

NASA Contractor Report 165868

NASA-CR-165868
19820014469

Study on Application of Aerospace
Technology to Improve Surgical Implants

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Contract NAS1-16567
March 1982

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NF01343

Errata
11-19-82

ERRATA

NASA Contractor Report 165868

STUDY ON APPLICATION OF AEROSPACE
TECHNOLOGY TO IMPROVE SURGICAL IMPLANTS

Robert E. Johnson and James L. Youngblood
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Page 40, table 5: The composition listed for ASTM F 562-78 is in error. The molybdenum content of 9-10.5% is incorrectly shown in the column for tungsten.

Attached is a corrected page 40 to be inserted in the report.

Issued 11-10-82

Final Report

STUDY ON APPLICATION OF
AEROSPACE TECHNOLOGY TO
IMPROVE SURGICAL IMPLANTS

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Contract NAS1-16567

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NAS 1-22343 #

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SUMMARY

This four-month study was sponsored by the NASA-Langley Research Center Office of Technology Utilization and Applications Programs to examine areas where aerospace technology could be of possible benefit to the orthopedic implant industry. Specifically, the study examined structural and materials approaches used by aerospace for high reliability components for possible applications in metallic implants.

The study involved gathering data from the literature, from a limited number of visits to manufacturers of implants, and from numerous teleconferences and correspondence with the Food and Drug Administration (FDA), universities, manufacturers, physicians, and material suppliers.

The findings of the study are:

- o No published, implant industry-wide design criteria such as minimum static factor-of-safety, scatter factors for use in fatigue analyses, and methods for determining expected life in use were available. Examples are provided in the report from NASA, Air Force, and FAA giving approaches to these analyses, criteria, and documentation.

- o The limited number of alloys used in implants have been tested in various programs for mechanical performance. However, there appears to be a need for MIL-HDBK-5-type design allowables to establish uniform values to be used in design. Examples of statistical data requirements and MIL-HDBK-5 data

presentation are provided in the report. The use of pre-cracked specimens to evaluate structural degradation of alloys in contact with fluids by the NASA manned space program is described and suggested as a way of evaluating body fluids and alloy structural compatibility.

- o Use of finite element stress analysis and fracture mechanics analyses in the implant design cycle will require additional loads and materials data but offer substantial potential in understanding of the implant performance and offer analytical tools that could shorten evaluation and verification times for new designs and materials. References are provided for the readers.

- o Examples of quantifying the results of nondestructive inspection from penetrant, radiography, and ultrasonic methods are provided from NASA programs. If Nondestructive Testing (NDT) is to be utilized as a basis for initial flaw size in fracture mechanics, the implant industry should develop similar data.

INTRODUCTION

The aerospace industry has been forced to face the problem of single-point failures in structures from the time of the Wright brothers to the current Space Shuttle program. Regardless of the level of redundancy allowed in some configurations, eventually, one finds a "critical" structural element. Perhaps it's a pressure vessel, a pressurized crew compartment wall, a landing gear trunnion or a separation bolt; the function, size, shape, and material can vary significantly but the criticality brings the bright light of scrutiny to every aspect of design, development, fabrication, qualification, and individual part acceptance procedures of these critical parts. Every reasonable effort is made to insure that these parts have the highest reliability--a safe life structure.

The progression from early aircraft to current supersonic aircraft and manned spacecraft has made the problem more severe and more visible. The need to achieve the most efficient structure consistent with high reliability has led NASA to general technologies and methodologies that could be used in any industry with similar problems. One such industry where NASA hopes these approaches can be used is biomedical engineering; this report examines the requirements of one very specific area in this broad field--metallic orthopedic implants.

Intuitively, and confirmed by discussions with implant fabricators, the most important requirement placed on the implant design is that of performance. Certainly, satisfying the need, whether for a fixation device to hold bone fragments together until natural fusion occurs or for an artificial joint to replace a section of bone as a "permanent" implant, is the most important aspect of the design. As part of the required performance, the engineer must determine the ability of the design to satisfy function and, hopefully, assure that the expected safe life of the device is sufficiently long for the body to heal itself (in the case of the internal fixative device) or for a long period of time before replacement is necessary (as with the prosthesis devices).

