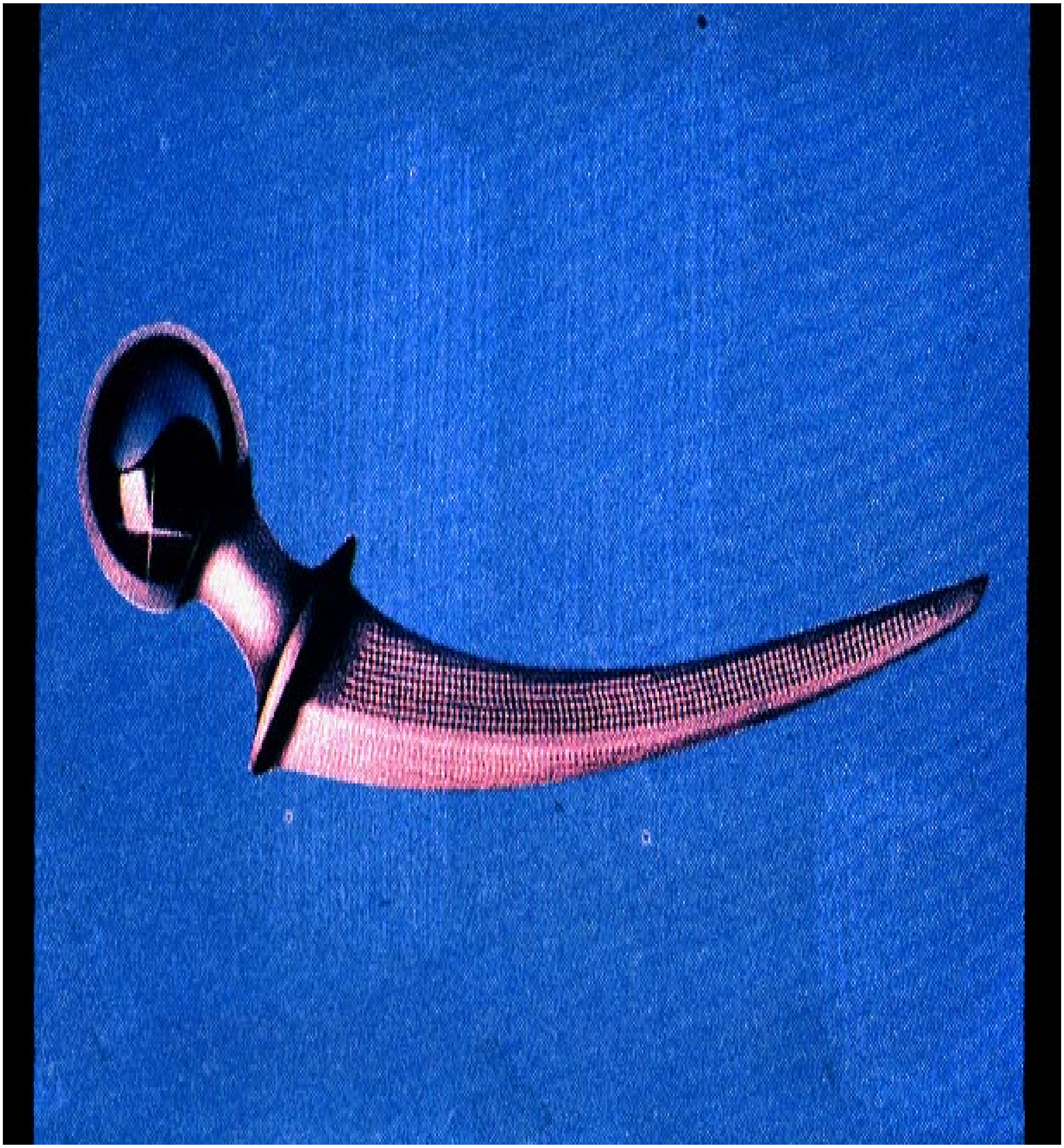
