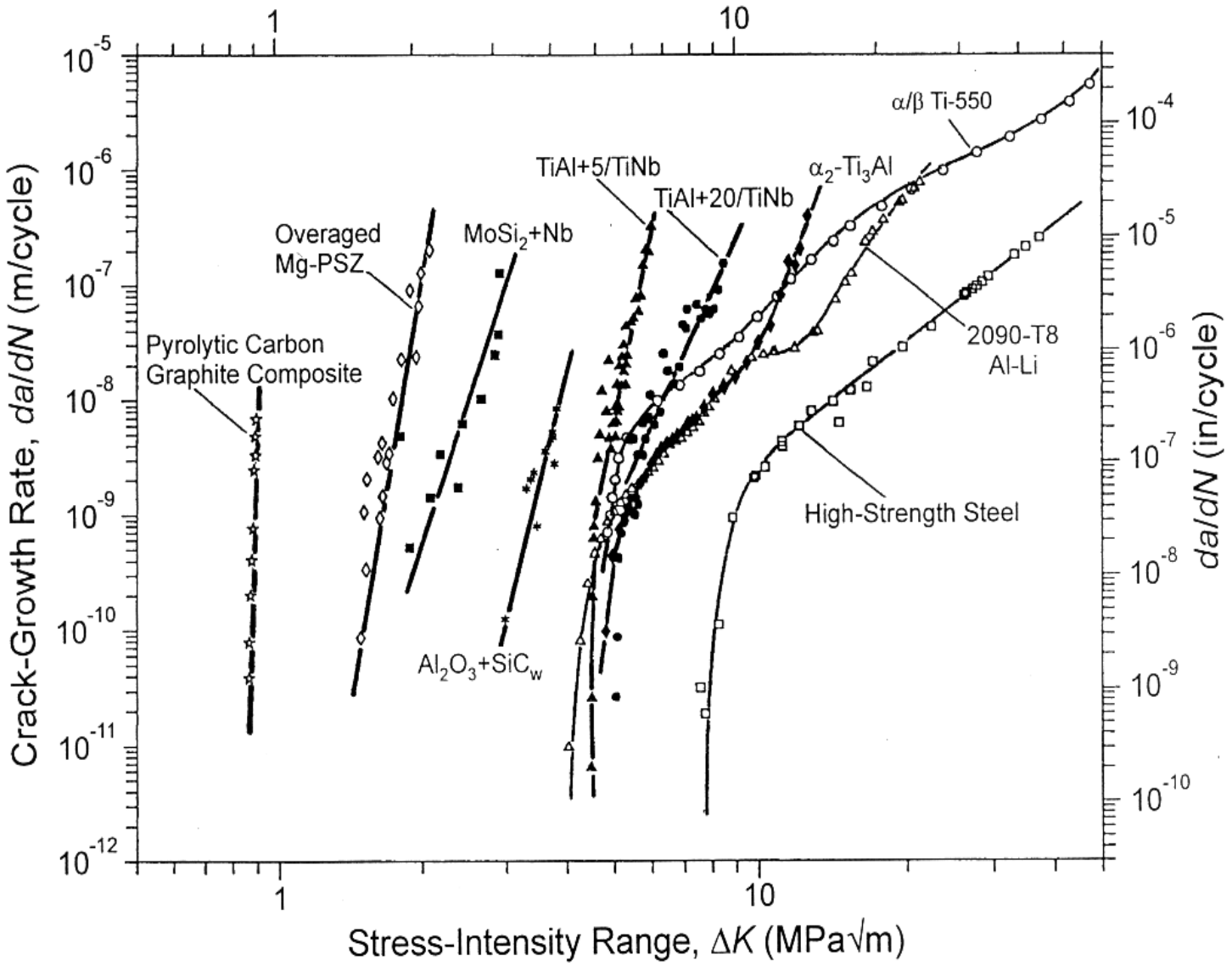
- for devices such as stents and heart valves, fatigue can be the limiting damage mechanism
- of the typical materials used (316 SS, Co-Cr, Ti, Ti-6Al-4V and NiTi), Nitinol has the worst fatigue-crack growth properties



- interestingly, Nitinol is invariably used in the superelastic austenitic condition, which is the worst microstructure for fatigue resistance

McKelvey & Ritchie, *J. Biomed. Mat. Res.,1999; Metall. Trans., A*,2001

….. and pyrolytic carbon is even worse!!!



Ritchie, *Mater. Sci. Eng.*,1989

Fracture Control Plan for Implant Devices

Motivation

- To quantify the severity of flaws (cracks) during production and handling of the device and to quantify their effect of its structural integrity
- To provide a methodology for conservative life prediction of the device *in vivo*
- To design a meaningful *quality control plan* to prevent premature failures both during production/handling and *in vivo*

Initial Approach

will it fail?

- Perform comprehensive stress analysis – compare to mechanical properties

how will it fail?

- Identify limiting *in vivo* damage mechanisms - invariably this is fatigue

where will it fail?

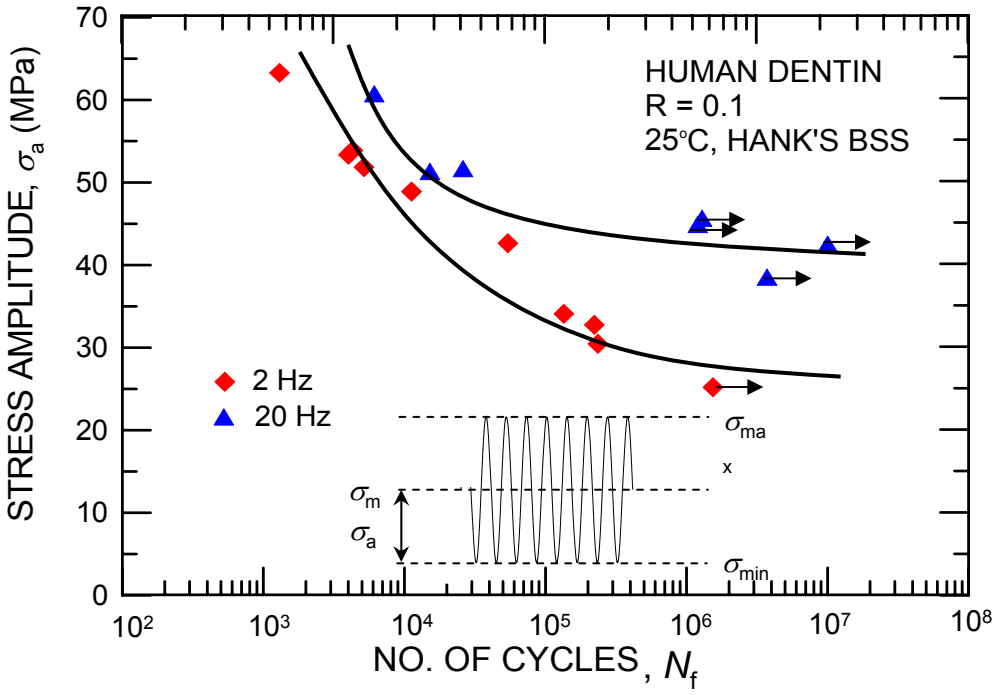
- Identify critical locations in the device - where there is the highest probability of failure (e.g., where the stresses are highest)

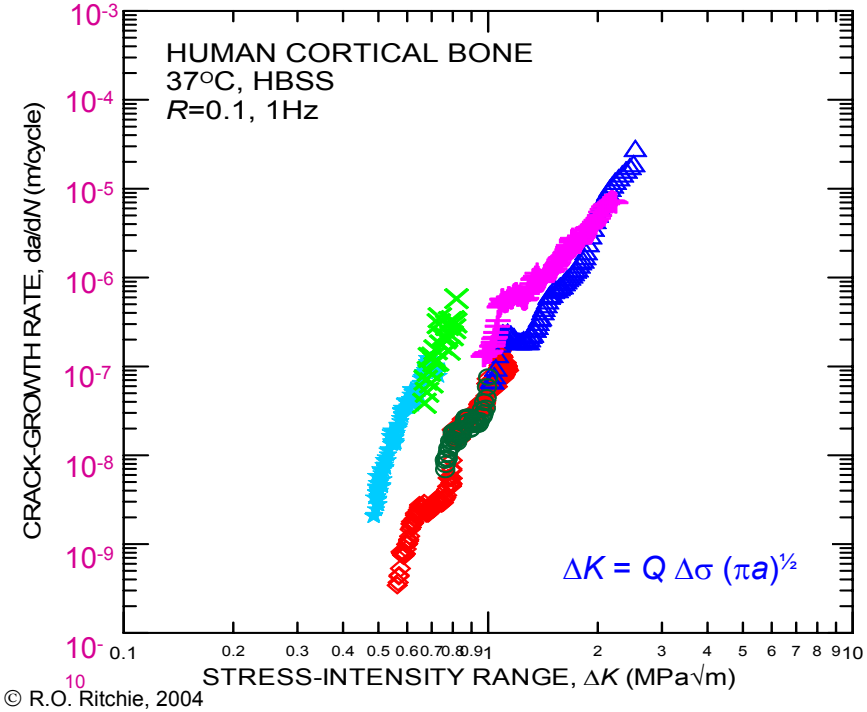
Paradigm change: Design, life-prediction and quality control should be based on *testing to failure,* not to survival

Methodologies for Fatigue Life Prediction

Stress-Strain/Life (S/N) Approach

- Traditional approach relating applied stresses/strains to the total fatigue life, i.e., cycles both to initiate and propagate a crack to failure
- Pros: simple testing and analysis
- Cons: not always conservative, cannot account for flaws, need many tests to give good statistics