Another point to consider is that the metal implant is only one component of a biomechanical "system" consisting of bone, cement, screws, and the metal implant in configurations and conditions that vary with the operating procedure and the individual patient. This study examines the metal implant only, as a way of studying one of the elements of the "system;" certainly, each element must be examined leading eventually to a complete understanding of the system.

The overall service record of metallic orthopedic implants is excellent; structural failures are reported to constitute less than 1% of the causes for removal of devices from patients whereas most requiring removal are because of corrosion, pain

or other forms of bioincompatibility (Ref.1-5). In a similar manner, the history of structural failures in manned spacecraft during flight is "acceptable" statistically, but the failure of any primary structural element that resulted in the loss of the astronaut would certainly be an international catastrophe. The patient who must endure the pain and trauma of removal of any premature structural failure of a metallic implant must certainly feel that the problem is a personal version of a catastrophe.

It is NASA's desire, indeed a part of its organization charter, to insure maximum dissemination of the knowledge gained in developing space activities for the general betterment of mankind. Therefore, the principal objectives of this study are to examine similarities in materials and structural requirements of high reliability aerospace components with the structural and material requirements for metallic orthopedic implants and to outline available aerospace approaches to the potential solutions of these problems. The sincere hope of the authors and the sponsor is that some of these approaches might be useful to the doctors, manufacturers, and researchers working in this very important technology. Measurement values in the report are generally expressed in the units used in the references from which the material was taken. No attempts were made to convert these data from conventional to SI units or vice versa.

DISCUSSION

General:

There are many ways to classify metallic internal orthopedic implants and to discuss requirements for these devices. One way is to divide the devices into internal fixative devices and internal prostheses. Some examples of the devices by these categories are:

Internal Fixative Devices

- o Nails, pins, wires
- o Plates, bars
- o Screws, staples

(Used to hold elements together until healing occurs)

Prostheses

- o Artificial hip, knee, elbow, shoulder prostheses
- o Mandibular prostheses
- o Proximal or distal ulna prostheses
- o Tibia prostheses

(Used to replace parted or degraded body elements)

A tabulation of many of the metallic implants and a description of their individual function is found in Table 1.

As a measure of the importance of this field, it is estimated that some 2 million to 3 million artificial or prosthetic parts are implanted into individuals in the United States each year (Ref. 6); the number worldwide is unknown, but obviously represents a very large field of activity.

TABLE 1

A CLASSIFICATION OF METALS TO IMPLANTLOCATIONS AND FUNCTIONS

<u>LOCATION NAME</u>	<u>IMPLANT NAME</u>	<u>IMPLANT FUNCTION</u>	<u>TYPE METAL</u>
Skull	Skull Plates, Screws, Wire Mesh	Cranioplasty	Co-Cr-Mo Titanium, Tantalum Type 316 SS
Arteries	Clips	Treatment of Aneurysm	Gold, Silver
Mandible	Mandibular Prosthesis, Bone Plate and Wire Mesh	Reconstruc- tive Appliances for the Jaw	Co-Cr-Mo
Vertebra	Harrington Rods	Treatment of Scoliosis	Type 316 SS
	Spinal Plates and Wires	Spinal Fusion	Type 316 SS
Clavicle	Clavicular Nails, Screws and pins	Fixation of clavicle dislocation or fracture	Type 316 SS
Scapula	Carpal Sca- phoid Screws	Reduction of fractures of the carpal scaphoid bone	Type 316 SS
Chest	Pacemaker	Heart-assist devices	Titanium, Plat- inum-Iridium, Nickel Alloys, Elgiloy
Shoulder	Shoulder Prosthesis	Proximal Humeral Re- placement	Co-Cr-Mo
	Jewett Nail and Plate Staples	Fixation of Proximal End of Humerus	Type 316 SS and Co-Cr-Mo

(Table 1, Cont'd)