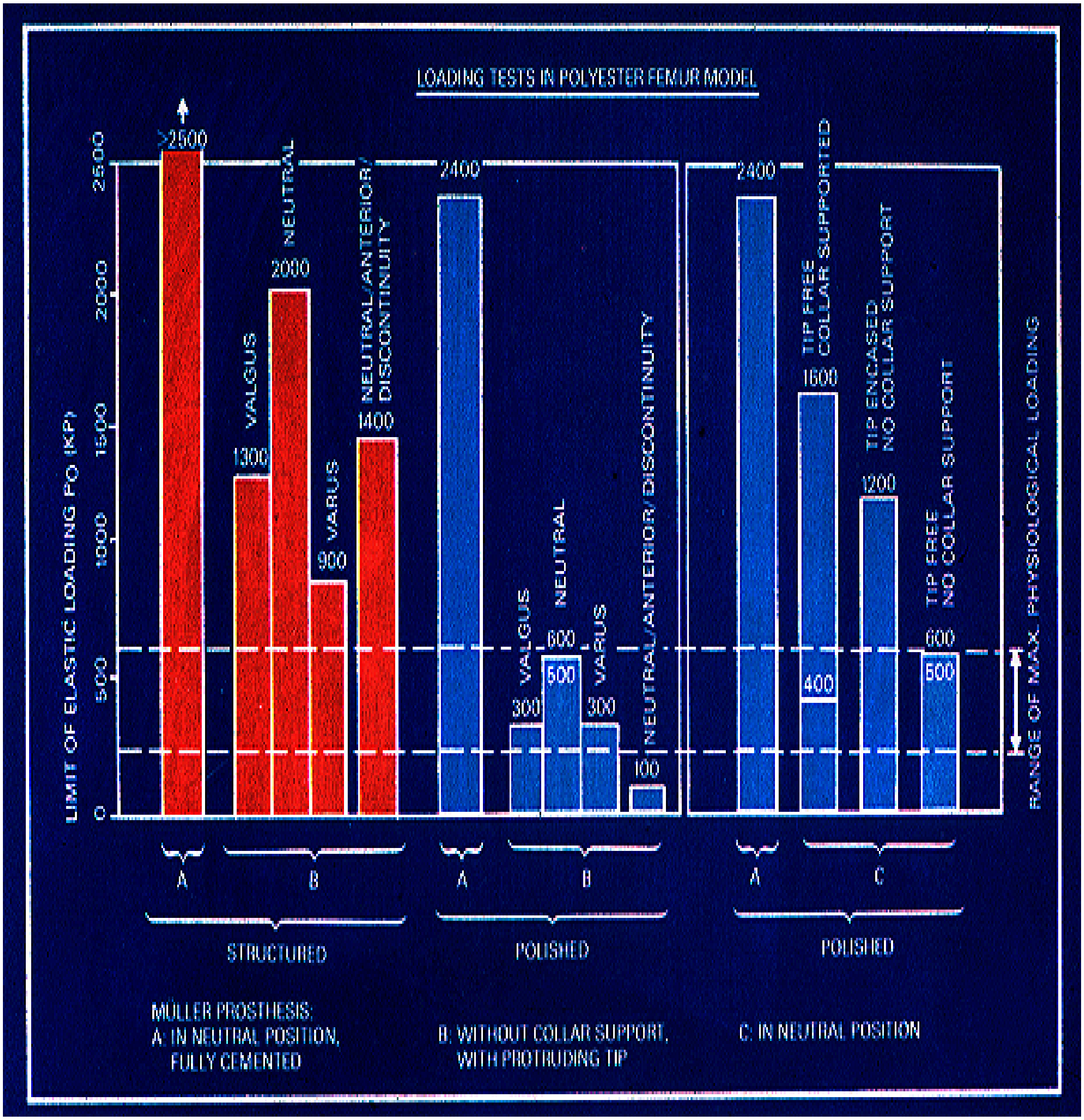