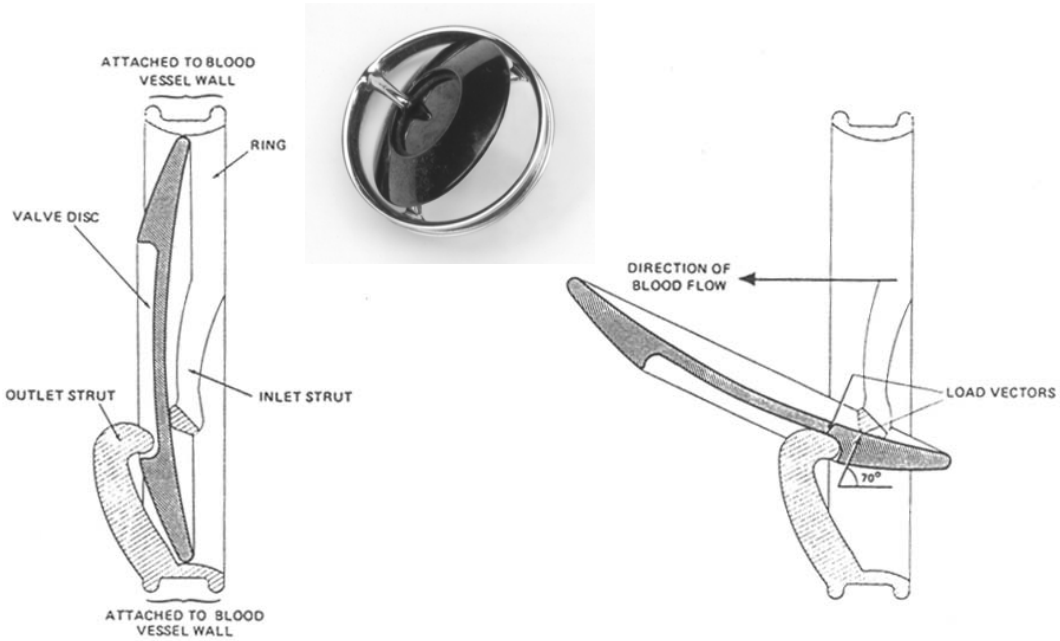




Damage-Tolerant Approach

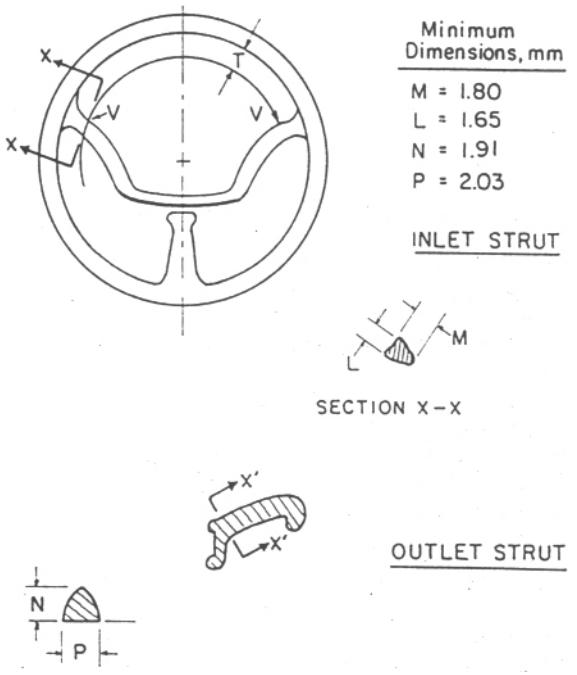
- Fracture mechanics approach where life is computed as the cycles for a pre-existing crack to propagate to failure
- Pros: generally conservative, can relate device lifetimes to device quality
- Cons: more difficult testing, problems with small cracks

Case Study: metallic mechanical heart valve



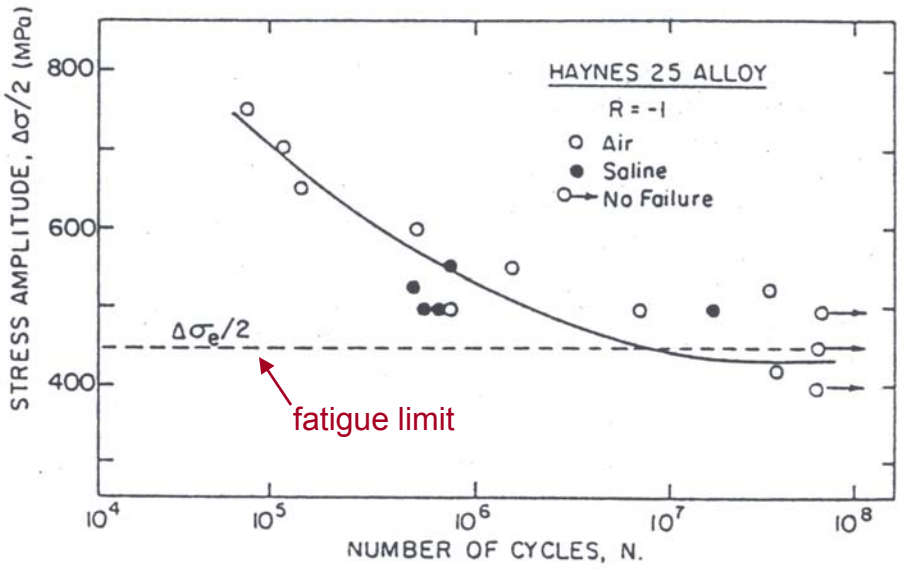
Shiley Monostrut valve

- Co-Cr (Haynes 25) housing
- pyrolytic carbon occluder
- no welds!



- critical locations identified at the base of the struts, as these experience the highest (bending) stresses
- outlet strut is particularly critical as it is plastically deformed during occluder insertion

Stress-Strain/Life (S-N) Analysis



- stress-life data represents the total lifetime as a function of stress amplitude
- depending upon the loading, data must be measured, or converted, to reflect role of mean stress (σ_m):

$$\frac{\Delta\sigma_R}{2} = \frac{\Delta\sigma_{R=-1}}{2}\left[1 - \frac{\sigma_m}{\sigma_{UTS}}\right]$$

($R = \sigma_{min}/\sigma_{max}$)

- identify limiting failure mechanism(s)
- define critical location(s)
- estimate worse-case *in vivo* loading (e.g., from pulse duplicator studies)
- compute worse-case *in vivo* stresses (e.g., from numerical analysis)
- measure residual stresses in device material (e.g., by x-ray diffraction)
- determine stress-life (*S-N*) data under simulated physiological conditions
- estimate safe life as a function of worse-case stresses

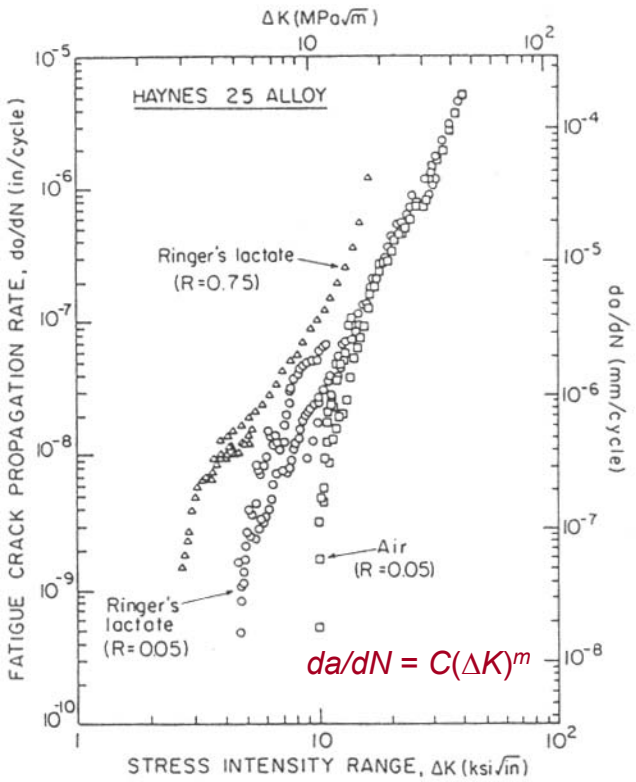
Ritchie & Lubock, *J. Biomech. Mech.*, 1986

Procedures for Damage-Tolerant Analysis

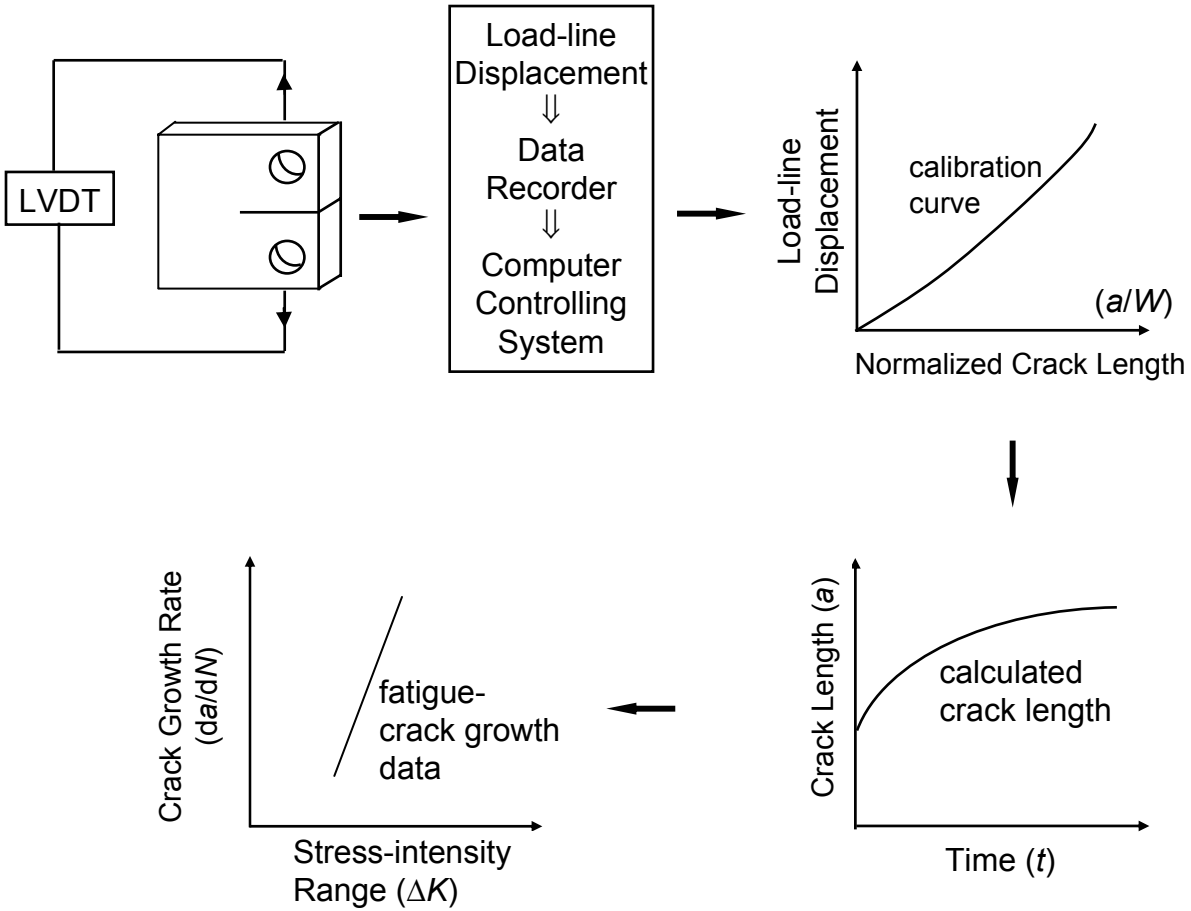
- identify limiting failure mechanism(s)
- define critical location(s)
- estimate worse-case *in vivo* loading
- compute worse-case *in vivo* stresses
- measure residual stresses
- compute of stress-intensity factors *K* for worse-case flaws in critical locations
- measure crack velocity-stress intensity (*v*-*K*) relationships *in vitro*
- determine critical (largest) defect size to cause final failure (*e.g.,* defined by the fracture toughness, K_{Ic})
- compute lifetimes as a function of initial flaw size
- calculate initial flaw size that can yield an acceptable life – *the required detectable flaw size*
- design of a non-destructive testing procedure to detect such flaws in every device - *this provides the basis for Quality Control of the device*