<u>LOCATION NAME</u>	<u>IMPLANT NAME</u>	<u>IMPLANT FUNCTION</u>	<u>TYPE METAL</u>
Humerus	Stevens-Street Elbow Pros- thesis	Reconstruction Device for the Elbow	Ti-6Al-4V
	Mechanical Elbow joint	Replacement Prosthesis	Co-Cr-Mo
	Kuntscher Humerus Nail	Humeral Fracture Fix- ation	Type 316 SS
Ulna	Proximal or Distal Ulna Prosthesis	Replacement of Proximal and Distal Ends of Ulna	Co-Cr-Mo
	Kuntscher V- type, Vesely- Street Split type, and Schneider Self- Broaching Intramedullary Nails	Fracture Fix- ation of Ulna	Type 316 SS
Radius	Radius Cap or Head Pros- thesis	Help Restore Function of Elbow joint	Co-Cr-Mo
	Y Plates and Kuntscher V- type Radius Nail	Radius Frac- ture Fixation	Type 316 SS
Hand and Fingers	Flatt Finger and Thumb Prosthesis	Restoration of Finger Joint Function	Co-Cr-Mo
	Finger Bone Plates and Screws	Fixation of Small Bone Fractures	Type 316 SS
Hip	Hip Pros- thesis Several Types	Replacement of Femoral Head	Co-Cr-Mo Titanium
	Hip Nails, Pins, Plates, Staples, and Screws	Hip Fracture Fixation	Type 316 SS

(Table 1, Concluded)

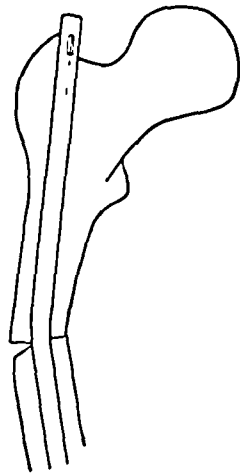
<u>LOCATION NAME</u>	<u>IMPLANT NAME</u>	<u>IMPLANT FUNCTION</u>	<u>TYPE METAL</u>
Femur	Femoral Blade Plates and Screw Combina- tions Bone Plate and Screw or Wire Devices Intramedullary Nail-Several Types	Fixation of Single and Multiple Fractures of the Femur	Type 316 SS
Knee	Knee Prosthesis- Several Types	Replacement of Diseased (e.g., arthritic) Knees	Co-Cr-Mo
Tibia	Tibia Pros- thesis-Several Types	Replacement of Tibia Shelf	Co-Cr-Mo
	Townley Tibia Plateau Plate and Screws	Replacement arthroplasty of the Tibia Shelf	Type 316 SS
	Tibia Bolt and Tibia (Intramedul- lary) Nail	Fracture Fixation of the Tibia Shaft	Type 316 SS
Fibula	Kuntscher Olecranur Fibula Flap Nail	Fracture Fixation of the Fibula	Type 316 SS
Tarsal and Metatar- sal	Small Bone Plates and Screws	Fracture Fixation of Small Bones	Type 316 SS

(REF. 27.)

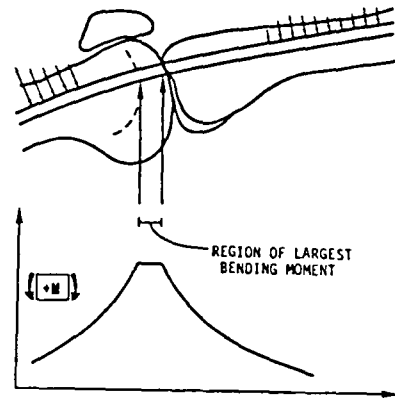
The major requirements for internal fixation devices such as pins, nails, and wires are biocompatibility, corrosion resistance, and mechanical strength. Certainly, an intramedullary nail to treat a fractured femur as illustrated in Figure 1-a is subject to bending loads of a cyclic nature and a Hansen-Street nail to fuse a knee joint is subject to bending loads as illustrated in Figure 1-b. Other devices such as wires, screws, and plates are subject to combined loads of varying magnitudes and for different periods of time and numbers of cycles. As will be seen later in the report, prostheses such as the total hip or total shoulder, elbow, or knee prostheses are also subject to loads that vary widely from design-to-design and are subject to load spectra that differ with patients and individual load conditions with each patient associated with different activities.

Reports citing causes of structural failures in orthopedic implants are numerous, but in an effort to examine the areas needing specific attention, summaries such as the ones cited in Table 2 are very helpful in defining locations of failures in the various designs and identifying the predominant failure modes. Continued evaluation and analysis of this type is certainly a worthwhile activity.

