





Introduction to Biomaterials

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Introduction

- Medical implants and therapeutic devices have had an immense impact on modern health care.
- This exciting and important field only began in earnest about sixty years ago.

Biomaterials

- Medical implants and devices are composed of a wide variety of materials, called “biomaterials”, which include polymers, metals, ceramics, carbons and natural tissues.
- Where did they find the materials for the earliest devices?
- How did these “off the shelf” materials evolve into safer and purer forms, having a variety of novel designs and shapes?

We will see that in the beginning of the modern era of biomaterials and implants:

- **Surgeons** were the innovators in the 1940s-50s.
- They soon realized they needed help, and got it from **materials scientists and engineers** in the 1960s to 1980s.
- The materials engineers soon realized they needed help, and got it from **biologists** in the 1990s, and that continues today. Indeed, **BIOLOGY** is the driving force in our field today.

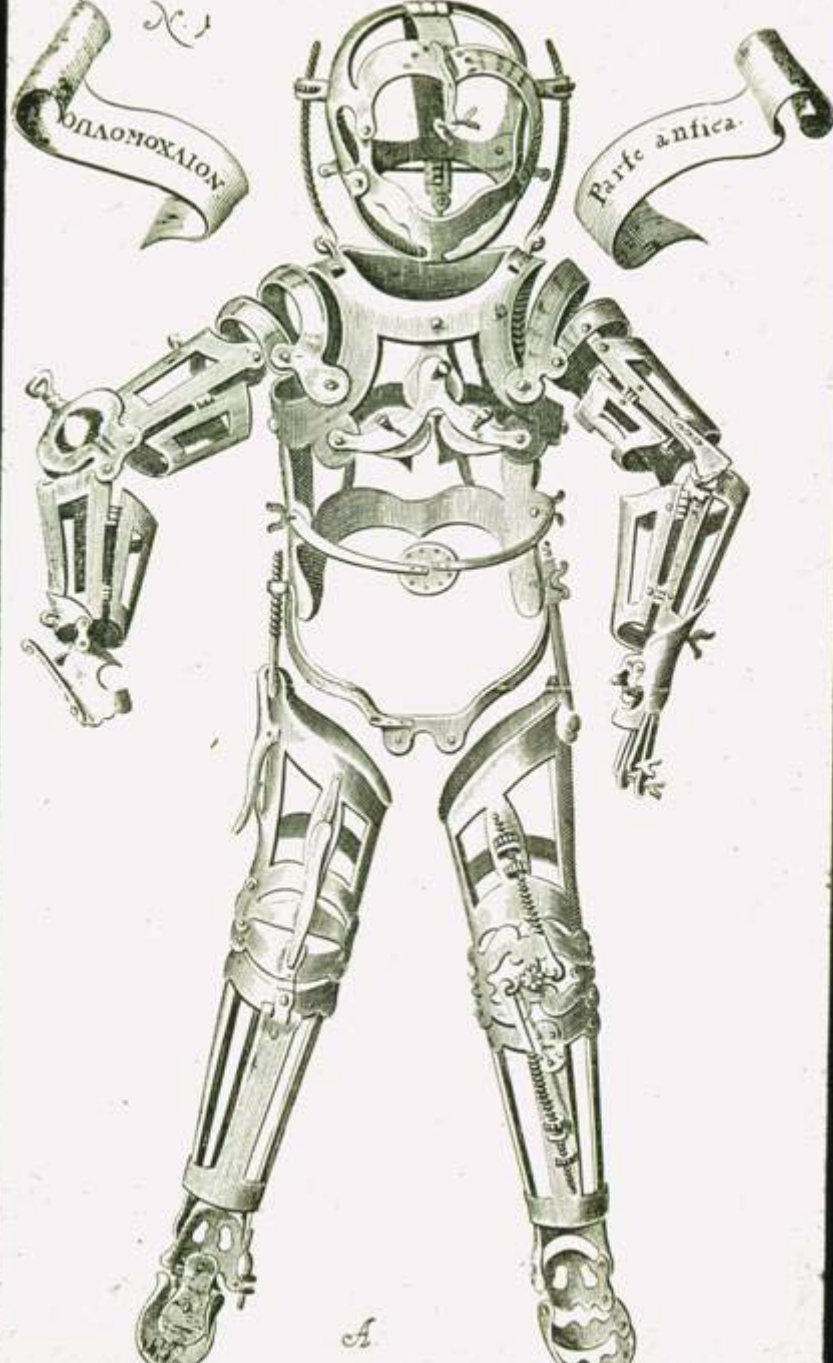
Here are some stories of how the earliest implants and devices were developed.....

What are the earliest known uses of biomaterials?

- Ancient Egyptians and Greeks used **gold** in dentistry.
- Around the time of Christ: Camel caravans used **copper** IUDs.
- 600 AD: Mayans used **sea shells** (nacre) as teeth implants.
- 1400S-1500S: **Da Vinci** and **Galileo** study “biomechanics” in **Italy**.
- 1600s-1900s: **Iron** was used in suits of armor and this led to its use in orthopedic supports.
- 1770s: George Washington, first President of USA, had a **wooden** tooth.

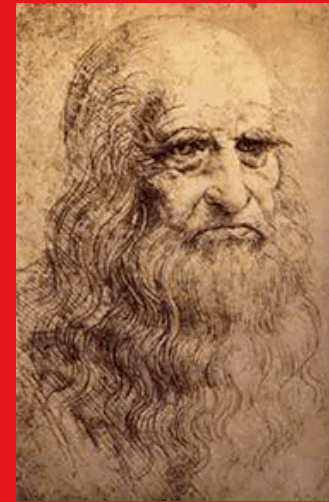
In WORLD WAR II, many new materials were developed--> **polymers**.

- 1940s: **Kolff** in The Netherlands develops artificial kidney using **sausage casing**.
- 1940/50s: **Ridley** in UK develops **PMMA** intraocular lens (IOL).
Wichterle in Prague develops **PHEMA** soft contact lens.
Failure of parachute **Nylon®** and **Teflon®** as vascular grafts
leads **DeBakey, Cooley, etc.** in USA to develop **Dacron®** grafts.
- 1950/60s: **Charnley** (with **Smith**) develop the artificial hip in UK using **Stainless® Steel, PE** and **MMA/PMMA** as bone cement.
- 1960/70s: **Kolff, Nose, Akutsu, etc.** in USA and Japan develop LVADs and artificial heart.
Yannas and **Burke** in USA develop **collagen/chondroitin sulfate** artificial skin for burn dressing.
- 1950/70s: Silicone injections (Japan) led to **silicones** in breast implants (USA).
- 1970-80s: **Schmitt and Frazza** in USA develop **PLA** degradable suture.
- 1980/90s: **Branemark** in Sweden discovers that bone binds to **Titanium** surface.
Hench in USA develops **ceramic glass** the bonds to bone.
Bottin in France develops **alumina** hip joint femoral head and cup.

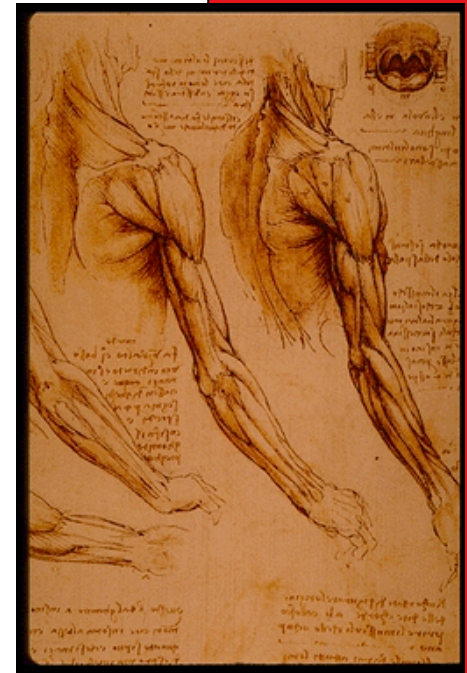
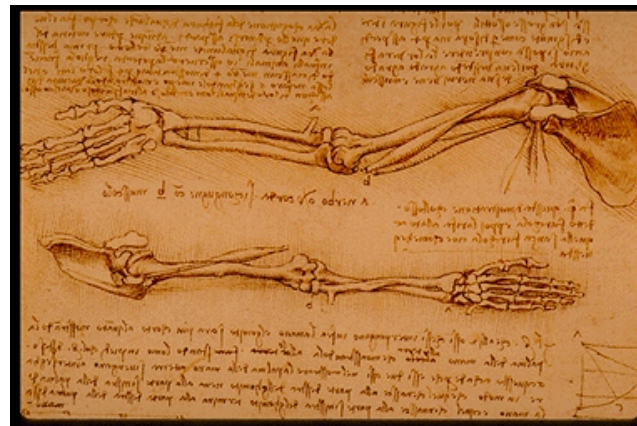
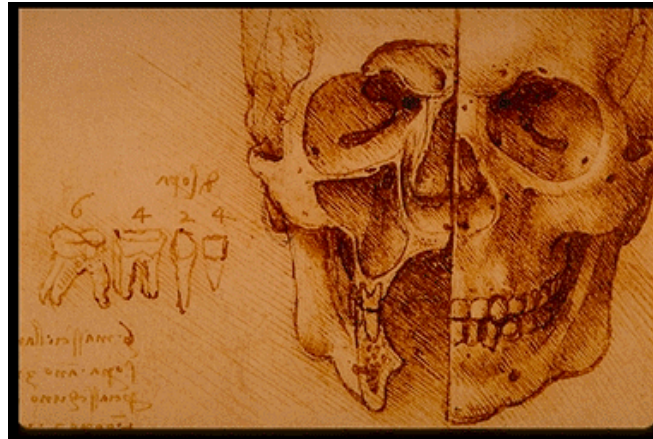
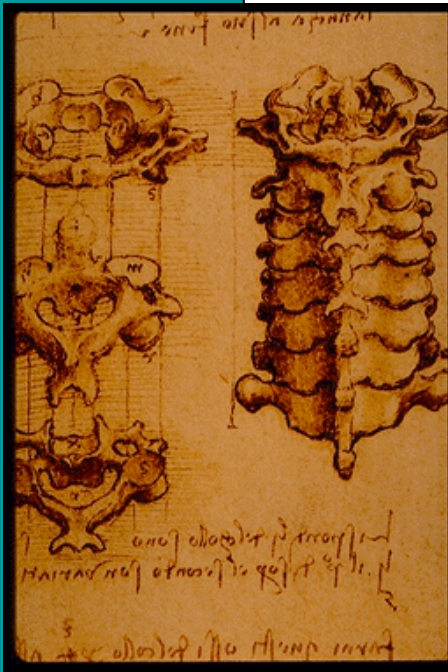




Perhaps
Leonardo
was the first
bioengineer!
(1452-1519)



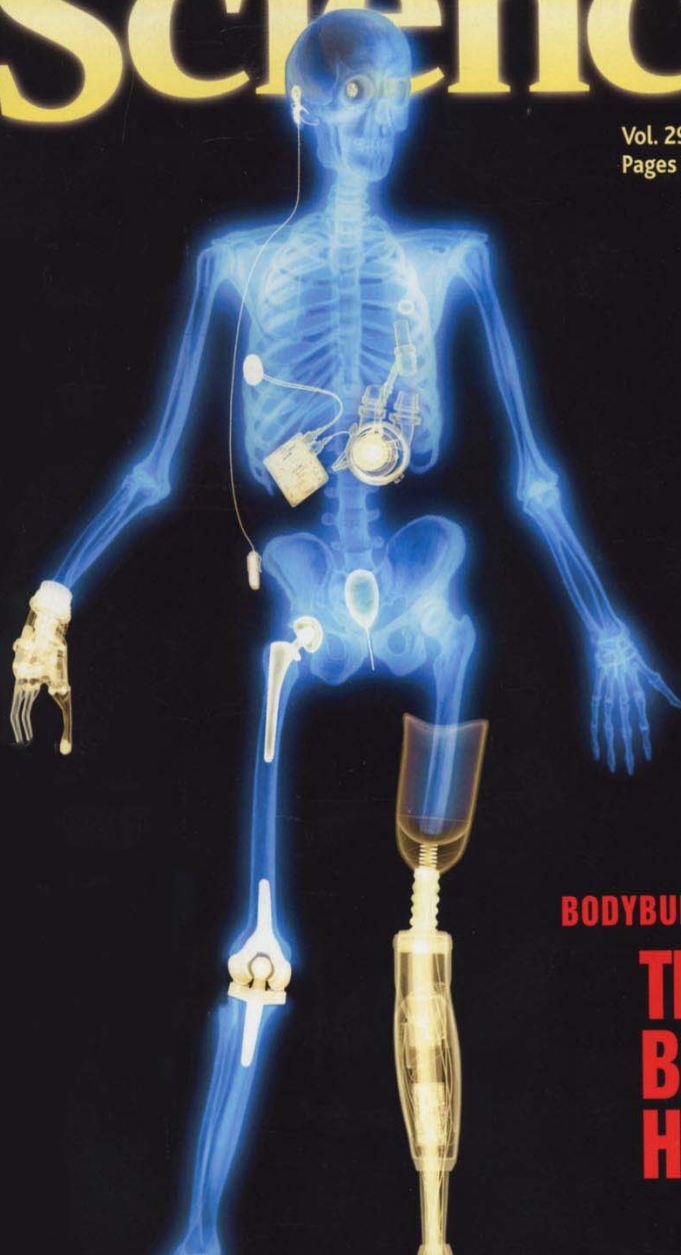
Leonardo made many detailed anatomical drawings. The cadavers he used in these observations were often stolen from a nearby morgue.



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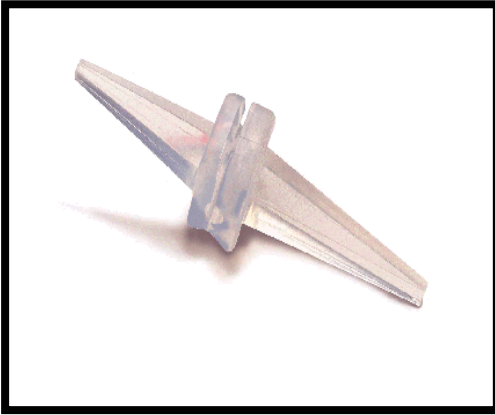


BODYBUILDING:

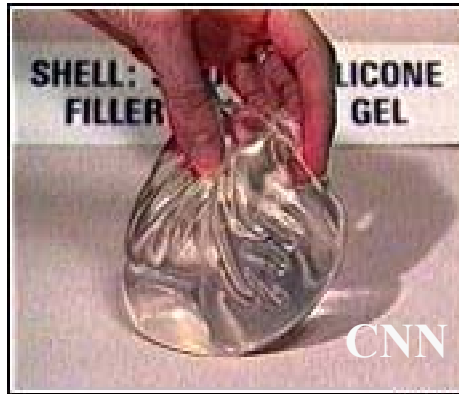
**The
Bionic
Human**

Common Medical Implants

Finger joint



Breast implant



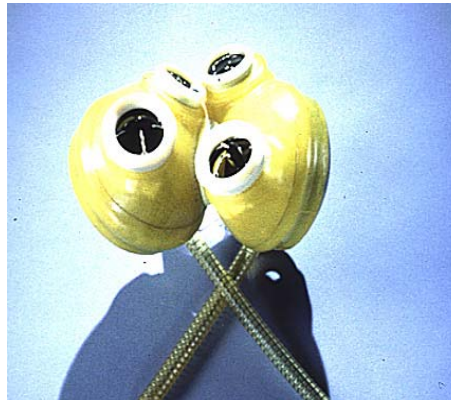
Heart valve



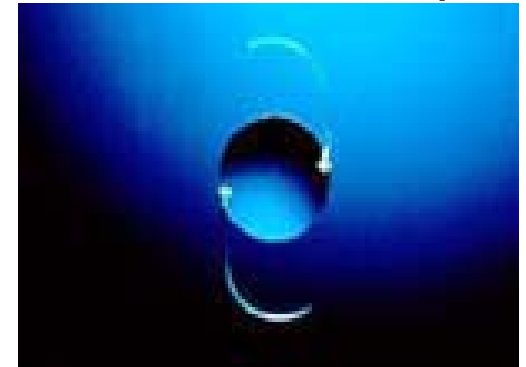
Hip joint



Artificial heart



Intraocular lens (IOL)



Medical implants save lives, improve quality of life -- but there are problems

Infection **inflammation** **thrombosis** **longevity**
fouling **loosening** **scarring** **lubricity**

Slide from Buddy Petner

Implants and Devices

1999 U.S. Estimates

Implants

Hip and knee joints	6,500,000
Pacemakers	5,000,000
Intra-ocular lenses (IOLs)	2,500,000
Stents	1,750,000
Heart valves	1,500,000
Vascular grafts	700,000

Devices

Oxygenators	1,000,000
Dialysers	825,000

\$250 billion = 7-9% of total US medical costs

CURRENT APPLICATIONS OF POLYMERIC BIOMATERIALS

IN VIVO

BIOMEDICAL

IMPLANTS

EX VIVO DEVICES

TOPICAL MATERIALS

DRUG DELIVERY SYSTEMS

**ARTIFICIAL TISSUES
AND ORGANS**

IN VITRO

BIOTECHNOLOGICAL

BIOSENSORS

DIAGNOSTICS

BIOSEPARATIONS

BIOPROCESSES

DIALYSIS
and
THE ARTIFICIAL KIDNEY



Willem Kolff, M.D.

*He invented the
artificial kidney
and has been a pioneer in the
development of
the artificial heart.*

*He is called the
“Father of artificial organs”*

*At some moment in The Netherlands
during World War II, he got the idea o
the artificial kidney.....*

The Kidneys

One major function of healthy kidneys is removal of the end products of protein metabolism. Every 24 hrs. they must remove:

~15 g of urea

~ 3 g of creatinine

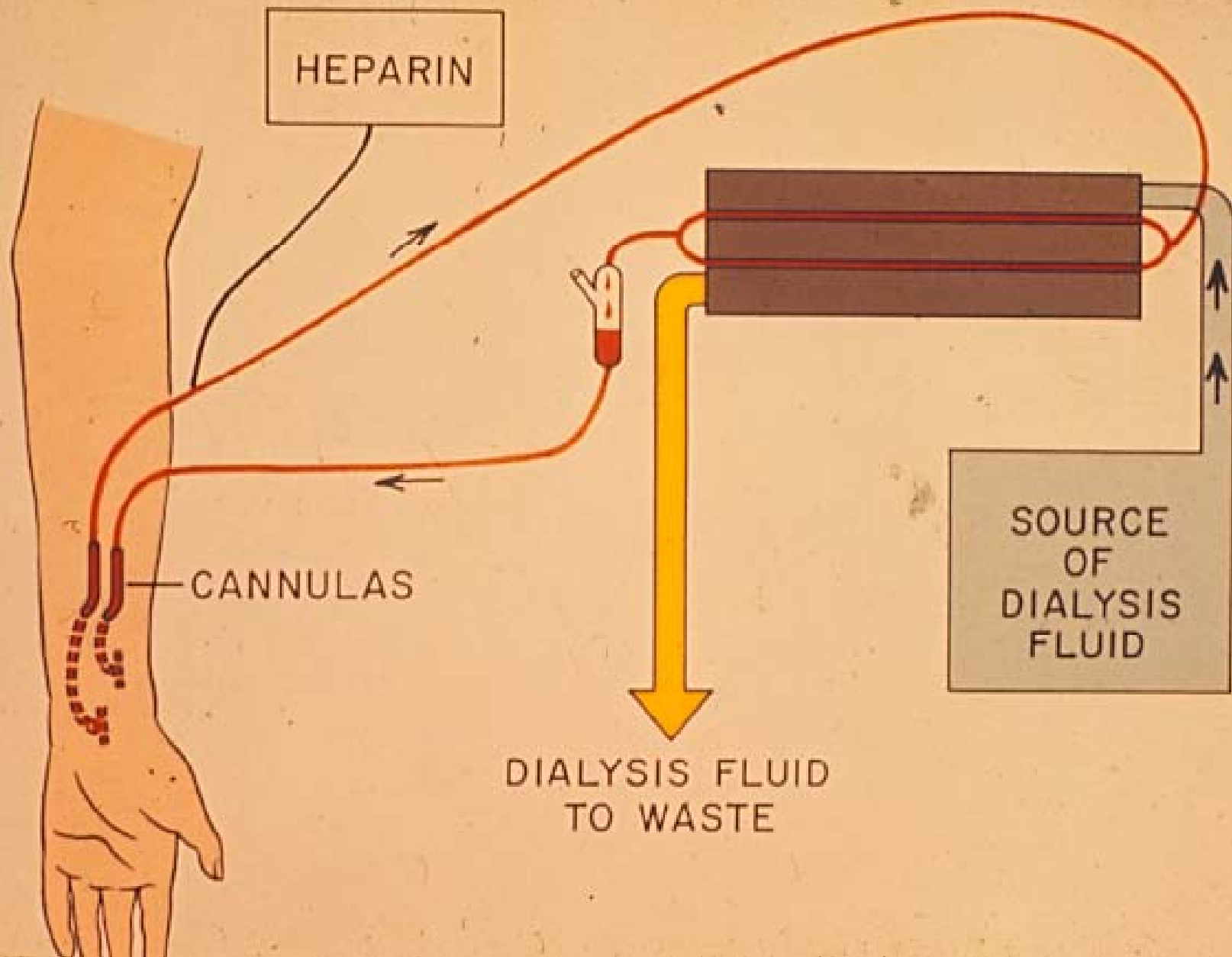
~ 1 g of uric acid

- The kidneys also balance electrolytes, remove fluid, and produce several hormones.

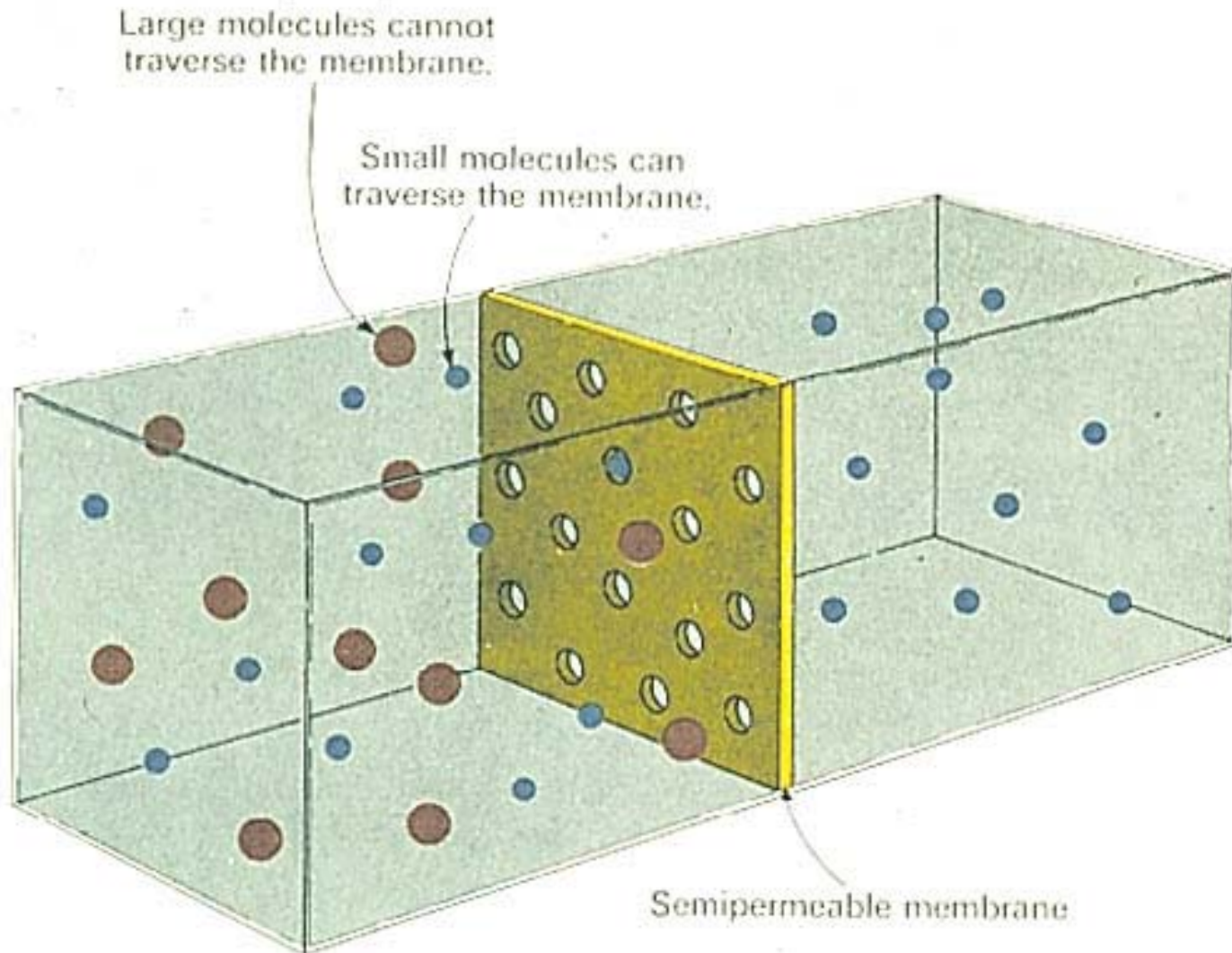


***Mannekin-Pis
Brussels, Belgium***

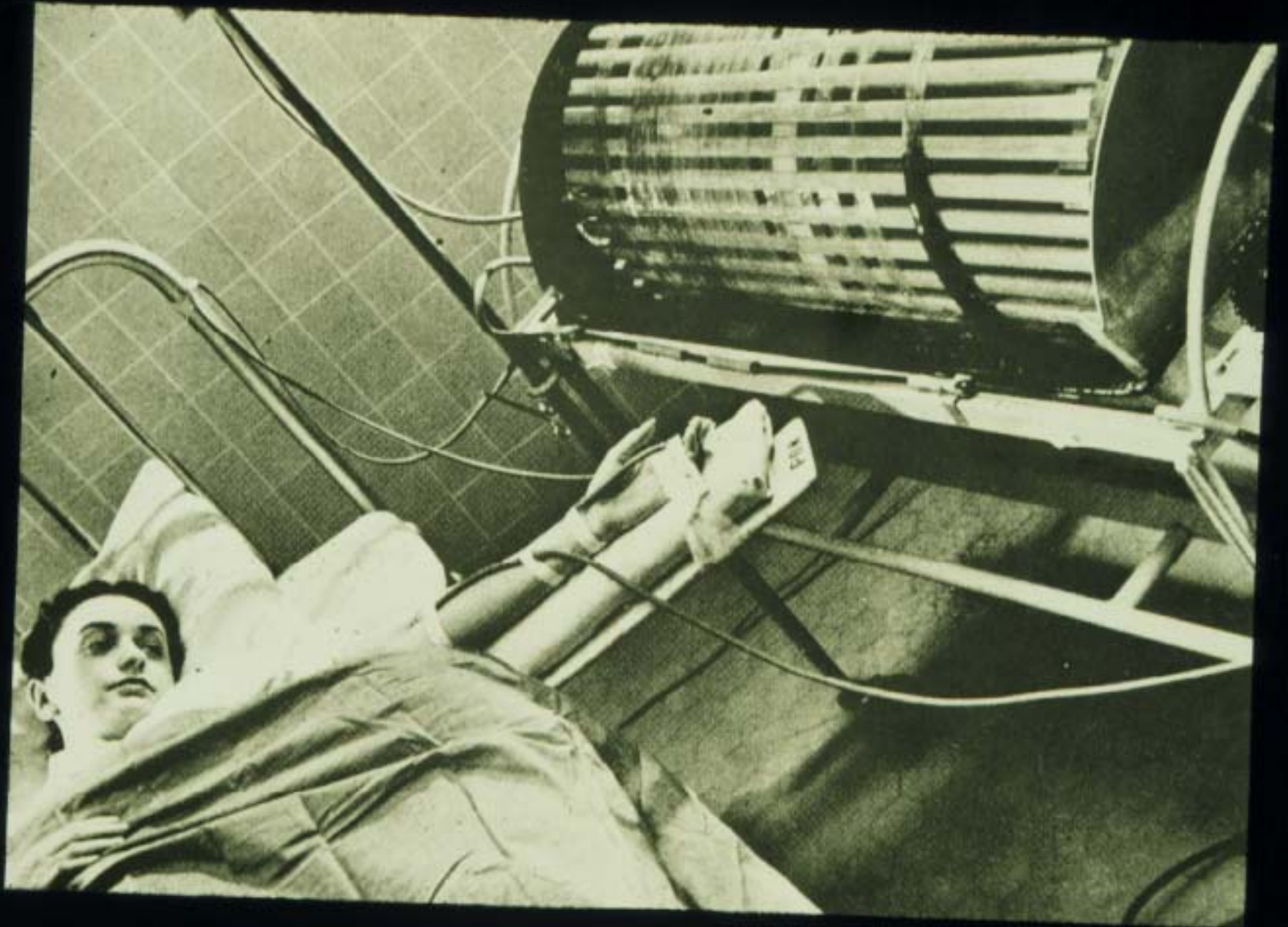
Schematic of the operation of an artificial kidney dialyser