$$K = Q\,\sigma\,(\pi a)^{1/2}$$

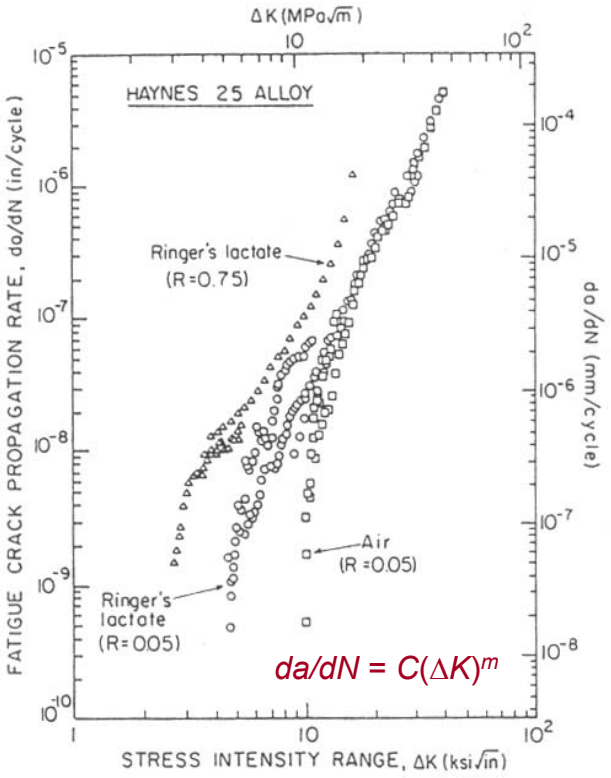
where *K* is the stress intensity
σ is the *total* in-service stress
a is the crack size
Q is a geometry factor (of order unity)



Measurement of Fatigue-Crack Growth Properties



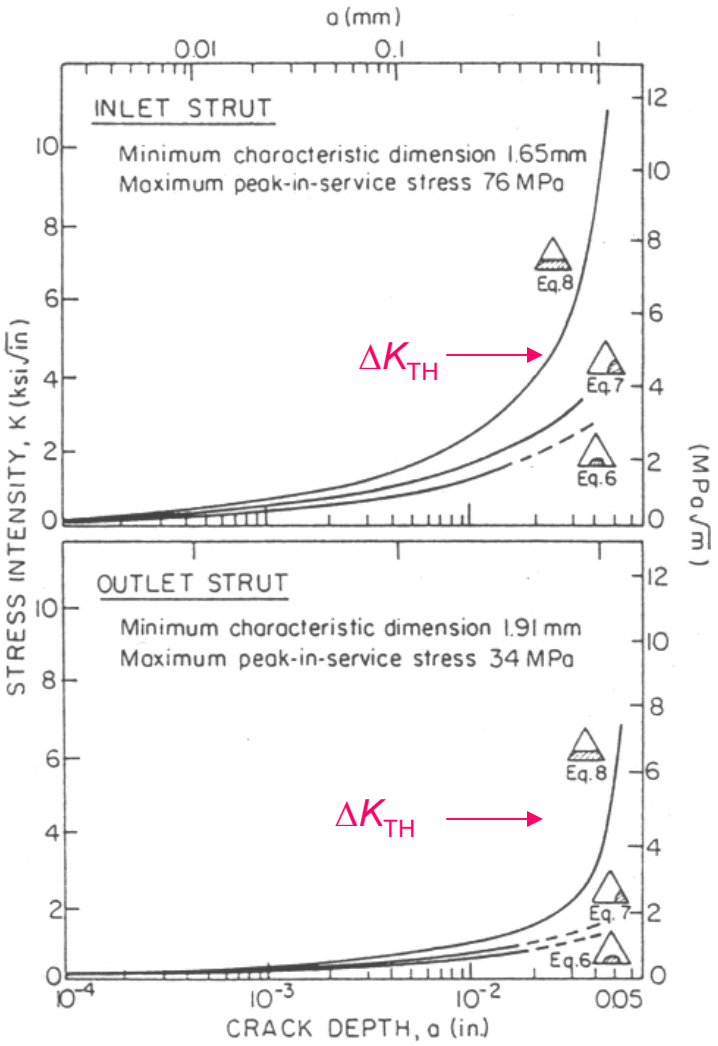
- crack-growth rates, with respect to time (*da/dt*) or cycles (*da/dN*), measured in simulated physiological environment



- results in Ringer's solution for Co-Cr alloy Haynes 25 show that fatigue cracks will propagate (for $R \sim 0$) above a fatigue threshold of $\Delta K_{TH} \sim 5$ MPa√m

Computation of Stress-Intensity Factors

- compute of stress-intensity factors, *K*, for worse-case flaws in critical locations
- compare *K* values, as a function of crack size, *a*, with critical values for failure:
  - K_{Ic} - fracture toughness
  - ΔK_{TH} - threshold for fatigue cracking
  - K_{Iscc} - threshold for sustained-load cracking
- This provides an initial quantification as a function of flaw size to whether the device will either:
  - experience device failure
  - suffer subcritical crack growth by sustained-load cracking or more likely fatigue



Ritchie & Lubock, *J. Biomech. Mech.*, 1986

Estimation of Fatigue Lifetimes

Inputs

- identify *K* solution for worst-case crack configuration, e.g., for a circular flaw:

$$K = Q\,\sigma\,(\pi\,a)^{1/2}\,, \quad \text{where } Q = 2/\pi$$

- determine crack-growth relationship:

$$da/dN = C\,(\Delta K)^m$$

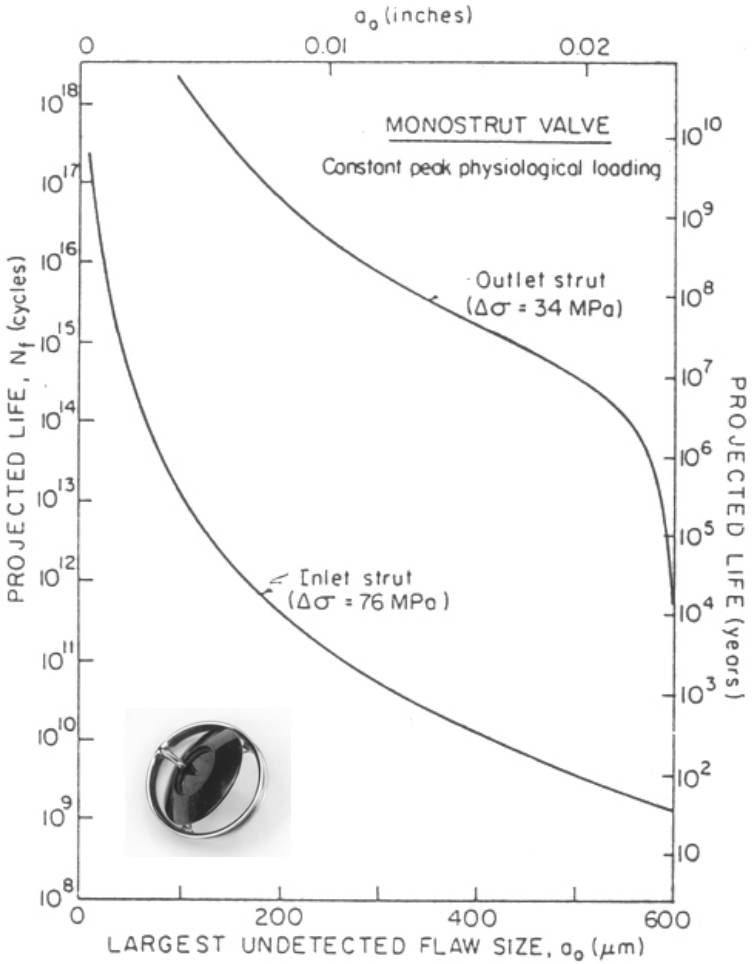
Damage-tolerant calculation

- integrate between the limits of the initial, a_o, and final, a_f, crack sizes to give the number of cycles to failure, N_f:

$$da/dN = C\,[Q\,\Delta\sigma\,(\pi a)^{1/2}]^m$$

$$N_f = \int_0^{N_f} dN = \int_{a_o}^{a_f} \frac{da}{C\,Q^m\,\Delta\sigma^m\,\pi^{m/2}\,a^{m/2}}$$

$$= \frac{2}{(m-2)\,C\,Q^m\,\Delta\sigma^m\,\pi^{m/2}} \left[\frac{1}{a_o^{(m-2)/2}} - \frac{1}{a_f^{(m-2)/2}} \right]$$