All materials used in both categories of internal implants must meet stringent requirements of compatibility with the host tissue and conversely, the body environment can also



(A) Intramedullary Nail



(B) Hansen-Street Nail

FIGURE 1

EXAMPLES OF BENDING LOADS OF A CYCLIC
NATURE IMPOSED ON METALLIC IMPLANTS
(REF. 7)

Location of Implant Fracture and Identification of Fracture Mode for Hip Prosthesis

Implant Fracture Location Location (Approx.) of Fracture Zone from Distal Stem Tip	Per cent
1 in. (2.5 cm)	4
2 in. (5.0 cm)	66
2½ in (6.4 cm)	8
3 in (7.6 cm)	6
3½ in (8.9 cm)	16 ^a
Fracture Mode ^b	
Mechanical fatigue	87
Corrosion fatigue	13 ^c

^aFracture associated with weld repair or serious casting defects

^bFracture origin predominately at the lateral surface and with a bending-torsional vector.

^cLimited to stainless steel

Location of Implant Fracture and Identification of Fracture Mode for Intramedullary Nails

Implant Fracture Location (Approx zone)	Per cent
1/3 length from proximal tip	75
1/2 length from proximal tip	17
At threads or broach area	8
Fracture Mode ^a	
Mechanical fatigue	45
Fatigue corrosion ^b	55

^aApproximately 17% of fractured nails possessed detectable bending prior to fracture

^bLimited to stainless steel.

Location of Implant Fracture and Identification of Fracture Mode for Bone Plate

Implant Fracture Location	Per cent
1st screw hole or slot from center of plate	95
2nd screw hole or slot from center of plate	5
Fracture Mode	
Mechanical fatigue	40
Fatigue corrosion ^a	60

^aLimited to stainless steel

Location of Implant Fracture Mode Identification (By per cent approximation)

Location of Metal Fracture	Intertrochanteric Nail/plate Combination			
	Per cent			
	Nail	Junction	1st Screw Hole	2nd Screw Hole
One piece	20	25	45	10
Two piece	10	20	55	15
Sliding nail	25	5	60	10
Failure Mode ^a				
Mechanical fatigue ^b	56			
Fatigue corrosion	40			
Bending	4			

^aCrevice and/or fretting corrosion of bone screw holes detected in 75% of the implants examined.

^bThe cross section penetrated by the fatigue crack is larger in the fatigue corrosion mode than mechanical fatigue

TABLE 2

SUMMARY OF FAILURE DATA ON
110 FAILED METALLIC IMPLANTS
(REF. 8)

affect the physical and mechanical properties of the alloys. Therefore, a mutually compatible material and environment must be assured for a successful design.

In addition, loads (stresses) and load spectra can be severe and can vary widely from patient to patient. For example, loads on implant components can be several times the body weight and, as in the case of the hip prosthesis, 400,000 cycles per year can be expected for normal activity and much higher for some classes of patients.

Limited usable volume for the implant coupled with the natural need to reduce weight of the device has led to unusual shapes and configurations made of high strength alloys.

Therefore, the overall design requirements picture for metals can be summarized in the following needs:

- o Biocompatibility with body tissue and fluids
- o Corrosion resistance in body environments
- o Satisfactory life under cyclic loads
- o High strength, low density alloys.

As a comparison, modern aircraft and spacecraft designs must meet many of the same requirements. For example, the designs of manned spacecraft of the 1970's certainly required compatibility of design and materials in very hostile environments, including resistance to corrosion from extremely corrosive fluids and gases. Obviously, weight and volume had to be minimized which led to the uses of high strength alloys in highly efficient (low margin-of-safety) designs. The

advent of the Space Shuttle in the 1980's has added the requirement for repeated loads and missions requiring millions of cycles on components while maintaining the high reliability required for single-load path critical structure.