LOADING TESTS IN POLYESTER FEMUR MODEL
LIMIT OF ELASTIC LOADING PO (KP)
0
500
1000
1500
2000
2500
>2500
VALGUS
1300
NEUTRAL
2000
VARUS
900
NEUTRAL/ANTERIOR/ DISCONTINUITY
1400
2400
VALGUS
300
NEUTRAL
600
500
VARUS
300
NEUTRAL/ANTERIOR/ DISCONTINUITY
100
2400
TIP FREE COLLAR SUPPORTED
1600
400
TIP ENCASED NO COLLAR SUPPORT
1200
TIP FREE NO COLLAR SUPPORT
600
500
RANGE OF MAX. PHYSIOLOGICAL LOADING
A
B
A
B
A
C
STRUCTURED
POLISHED
POLISHED
MÜLLER PROSTHESIS:
A: IN NEUTRAL POSITION, FULLY CEMENTED
B: WITHOUT COLLAR SUPPORT, WITH PROTRUDING TIP
C: IN NEUTRAL POSITION

BIOMATERIALS

PRESENT AND FUTURE DEVICES

THE GOAL:

IMPROVED PROPERTIES:

INITIALLY AND

AFTER USE

Materials and Design are immutably linked:

Design expresses the properties of

Materials, New Materials thus

call forth New Designs

PROPERTIES OF CURRENTLY USED ALLOYS

CHEMICAL PROPERTIES

MAJOR ELEMENT COMPOSITION (%)

Alloy	Ref.	Major element composition (%)
LOW CARBON STAINLESS STEEL 316L	(1)	IRON · Cr 17-20 · Ni 10-14 · *
CAST Co-Cr ALLOY & H.I.P. ALLOY	(2)	COBALT · Cr 27-30 · Mo 6 · Ni 2.5 · *
WROUGHT Co-Cr ALLOY	(3)	COBALT · Cr 19-21 · Tu 14-16 · Ni 9-11 · *
FORGED Co-Cr ALLOY		COBALT · Cr 26-28 · Mo 5-7 · *
TITANIUM UNALLOYED	(4)	TITANIUM · *
TITANIUM 6 AL - 4V	(5)	TITANIUM · Al 5.5-6.5 · Va 3.5-4.5 · *
MP - 35N (MULTIPHASE)		COBALT · Cr 19-21 · Mo 9-10.5 · Ni 33-37 · *

1. ASTM [illegible] Specification – F 138-[illegible] & F 139-[illegible]
2. ASTM [illegible] Specification – F [illegible]
3. ASTM [illegible] Specification – F [illegible]
4. ASTM [illegible] Specification – F [illegible]
5. ASTM [illegible] Specification – F 136-[illegible]

* All other material less than 1%

** AMERICAN SOCIETY FOR TESTING AND MATERIALS

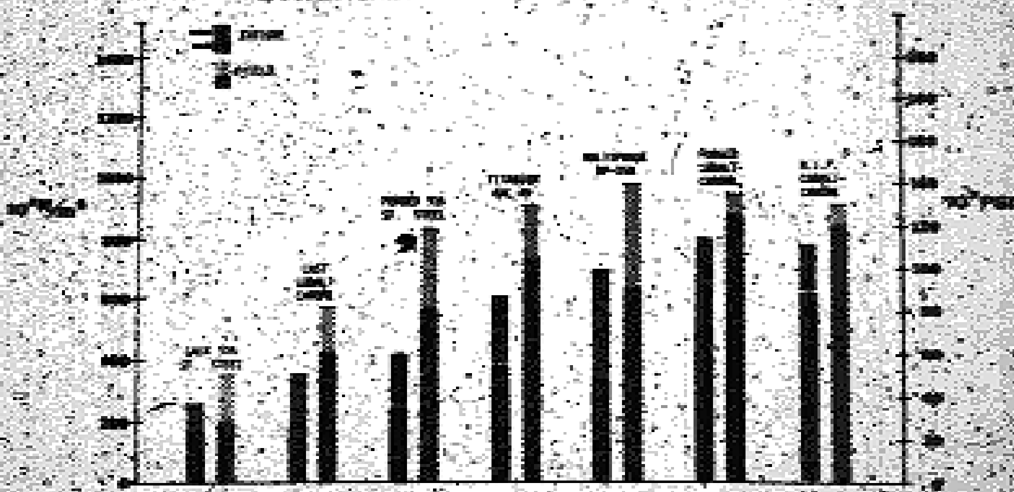
ALLOYS	ADVANTAGES	USES
IRON-BASE	GOOD FATIGUE STRENGTH INEXPENSIVE GOOD MACHINABILITY	PINS, PLATES, NAILS SOME PROSTHESES
COBALT-BASE	HIGH CORROSION RESISTANCE BIOCOMPATIBILITY EXCELLENT MECHANICAL PROPERTIES WITH NEW PRODUCTION TECHNIQUES	MOST PROSTHESES MANY DIFFERENT IMPLANTS
TITANIUM-BASE	VERY HIGH CORROSION RESISTANCE LIGHT IN WEIGHT (40% LOWER DENSITY) HIGH ELASTICITY (YOUNG'S MODULUS 1/2 OF STEEL)	PROSTHESES, PLATES SOME I.M. RODS