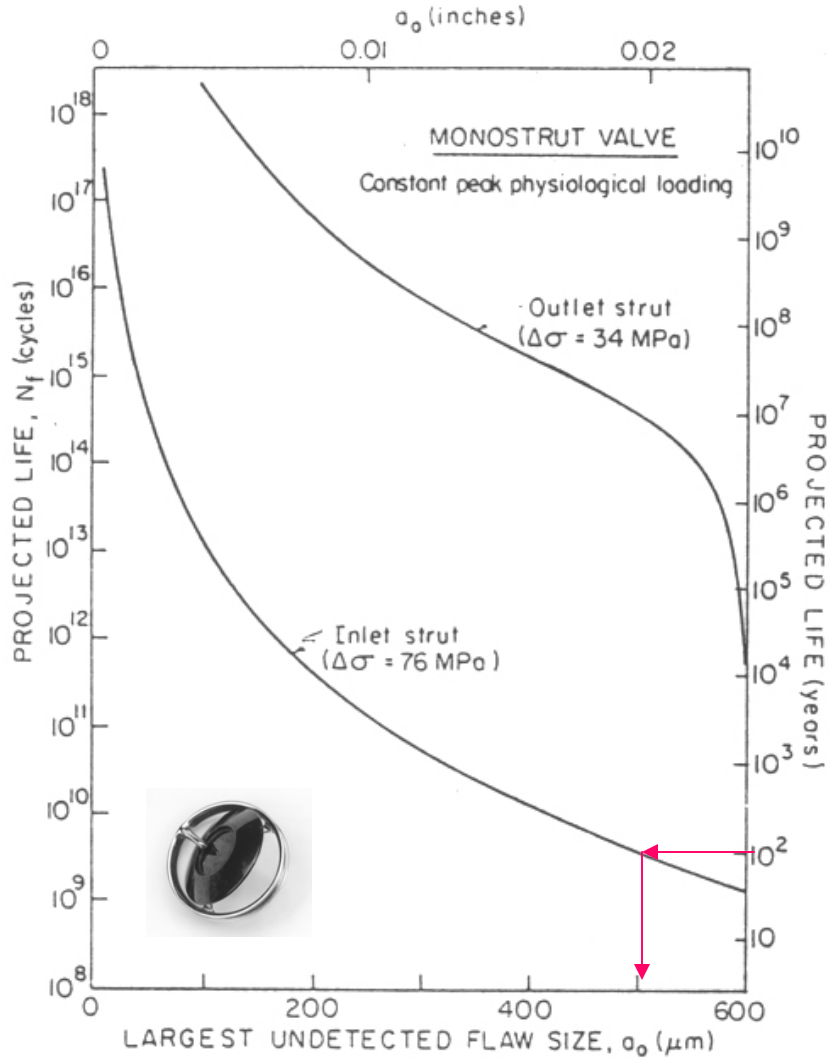


where $a_f = a_c = (1/\pi)\,(K_{max}/Q\,\sigma_{max})^2$

i.e., when $K_{max} = K_{Ic}$

Ritchie & Lubock, *J. Biomech. Mech.*, 1986

Relevance of Fatigue Lifetimes vs. Flaw Size Data



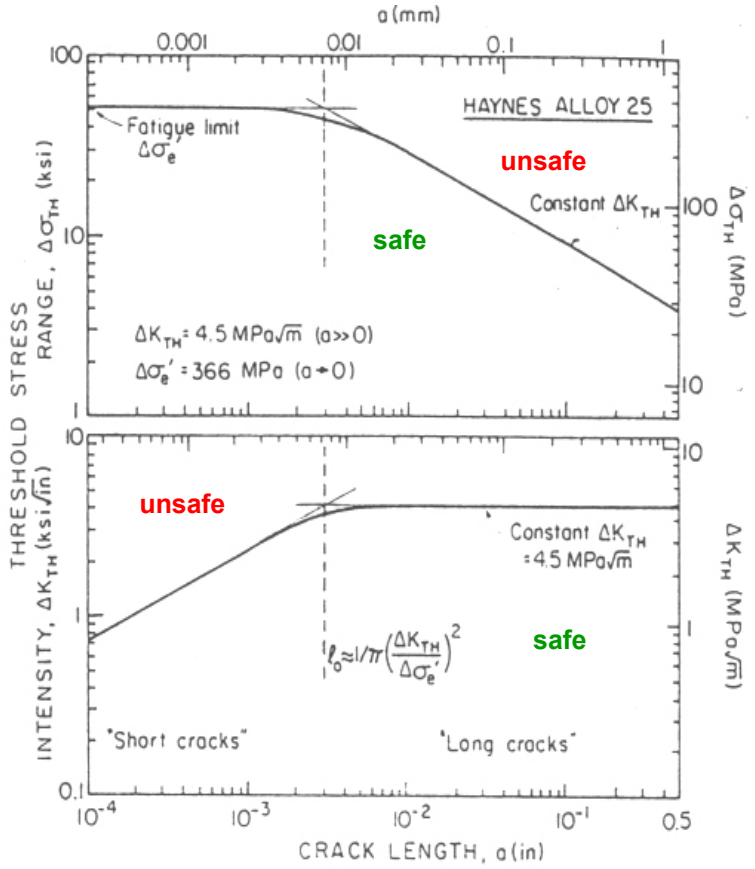
Projected Lifetime vs. Flaw Size Plots

- gives conservate estimate of lifetime of device (under worst-case *ex vivo* loading) in terms of size of pre-existing flaws
- use to define limiting flaw size that cannot grow to failure during patient lifetime
- for the present case, to achieve a life of ~100 years, pre-existing crack sizes must be <500 μm
- this represents the ***required detectable flaw size***
- ***Quality control*** is thus achieved by inspecting every valve and rejecting all valves containing flaw sizes greater than this size

Ritchie & Lubock, *J. Biomech. Mech.*, 1986

Problem of Small Cracks

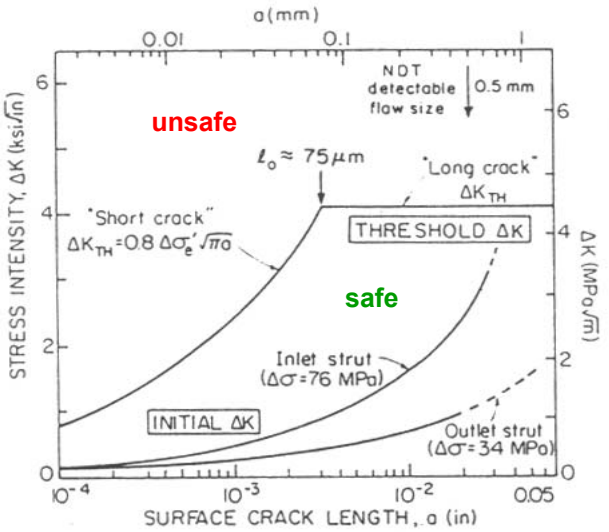
Kitagawa-Takahashi diagram



- when cracks are physically very small, fatigue threshold ΔK_{TH} is no longer constant and decreases with decreasing crack size
- this is the "small-crack effect" and can lead to non-conservative life predictions
- in engineering terms, this effect occurs at crack sizes defined by:

$$l_o \approx (1/\pi)\,(\Delta K_{TH}/Q\Delta\sigma_e)^2$$

ΔK_{TH} = large-crack fatigue threshold
$\Delta\sigma_e$ = smooth-bar fatigue limit
and $K = Q\sigma(\pi a)^{1/2}$

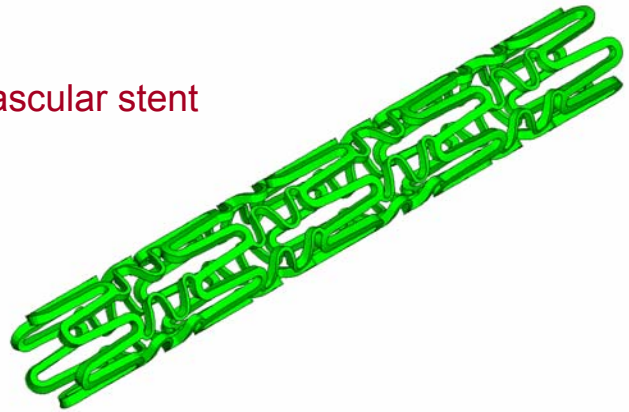


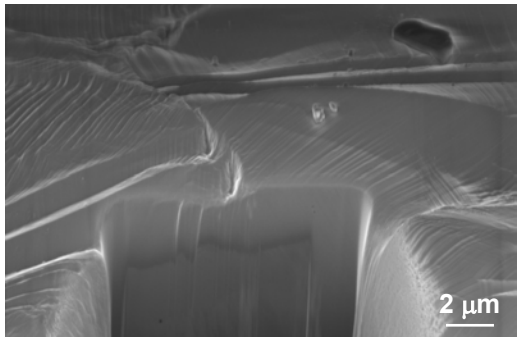
- in the example of the Monostrut valve, the small crack effect in Co-Cr alloy only occurred for crack sizes less than ~75 μm and thus was not relevant

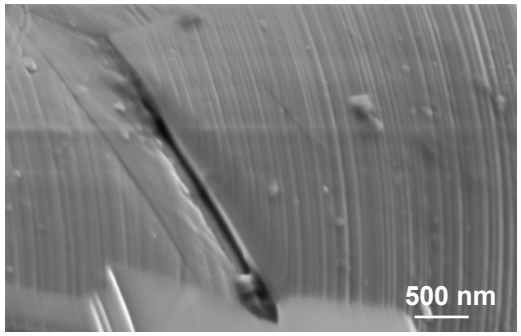
Ritchie & Lubock, *J. Biomech. Eng.*, 1986