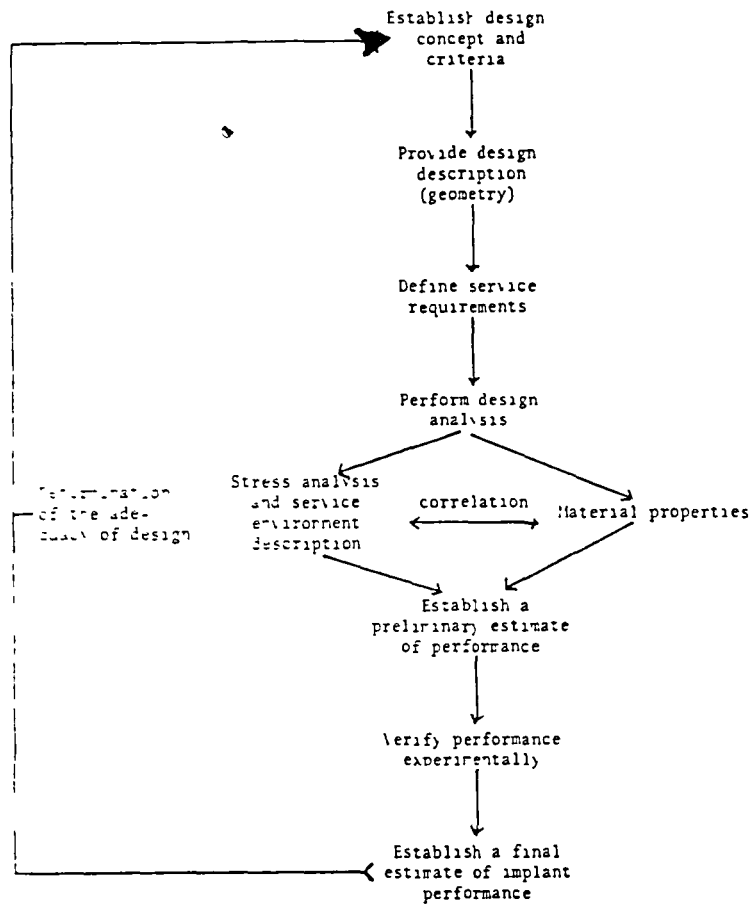
Therefore, an interesting and helpful comparison can be made of the approaches to these problems by both industries. The comparisons are organized under the following headings:

- o Design definition and design criteria
- o Material selection and data base for design
- o Analysis methods/certification
- o Acceptance testing and inspection.

Where information is available on orthopedic implants, a discussion is given and comparisons with aerospace approaches are provided; in several areas, the information on implants is not available so that only the aerospace approach is described for that particular area. It is hoped that the examples supplied from aerospace experience can be used by readers working in the field of metallic implants to their advantage.

A systematic approach to design qualification and performance verification is not new to the orthopedic implant industry. An example of a logic diagram that closely resembles those in use by the aerospace industry is found in the following figure.

STANDARD OPERATING PRACTICES FOR DESIGN QUALIFICATION
AND PERFORMANCE VERIFICATION



This chart was used by Mr. J. Howard Butler in a 1978 (Ref. 9) briefing to the Orthopedic Device Classification Panel of the Food and Drug Administration. The use, acceptance, or rejection of elements of the cycle by the industry are discussed in later sections of the report.

Design Definition and Design Criteria

Aerospace:

In a classical aerospace structural design problem, after the hardware function is well defined, the first piece of needed information is an evaluation of the loads and the load spectrum. Usually, some preliminary loads data are available from previous applicable experiences which can be combined with other inputs such as environments, functional limits, or special needs placed on the design. A good example of "other limitations" might be the volume available for the hardware or details on interfacing hardware that must work in combination with the design in question. From the loads input, the designer can make a rough evaluation of the critical load path and the sense of the load; i.e., is the part critical in tension?, compression?, stiffness critical? Does the interfacing hardware pose special needs for joining or deflection load path compatibility? Is the load predominantly static or is it highly cyclic in nature?

Next, the designer must consider any applicable mandatory design criteria which must be met in order to comply with the customers' requirements. Examples in industry might be the American Society of Mechanical Engineers Unfired Pressure Vessel Code or in aerospace, might be the FAA Airworthiness Standards (Ref. 10), or MIL-A-8868 "Airplane Strength and Rigidity-Reliability Requirements, Repeated Loads and

Fatigue" (Ref. 11). NASA has issued a series of Special Publications providing design criteria for various elements of spacecraft design; perhaps the most applicable being SP-8057 "Structural Design Criteria Applicable to a Space Shuttle" (Ref. 12). The significant sections of this document are discussed in the report.