Separation of molecules on the basis of size by dialysis



Kolff Dialysis in The Netherlands circa 1940s





**Willem Kolff, MD, and the washing machine dialyser
(Cleveland Clinic, 1950s)**

The Vessel Access Breakthrough



Dr. Belding Scribner, M.D.
University of Washington, Seattle, 1950/60s

The Quinton-Scribner shunt circa 1950s-1960s

Teflon® tubing

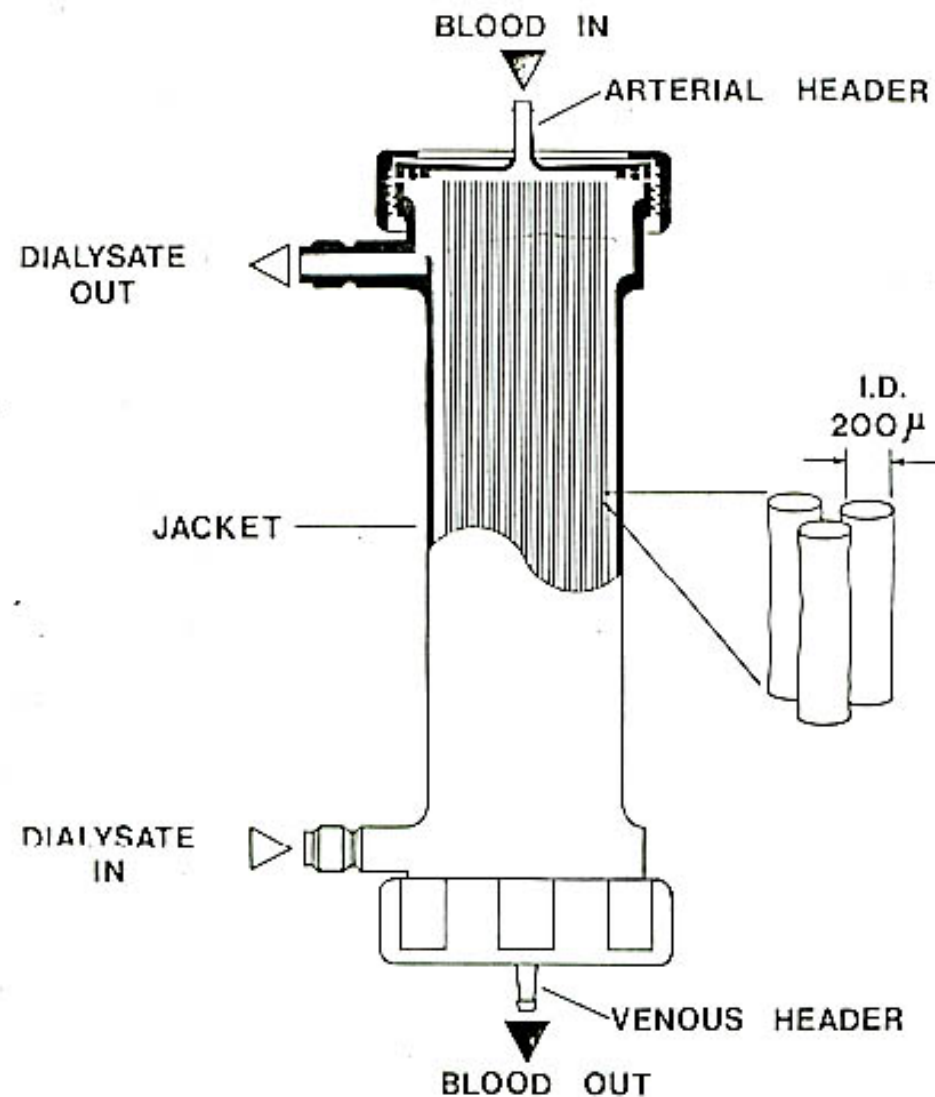


The hollow fiber artificial kidney (HFAK) with Cellulose Acetate hollow fibers, circa 1970s-1980s



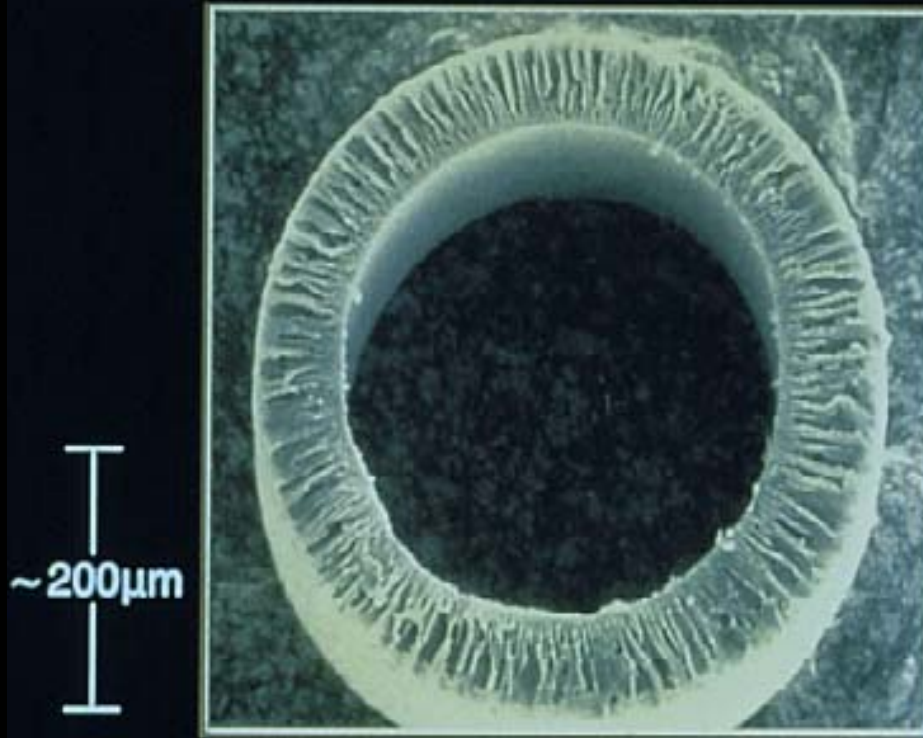


Schematic operation of HFAK



PERMSELECTIVE MEMBRANE

Inner Skin, Wall, Outer Surface



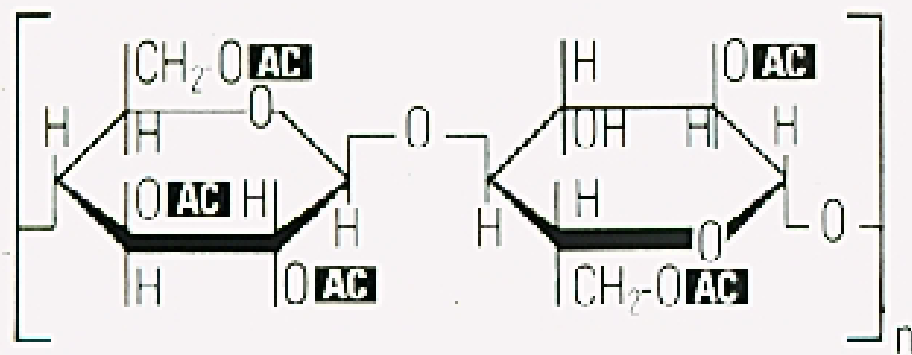
**HOLLOW FIBER MADE OF
CELLULOSE ACETATE**

Cellulose Acetate

ENKA Cellulose Acetate membranes were particularly developed specifically for plasma fractionation, hemofiltration and high-flux dialysis.

Figure 17

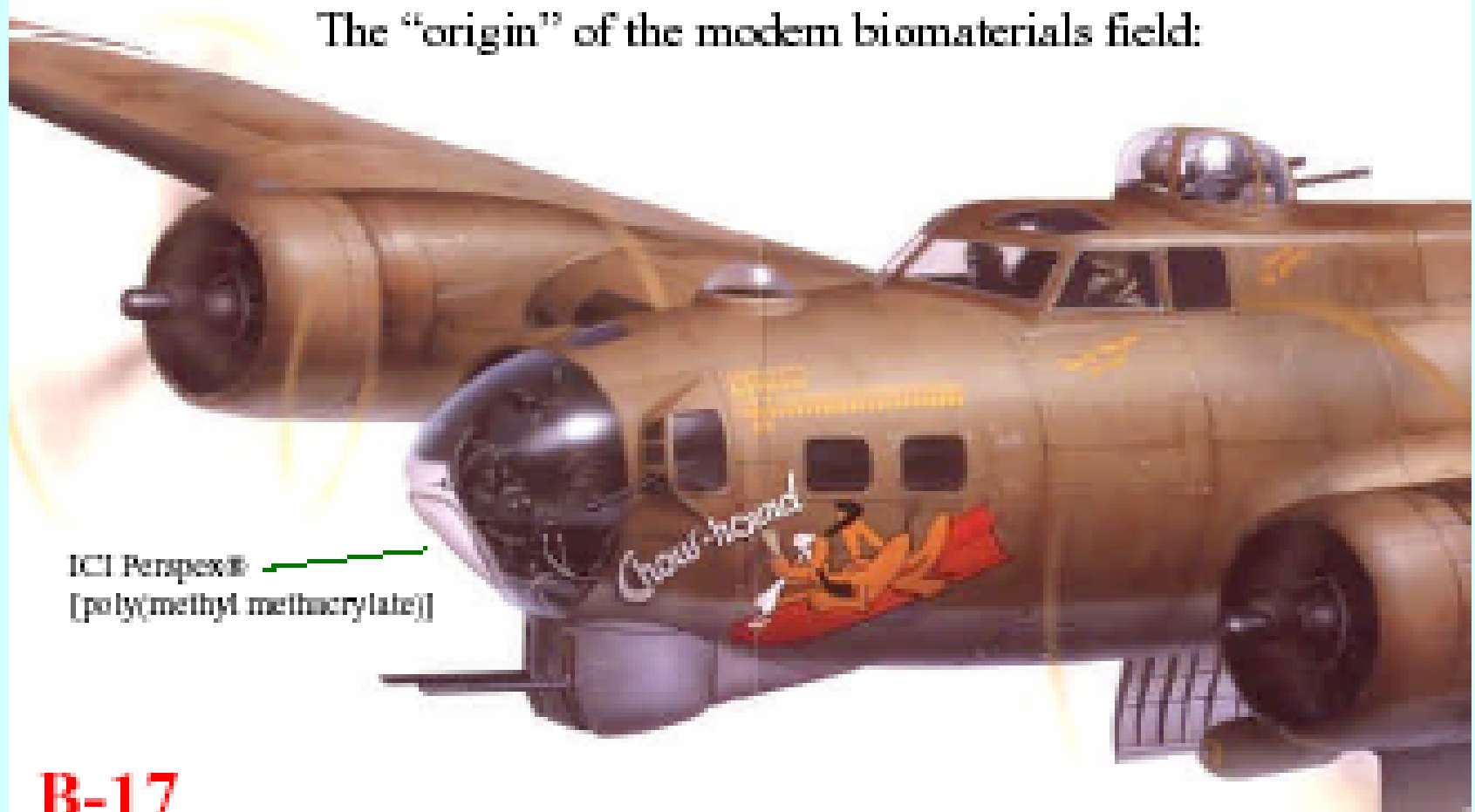
Structural formula



This is the polymer used to form thin skin, hollow fibers for the HFAK.

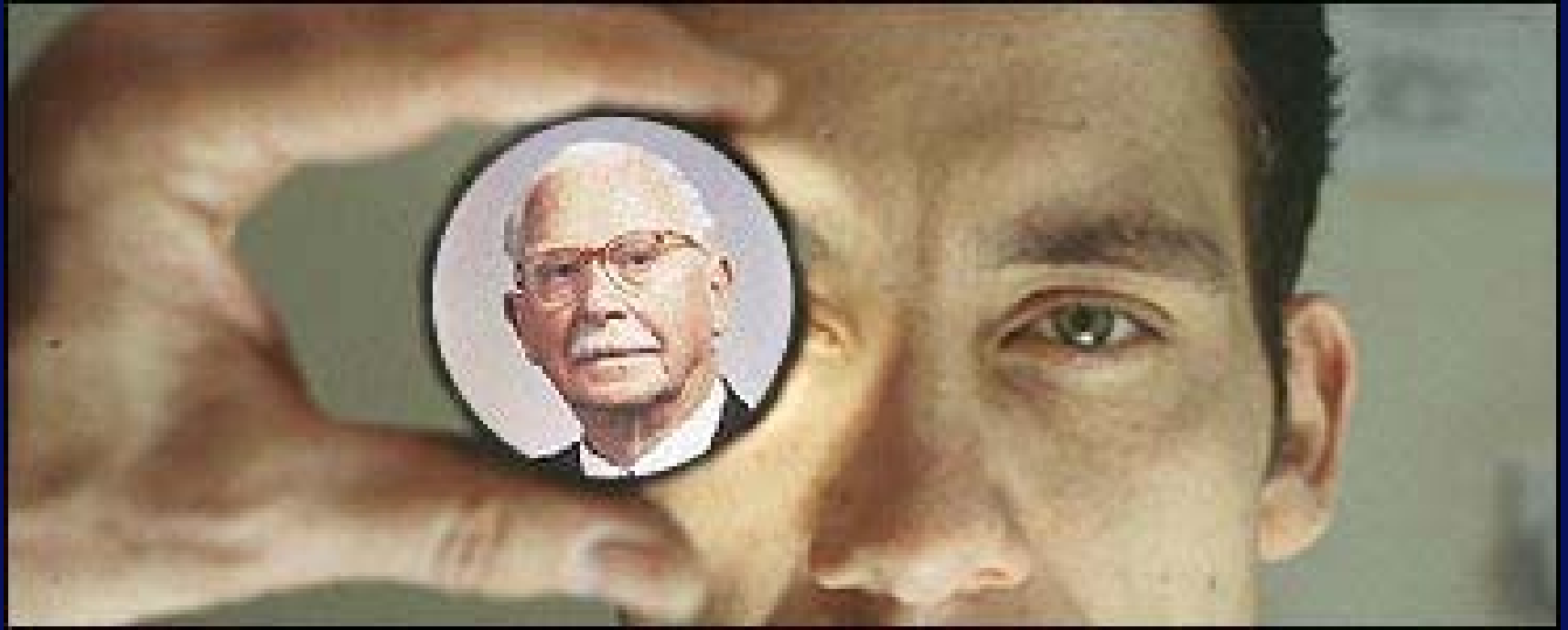
THE INTRAOCULAR LENS (IOL) AND THE CONTACT LENS

The “origin” of the modern biomaterials field:



ICI Perspex®
[poly(methyl methacrylate)]

B-17



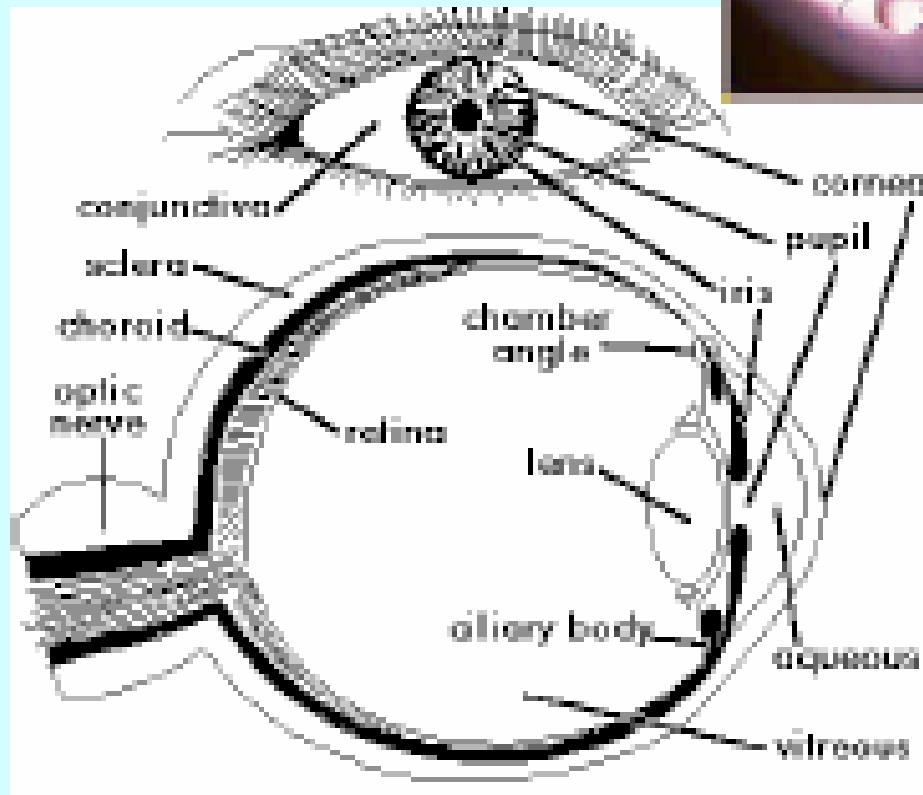
During the Second World War, the British ophthalmologist Harold Ridley encountered several fighter pilots who had eye injuries caused by small plastic pieces from shattered cockpit windows. They did not inflame the eye and were not rejected. From these observations, Ridley got the idea of replacing a lens suffering from cataracts with a plastic lens, and on 29 November 1949 he performed the first intraocular lens (IOL) implantation at St Thomas's Hospital.

Intraocular Lenses (IOLs) - 7,000,000 worldwide/year

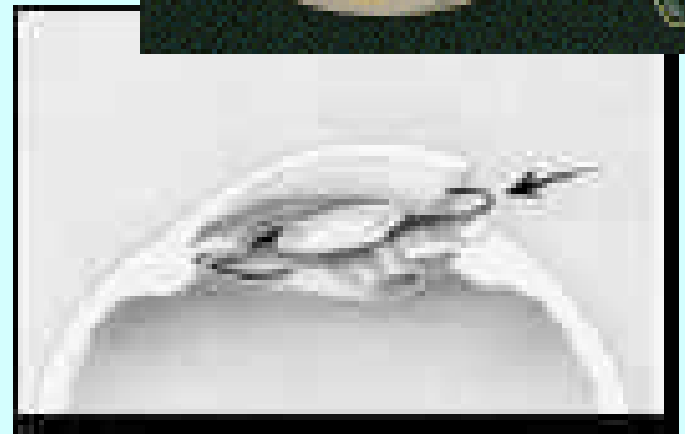
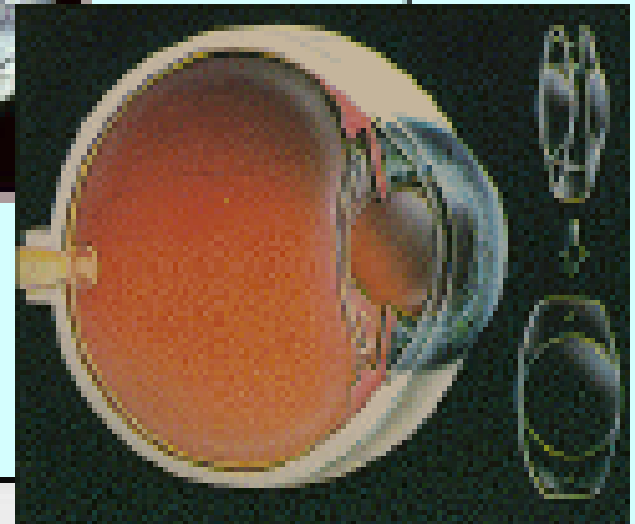
- Poly(methyl methacrylate)
- Silicone rubber
- Hydrogel
- Acrysoft®



<http://www.ayoclinicbba.com/IntraocularLensesImplant.htm>



<http://www.richmondeyes.com/synovus.html>



http://www.ayoclinicbba.com/public/faq/cataract/cataract_surgery_faq.html

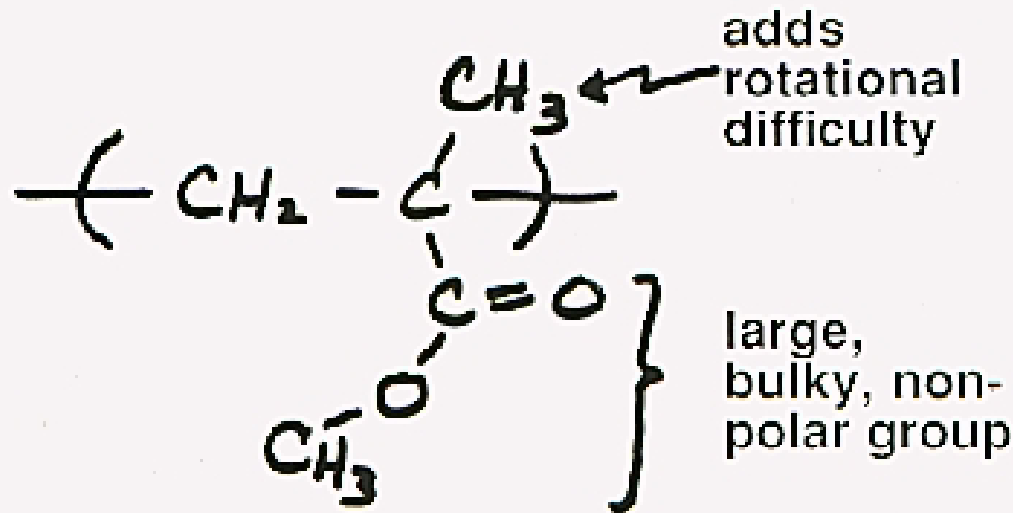
PP
"haptic"



PMMA lens



The PMMA Molecule



- Stiff chain
- Hydrophobic
- Irregular chain repeat unit

Uses

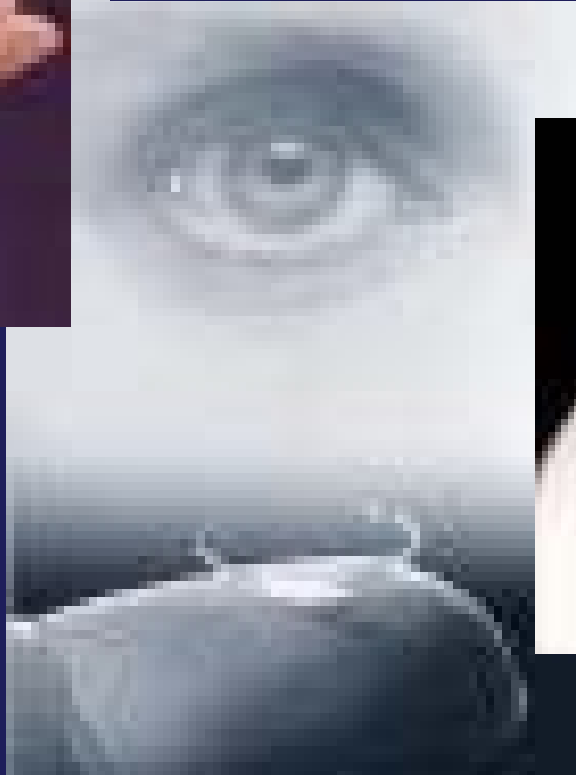
The hard contact lens, the IOL and bone and dental cement

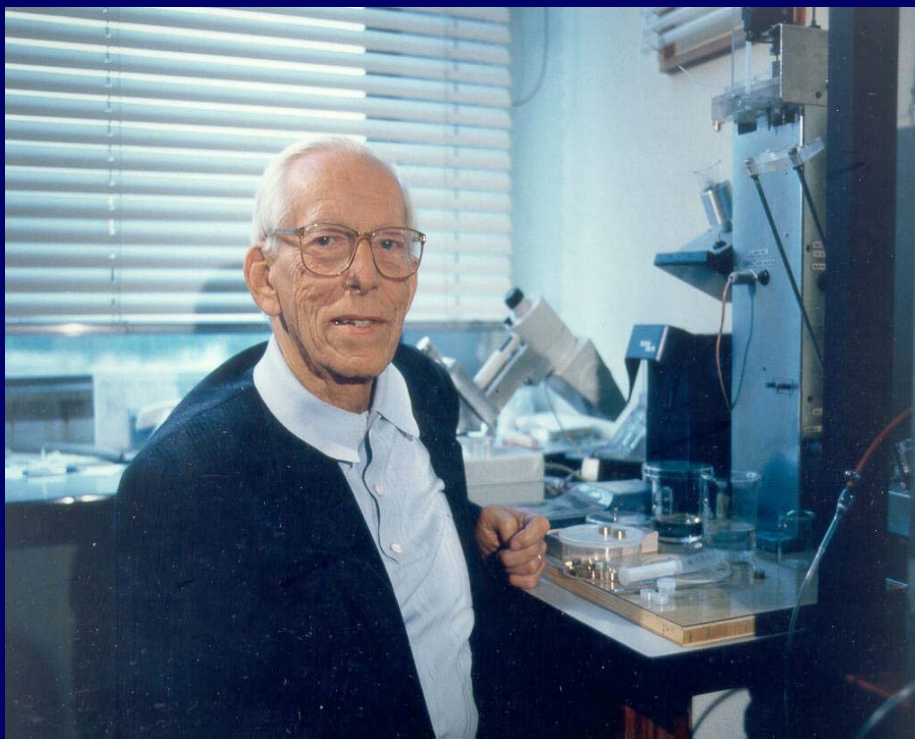
All these lead to an amorphous, glassy, low water sorption polymer, useful as a molded plastic.