Fracture Control Analysis for Stents

Cordis
endovascular stent





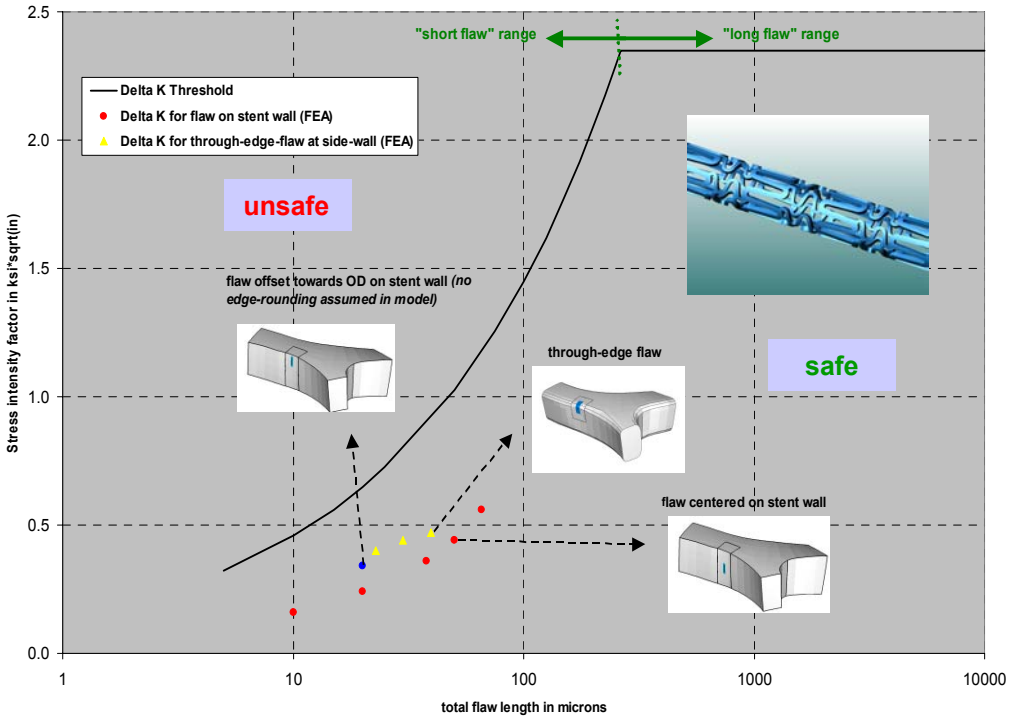


- flaws were numerically introduced in the expanded stent in critical locations
- flaw profile assumed to be semi-elliptical with a depth-to-length ($c/2a$) ratio of 1/3 (a = half surface length; c = depth), as verified by FIB microscopy of actual flaws
- for stress-life predictions, an infinite-life endurance limit and UTS (both determined at 95% confidence/99% reliability) used to calculate an "adjusted" endurance limit based on predicted maximum mean stresses
- corresponding damage-tolerant analysis assumes a threshold of ΔK_{TH} = 2.58 MPa$\sqrt{m}$ (R = 0.75) (Ritchie & Lubock, *J. Biomech. Eng.*, 1986)

Ramesh, Bergermeister, Grishaber, Ritchie, 2004

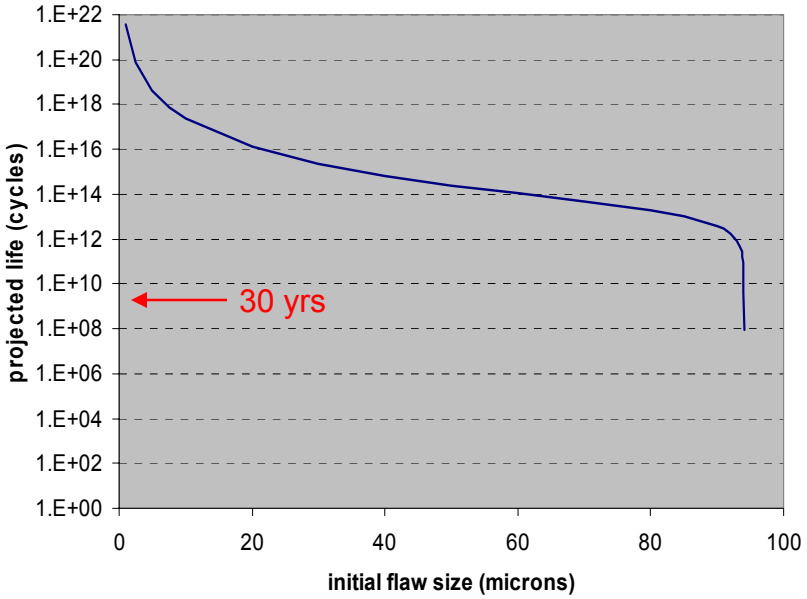
Cordis
a Johnson & Johnson company

Fracture Mechanics Analysis of Stent



- stress intensities for worst-case cracks in stent computed from numerical analysis
- thresholds as a function of flaw size estimated using Kitagawa diagrams from experimental *S/N* and ΔK_{TH} data

- lifetimes determined by integration of crack-growth laws
- predicted life is a function of pre-existing flaw size – *basis for quality control*



Ramesh, Bergermeister, Grishaber, Ritchie, 2004

Cordis
a Johnson & Johnson company

What about pyrolytic carbon heart valves?

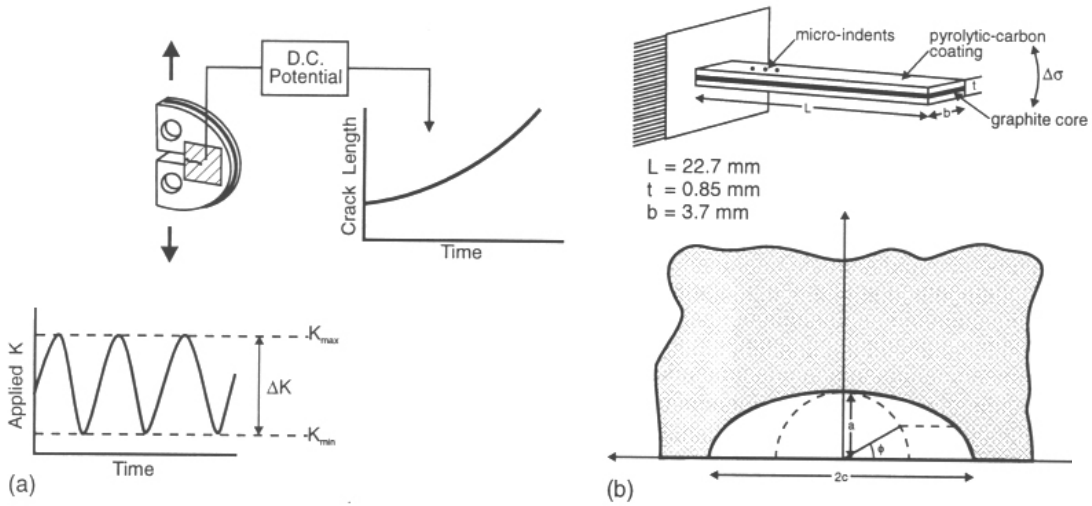
Material	Fracture toughness, K_{Ic}	Fatigue threshold, ΔK_{TH}	Paris exponent m	Required detectable flaw size
	(MPa √m)	(MPa √m)	(slope of da/dN-ΔK curve)	(μm)
Pyrolytic carbon	**1 - 2**	~0.7 - 2	**~50 - 100**	**tens of microns**
Co-Cr (Haynes 25) alloy	**60**	4.5	**~2 - 4**	**~0.5 to 1 mm**

- compared to metallic Co-Cr and Ti alloys, pyrolytic carbon is more than an order of magnitude more brittle
- as brittle materials are extremely sensitive to stress and presence of flaws, life prediction can be quite difficult - *i.e.,* extremely sensitive to stress and flaw size, as:

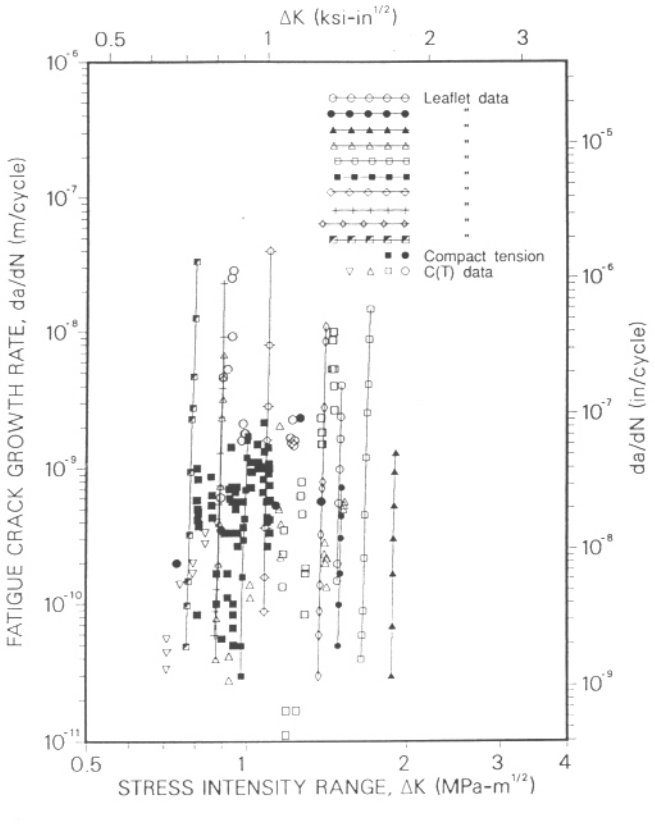
$$N_f \propto \sigma^{-m} \quad \& \quad a^{-(m-2)/2}$$

- residual stresses in pyrolytic carbon and pyrolytic-carbon coated graphite can be large (~30-100 MPa) and are difficult to measure
- required detectable flaw sizes can be extremely small (~tens of microns)

Measurement of Fatigue-Crack Growth Properties in Pyrolytic Carbon Materials



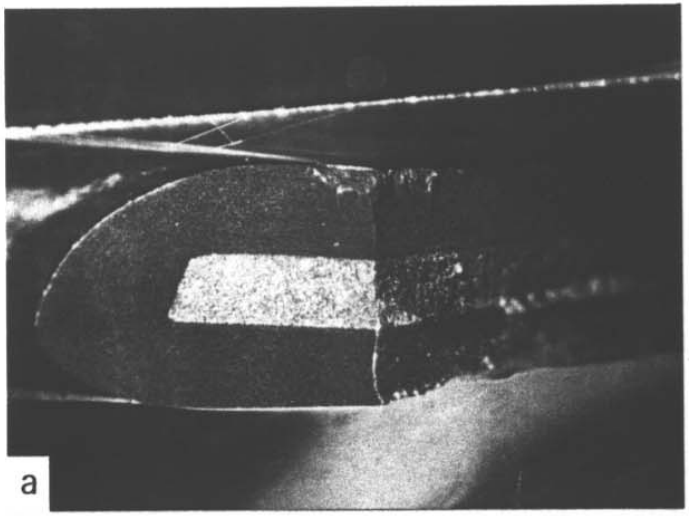
- as pyrolyric carbon is so brittle, initiating cracks and controlling crack growth can be quite difficult