The designer then considers all of the inputs and limits to develop a design that:

- (a) Meets the functional needs
- (b) Meets the contractual or mandatory design criteria
- (c) Can be analyzed by stress analysis methods for detailed sizing, life calculations, factors of safety, etc., to prove conformance to requirements.

Together with the stress analyst, the designer determines critical load conditions that are resolved into stresses by considering areas, inertias, and by using appropriate stress formulas and the preliminary selection of a material with the requisite mechanical properties. Most often, iterations back through the cycle are needed as more load definition is made available from tests or analysis and new requirements are developed.

In the case of aerospace hardware, many examples of design criteria are found in both guideline form and mandatory design performance specifications. For example, in NASA SP-8057 (Ref. 12) the following are found:

" 4.8 SERVICE LIFE

4.8.1 SAFE-LIFE

Safe-life design concepts shall be applied to all structure vital to the integrity of the vehicle or the safety of personnel. The safe-life shall be determined by analysis and test to be at least four times the specified service life.

The determination of structural safe-life shall take into consideration the effects of the following factors in combination with the expected operating environments:

- o Material properties and failure mechanisms
- o Load spectra
- o Cyclic-loads effects
- o Sustained-loads effects
- o Cumulative combined damage.

For structure requiring a safe-life design, such as metallic pressure vessels or landing gears, any flaws that cannot be detected in a regularly scheduled inspection should not grow enough before the next scheduled inspection to degrade the strength of the structure below that required to sustain loads at temperatures defined by the limit-load and critical-temperature envelopes. Analysis of flaw growth should account for materials properties, structural concepts, and operating stress levels throughout the structure, including adverse effects from variations in operational usage and environments. The inspection procedures should be considered adequate only when they can readily detect all flaws or defects greater than the allowable sizes."

In Section 7, "Proof of Design," section 7.1.2 states:

7.1.2 ANALYSIS

- " Reports shall be prepared on analyses performed to verify structural adequacy. The reports shall be divided logically by subject and shall include results of at least the following: (1) loads analyses;

(2) thermal analyses; (3) stress analyses; and (4) structural dynamic response and stability analyses. "

To guard against premature fracture of critical structural elements, Rockwell International, the company building the Orbiter flight vehicle for the Shuttle program has contractually imposed a fracture control plan (Ref. 13) that requires, by analysis and test, demonstration that "all primary structural components shall be designed to service a minimum of four service lifetimes". A detailed plan for the necessary analysis is included in this document.

All design drawings in the Space Shuttle Orbiter program are to be signed and approved by the design group, the stress group and a materials engineer at a minimum to insure that all significant technical disciplines are involved. The argument that this is costly and time-consuming is countered by numerous examples where hardware failures or field retrofitting cost many times more than the review cycle that would have brought the problem to light and likely avoided it.

The Department of Transportation, Federal Aviation Administration, has also published methods and design criteria for structures such as critical wing structure of small airplanes (Appendix B). In a similar manner to NASA's approach, the FAA has determined fatigue factors for safe-life structures that vary with the level of analysis, testing, or combinations. These factors and the discussion of the rationale that is used for the various factors are provided in Appendix

B. Other criteria for static loads and analysis requirements are available from the Federal Aviation Agency.

Orthopedic Implants:

In the case of metallic implants, the Federal Food, Drug and Cosmetic Act with amendments in 1976, covering medical devices such as implants, groups devices into three categories;

Class I. General controls which include regulations concerning good manufacturing practice and fraudulent mislabeling.

Class II. Performance standards which must be met to control device risks.

Class III. Premarket approval, for those devices for which performance standards cannot control device risks adequately.

The decision as to which class is appropriate is made by the Bureau of Medical Devices on the basis of recommendations from a classification panel, which reaches its decision on the basis of existing data and polling of expert opinion. To date, the Orthopedic Classification Panel has placed the vast majority of orthopedic implants into Class II, "performance standards."

A new design for a device or a change in materials technology or manufacturing methods could result in a Class III category by the FDA, which can require clinical evaluation by more than one physician-investigator using the implant at one or more institutions.

These FDA regulations deal more with development of in-vivo pre-commercialization use history and not with requirements for detailed design data and structural qualification tests and analysis. Indeed, there appears to be no published, uniform design criterion applicable to the metallic implants. While several articles in the literature cite general statements regarding implant loads as a function of body weight or physical function, only a few describe a "biomechanic" approach to defining loads and reactions and little or no information is available from the literature or from limited discussions with manufacturers regarding stress analyses, design life criteria, factors-of-safety, or other criteria for comparison with aerospace design approaches.