PROPERTIES OF CURRENTLY USED ALLOYS

MECHANICAL/PHYSICAL PROPERTIES

This graph is a composite of values received from manufacturers. Only the yield strengths of 316 Cast Stainless Steel,, 316 Forged Stainless Steel, Cast Cobalt Chrome and Titanium 6Al-4V reflect ASTM minimum specifications.

STRENGTHS OF IMPLANT ALLOYS



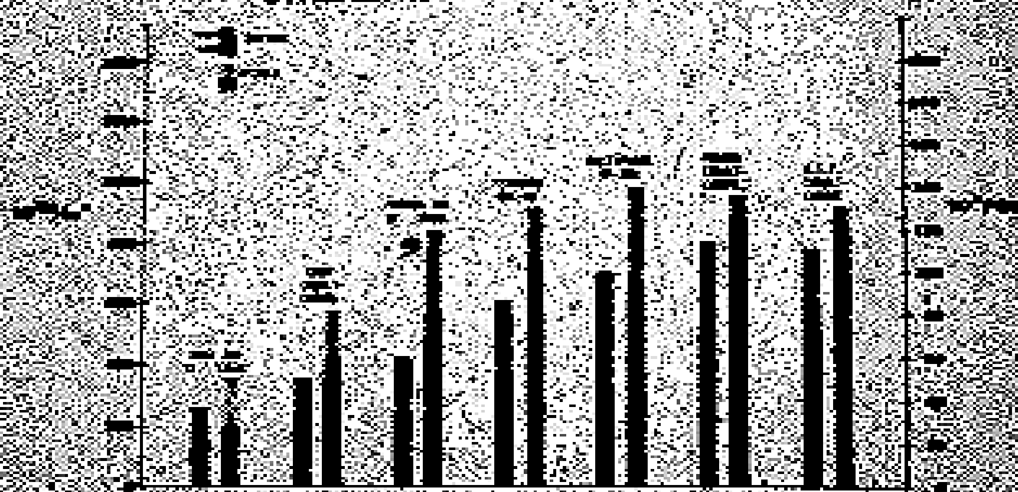
The "super alloys" (Multiphase MP-35N, Forged Cobalt Chrome, and H.I.P. Cobalt Chrome) show superior strengths. Universal testing standards have not as yet been established for fatigue strength, most important for prosthetic implants.