The *hard* contact lens...*PMMA*.
A biomedical engineering success
story!

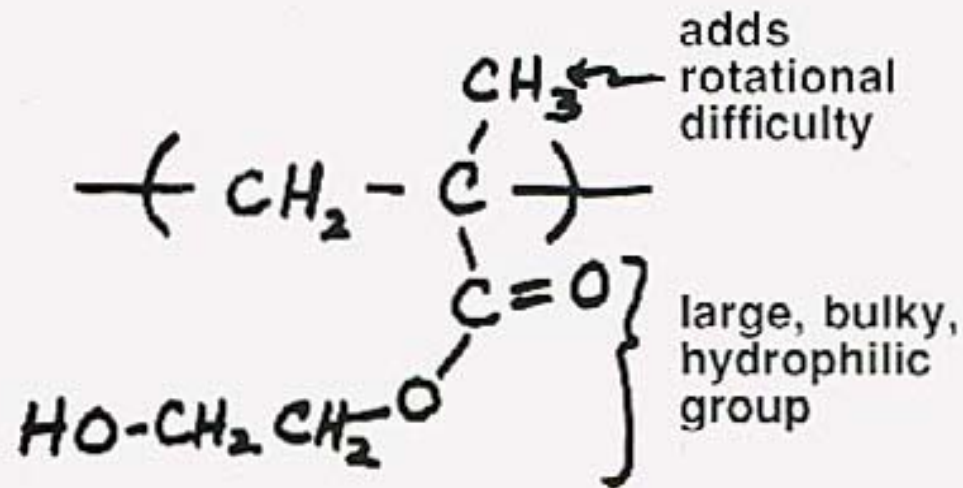
The *soft* contact lens....*PHEMA*.
A biomedical polymer chemistry
triumph!





Elsewhere in the 1950s, a Czech polymer chemist named Otto Wichterle was working in his kitchen at home to polymerize a new monomer that he had synthesized in his Institute at work. It was HEMA, or hydroxyethyl methacrylate, and he had the idea to make it into a hydrogel, which he thought should be a more “compatible” contact lens than the hard contact lens, PMMA. PHEMA became the first “soft” contact lens, Prof. Wichterle patented and licensed it, and he became the richest man in Czechoslovakia.

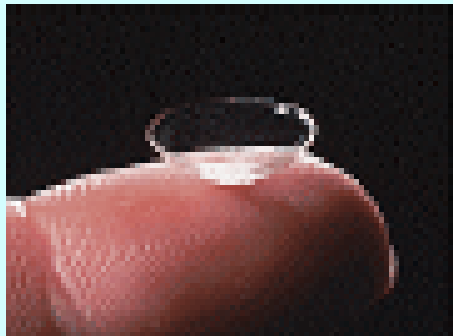
The PolyHEMA Molecule



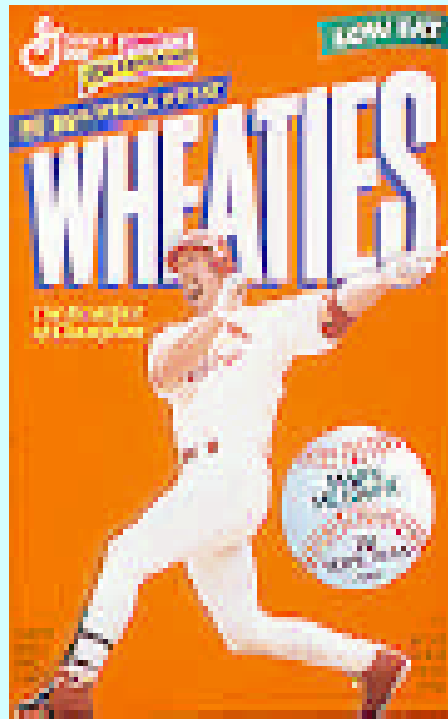
- Stiff chain when dry, but flexible when swollen with water
- Hydrophilic side group
- Irregular chain repeat unit

Uses
The soft contact lens

All these lead to an amorphous, glassy, polymer when dry, and a soft and flexible polymer when water swollen. When lightly crosslinked, it should be useful as a hydrogel.



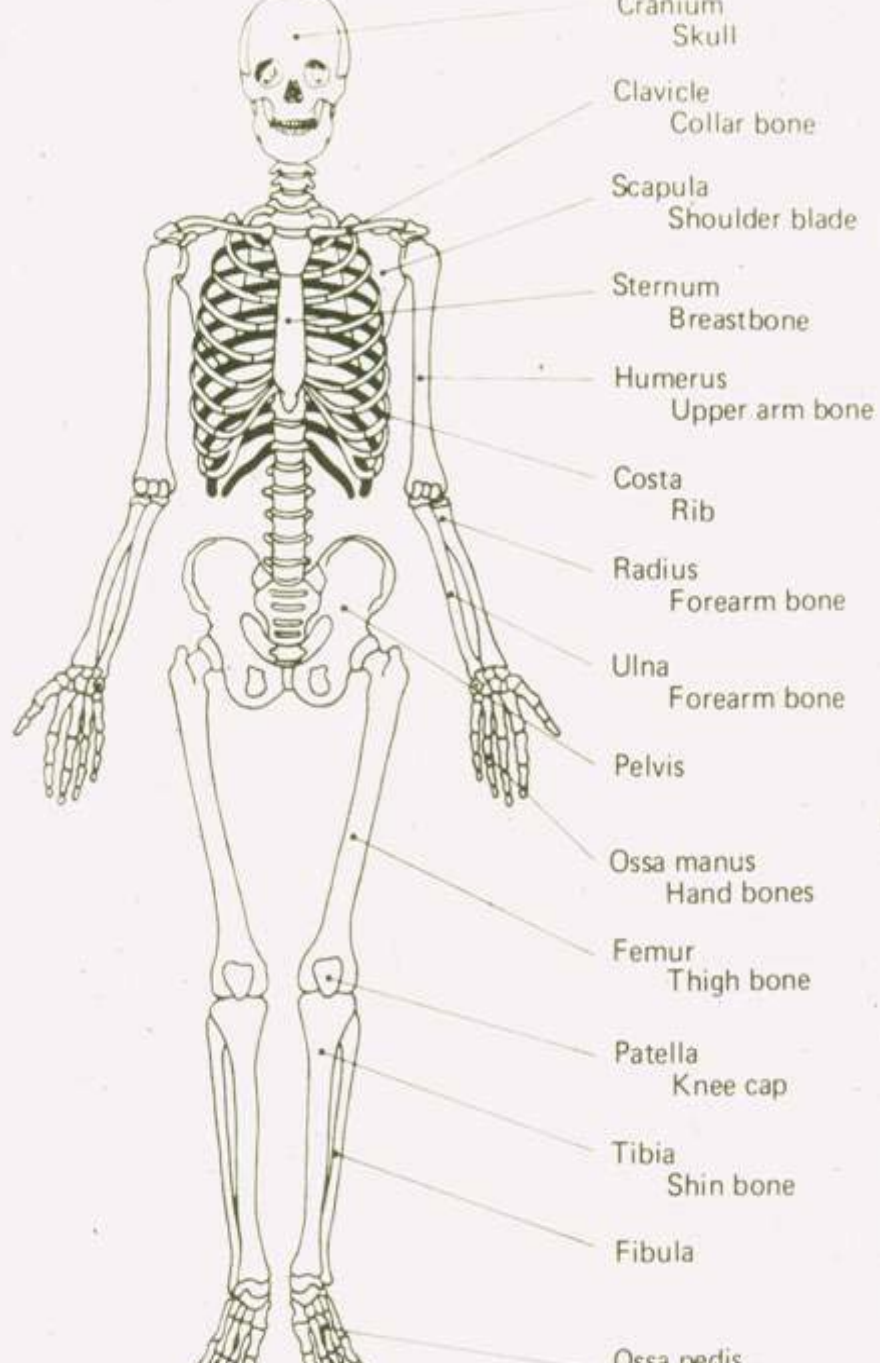
<http://www.dailyvision.com/members/contactlenses.html>



Contact Lenses and Mark McGwire

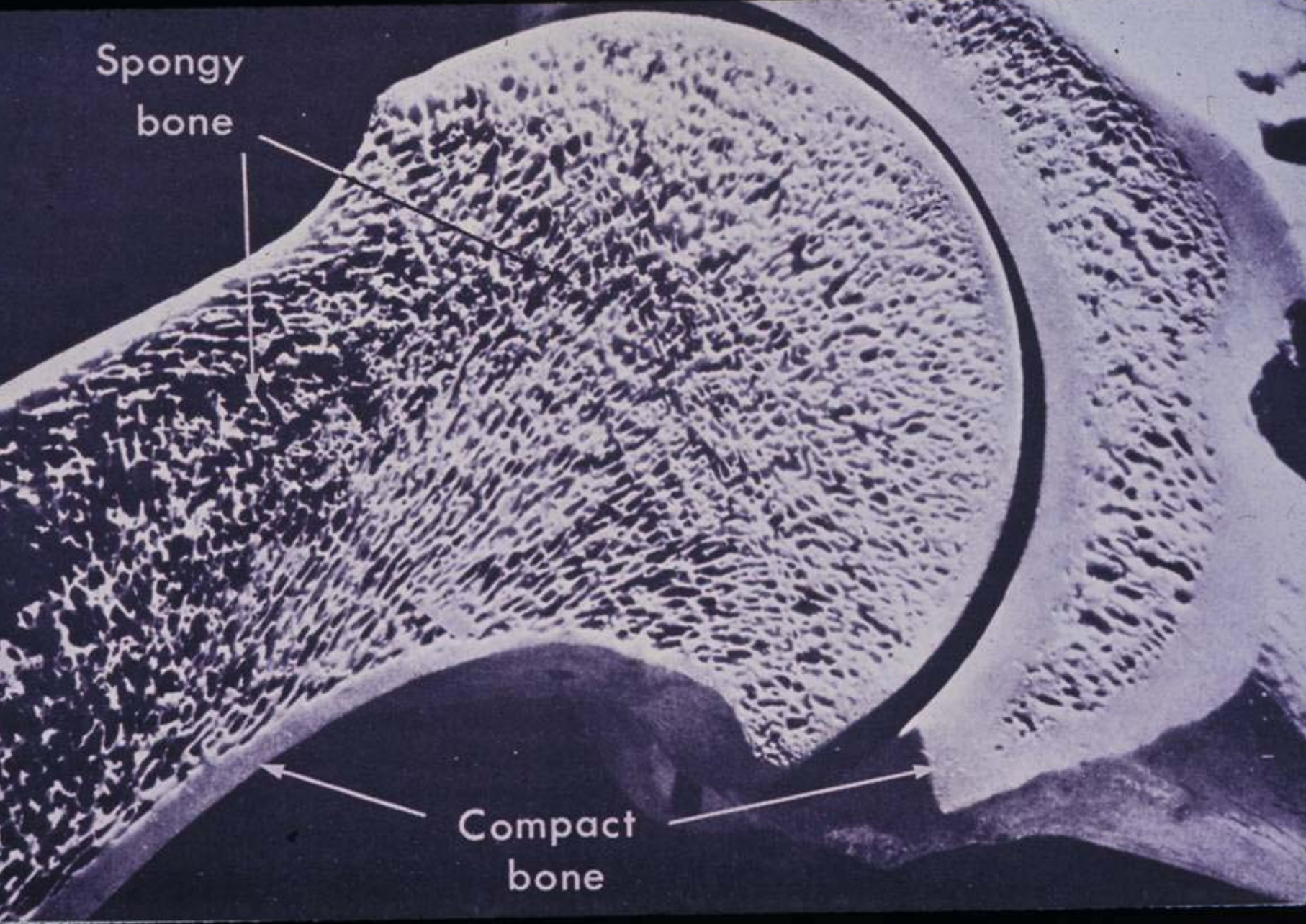
Mark McGwire is a contact lens wearer. McGwire is an uncorrected 20/500 and suffers from astigmatism and dry eye. In 1989, McGwire's existing lenses were replaced with custom designed softtorics. They're tinted yellow, like shooting glasses or ski goggles, to improve sharpness. Corrected, McGwire's vision is better than 20/10.

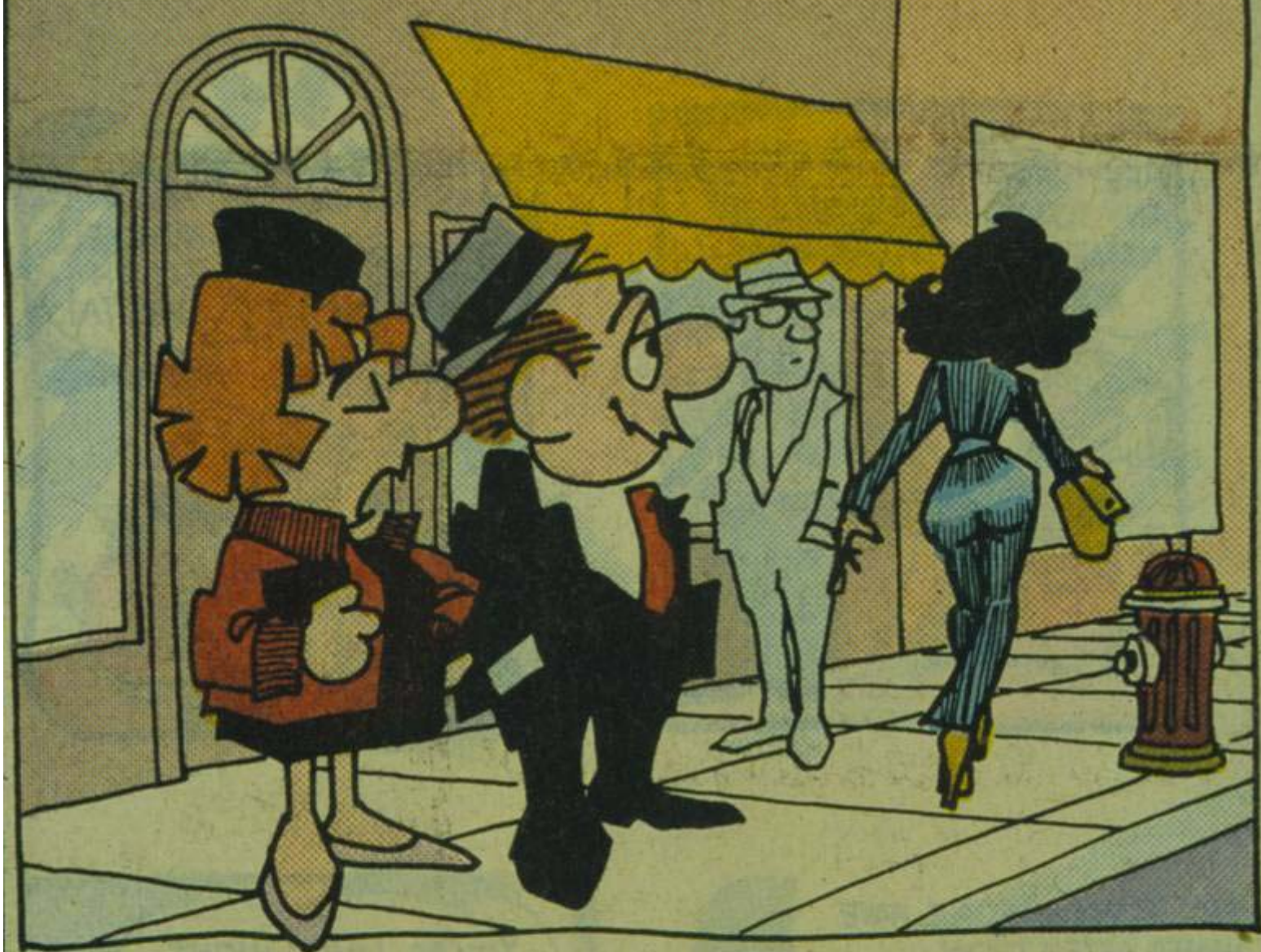
THE ARTIFICIAL HIP



Spongy
bone

Compact
bone





"IN A FEW YEARS SHE'LL NEED A
HIP OPERATION."

PELVIS

HIP PROSTHESIS

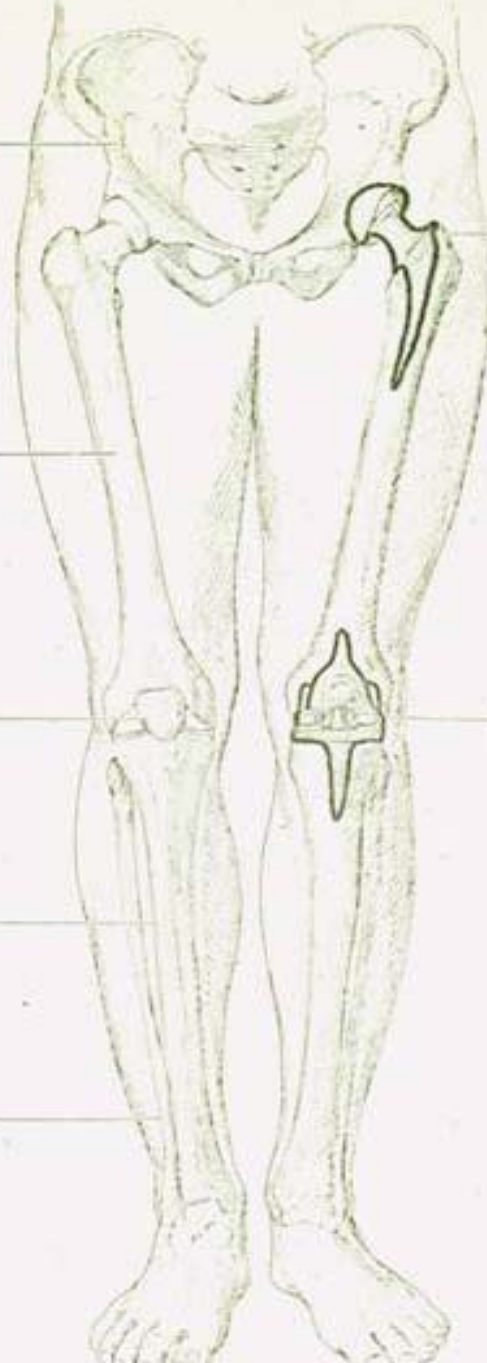
FEMUR

PATELLA

KNEE PROSTHESIS

TIBIA

FIBULA



Sir John Charnley



One of the greatest surgical advances of the twentieth century has been the development of the hip replacement operation. The pioneer and innovator in the field was Sir John Charnley, an English orthopedic surgeon.

He invented the low friction hip replacement in the early 1960's at the Center for Hip Surgery at Wrightington, England. Surgeons from all over the world made their way to Wrightington to learn his techniques. He was a master surgeon, innovator and bioengineer.

Knee and shoulder replacement surgery developed directly out of his work on the artificial hip. His work has been an outstanding contribution to the relief of human suffering.





The University of Manchester

1851-2001

one hundred and fifty years of excellence



A 40th Anniversary Symposium on Acrylic Bone Cement in the New Millennium

May 13-14, 2002

This academic year 2001-2002 we are celebrating the the 40th anniversary of the clinical use of acrylic bone cement following its development by Charnley and Smith at the University of Manchester. Many millions of patients have benefitted from cemented artificial joints, and currently more than 500,000 hip and knee joints are replaced every year.

STERILE

Sterilization Indicator



SIMPLEX

P

**radiopaque
POWDER**

40g

(Mixture of Polymethyl methacrylate, Methyl methacrylate-Styrene copolymer and Barium Sulfate U.S.P.)

Each packet contains 40g. of powder consisting of 6.0g. of Polymethyl methacrylate (15% w/w), 30.0g. of Methyl methacrylate-Styrene copolymer (75% w/w) and 4.0g. of Barium Sulfate U.S.P. (10% w/w).

WARNING:

See Package Insert for dosage and administration.

CAUTION:

Federal law prohibits dispensing without prescription.

Batch
No:

043 IF

Sterilization
No:

111172

Expiration
Date:

NOVEMBER 1973

Made by North Hill Plastics Ltd., London, N.16, England.

Distributed in the United States by
Howmedica Inc. Medical Division, Rutherford, New Jersey 07070.

**OPEN
HERE**

SURGICAL SIMPLEX
(Methyl methacrylate)

Sterile Liquid 20 ml.

Each ampul contains 20 ml. of liquid consisting of
19.5 ml. of Methyl methacrylate (97.4% v/v), 0.5 ml. N.

**SURGICAL
SIMPLEX**

WARNING: 1. FLAMMABLE.
2. Store in a cool, dark place.
3. See Package Insert for dosage
and administration.

Batch No.
Sterilization No.
Expiration Date:

819 HF
121072
JAN 74

(Methyl Methacrylate)
Sterile Liquid 20ml.

Each ampul contains 20ml. of liquid consisting of 19.5ml. of
Methyl methacrylate (97.4% v/v), 0.5ml. of N, N - dimethyl-
paratoluidine (2.6% v/v), and 75 ± 15 ppm. of hydroquinone.

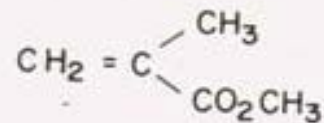
CAUTION: Federal law prohibits dispensing without prescription.

Distributed in the United States by
Howmedica, Inc. Medical Div.,
Rutherford, New Jersey 07070.

ACRYLIC BONE CEMENT

LIQUID (20ml.)