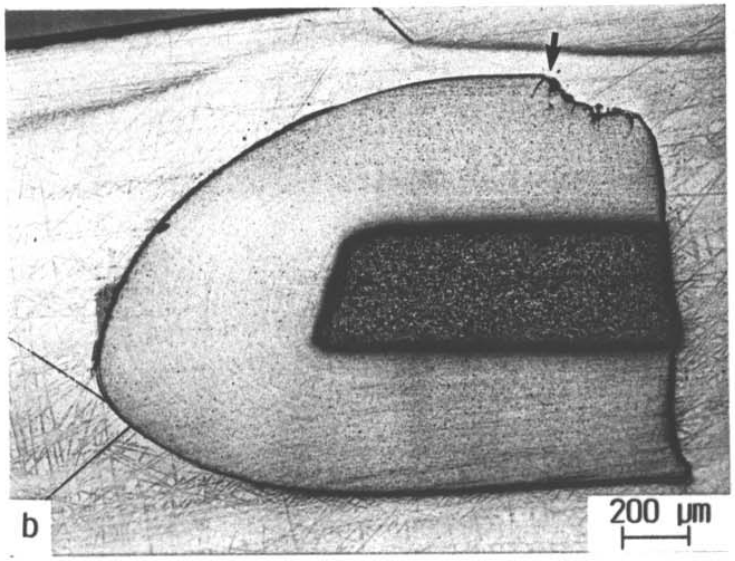
- resulting crack-growth rate data, in the form of *da/dN* vs. ΔK plots, can show:
  - significant scatter
  - low thresholds (ΔK_{TH} ~ 0.7 to 2 MPa$\sqrt{m}$)
  - very high Paris exponents of *m* ~ 50 - 100

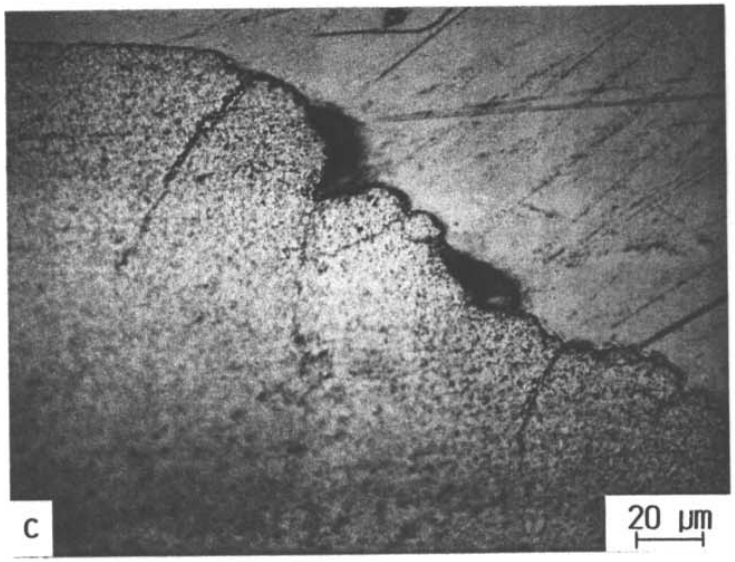
Ritchie *et al.*, *J. Biomed. Mat. Res.*, 1990

Cavitation-Induced Fatigue Cracks in Pyrolytic Carbon

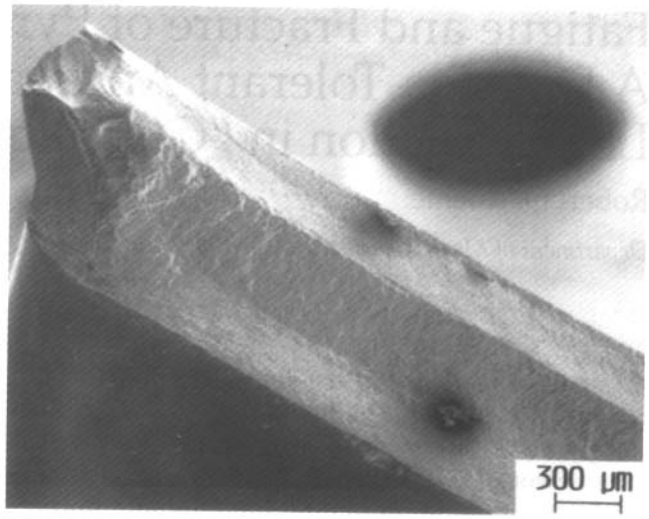


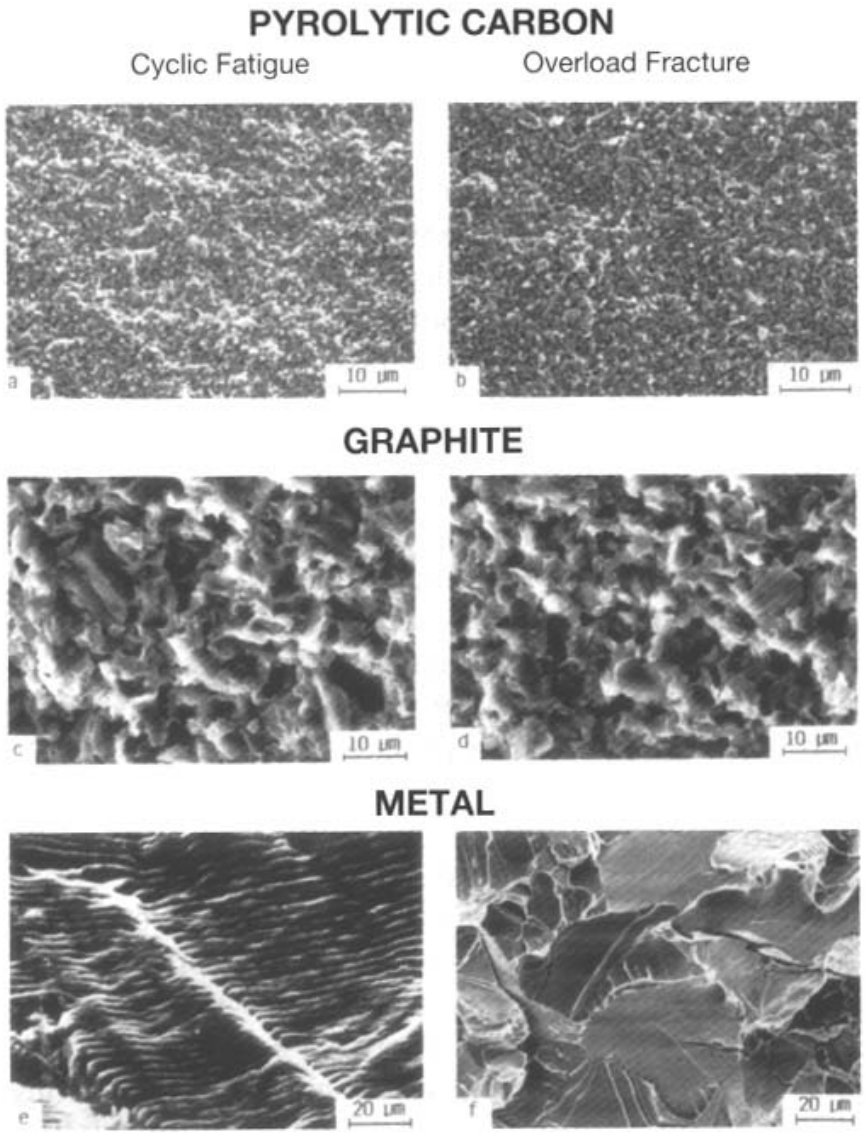
Retrieved clinical valve: mitral position





Fractography of Pyrolytic Carbon

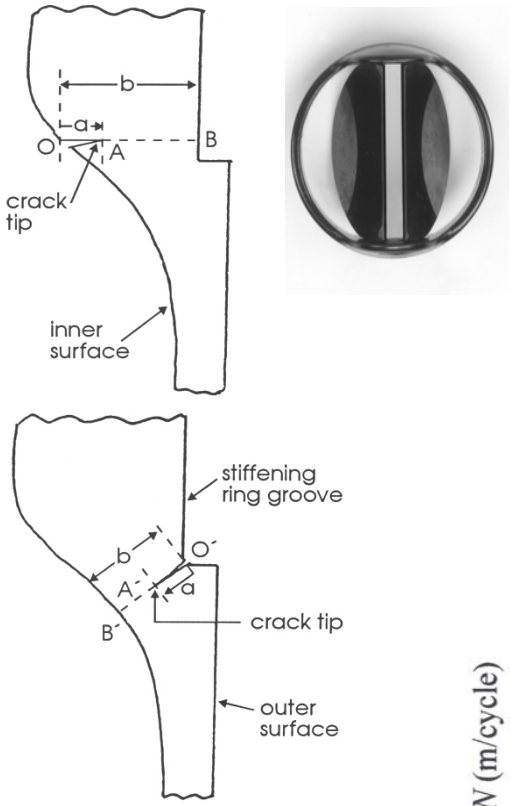




- in metallic materials, fatigue cracks have a unique morphology (*e.g.*, fatigue striations)
- in pyrolytic carbon and graphite (like other brittle solids), the morphology of fatigue failures is essentially identical to overload failures