CURRENTLY USED ALLOYS

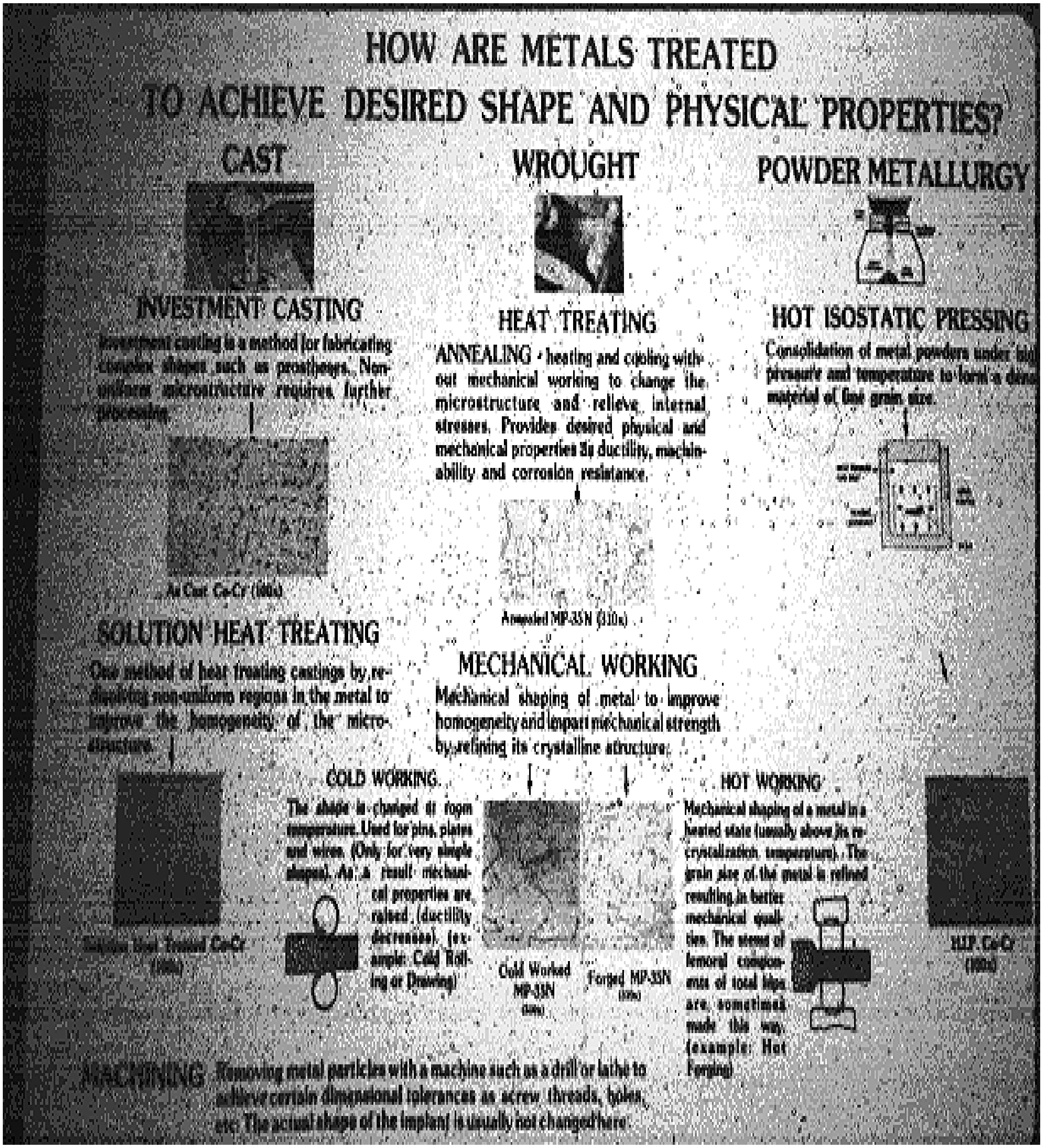
MECHANICAL/PHYSICAL PROPERTIES

This graph is a composite of values received from manufacturers. Only the yield strengths of 316 Cast Stainless Steel, 316 Forged Stainless Steel, Cast Cobalt Chrome and Titanium 6Al-4V reflect ASTM minimum specifications.

STRENGTHS OF IMPLANT ALLOYS



The "super alloys" (Multiphase MP 35N, Forged Cobalt Chrome, and HIP Cobalt Chrome) show superior strengths. Universal testing standards have not as yet been established for fatigue [illegible] [illegible] dependent [illegible] procedures [illegible] testing.


HOW ARE METALS TREATED
TO ACHIEVE DESIRED SHAPE AND PHYSICAL PROPERTIES?
CAST
WROUGHT
POWDER METALLURGY
INVESTMENT CASTING
Investment casting is a method for fabricating complex shapes such as prostheses. Non-uniform microstructure requires further processing.
As Cast Co-Cr
HEAT TREATING
ANNEALING - heating and cooling without mechanical working to change the microstructure and relieve internal stresses. Provides desired physical and mechanical properties as ductility, machinability and corrosion resistance.
Annealed MP-35N
HOT ISOSTATIC PRESSING
Consolidation of metal powders under
pressure and temperature to form a
material of fine grain size.
SOLUTION HEAT TREATING
One method of heat treating castings by re-dissolving non-uniform regions in the metal to improve the homogeneity of the microstructure.
MECHANICAL WORKING
Mechanical shaping of metal to improve homogeneity and impart mechanical strength by refining its crystalline structure.
COLD WORKING
The shape is changed at room temperature. Used for pins, plates and wires. (Only for very simple shapes). As a result mechanical properties are raised. (ductility decreases). (example: Cold Rolling or Drawing)
Cold Worked MP-35N
Forged MP-35N
HOT WORKING
Mechanical shaping of a metal in a heated state (usually above its recrystalization temperature). The grain size of the metal is refined resulting in better mechanical qualities. The stems of femoral components of total hips are sometimes made this way. (example: Hot Forging)
H.I.P. Co-Cr
MACHINING
Removing metal particles with a machine such as a drill or lathe to achieve certain dimensional tolerances as screw threads, holes, etc. The actual shape of the implant is usually not changed here.