Methyl Methacrylate (MMA)



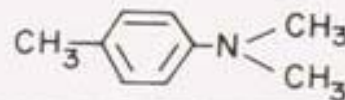
97.4% $\frac{\text{V}}{\text{V}}$

Hydroquinone



2.6% $\frac{\text{V}}{\text{V}}$

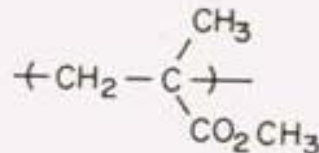
N-N dimethyl p-toluidine



~ 75 ppm

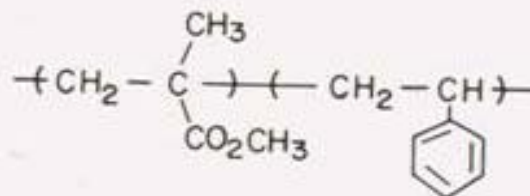
SOLID (40g)

PMMA



15% $\frac{\text{W}}{\text{W}}$

Copoly (MMA/sty)

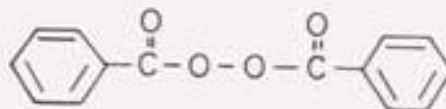


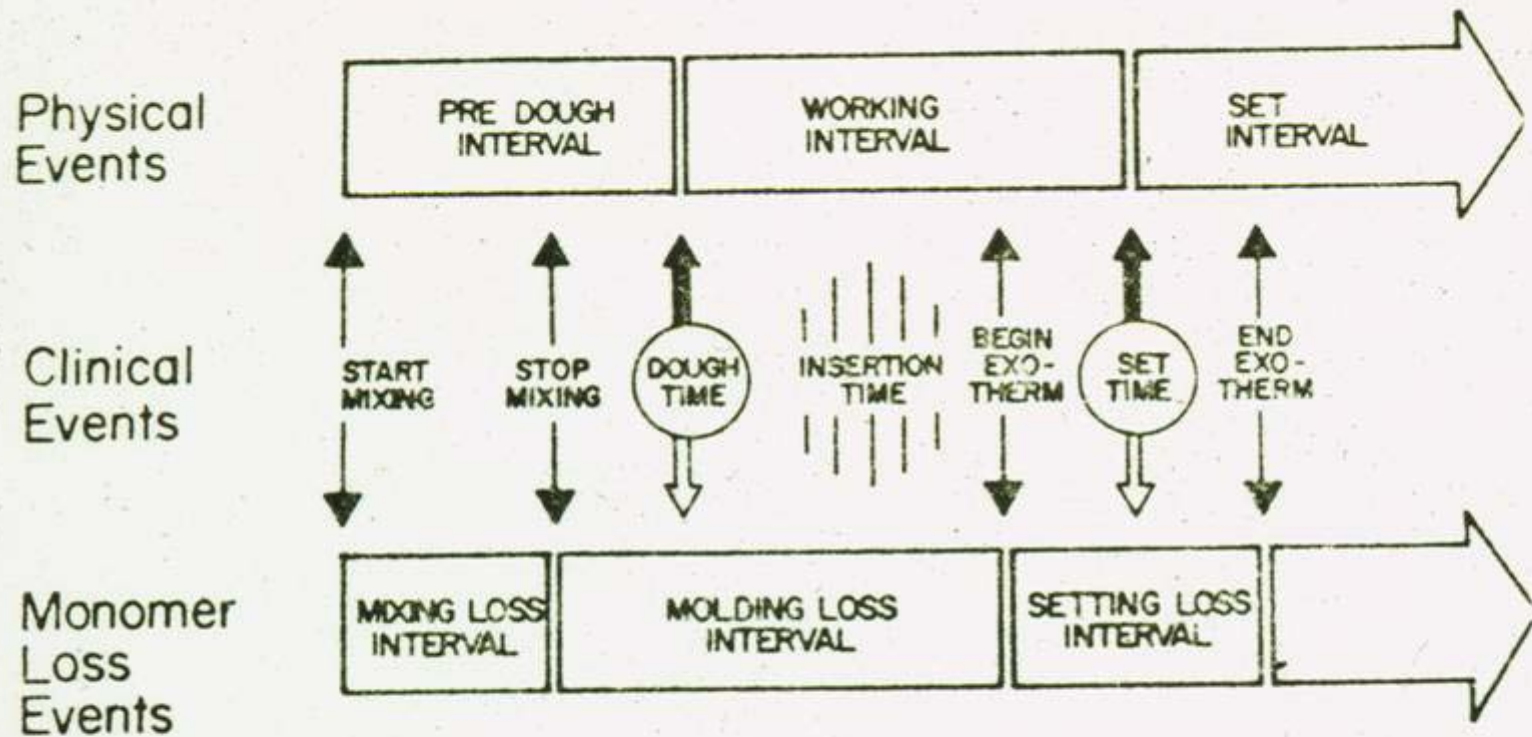
75% $\frac{\text{W}}{\text{W}}$

Ba SO₄

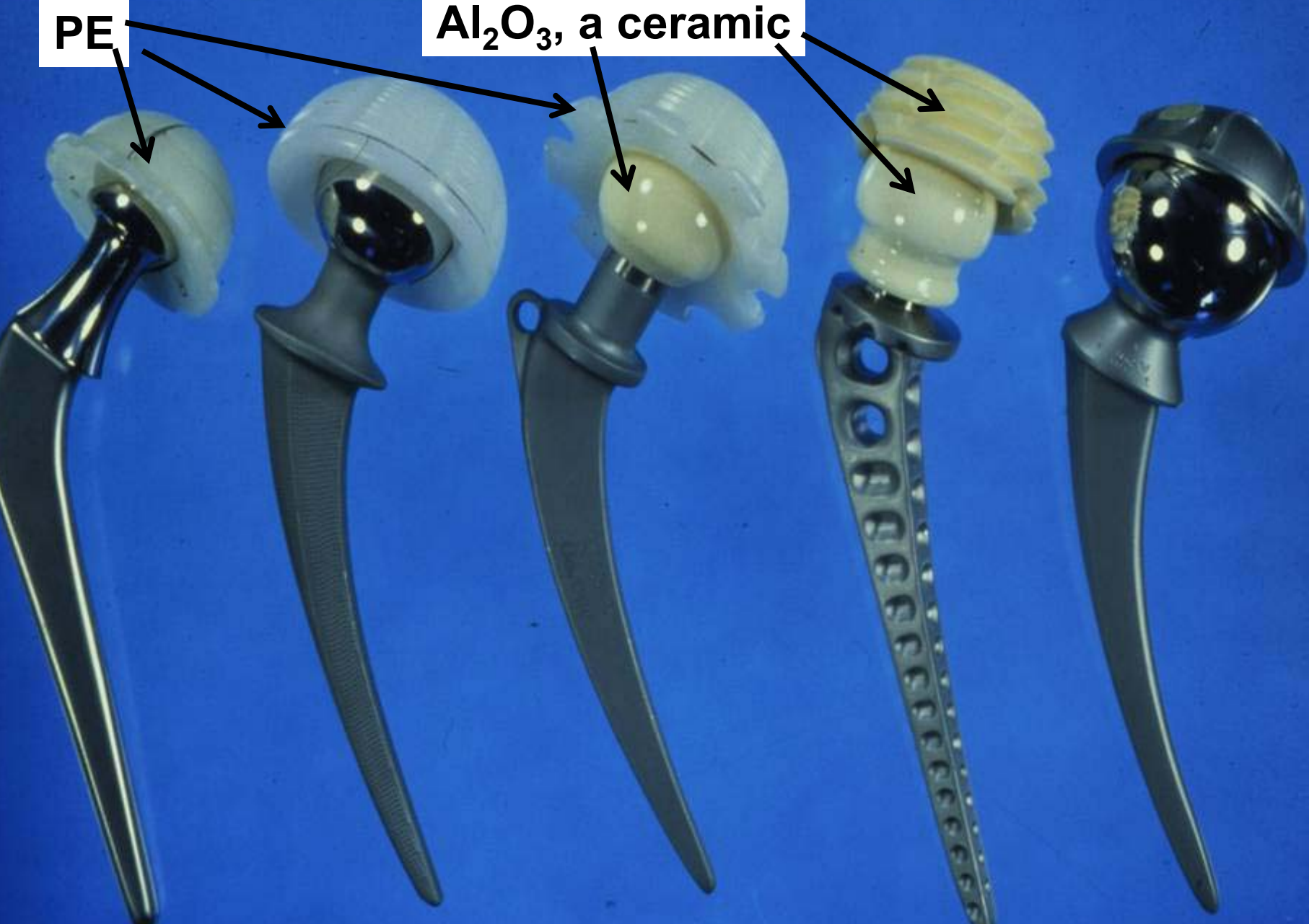
10% $\frac{\text{W}}{\text{W}}$

Benzoyl Peroxide





Chronological comparison of cement terminology and clinical landmarks
vs. monomer loss. *(Bayne et.al., 1977)*

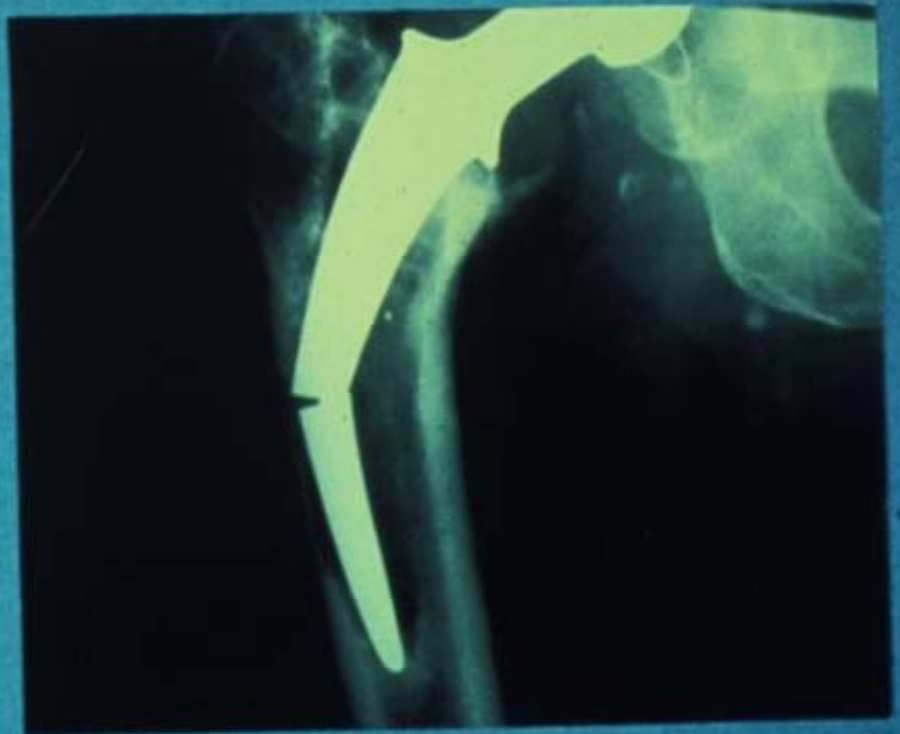
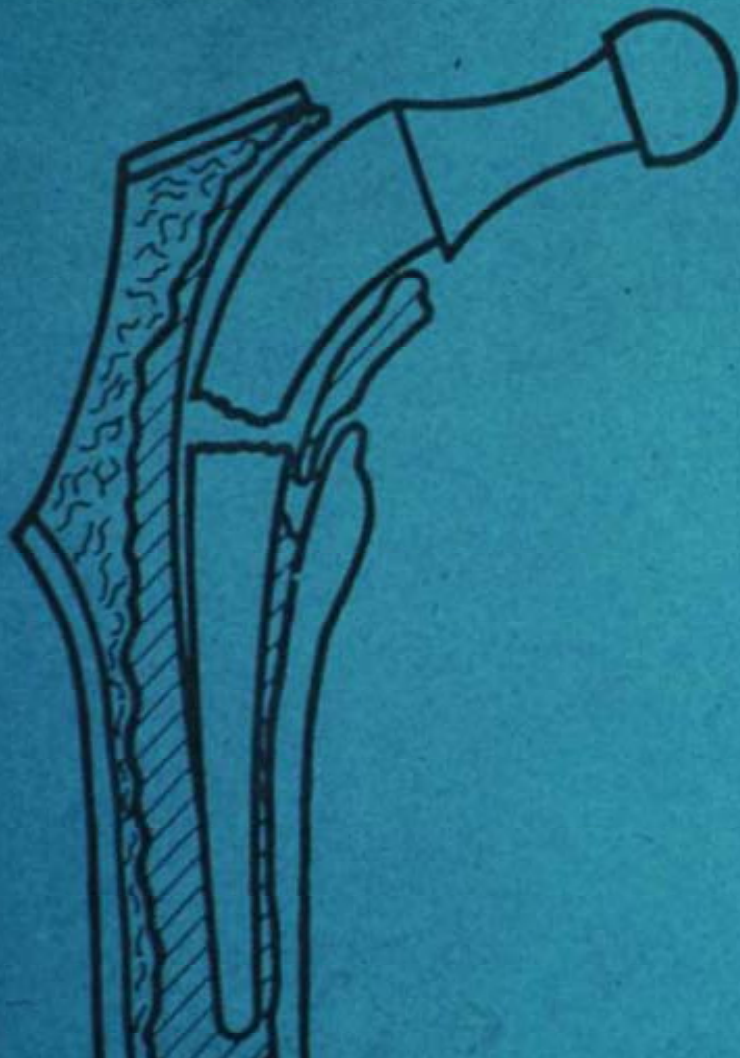


PE

Al₂O₃, a ceramic

Metals may be Stainless Steel, Co-Cr alloy, and Titanium

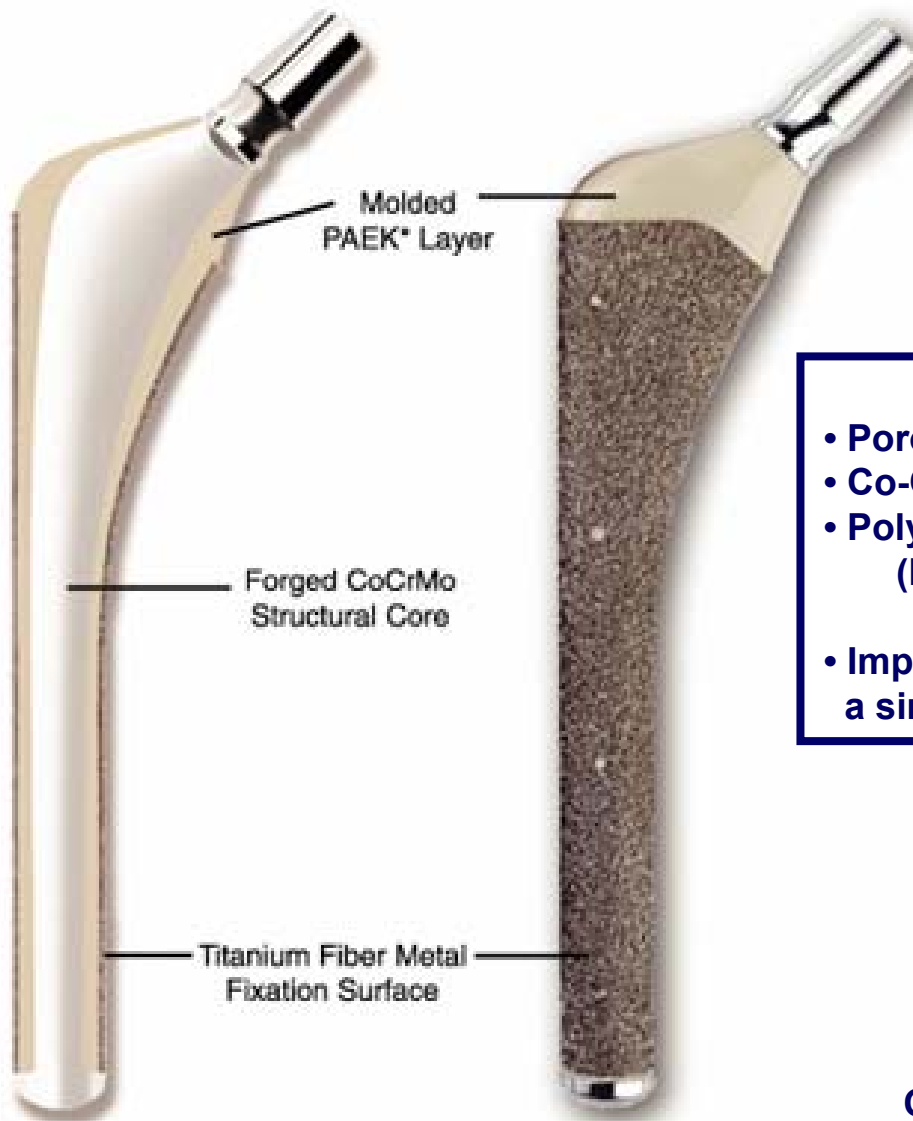
PROSTHESIS FAILURE.





***Zimmer porous metal
Co-Cr hip prosthesis***

Zimmer Epoch® Femoral Stem Implant



Composition

- Porous Ti fixation surface
- Co-Cr-Mo core
- Poly(aryl-ether-ketone) (PAEK) matrix
- Implant is designed to have a similar density to bone.

*polyaryletherketone polymer matrix



Modularity

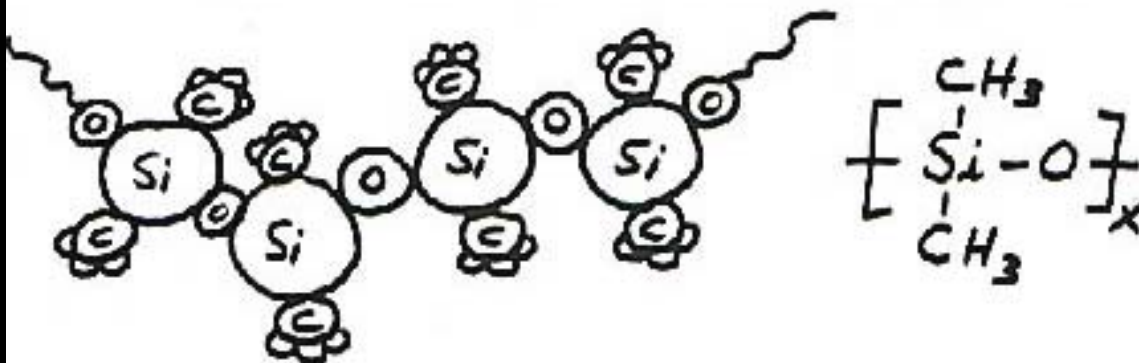
- Offers flexibility
 - Leg length
 - Offset
 - Joint stability
 - Address bone loss or deformity
- Decreases inventory?



SILICONE IMPLANTS:

*A case study involving polymer scientists,
medical doctors, patients, lawyers,
judges, politicians and the FDA.*

The Silicone Rubber Molecule



- Flexible -O- group along main chain
- Hydrophobic -CH₃ groups vs. polar -O- groups (hydrophobic groups dominate)
- Regular, streamlined main chain

All these should lead to a soft, crystalline, low water sorption plastic, but the very flexible chain (due to the large size of the silicon atom and the small, unhindered oxygens, which create large spaces between the -CH₃ groups) makes the regularity less important, so this molecule is a useful rubber (with a crystalline melt temperature well below room temperature).



Otoplasty Prosthesis

A soft, resilient otoplasty prosthesis molded to the shape of the natural external ear. Made of a SURGITEK medical grade silicone which closely approximates the normal variance in cartilage consistency from the center to the periphery of the external ear. The perforations in the prosthesis are covered with a very thin membrane of SURGITEK medical grade silicone which may be easily dissected according to individual case requirements. Available in left and right, with or without Dacron® Felt reinforcement.



Orbital Prosthesis

An orbital prosthesis of SURGITEK medical grade silicone designed to conform to the contours of the orbital floor, with Dacron® Felt attachment. Available in three sizes, individual left and right design.



SURGITEK PRODUCTS FOR SURGERY

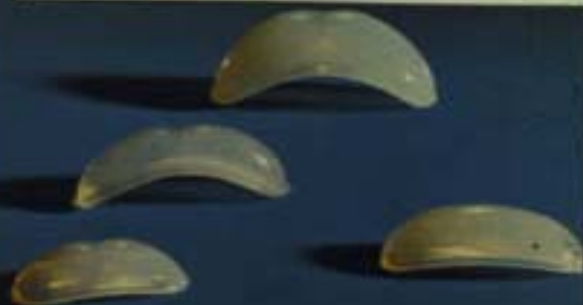
Rhinoplasty Prosthesis

A rhinoplasty prosthesis made of a resilient SURGITEK medical grade silicone. Primarily designed for augmenting a concave bridge of the nose. Available in two sizes. Available with or without flared tip.



Chin Prosthesis

A smooth, pre-formed chin prosthesis of SURGITEK medical grade silicone shaped to follow natural chin contours. Available in four sizes (different center thicknesses) with or without cleft. Available with or without Dacron® Felt attachment.



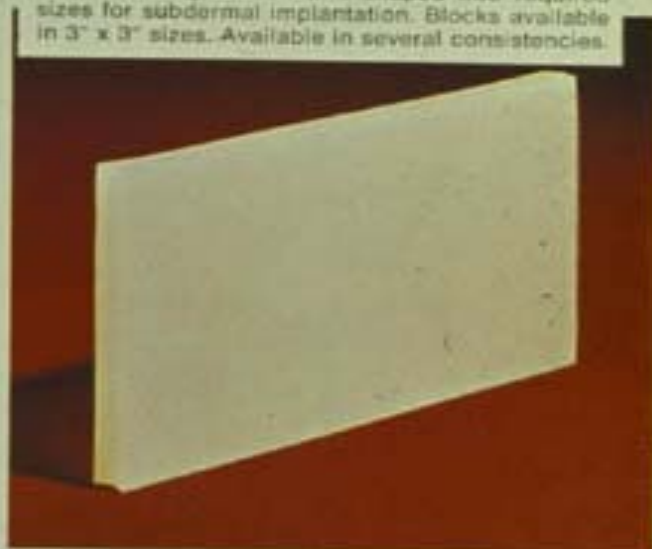
Testicular Prosthesis

A soft, smooth, testicle-shaped prosthesis of SURGITEK medical grade silicone filled with a SURGITEK medical grade silicone gel which closely simulates the weight and consistency of the natural testicle. Available in two sizes.



Block

A block of SURGITEK medical grade silicone which may be easily carved and shaped into required sizes for subdermal implantation. Blocks available in 3" x 3" sizes. Available in several consistencies.



Felt

Dacron® Felt material for use in conjunction with other implantable materials. Available in 2" x 4" pieces.

Adhesive/Sealant

SURGITEK medical grade silicone adhesive/sealant for use in bonding silicone to itself and to other materials.



The *Uni-Flate 1000*, from Surgitek, is the first fully assembled and pre-filled inflatable penile implant on the market.

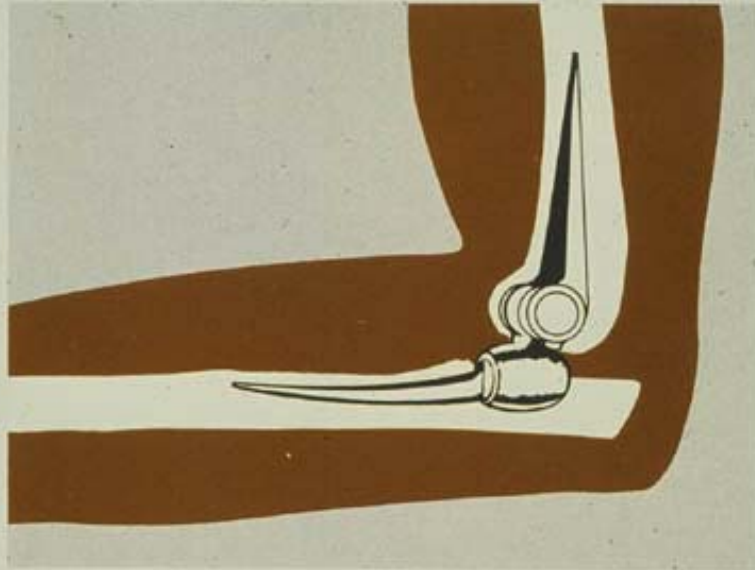


Figure 5. Total elbow replacement. A simple hinge with high density polyethylene bearings.

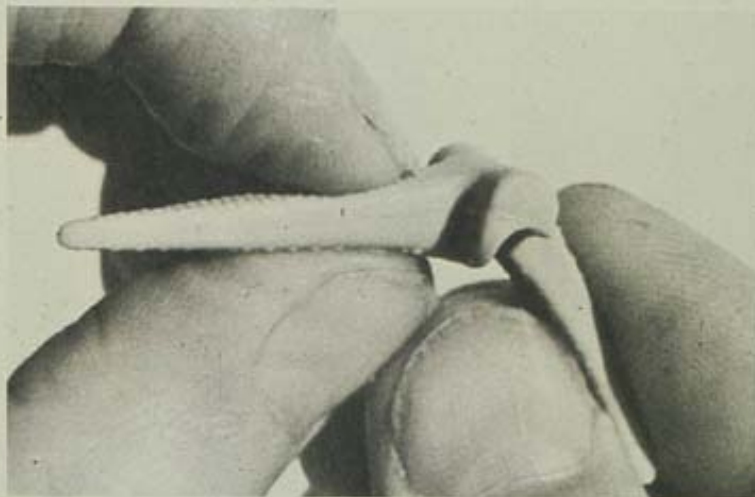


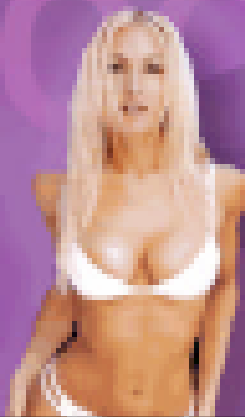
Figure 6. Silicone rubber finger prosthesis. The stems are inserted down the shafts of the adjacent bones. The prosthesis is pliable to allow movement.



are in varying stages of deterioration after prolonged use. The failures were the result of the absorption of lipids and cholesterol from body fluids by the silicone rubbers used in the prostheses. This absorption causes swelling, leading to surface cracks as demonstrated by the scanning electron micrograph (1400x). Stress concentrates in these cracks, accelerating the process of absorption and swelling, leading to the eventual dissolution of the prosthesis.



The first “hit” using the Google search engine with the term “breast implants”
(120,000 hits)



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Looks for Less

1-800-842-8424

GUARANTEED LOWEST PRICES

Why are our cosmetic procedures so affordable?

Many people wonder how we can offer such high quality cosmetic procedures at such low prices. The answer is simply that our company manages cosmetic surgery practices for board certified cosmetic and plastic surgeons. The focus of our management agreement is to minimize the cost of marketing the surgeons practice. By purchasing national media at highly discounted prices we can create a high volume of patients for the doctor's practice, while at the same time greatly minimizing the cost of marketing and passing those savings directly to you the consumer.



Our Price Guarantee

Have your surgery with us now and if within the next six months you find a surgeon of equal board certification that is willing to do the same

We Offer the Following Procedures at Unbeatable Prices

Breast Enlargement	\$2,799
Operating room fee	\$600
Complete Package NO COPIES	\$3,399

Time, 4/14/75

Reconstructed Breast

Silicone gel
encased in
compartmented
plastic sac

Nipple
grafting
(optional
second stage)

Incision made
here. Plastic
sac inserted

TIME Diagram by V. Puglisi

RANDOLPH GUTHRIE, M.D.