Ritchie, Dauskardt & Pennisi, *J. Biomed. Mater. Res.*, 1992

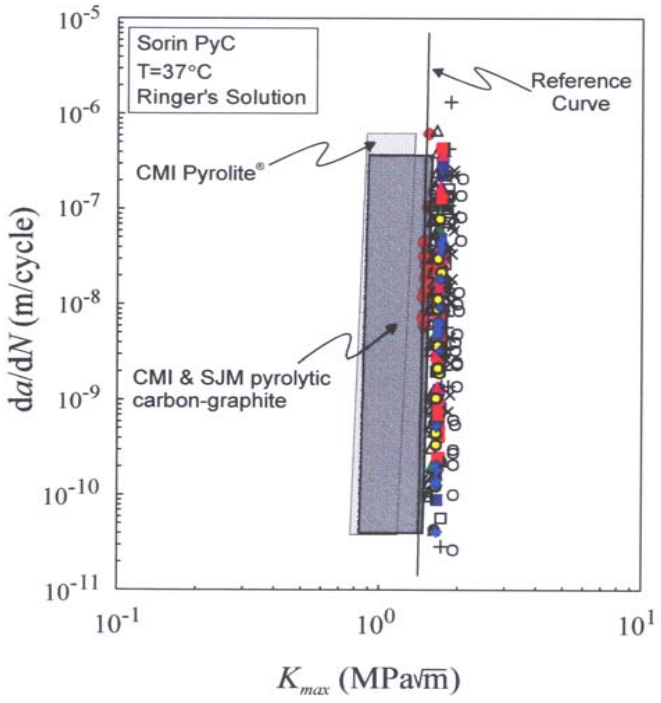
Case Study: Pyrolytic Carbon Mechanical Heart Valve

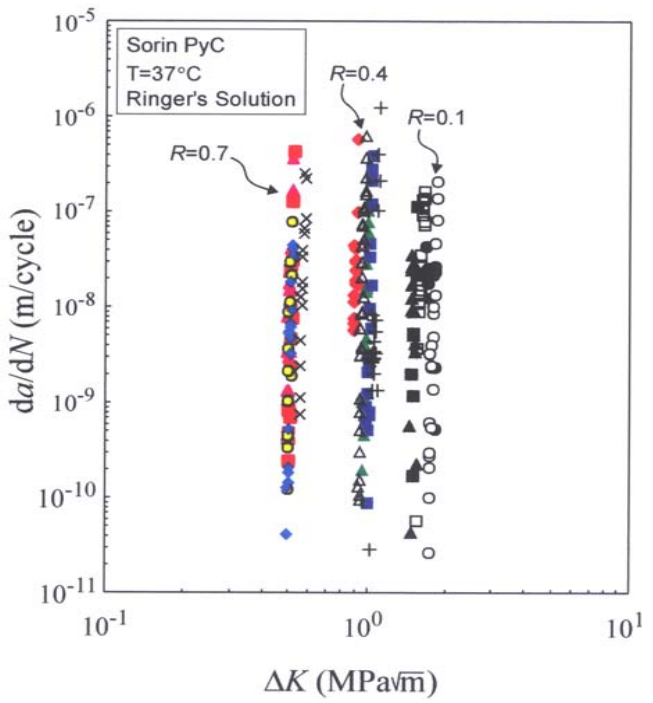


- damage-tolerant lifetime analyses can be performed for brittle implants in similar manner to metallic devices

$$N_f = \int_0^{N_f} dN = \int_{a_o}^{a_f} \frac{da}{CQ^m \Delta\sigma^m \pi^{m/2} a^{m/2}} = \frac{2}{(m-2)\, CQ^m \Delta\sigma^m \pi^{m/2}} \left[\frac{1}{a_o^{(m-2)/2}} - \frac{1}{a_f^{(m-2)/2}} \right]$$

- analyses are complicated by scatter in toughness and fatigue data and by the large crack-growth exponents

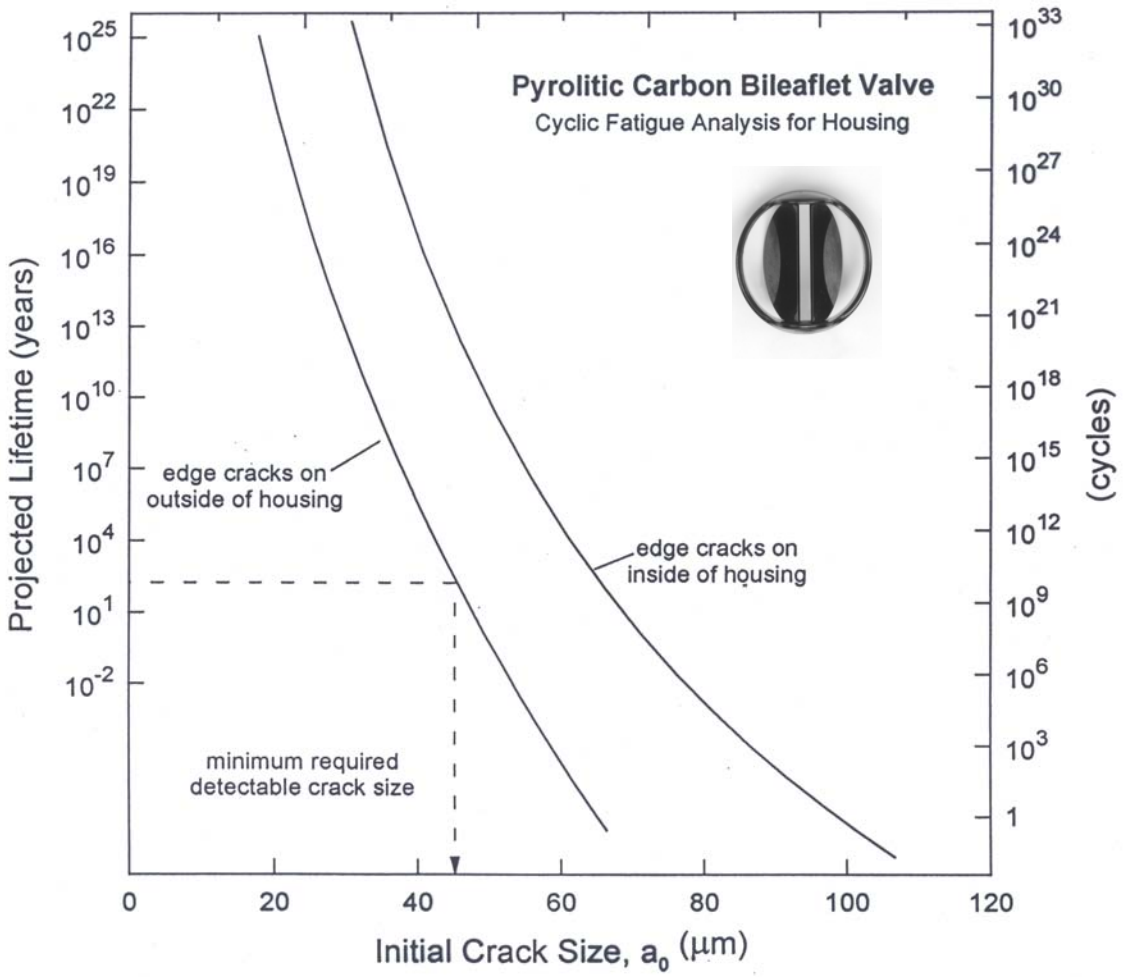




- *da/dN* data in pyrolytic carbon is primarily a function of K_{max},
- $da/dN = C' (K_{max})^m$
- with $K_{max,TH} \sim 1$ MPa√m
- $m \sim 50 - 100$

Ritchie, *J. Heart Valve Disease*, 1996

Relevance of Fatigue Lifetimes vs. Flaw Size Data



$$N_f = \int_0^{N_f} dN = \int_{a_o}^{a_f} \frac{da}{C\,Q^m\,\Delta\sigma^m\,\pi^{m/2}\,a^{m/2}} = \frac{2}{(m-2)\,C\,Q^m\,\Delta\sigma^m\,\pi^{m/2}}\left[\frac{1}{a_o^{(m-2)/2}} - \frac{1}{a_f^{(m-2)/2}}\right]$$

- large crack-growth exponents of $m \sim 50 - 100$ in brittle materials leads to an extreme sensitivity of the life to stress and flaw size:

$$N_f \propto \sigma^{-(50\text{-}100)} \quad \& \quad a_o^{-(25\text{-}50)}$$

- for device lifetime of ~100 yrs, initial flaw sizes must, in this case, be less than ~40 μm
- for quality control, this requires NDT procedures that can detect and reject all components that contain pre-existing flaws larger than this *micron-scale* size

Ritchie, *J. Heart Valve Disease,* 1996

Quality Control: Defect Detection (NDT)

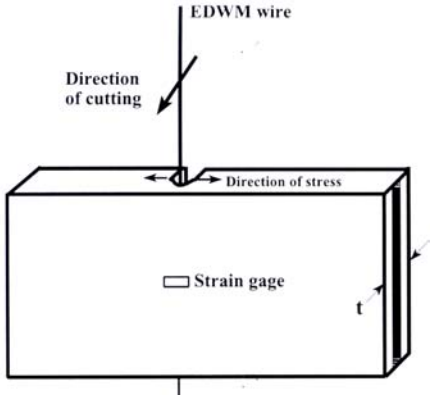
- based on typical damage-tolerant life-prediction calculations, the *required detectable defect sizes* are:
  - many hundred microns in metallic valves
  - tens of microns in pyrocarbon valves