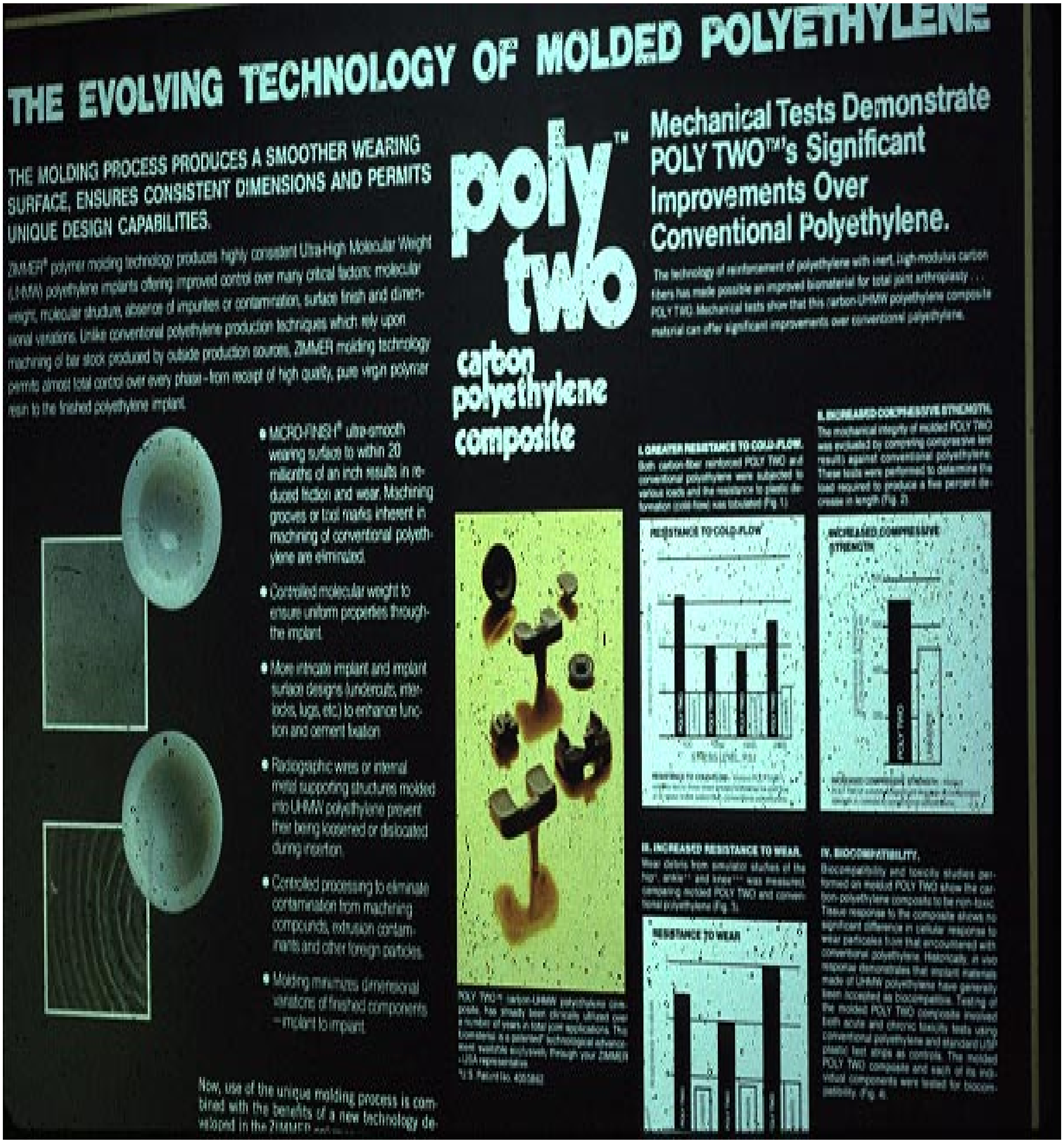
SUMMARY

1. There is no ideal metal for all implants.
2. The physical, mechanical and biochemical properties of each metal determine its selection for a specific implant.
3. Fatigue strength is a most important mechanical quality for implants such as prostheses subjected to stresses for unlimited time.
4. Elasticity and ductility can be important in some fracture fixation devices.
5. All metals must be biocompatible and corrosion resistant.
6. Stronger metals and improved designs have provided better implants in recent years, but success depends on high manufacturing standards, proper patient selection, application and surgical technique.