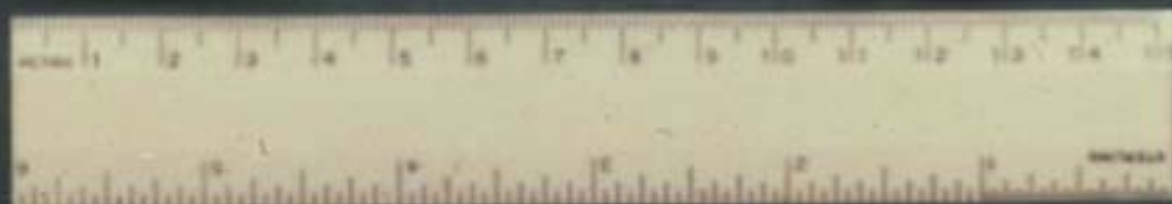


BREAST AFTER RECONSTRUCTION

JIM OLIVE



DR. THOMAS CRONIN WITH IMPLANT



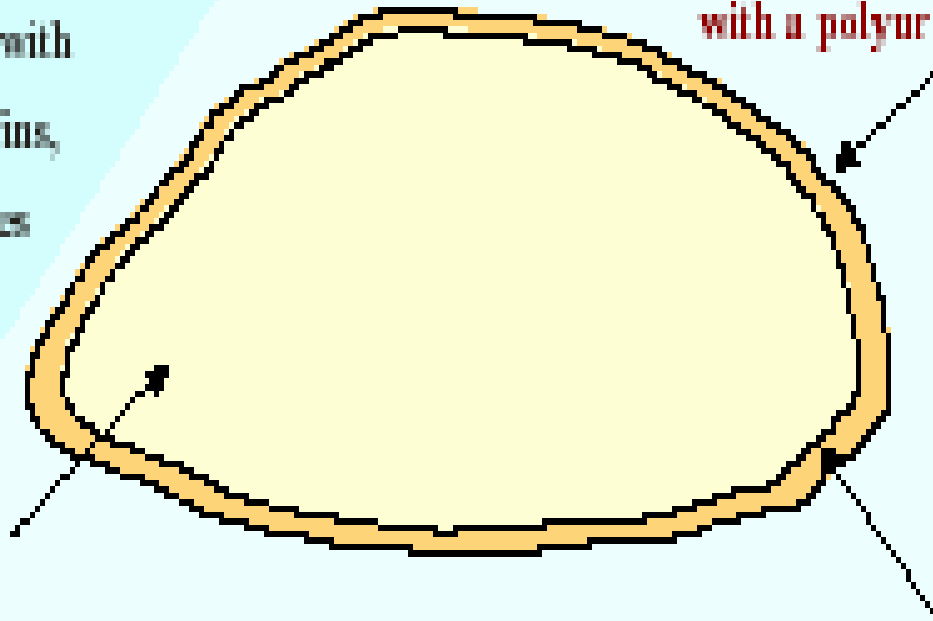
Modern Breast Implants - General Description

The Inspiration for the gel-filled bag

In the 1950's, breast augmentations were performed in Japan with injections of liquid paraffins, petroleum jelly or silicones contaminated olive oil

- gel filled
- saline filled
- soy oil filled
- (some implants have a silicone

external surface can be textured
silicone rubber or covered
with a polyurethane foam



envelope (shell) is usually
crosslinked, filled PDMS

Lawyers

Santa Claus, the tooth fairy, an honest lawyer and a old drunk are walking down the street together when they simultaneously spot a hundred dollar bill. Who gets it?

A Woman with autoimmune disease was awarded by jury
\$7.3 Million (Dec. 1991)

Dow Corning and other breast implant companies settle for \$4 billion

- the biomaterials crisis precipitated by liability concerns
- what is the impact on US competitiveness?

Conclusions

**After many huge payments to lawyers
and their clients,**

and

**much additional biological and
physiological testing,**

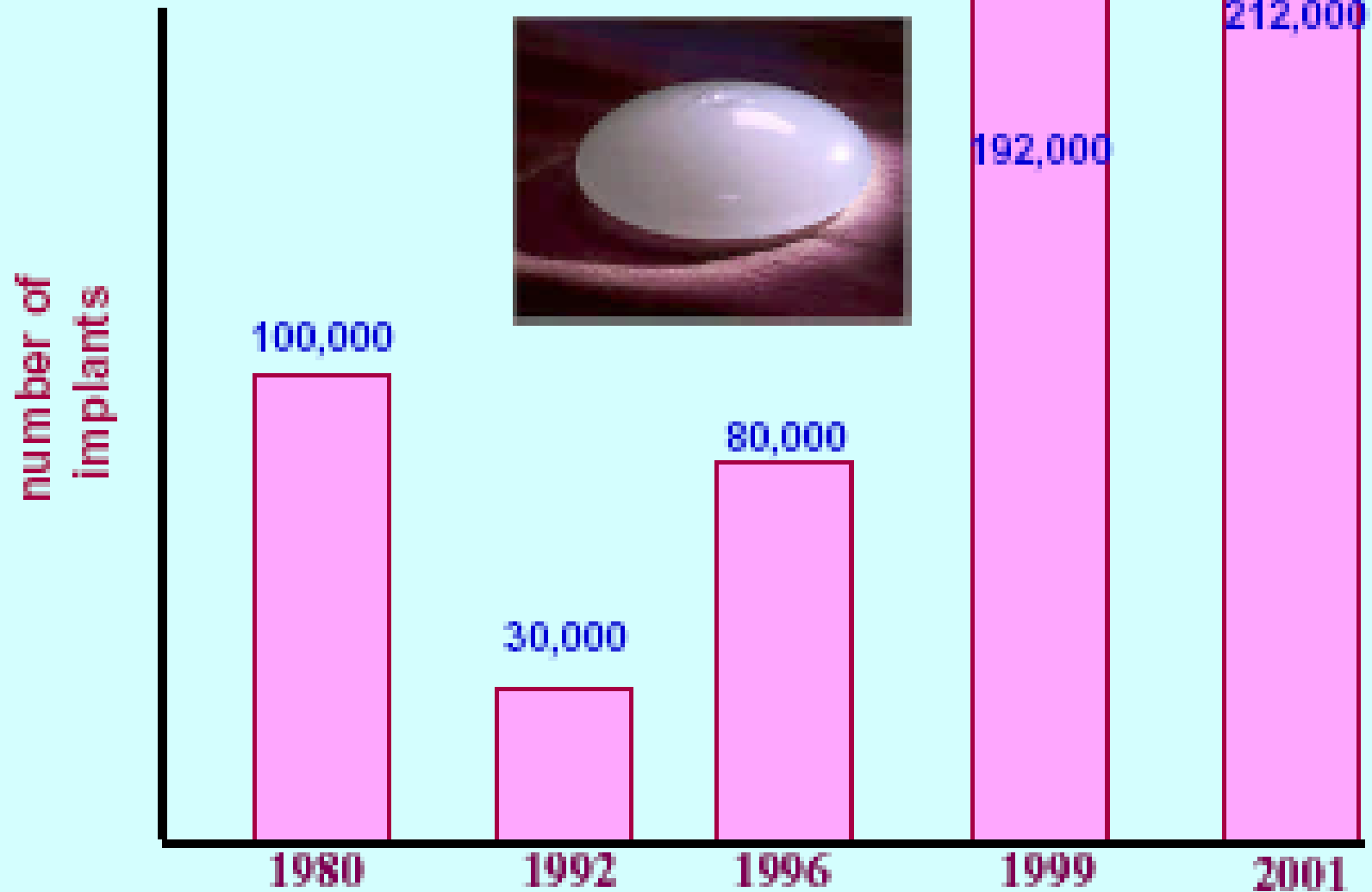
there is **no valid scientific evidence to
show that silicone breast implants cause
auto-immune disease or any other
dangerous condition.**

Failure of an implant...

- is **NOT** unexpected, because every man-made implant and device will have a finite failure rate in a large population.
- may or may **NOT** be due to materials, design, or handling.
- can be due to the patient's own abnormal physiologic responses, as usually seen in the “dose-response” statistics for a large population.
- has led to huge legal settlements to plaintiffs and their lawyers, which are having a significant negative impact on the future of medical implants and devices.
- There is a great need to alert the public to these facts.

Allan Hoffman

Number of Breast Implants Procedures (U.S.)



*DEGRADABLE POLYMERS
FOR USE AS SUTURES
AND IN DRUG DELIVERY*

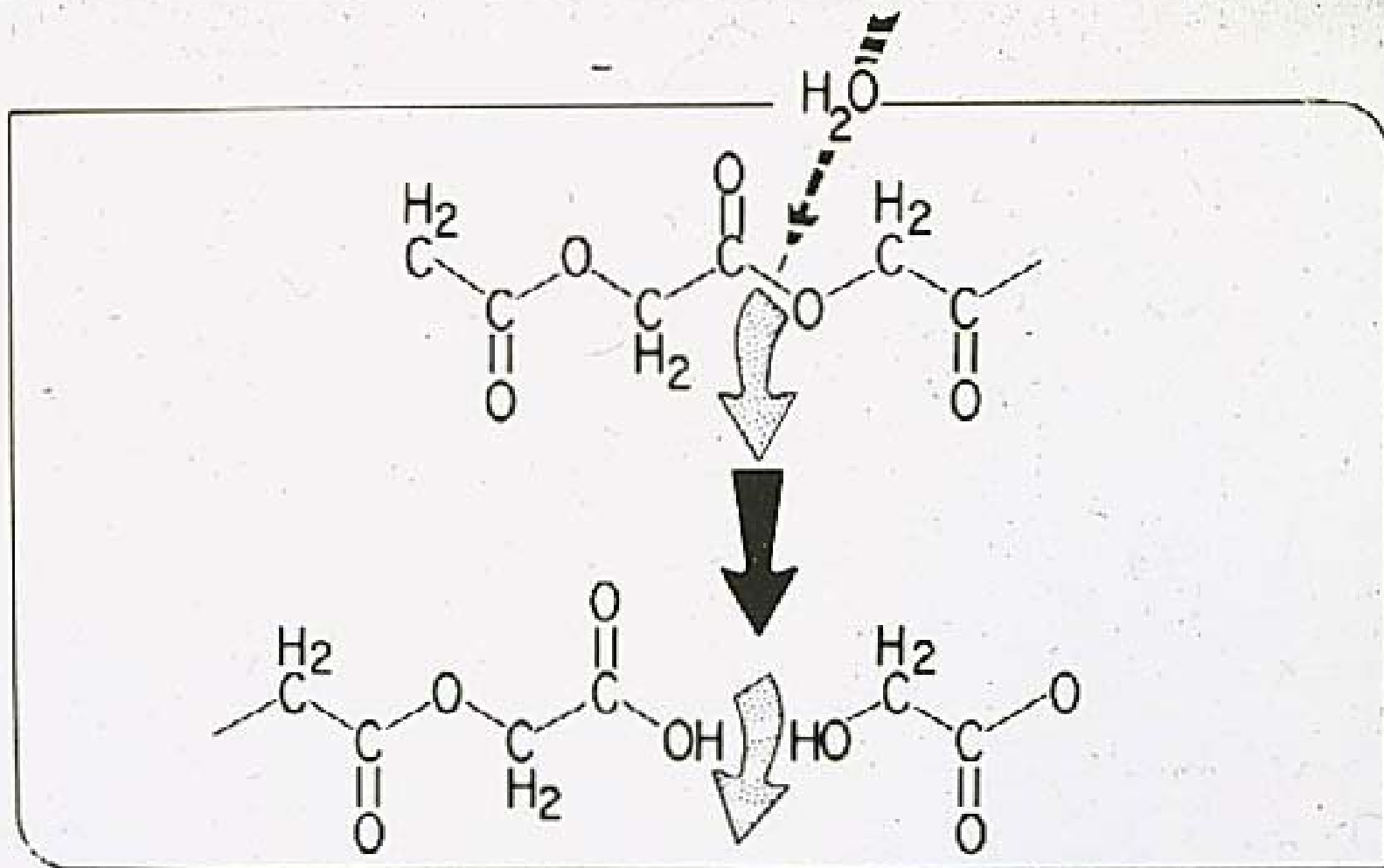
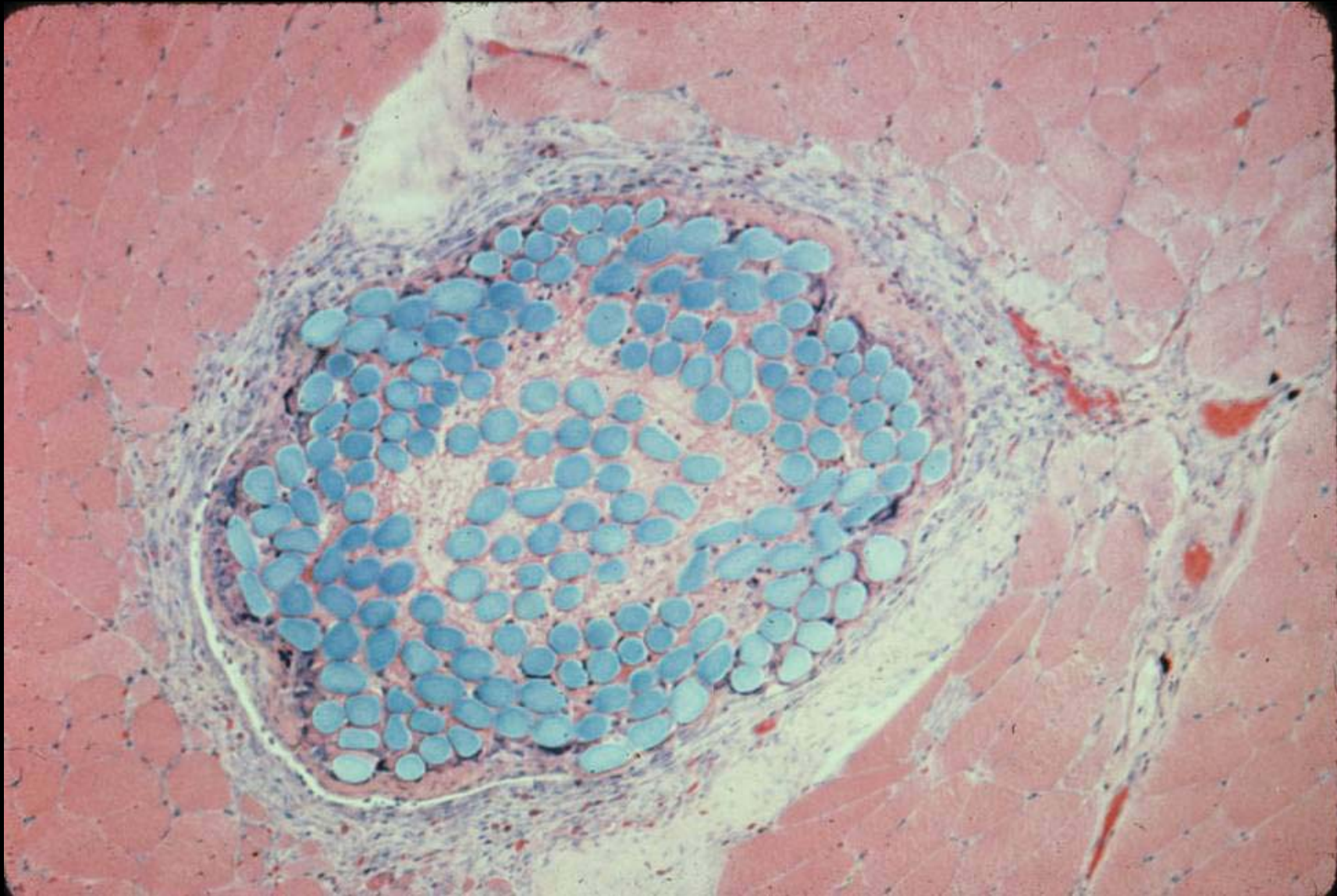
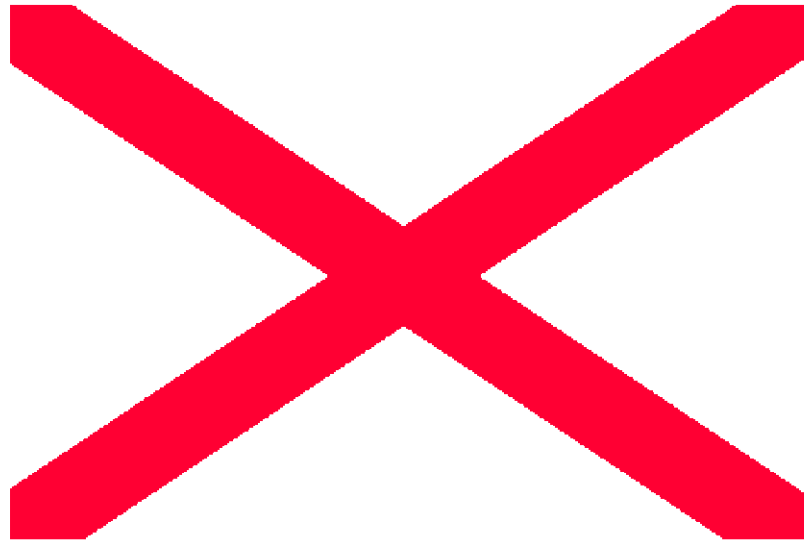


FIG. 11. Polyglycolic acid as a suture material. Chain scission by gradual hydrolysis of the ester linkage.

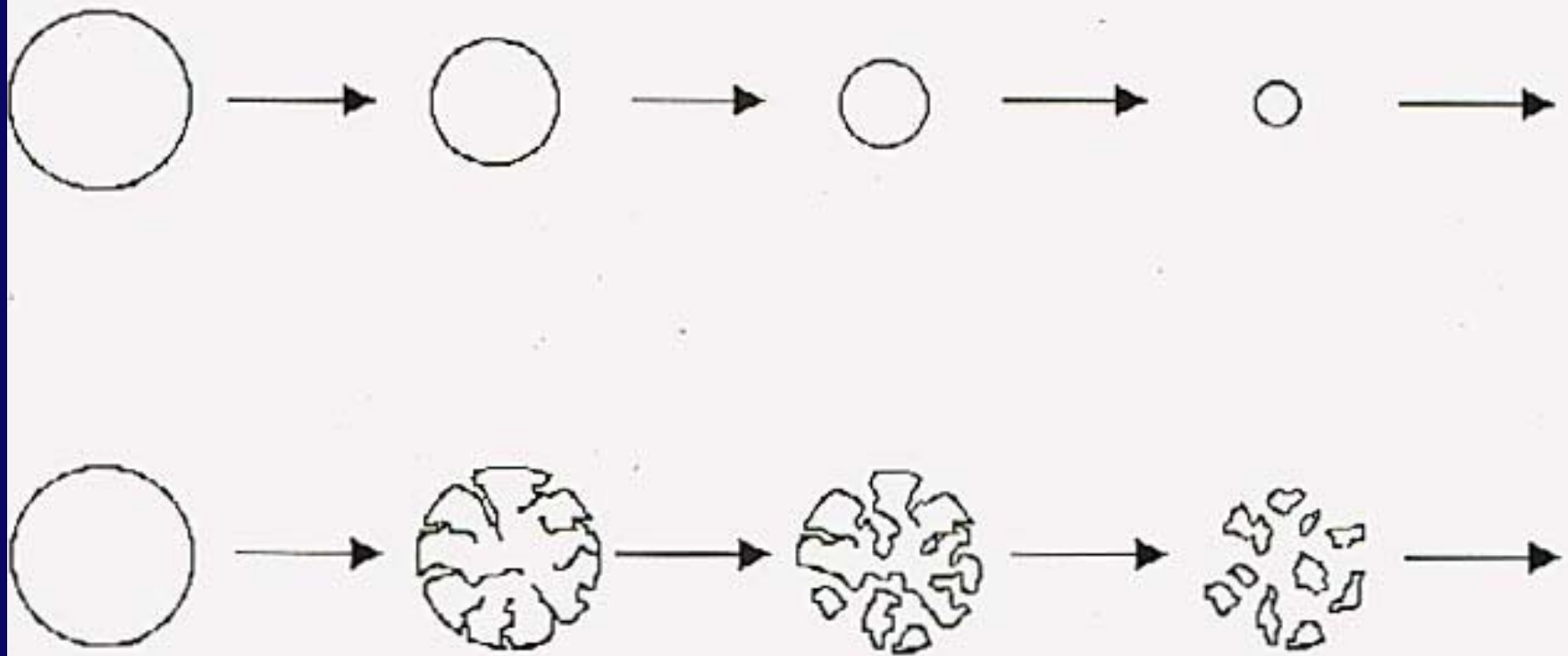
Vicryl® (PGA) after 7 days in rat muscle



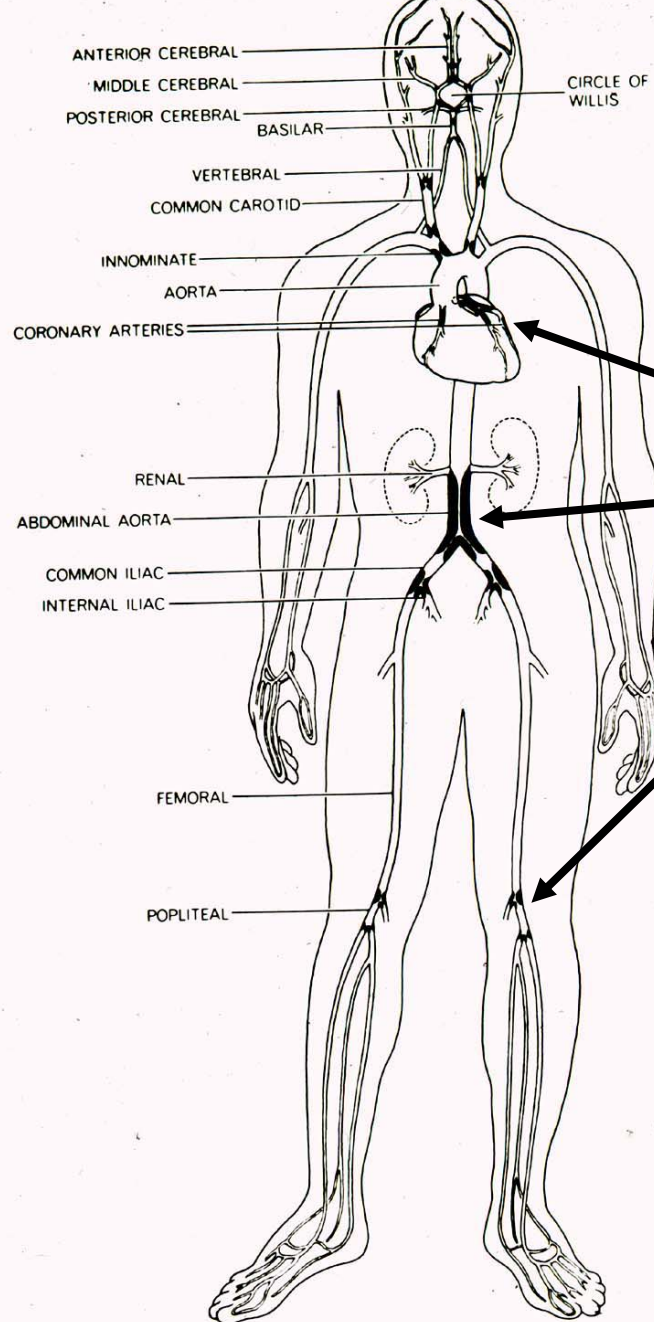
Vicryl® (PGA) after 56 days in rat muscle



BIODEGRADABLE MICROSPHERES



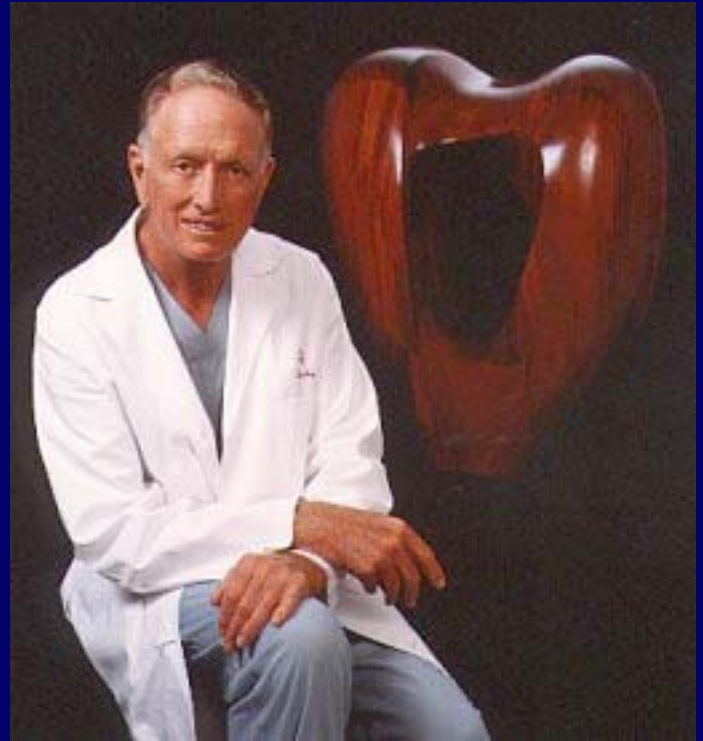
VASCULAR GRAFTS



**Common sites
of thrombus
deposition**



Dr. Michael E. DeBakey, M.D.



Dr. Denton A. Cooley, M.D.

Drs. DeBakey and Cooley, world famous surgeons, were pioneers (and competitors) in the development of Dacron® vascular grafts.



FIG. 3A. Appearance of knitted Dacron graft material $\times 85$. B, Crimped tube graft.