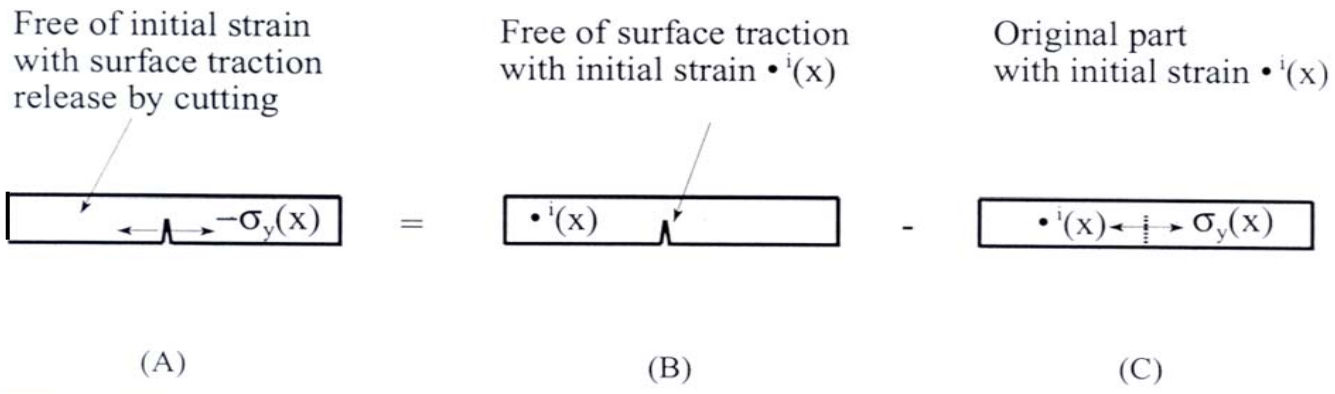
- to detect such defect sizes in metallic valves, SEM can be used
- to detect the smaller defects in pyrocarbon valves, a proof test must be used
  - *e.g.,* pneumatic pressure on the leaflets of the valve at a proof stress σ_p ~ 5 times physiological pressure
  - if the valve does not fail, then the maximum initial defect size a_o must the less than the critical defect size, a_c, at that proof stress:

$$a_o < 1/\pi \, (K_{Ic}/Q \, \sigma_p)^2$$

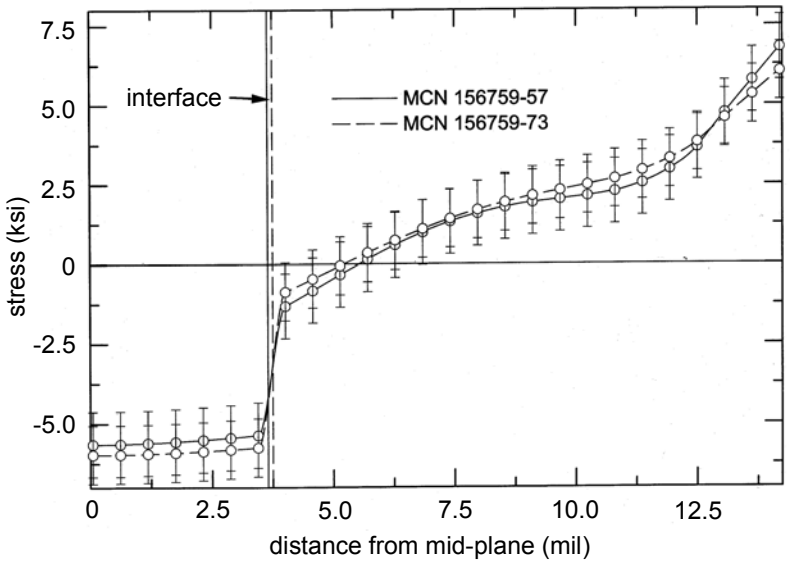
  - survival of the valve at a given σ_p implies a maximum a_o, which in turn implies a minimum lifetime, N_f
  - proof test must (i) simulate *in vivo* loading, (ii) not damage component, and (iii) must use upper-bound K_{Ic} (*c.f.,* life prediction uses lower-bound)

Residual Stress Measurement





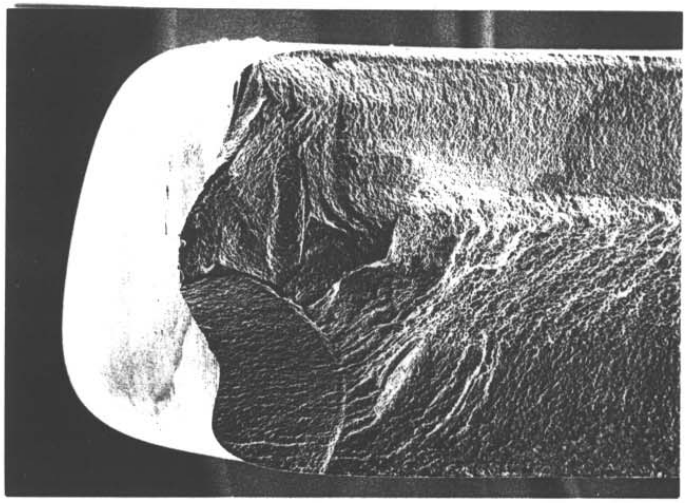
- in pyrolytic carbon, CVD processing can leave residual stresses far larger than *in vivo* stresses
- measurement complicated by the semi-crystalline structure and scatter in near-surface stresses
- accurate measurements can be obtained using a *crack compliance* technique
- an EDM crack is progressively cut into the component section and the resulting strain due to cutting recorded
- using linear superposition, the gradient in residual strain and stress can be accurately determined



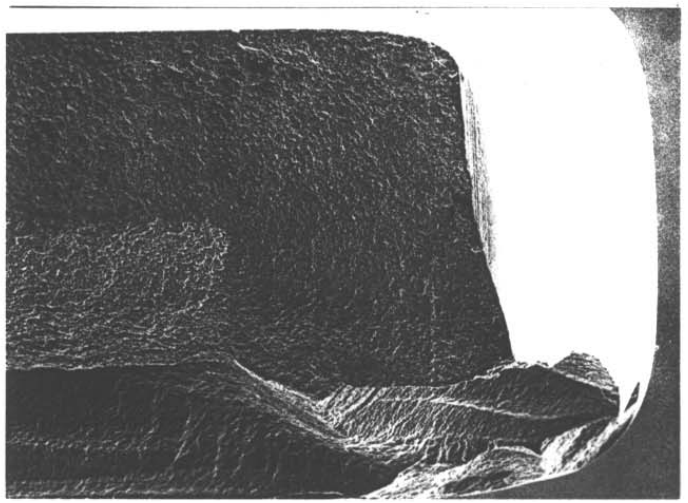
Cheng, Finnie, Ritchie, *SEM,* 2001

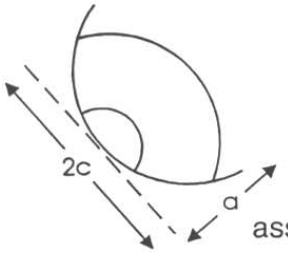
Failure Analysis: identifying critical flaw sizes

- Critical crack sizes for fatigue-crack growth and catastrophic failure



100 μm





$$K = Q(a/c, b/2t)\left(\sigma_{app} + \sigma_{res}^{max}\right)\sqrt{\pi a}$$

assuming linear gradient in residual stress

- at catastrophic failure, $K = K_{Ic} \sim 1 MPa\sqrt{m}$

for $a/c \sim 0.5$

– $a_c = \frac{1}{\pi}\left[\frac{1}{Q\left(\sigma_{app} + \sigma_{res}^{max}\right)}\right]^2 \approx 200\ \mu m$

– $2c_c \approx 800\ \mu m$

valve failed after 5 years, causing loss of life

- initial crack size to cause fatigue failure

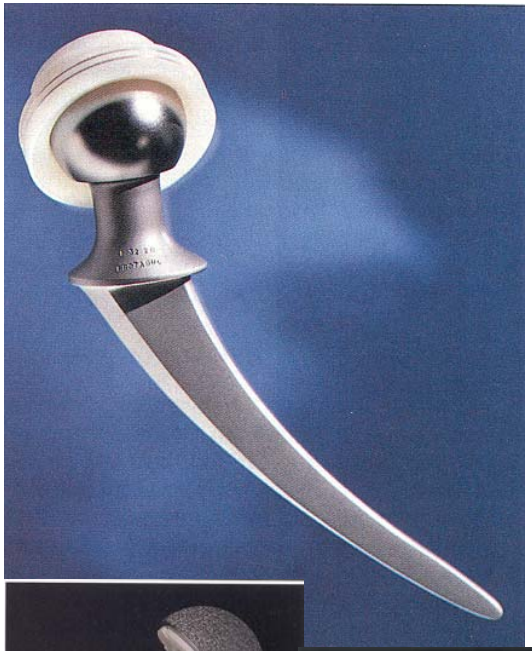
$$N_f = 2 \times 10^8 = \frac{2}{(m-2)CQ^m \pi^{m/2} \Delta\sigma^m}\left[a_i^{-\left(\frac{m-2}{2}\right)} - a_c^{-\left(\frac{m-2}{2}\right)}\right]$$

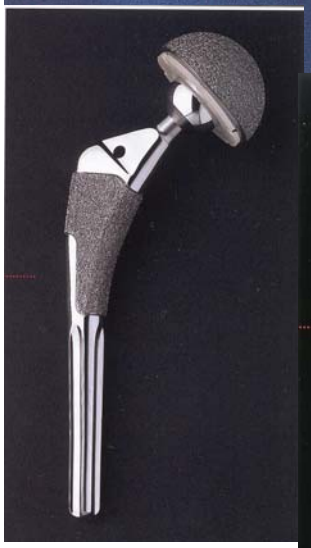
– $a_i \approx 40\ \mu m$

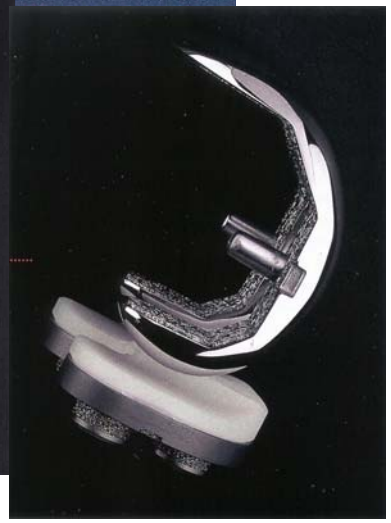
– $2c_i \approx 160 \mu m$

Ritchie, *J. Heart Valve Disease,* 1996

Life Prediction for Medical Prostheses







- over 500,000 knee and hip prostheses are implanted in the U.S. each year
- corresponding dental implants can be measured in the millions
- few studies devoted to estimating the life of such implants

- similar methodologies/analyses can be used for knee and hip implants
- prime failure processes involve interfacial mechanisms, *i.e.,* between the tissue and the implant
- damage-tolerant analyses therefore must rely on data for interfacial or near-interfacial crack growth

Conclusions

- Life prediction analyses represent the culmination of understanding of all aspects of the behavior and failure of an implant device
- For structural failures, critical inputs are the determination of peak *in vivo* stresses/strains and the limiting mechanism(s) of failure
- Design, life-prediction and quality control should be based on *testing to failure,* not to survival
- If a fracture mechanics (damage-tolerant) approach can be utilized, life prediction and risk assessment analyses can be directly translated into a rational quantitative basis for device quality control
- Critically important factors are an ability to detect flaws of a specific size (NDT) and the quantification of residual stresses
- Whereas such life prediction and quality control methodologies are established for heart valves, few corresponding analyses exist for other medical prostheses currently implanted in the human body