SELECTED PROPERTIES OF NOMINAL NITINOL 55

TREATMENT	TENSILE STRENGTH, PSI	YIELD STRENGTH, PSI	ELONGATION %	ELASTIC MODULUS, PSI
ANNEALED SPECIMEN AT ROOM TEMP. (BELOW TRANS TEMP.)	125,000	15,000 to* 20,000	60	10.2×10^6*
COLD WORKED SPECIMEN AT ROOM TEMP.	200,000	50,000	12	---

* STRONGLY DEPENDENT ON TEMPERATURE AND A_s TEMPERATURE OF TRANSITION


THE EVOLVING TECHNOLOGY OF MOLDED POLYETHYLENE
THE MOLDING PROCESS PRODUCES A SMOOTHER WEARING SURFACE, ENSURES CONSISTENT DIMENSIONS AND PERMITS UNIQUE DESIGN CAPABILITIES.
ZIMMER® polymer molding technology produces highly consistent Ultra-High Molecular Weight (UHMW) polyethylene implants offering improved control over many critical factors: molecular weight, molecular structure, absence of impurities or contamination, surface finish and dimensional variations. Unlike conventional polyethylene production techniques which rely upon machining of bar stock produced by outside production sources, ZIMMER molding technology permits almost total control over every phase – from receipt of high quality, pure virgin polymer resin to the finished polyethylene implant.
• MICRO-FINISH® ultra-smooth wearing surface to within 20 millionths of an inch results in reduced friction and wear. Machining grooves or tool marks inherent in machining of conventional polyethylene are eliminated.
• Controlled molecular weight to ensure uniform properties through the implant.
• More intricate implant and implant surface designs (undercuts, interlocks, lugs, etc) to enhance function and cement fixation.
• Radiographic wires or internal metal supporting structures molded into UHMW polyethylene prevent their being loosened or dislocated during insertion.
• Controlled processing to eliminate contamination from machining compounds, extrusion contaminants and other foreign particles.
• Molding minimizes dimensional variations of finished components – implant to implant.
Now, use of the unique molding process is combined with the benefits of a new technology de-
poly two™
carbon polyethylene composite
Mechanical Tests Demonstrate POLY TWO™'s Significant Improvements Over Conventional Polyethylene.
The technology of reinforcement of polyethylene with inert, high-modulus carbon fibers has made possible an improved biomaterial for total joint arthroplasty . . . POLY TWO. Mechanical tests show that this carbon-UHMW polyethylene composite material can offer significant improvements over conventional polyethylene.
I. GREATER RESISTANCE TO COLD-FLOW.
RESISTANCE TO COLD-FLOW
II. INCREASED COMPRESSIVE STRENGTH.
INCREASED COMPRESSIVE STRENGTH
III. INCREASED RESISTANCE TO WEAR.
RESISTANCE TO WEAR
IV. BIOCOMPATIBILITY.