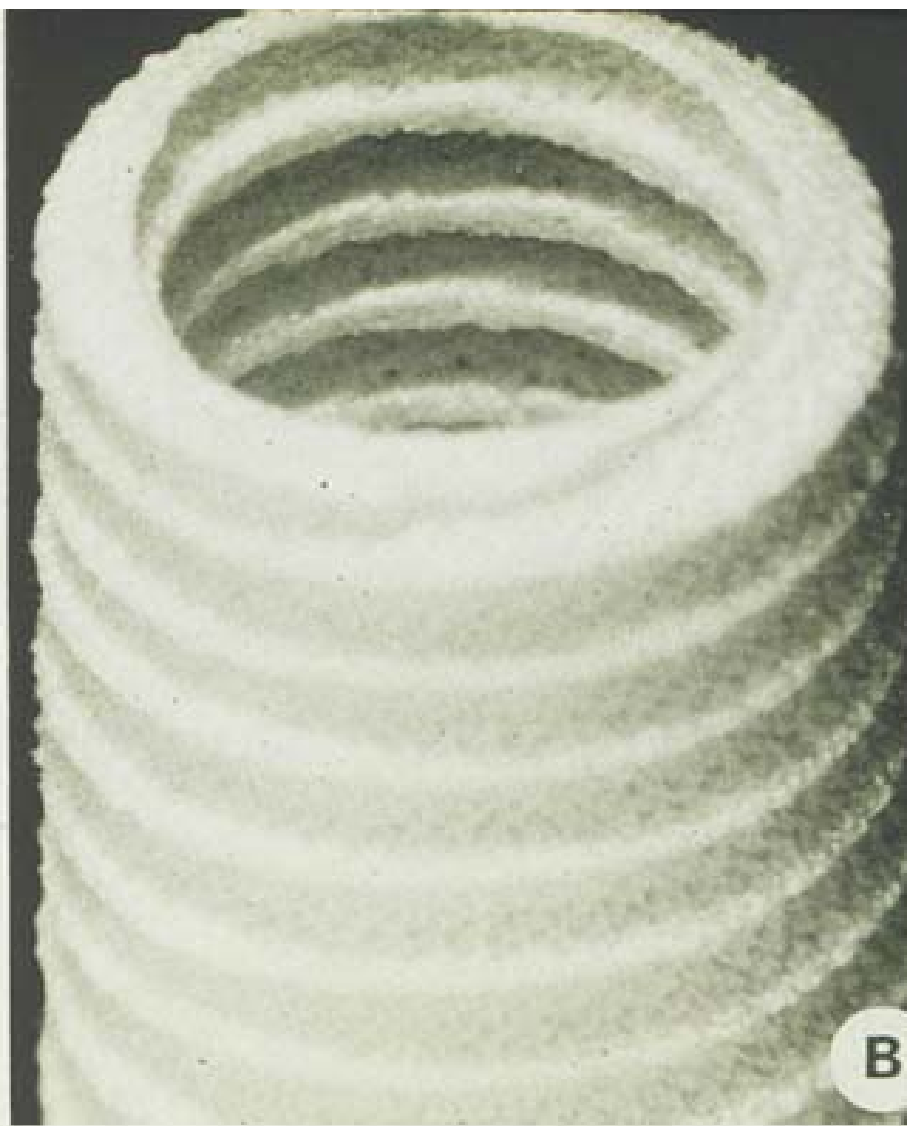
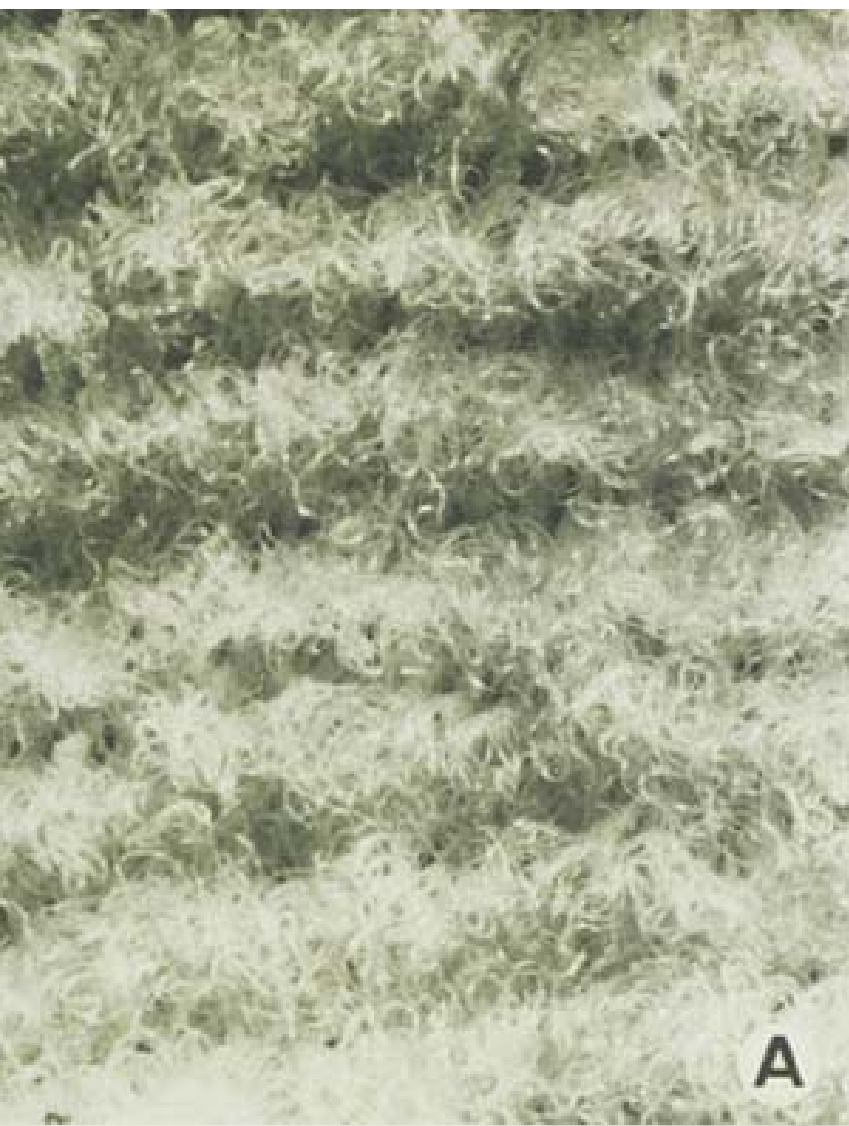
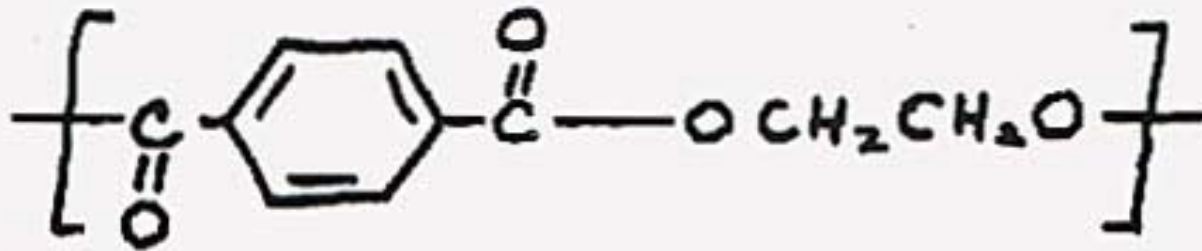


FIG. 4A. Appearance of Dacron velour graft material $\times 85$. B, Crimped tube graft.

The PET Molecule



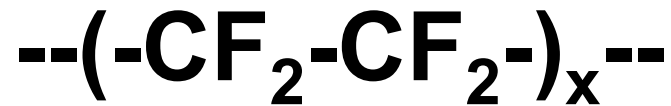
stiff group
(dominates)

flexible group

- Stiff groups along main chain:
- Low polarity
(electrons above and below stiff group)
- Regular, "streamlined" shape along chain

Uses
**Vascular grafts,
Implant fixation
(e.g., sewing rings)
Ingrowth felts**

*All these lead to a crystalline, high melting,
low water sorption polymer, useful as a fiber.*



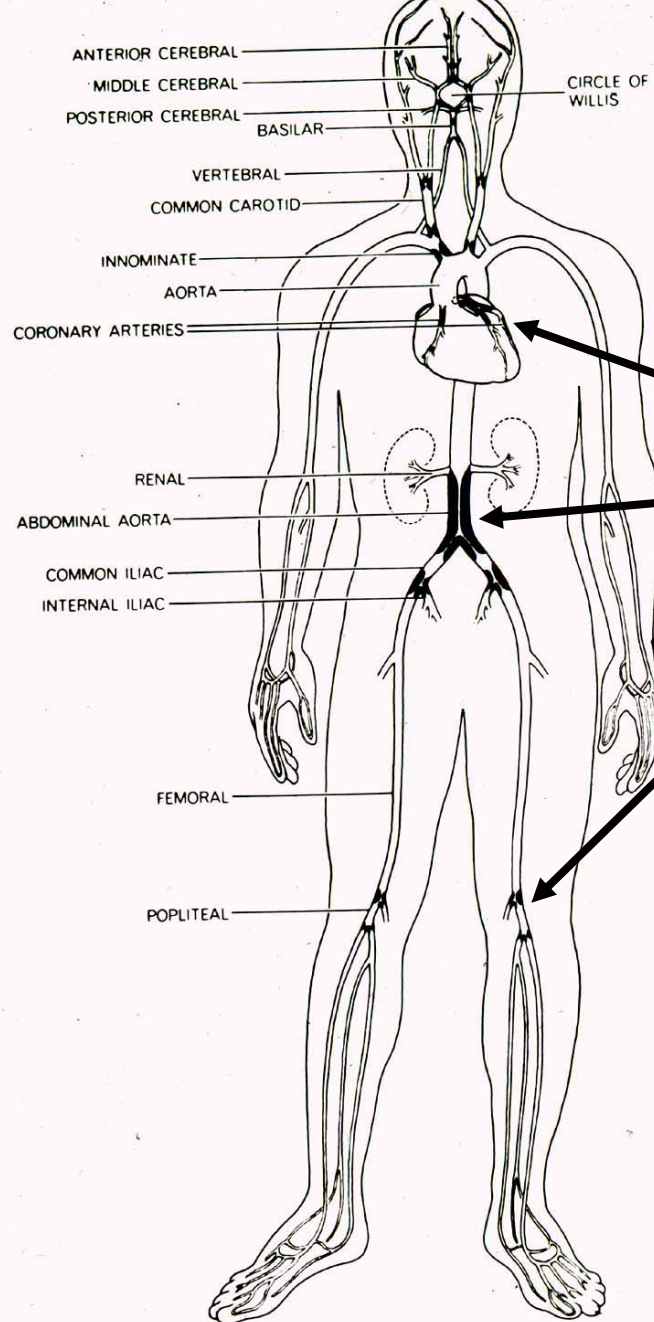
Poly(tetrafluoroethylene) Teflon®

**A highly symmetrical chain,
but very stiff, so it is both
crystalline and high melting (327°C)**

In the early days, *woven* Teflon® was used as a vascular graft. It was not strong enough and often burst under the blood pressure. Later, *expanded* Teflon® or e-PTFE has been successfully used as a vascular graft. It is widely known as Gore-Tex®.



FIG. 1. Photographs of operative specimens showing two causes of delayed false aneurysm following arterial prosthetic implantation. A. Specimen at femoral anastomosis 7 years after implantation of a 40 needle-per-inch prosthesis with completely intact suture (arrow) attached to prosthesis. This false aneurysm resulted from progression of the patient's aneurysmal disease and was successfully repaired. B. Blow-out of a woven Edward's Teflon graft 8 years after implantation. Photograph kindly supplied by R.H. Hayward, M.D., Scott and White Clinic, Temple, Texas.¹ This aneurysm is the obvious result of deterioration of the Teflon yarn which has been widely advertised as indestructible in the body.



**Common sites
of thrombus
deposition**

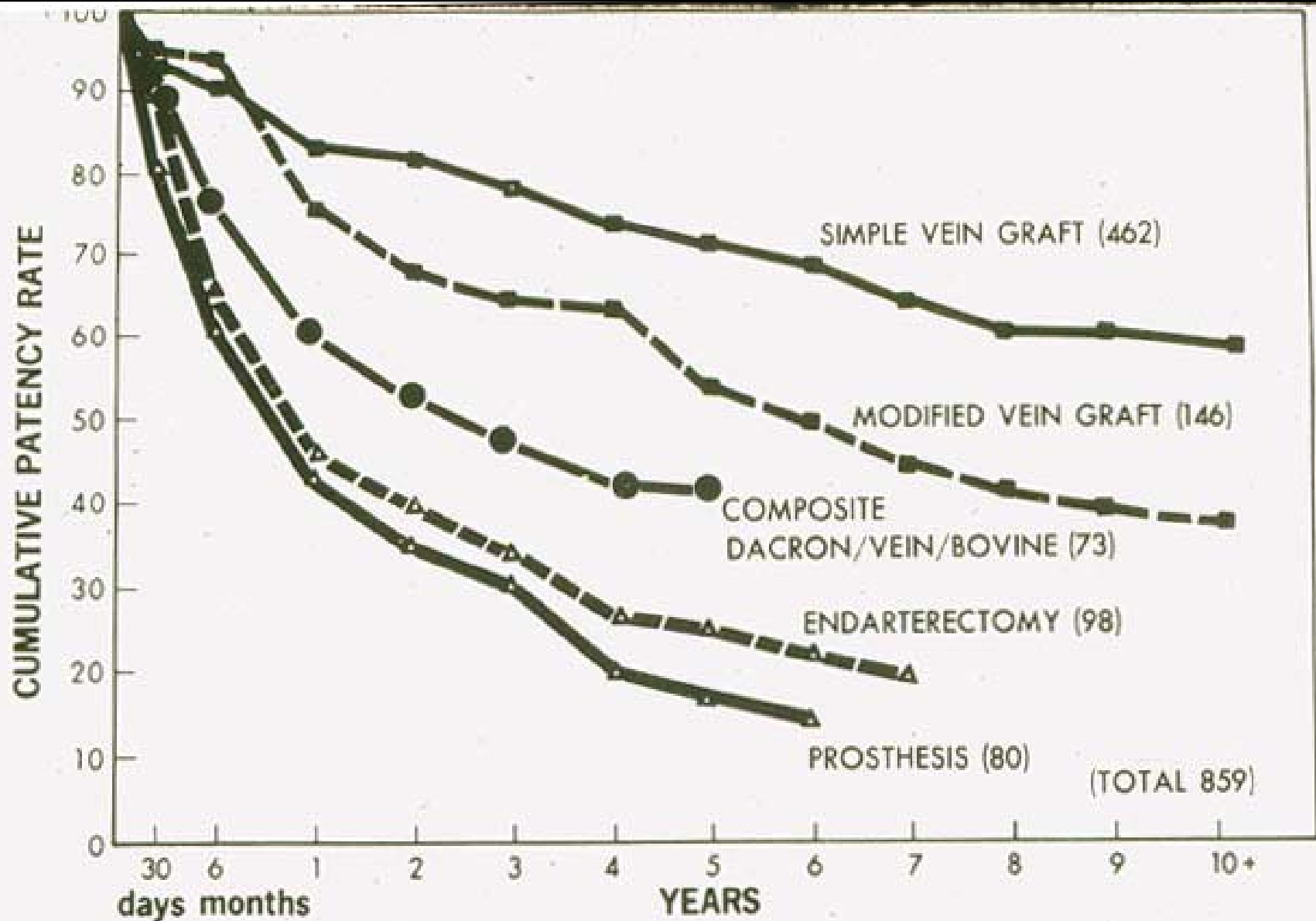
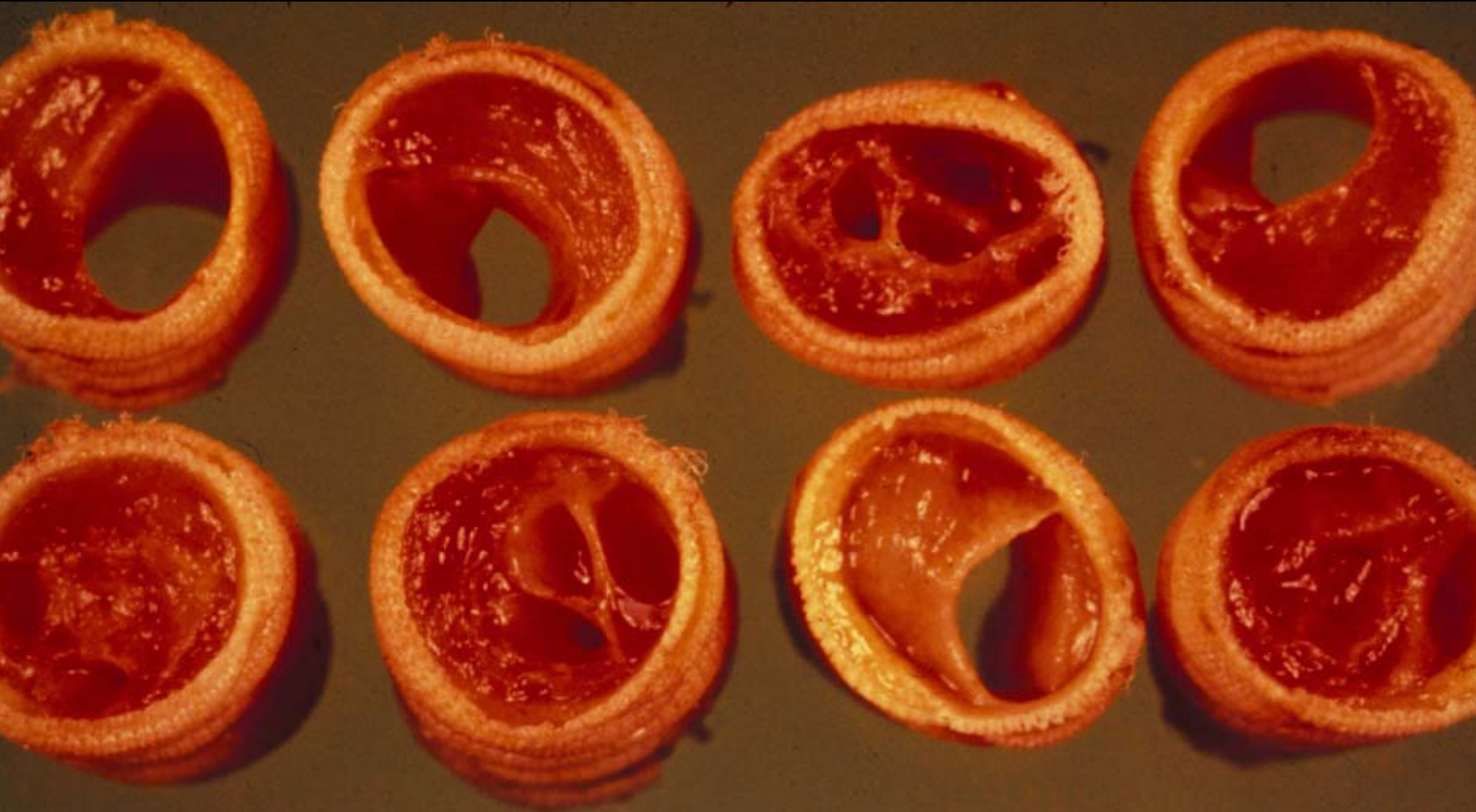


FIG. 3. Patency rates of 859 femoropopliteal grafts, as determined by life table method (1960-1974).

Thrombosed small diameter Dacron vascular grafts



ANGIOPLASTY AND STENTS

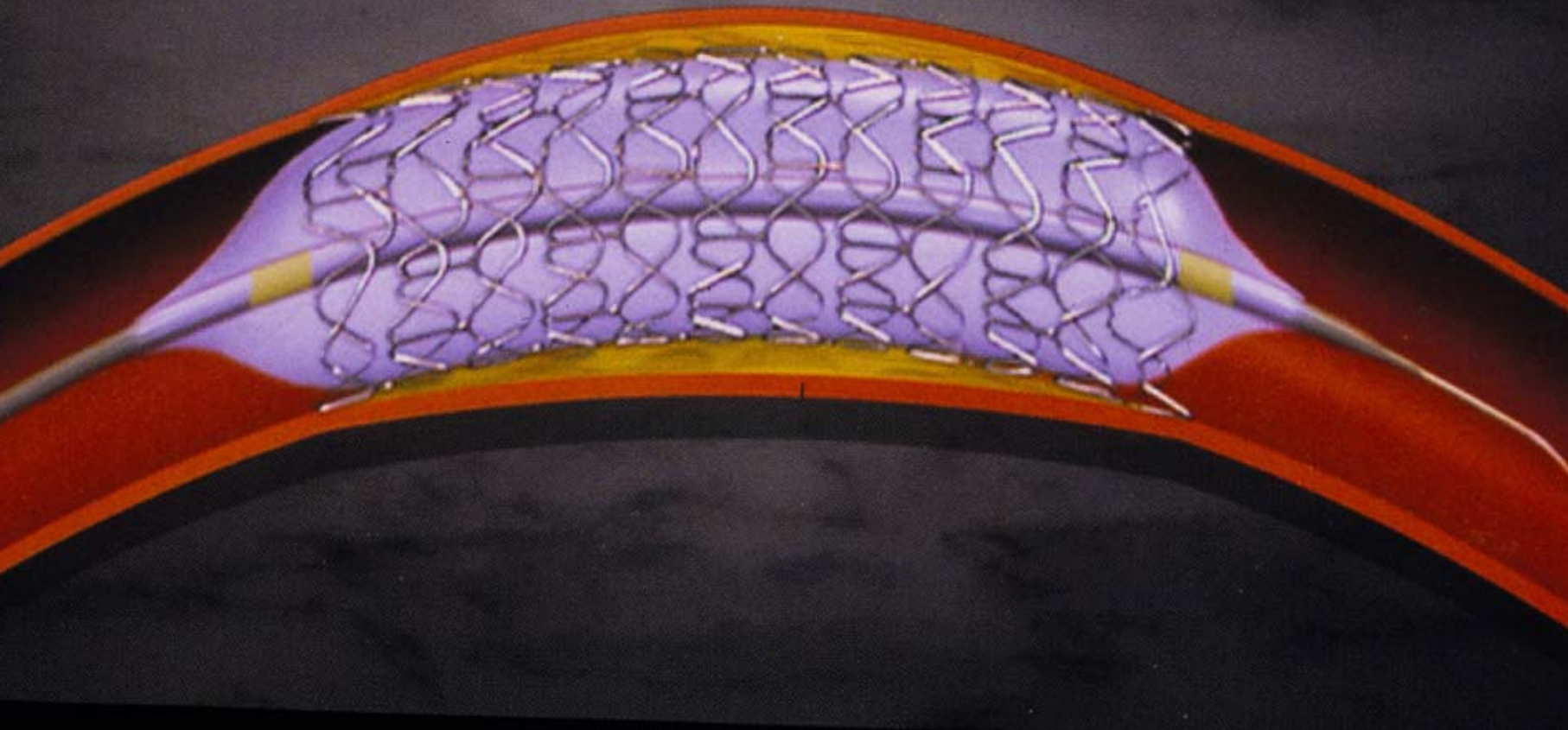
**Angioplasty in action:
Balloon and stent on catheter arrive at site of blockage.**





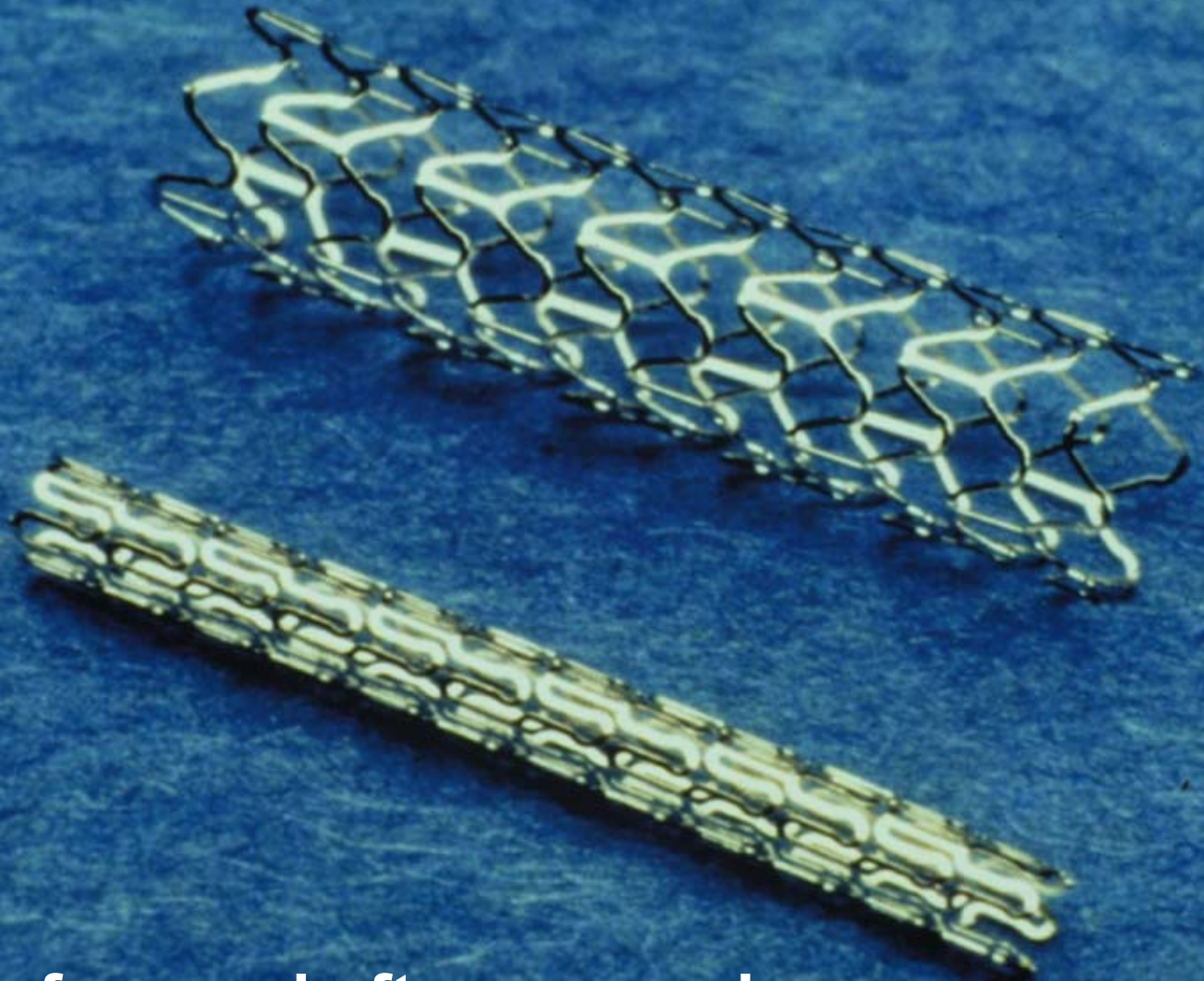
Balloon and stent partially expanded

**Balloon is inflated, expanding stent
and compressing blockage**



**Balloon is deflated, catheter is removed,
leaving stent behind to maintain patency.**



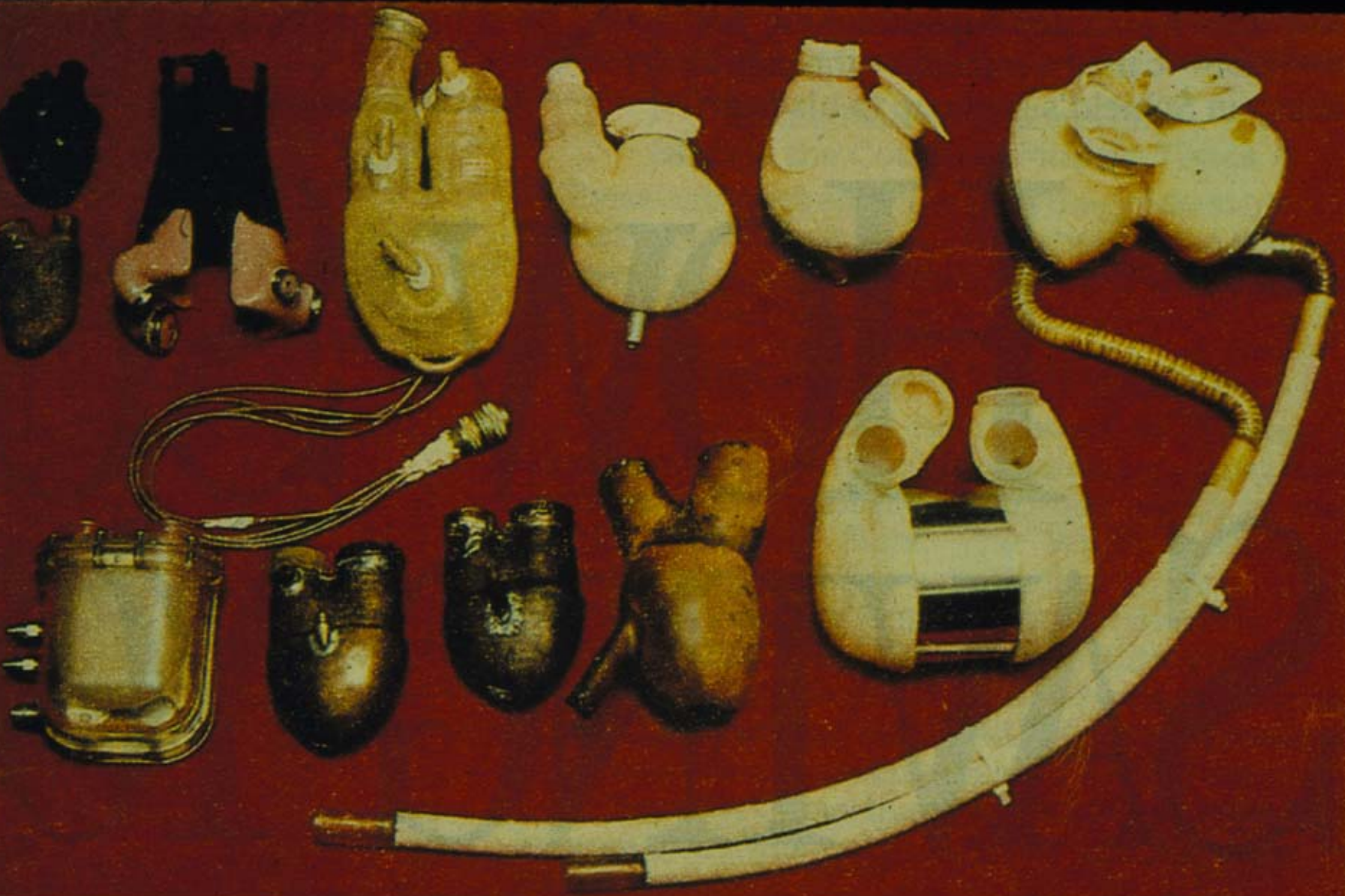


Stent before and after expansion

*LVAD ASSIST DEVICES
AND
TOTAL ARTIFICIAL HEART*

The Tin Woodman of Oz





st models of artificial hearts: Doctors are seeking cheaper, simpler ones.



Willem "Pim" Kolff

*Inventor of the
artificial kidney
and a pioneer in
development of
the artificial heart*

Evolution of the Total Artificial Heart

***Kolff
1958***



PVC

***Kolff
1965***

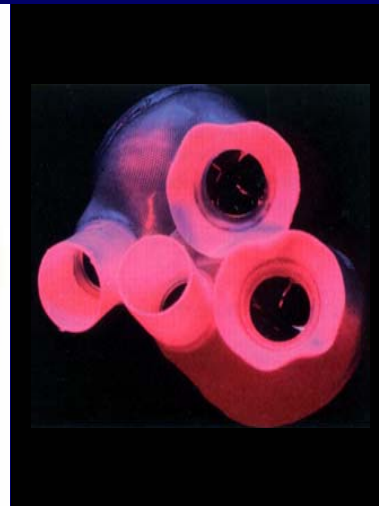


**Silicone
Rubber**

***Liotta
1969***



***Jarvik
1982***



**Lycra
Spandex**

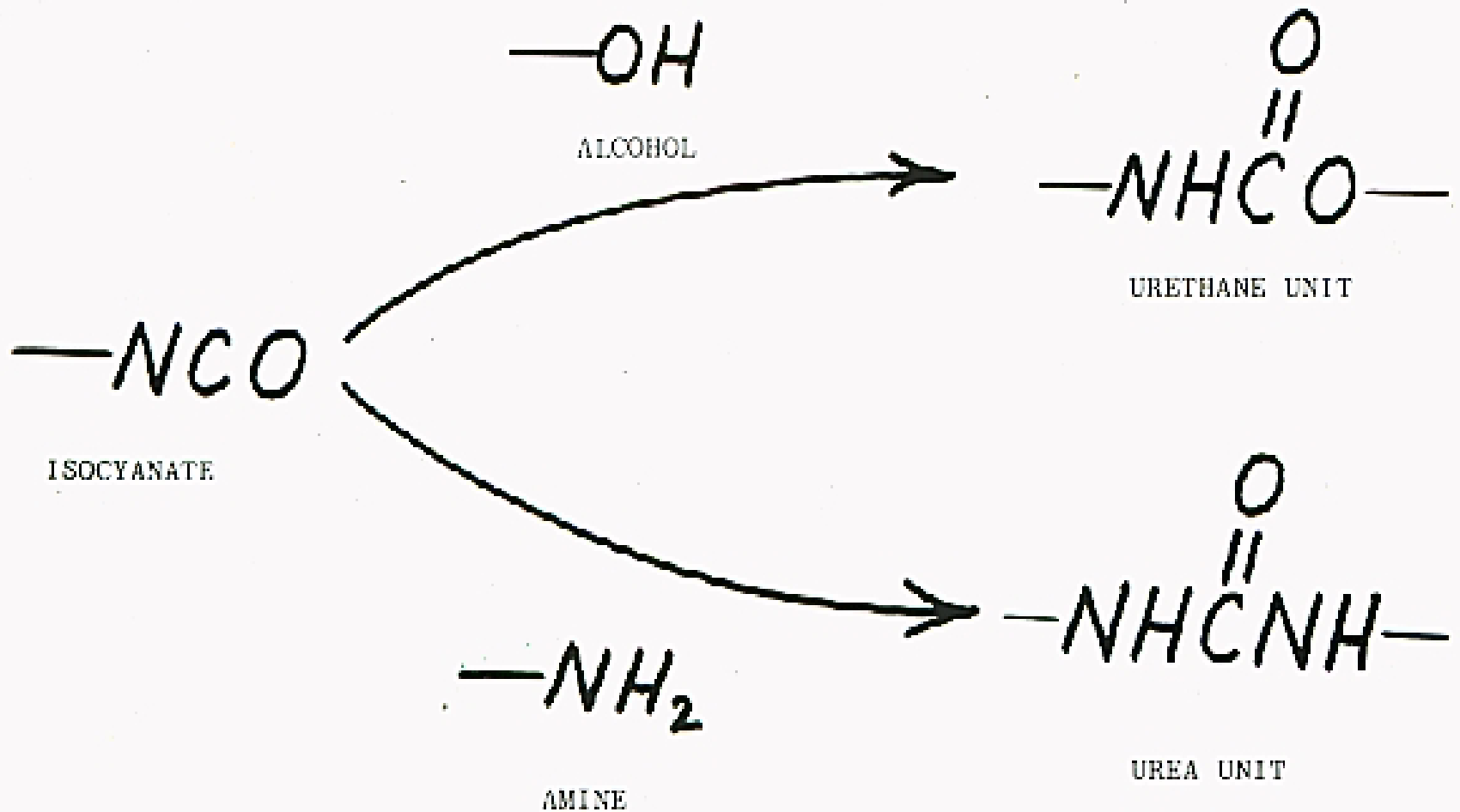
***Abiomed
2001***



**Purified
TPU**

Courtesy of Bob Ward

POLYURETHANE BIOMATERIALS



PEU = POLY (ETHER-URETHANE)

PEUU = POLY (ETHER-URETHANE-UREA)

LIFE

Can Women Cut It



in the Military?

September 1981/\$2.00

THE ARTIFICIAL HEART IS HERE



EXCLUSIVE PICTURES
OF DR. COOLEY'S
HISTORIC
HEART
SURGERY



Man Given Artificial Heart

n of Long Beach

His Campus Also His Battlefield

MAURA DOLAN,
Times Staff Writer

group of 10 men and women sat around a conference table in a rooming the campus office of Ste-Horn, president of California University, Long Beach. Geological Christians and aides toervative Republican legislators led Horn to remove a book on lesbian sex from a class reading list. The aide to Assemblyman Dennis Horn of Signal Hill tried to explain his dislike of the book did not think he is naive or prudish.

"We've all read books like this at one time or another," said the aide, in the kind of tone that is usually accompanied by a wink or a nudge. Horn, who was allowing his deans to decide presidents to run the meeting, suddenly perked up.

"Young man, I am 50 years old and have never read pornography," participants quoted the bearded, balding president as he said, "You are wrong to assume we all read this kind of materi-



Los Angeles Times

Sen. Edward M. Kennedy as he bowed out of presidential race.

Sen. Kennedy Won't Enter 1984 Race

By ROBERT SHOGAN,
Times Political Writer

WASHINGTON—Sen. Edward M. Kennedy took himself out of the 1984 contest for the White House Wednesday, setting off a scramble among the remaining Democratic presidential prospects for the support that had made him a principal contender.

The Massachusetts senator's withdrawal, which he attributed to concern for his children, appeared to make former Vice President Walter F. Mondale the front-runner, at least for the time being.

Kennedy indicated that he was bowing to the wishes of his children—Kara, 22, Edward Jr., 21, and Patrick, 15. They reportedly were concerned that another presidential campaign would bring more attacks on his character and perhaps further threats against his life.

Might Run in 1988

"My first and overriding obligation now is to Patrick and Kara and Teddy," Kennedy said. "I will not be a candidate for the presidency of the United States in 1984."

In announcing his withdrawal, Kennedy made it plain that he intends to maintain his role as the Democratic Party's most vigorous

Tides Threaten Mobile Homes on Irvine Coast

By LEO C. WOLINSKY
and JACK JONES,
Times Staff Writers

Wind-blown waves accompanied by unusually high tides battered portions of Southern California's



Associated Press

Model of artificial heart implanted by Salt Lake City surgeons.

Implant of Permanent Pump a First

SALT LAKE CITY (UPI)—Surgeons replaced the dying heart of a 61-year-old dentist today with the first permanent artificial heart implanted in a human.

The historic operation at the University of Utah was a last-ditch effort to save the life of Barney Clark of Seattle.

The second of two plastic pump chambers was snapped into place in his chest cavity about 3½ hours after the procedure began, officials said.

"Blood is actually flowing through the heart now," John Dwan, a spokesman for the University of Utah Medical Center, said as surgery drew to a close early today.

He said doctors had begun the painstaking process of weaning the patient from a heart-lung machine to the new heart.

Surgeons had to complete sewing up the connections to natural tissue before activating the artificial heart. That was to be done before the opening in the chest was closed.

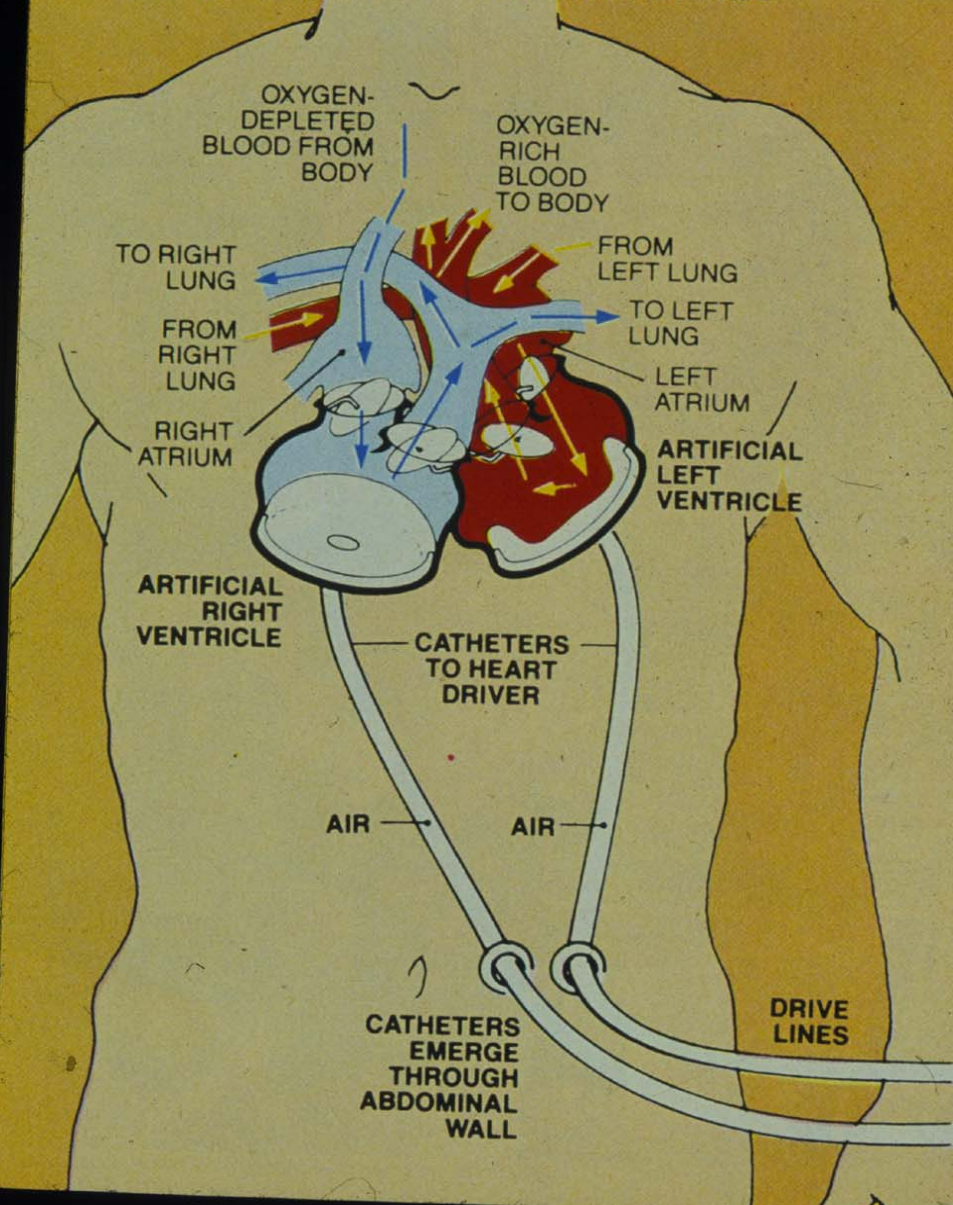
If successful, the operation would mean Clark must be connected for the rest of his life by two tubes to an external air compressor running the implanted device.

'Bound to Bed'

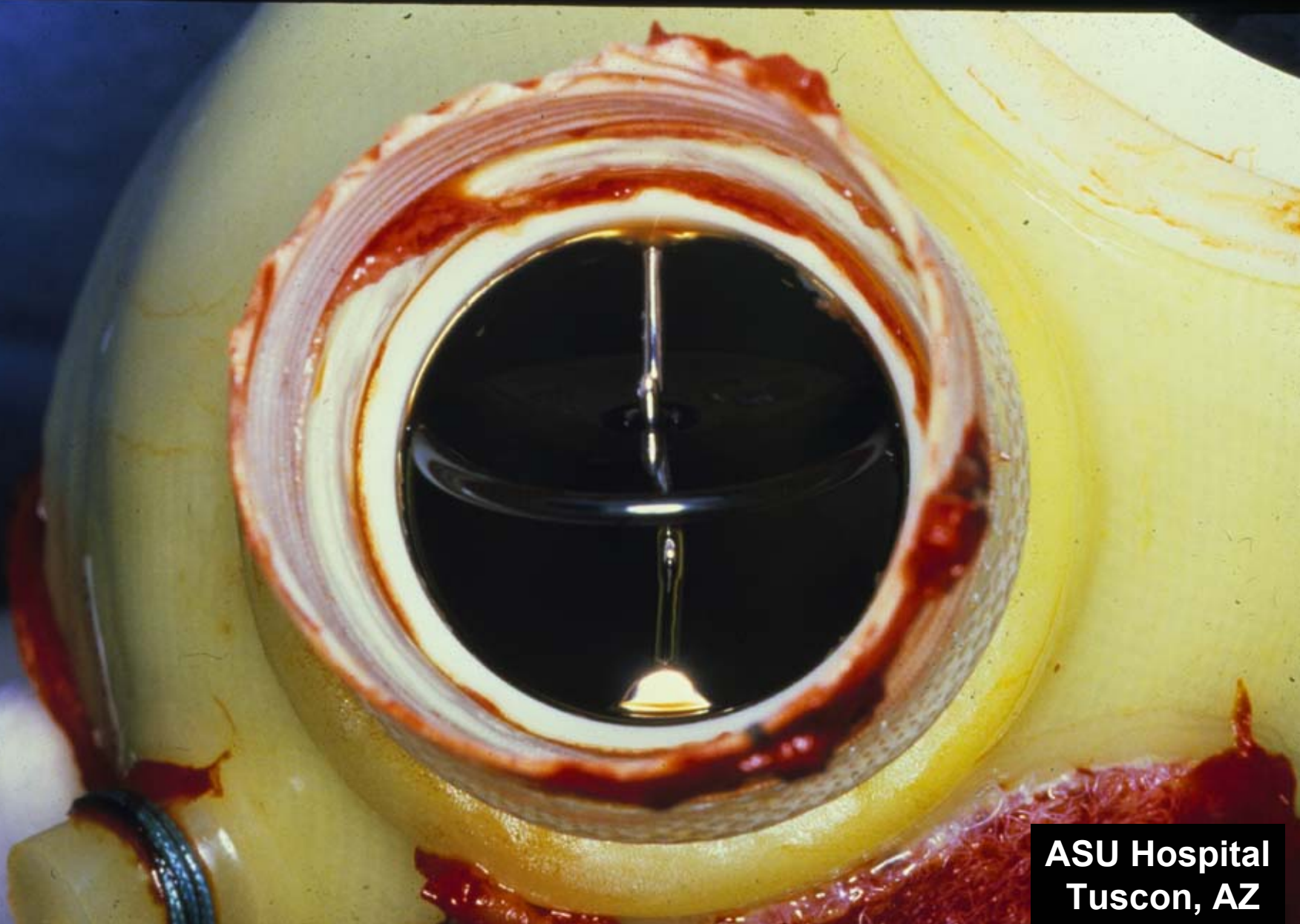
Dr. Chase Peterson, university vice president for medical services, likened it to "life tethered to a

THE IMPLANT

About the size of a normal male heart, the artificial device is sutured to the atria and assumes the function of the ventricles, pumping blood through the circulatory system. It is powered by pulses of compressed air fed through two permanent lines linked to the heart.



Thrombus on outlet from valve in Jarvik TAH



ASU Hospital
Tuscon, AZ

THE VALVE THAT BROKE



Open: The disc tilts down to let blood pour from the atrium into the ventricle

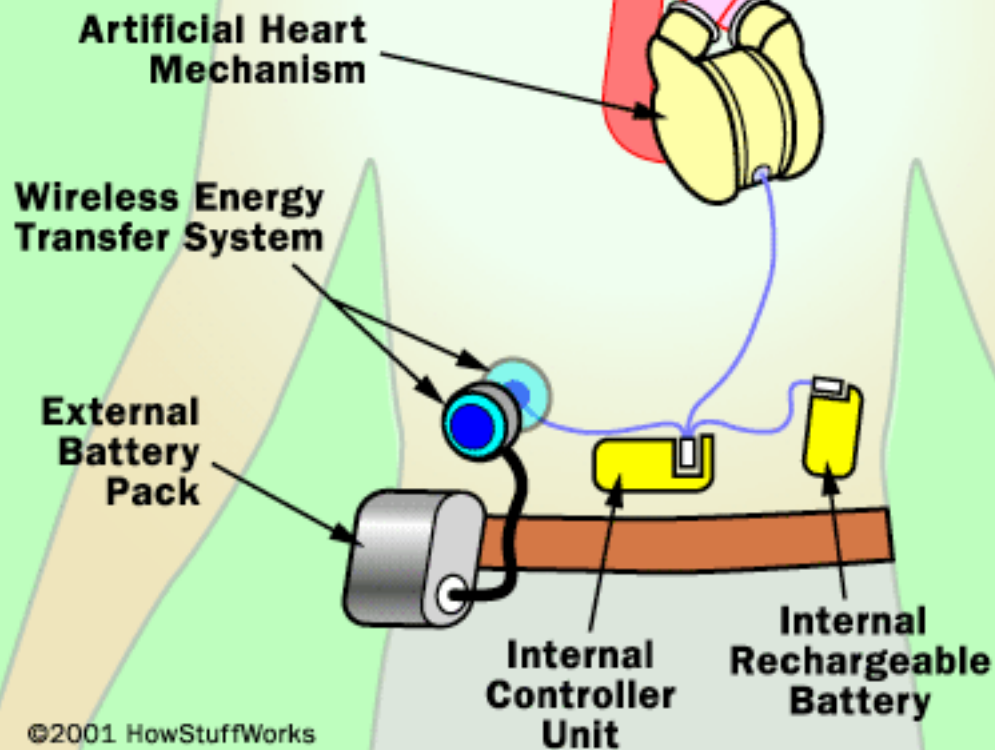


Closed: As the ventricle fills, the rising blood pushes the disc shut



Broken: The disc will not seal properly; it can now slip out of the metal housing

The AbioCor Artificial Heart System

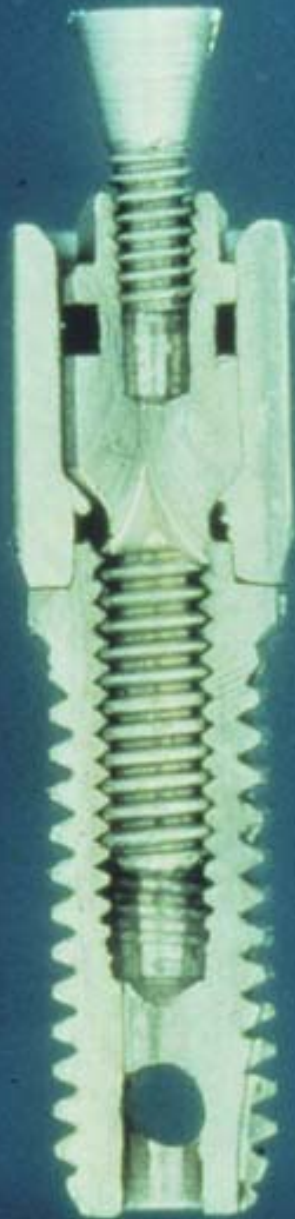






THE "MIRACLE" MATERIAL: TITANIUM

Some time in the 1980s, Branemark in Sweden noticed that titanium metal nails could not be easily removed from bone. This has led to the widespread use of Ti in dental and orthopedic implants. We are still trying to understand why Ti bonds so well to bone.