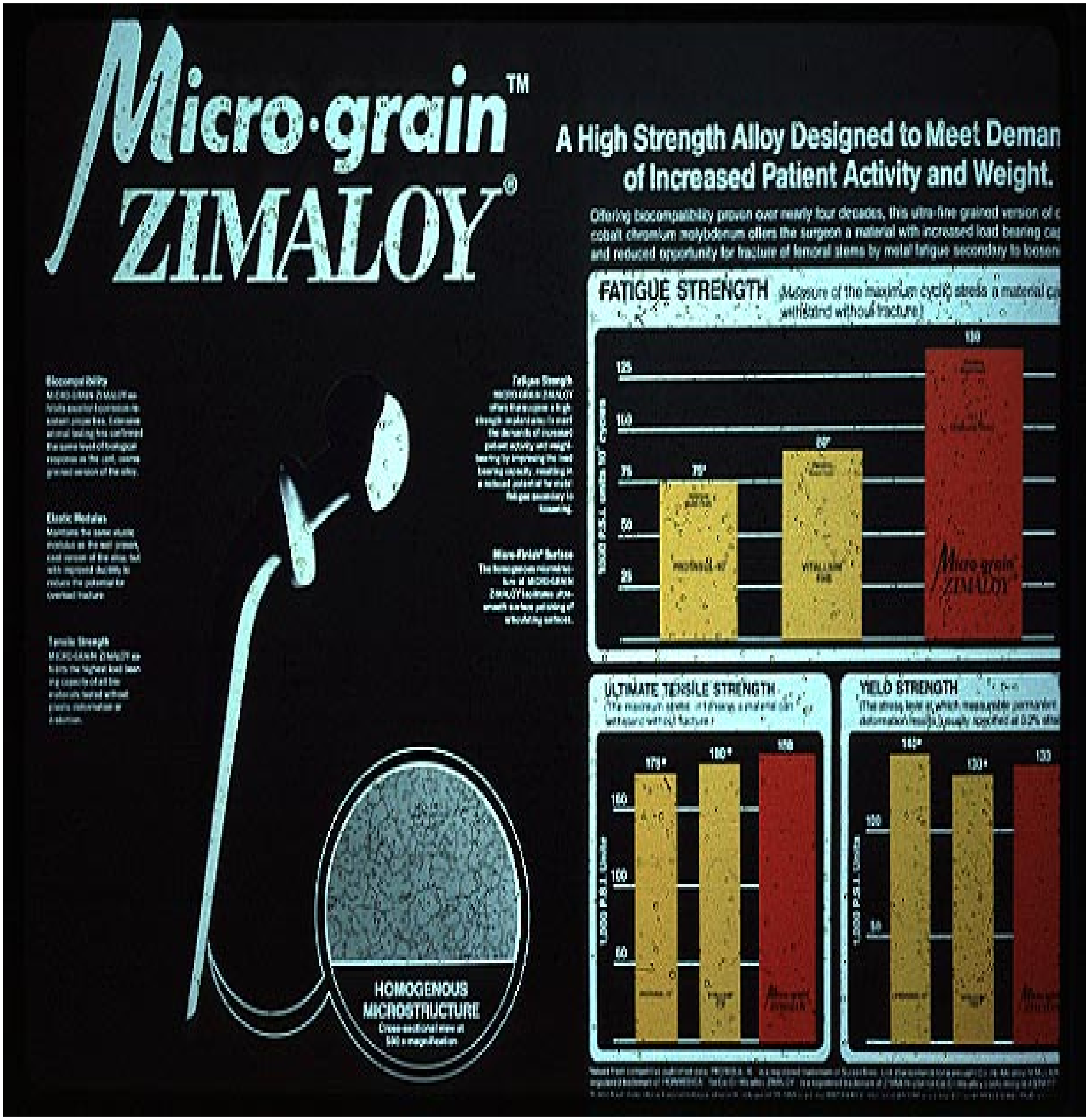

Micro·grain™
ZIMALOY®
A High Strength Alloy Designed to Meet Deman
of Increased Patient Activity and Weight.
Offering biocompatibility proven over nearly four decades, this ultra-fine grained version of c
cobalt chromium molybdenum offers the surgeon a material with increased load bearing cap
and reduced opportunity for fracture of femoral stems by metal fatigue secondary to loosen
FATIGUE STRENGTH
ULTIMATE TENSILE STRENGTH
YIELD STRENGTH
HOMOGENOUS MICROSTRUCTURE

TABLE I

Representative Properties of Candidate Biocarbons

	Tensile Strength (psi)	Modulus of Elasticity (psi x 10^6)	Strain to Fracture (percent)
ATJS	5,000	1.0	0.5
Glassy Carbon	17,000	4.0	0.4
Isotropic Carbon	30,000[a]	3.4	0.9
Pyrostrand	4,000-33,000	1.4/2.0	1.0/1.8
PG/SiC	12,000-28,000	3.6/5.7	0.3/0.6

[a] Estimated from flexure data.