Titanium
Dental
Implant



BEFORE

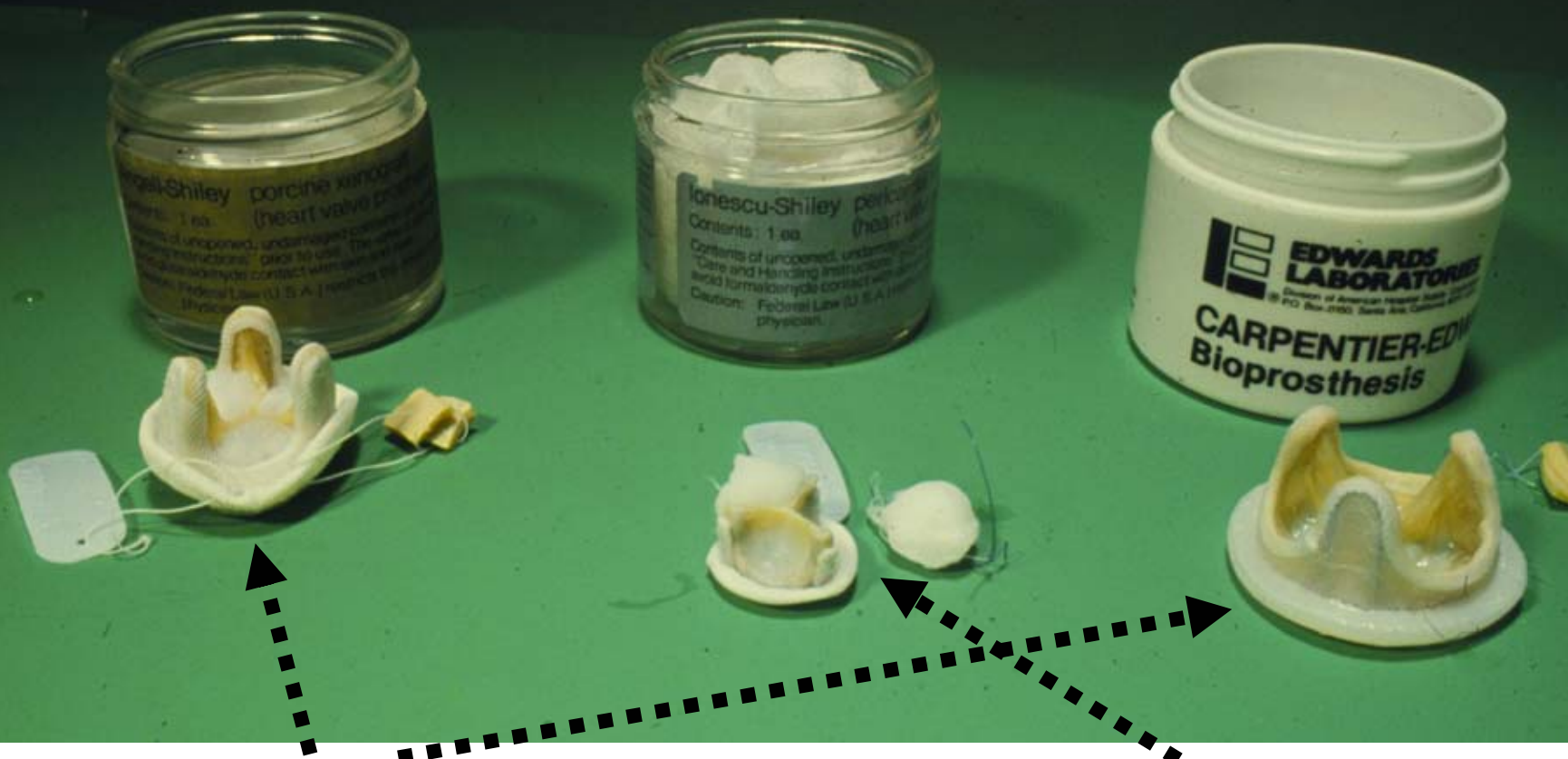


AFTER

HEART VALVES

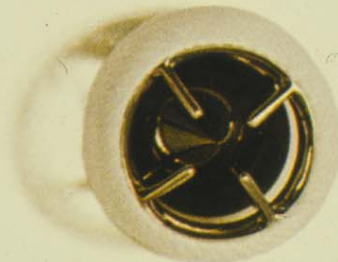
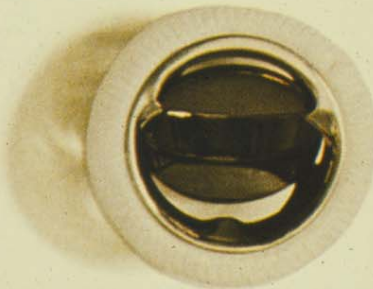
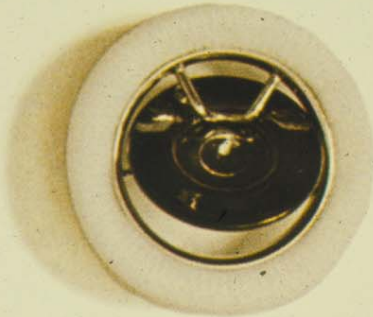
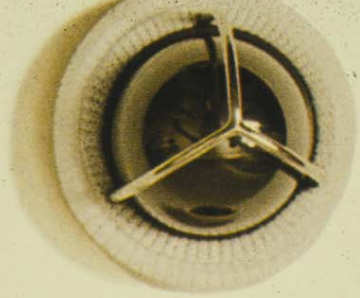
Three Star-Edwards (“surgeon-company”) silicone ball-in-cage heart valves





Natural pig valves and pericardial tissue valve

**Pyrolytic Carbon®
heart valves:
(one ball-in-cage and
three tilting disc valves)**

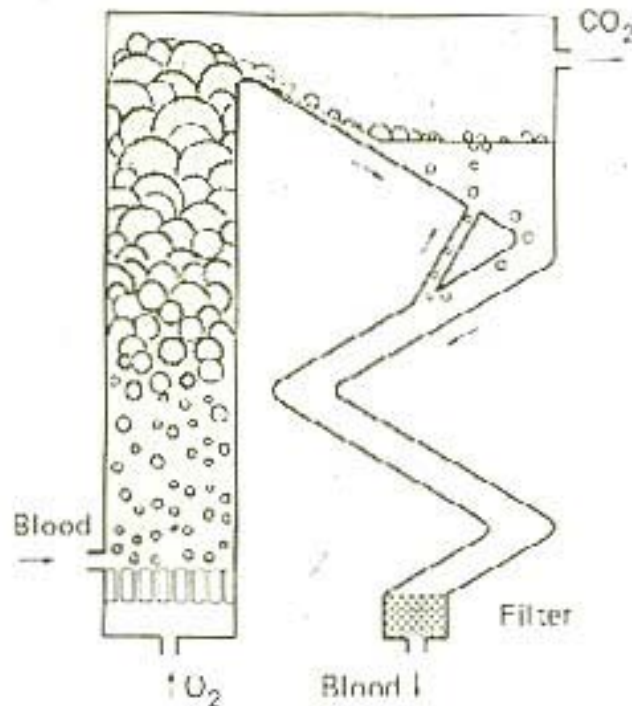


Heart valve prostheses

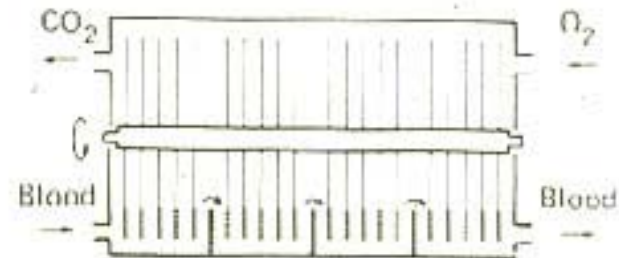
BLOOD OXYGENATORS

Various designs of blood oxygenators

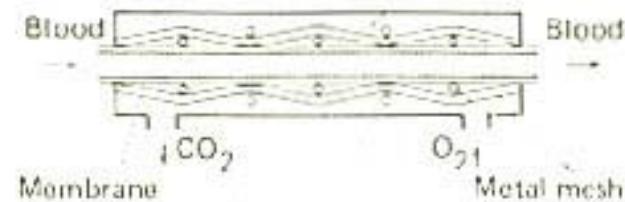
BUBBLE OXYGENATOR



FILM OXYGENATOR
(Disc type oxygenator)



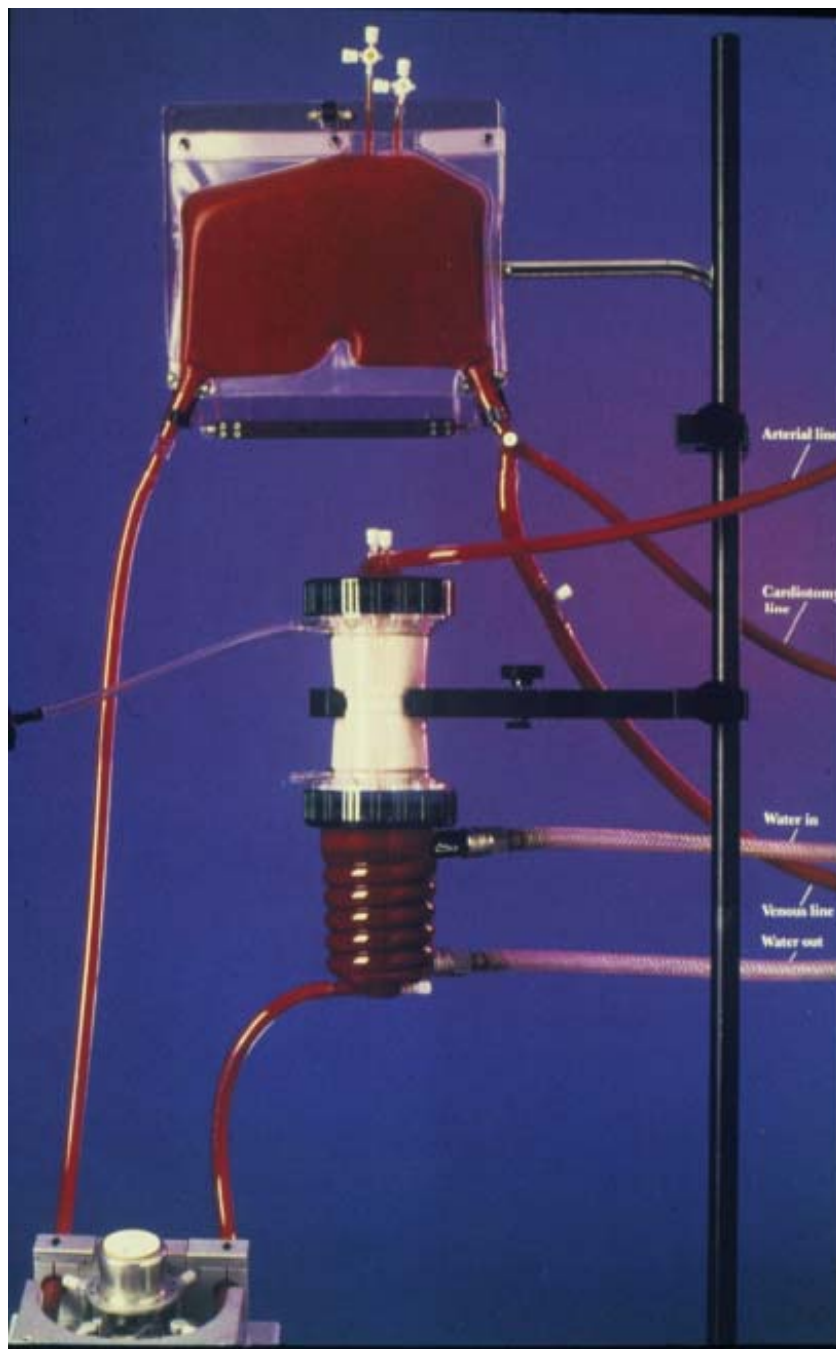
MEMBRANE OXYGENATOR



LIQUID-LIQUID OXYGENATOR



Figure 11.11 Various types of oxygenators.



**HOLLOW FIBER
MEMBRANE BLOOD
OXYGENATOR**
(Uses porous PP
hollow fibers)

Evolution of Tissue Engineering

***Tissue injury,
disease or failure***



**Synthetic implant
(if available)**



**Implantation of
biocompatible
scaffold + cells
(“*tissue-engineered*”
tissue or organ)**



New tissue or organ

***Organ injury,
disease or failure***



**Extracorporeal
treatment (+/- cells)**



**Transplantation
(if organ available)**



**Implantation of
cells encapsulated
in polymer
(“bioartificial organ”)**

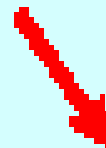


Tissue Engineering...

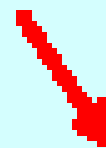


Ioannis V Yannas

Research on seeding cells in porous scaffolds started in the early 70's



Yannas,IV; Burke,JF; Orgill,DP; Skrabut,EM (1982):
Wound tissue can utilize a polymeric template to
synthesize a functional extension of skin.
Science 215, 174-176.



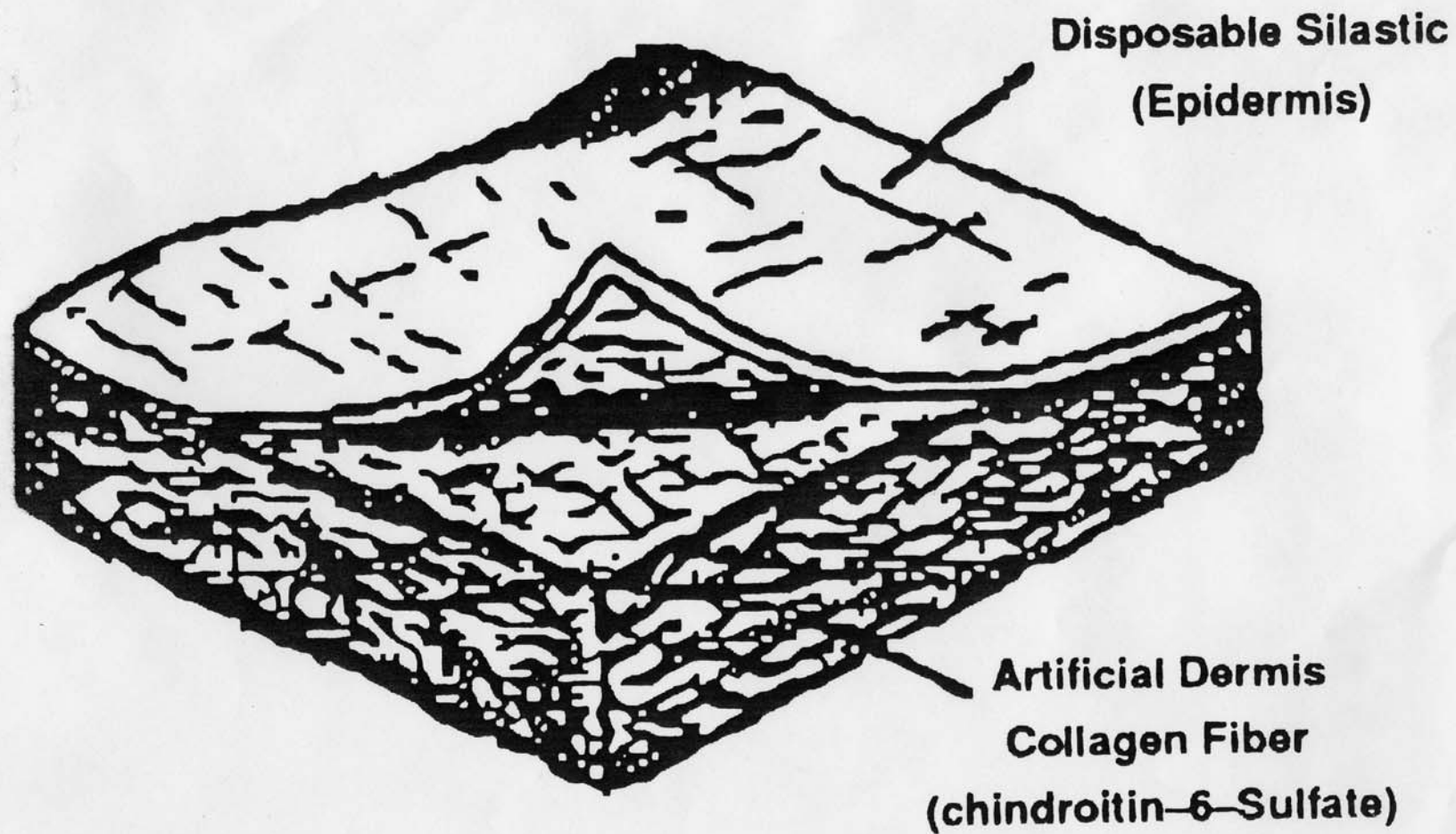
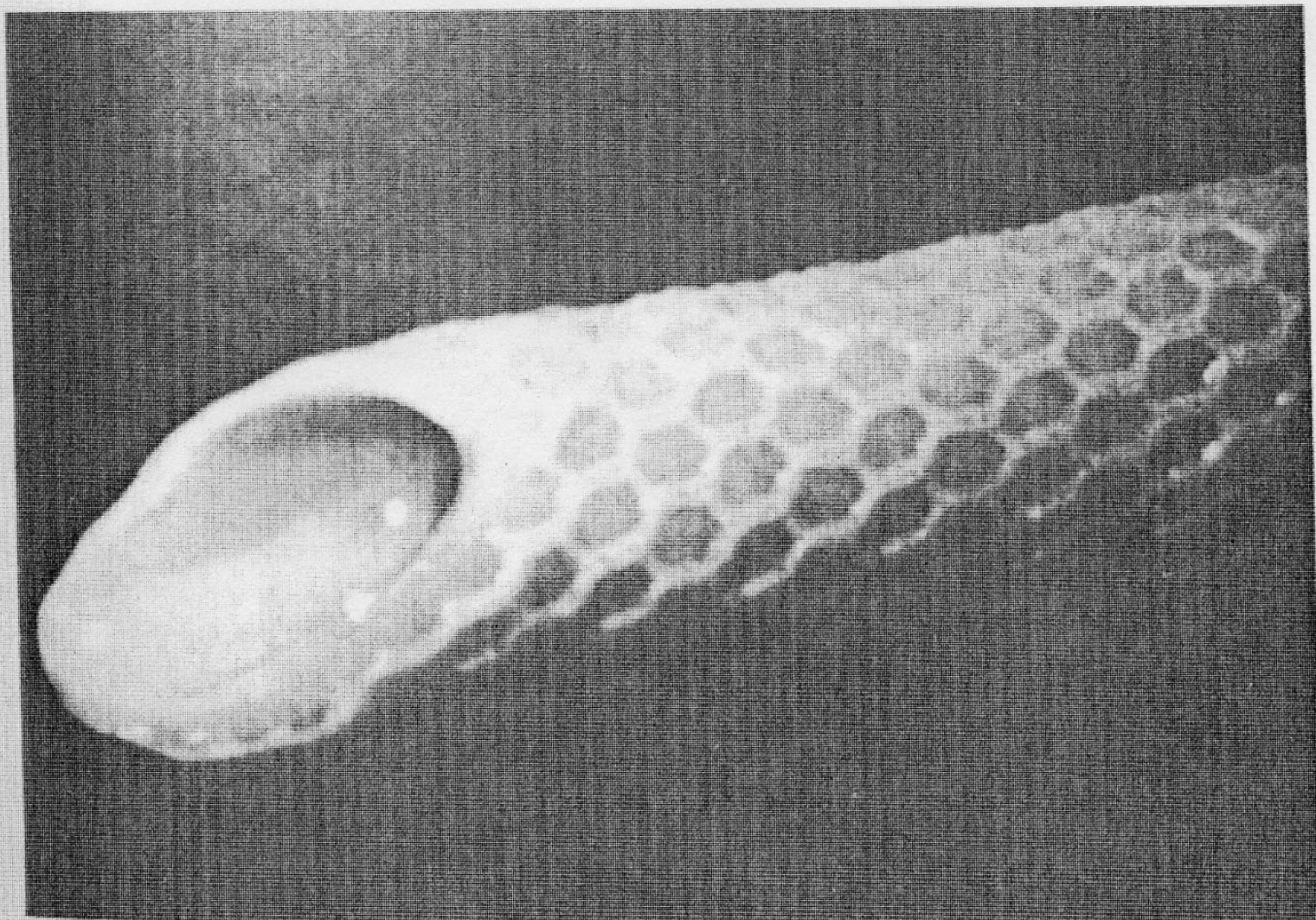


FIG. 8. Diagram of Burke and Yannas artificial skin (from Heimbach *et al.*, 1988).



REFERENCE: Dardik, H., "Lower Extremity Revascularization with the Glutaraldehyde Stabilized Human Umbilical Cord Vein Graft," *Vascular Graft Update: Safety and Performance*, ASTM STP 898, Helen E. Kambic, Adrian Kantrowitz, and Pei Sun, Eds., American Society for Testing and Materials, Philadelphia, 1986, pp. 50-50.

Evolution of Tissue Engineering

*Tissue injury,
disease or failure*



**Synthetic implant
(if available)**



**Implantation of
biocompatible
scaffold + cells
("tissue-engineered"
tissue or organ)**



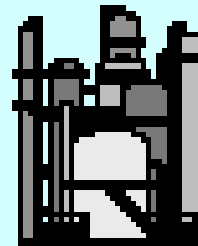
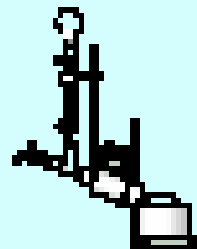
New tissue or organ

*Organ injury,
disease or failure*

**Synthetic polymers such as
PLGA, PHEMA and PEO, and
natural polymers such as
collagen, fibrin, silk fibroin,
alginate, dextran and
hyaluronic acid are currently
being investigated as
biocompatible scaffolds.**

**Implantation of
cells encapsulated
in polymer
("bioartificial organ")**

Careers Involving Biomaterials



Medicine

Science

Engineering

Business

Physician

Chemist

Bioengineering

Medical Device
Company

Nurse

Biochemist

Chemical

Hospital

Bioengineer

Biologist

Mechanical

Venture Capital

Hospital
Technician

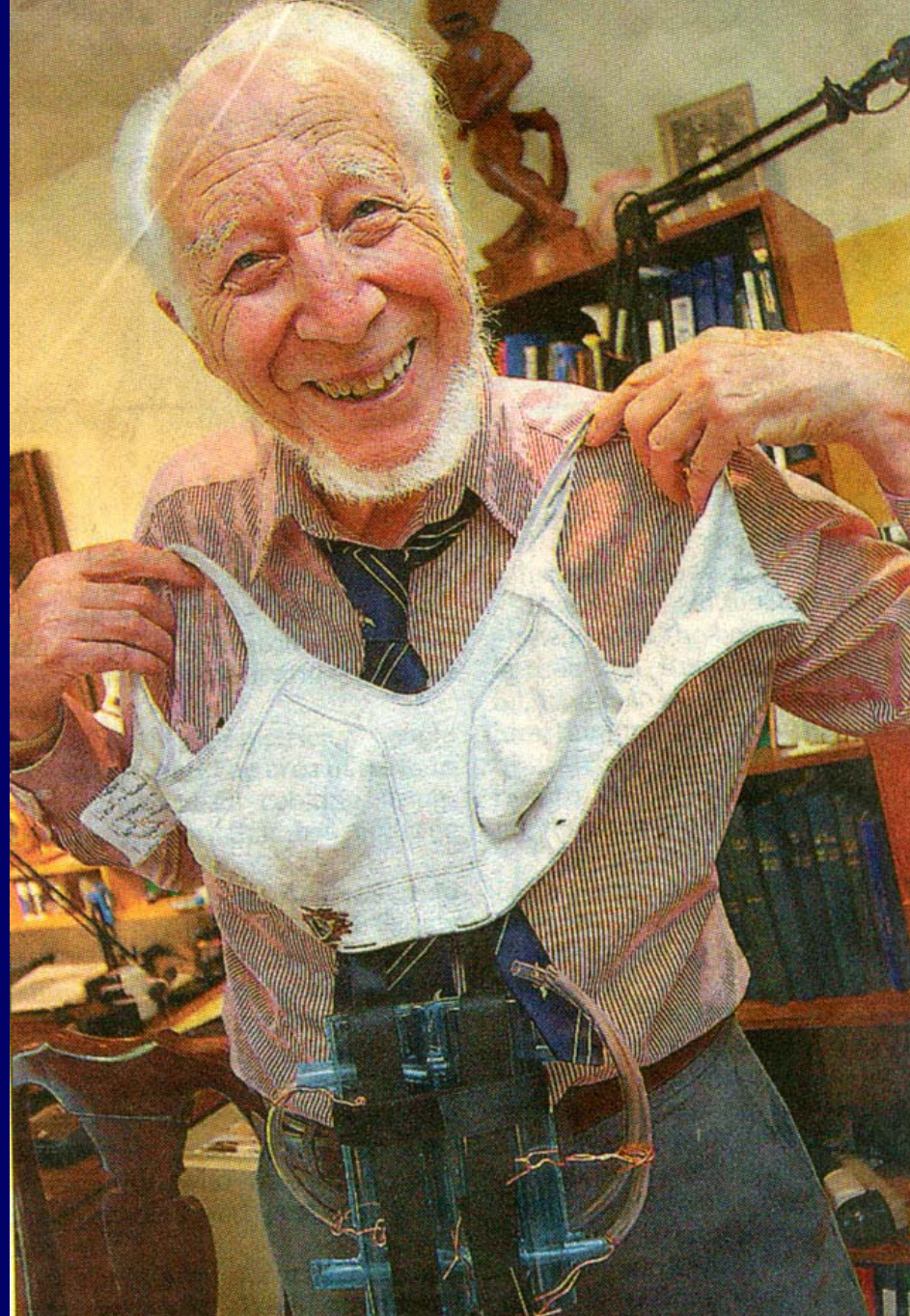
Physicist

Electrical

Legal

Lab Technician

Materials
Science



At 91, he's still working on ways to save lives

Dr. Willem Kolff has helped save millions of lives with his invention of the kidney-dialysis machine more than 60 years ago.

But at 91, the recent winner of a prestigious Lasker Award for medical research, is pushing his most recent invention. This time it's a portable artificial lung.

*Bill Bergstrom in
The Seattle Times, Nov. 3, 2002*

Seattle, Washington is
one of the most beautiful and colorful
cities in America. Come and see for yourself!



Seattle is **green** for trees (and for **\$** from Boeing and Microsoft), **brown** for Starbucks coffee, **blue** for water (rivers, lakes, ocean.....and **rain**, very well **red** (for all the books we read) and **purple** and **gold** for the University of Washington!!


```

graph TD
    CP[COMMERCIAL POLYMERS] --> MGP[MEDICAL-GRADE POLYMERS]
    MGP --> NPC[NEW POLYMER COMPOSITIONS]
    MGP --> NPF[NEW PHYSICAL FORMS]
    SFT[SPECIAL FABRICATION TECHNIQUES] --> NPF
    CPT[COMMERCIAL PROCESS TECHNIQUES] --> SFT
    NPF --> PID[PASSIVE IMPLANTS AND DEVICES]
    NPF --> NSM[NOVEL SURFACE MODIFICATION AND CHARACTERIZATION TECHNIQUES]
    NSM --> NBM[NEW BIOMOLECULES AND RECOGNITION SEQUENCES]
    NPF --> NDF[NEW DESIGNS AND FABRICATION TECHNIQUES]
    NDF --> MAS[MACROMOLECULAR SELF-ASSEMBLIES]
    NBM --> MC[MAMMALIAN CELLS]
    MAS --> MC
    MC --> NBBI[NEW BIOCOMPATIBLE AND BIOFUNCTIONAL IMPLANTS AND DEVICES]
    NBBI --> IHFI[IMPROVED HEALING AND FUNCTIONING OF IMPLANTS]
    NBBI --> TSD[TARGETED AND STIMULI-RESPONSIVE DRUG DELIVERY SYSTEMS]
    NBBI --> NBS[NEW BIOSENSORS, DIAGNOSTIC ASSAYS, BIOSEPARATIONS, AND BIOPROCESSES]
    NBBI --> OI[ORGANOID IMPLANTS, DRUG DELIVERY SYSTEMS AND ARTIFICIAL ORGANS]
    IHFI --> RTO[REGENERATION OF TISSUES AND ORGANS USING BIODEGRADABLE AND BIOFUNCTIONAL SCAFFOLDS]
    TSD --> RTO
    NBS --> RTO
    OI --> RTO
  
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