The development of such criteria to provide a minimum acceptable level of design capability is indeed a formidable task in that the loads are highly variable and the factor to be placed on a use load, for example, to arrive at a "limit" or "design ultimate" load could easily require a configuration that is incompatible with the useful volume for the implant. In addition, as in the case of the femoral stem of a hip prosthesis, the design objectives are not well defined. For example the following is cited:

"Stem design reduces to a problem of determining optimal geometry if the material properties are known. But what should the design objective be? At this point, the answer is not clear. If the goal is to reduce bending stresses in the stem, then

the approximate I-sections proposed recently by some are not optimum since the stresses can be further reduced by adding additional material to increase the section modulus. But this procedure will reduce the amount of cement in the cavity, and the question then becomes one of determining the effects of cement thickness on stresses in the cement. Further parametric studies are needed to document these effects and to identify appropriate design objectives which can, in turn, provide the basis for routine design procedures and standards." (Ref. 15 .)

Coupled with this basic uncertainty is the concern over legal aspects of "design standardization" and the implications that such regulations citing these standards bring. For example:

"Naturally, as I previously stated, as a result of all of the findings, certain standards and possible even laws or regulations will be enacted by independent bodies such as ASTM or through regulations enacted by Congress. One of the greatest dangers we have in this area and one that you should be aware of is the legal result of the imposition of standards which cannot be reasonably met or followed or are arbitrary to an industry as a whole and apply to devices for which the standards really do apply." (Ref. 16 .)

While these arguments and impediments call for caution and discretion, the first step toward development of usable and useful design criteria should likely begin with an assessment of the capability of existing, successful devices. It would seem prudent to determine and apply criteria derived

from successful designs to newer models or modifications, or for that matter, to similar devices. Indeed, such an approach might be useful in reducing the approval times for new designs from a mechanical standpoint. "Qualification by-similarity" is an accepted approach in aerospace if the hardware in question is (from an engineering standpoint) proved sufficiently similar to existing, flight-qualified components.

Perhaps as an oversimplification, one might consider that a particular design of a femoral component of a hip prosthesis is highly successful from a use standpoint while another design for the same application has suffered from limited life or other structural shortcomings. Stress analysis supplemented by tests may show some very significant differences in maximum stress level, fatigue stress ratio, material strength level, etc. Certainly, any criterion such as a factor of safety based on ultimate tensile strength or a minimum moment of inertia or other major differences in design characteristics should lead to a beginning of a design criterion useful to the field. A good example of this approach is alluded to in the following:

"Fatigue life, as a function of mean and alternating stress, can be represented using a Goodman diagram; and this procedure has been used to estimate factors of safety for various situations. For a Charnley stem in a neutral orientation in a 150 lb. patient, the factor of safety is estimated to be 1.85 for infinite life. For the Aufranc-Turner stem, where the peak tensile stresses are about 13 ksi, the factor of safety on the tensile side

is about 1.42. For a neutrally oriented Charnley stem in a 200 lb. patient, the factor of safety is 1.39, and for varus orientation in a 200 lb. patient, the factor of safety is about 1.1.

These rough estimates, based on beam-theory considerations and loading in the mediallylateral plane only, suggest that some existing hip implant systems may be operating at the limit of their strength. Furthermore, the effects of larger peak loads, due to greater activity in younger patients, and the effects of corrosion will further reduce the factor of safety of the device. Consequently, it is possible that fatigue failure of bone-implant systems may not be a rare occurrence when these devices are used in younger, more active patients. At the very least, the question of fatigue strength should be one of continuing concern as better information becomes available." (Ref. 17.)

As an example, the static factors-of-safety used in various structural elements of manned spacecraft are found in the table below:

FACTORS OF SAFETY

COMPONENT	ULTIMATE
General unpressurized structure	1.5
Windows, doors, and hatches	3.0
Pressurized structure	1.5 2.0
Pressurized lines and fittings	2.5
Main propellant tank	1.4
Pressure vessels (other than propellant tanks)	2.0

(Ref. 12 .)

It would seem to be a logical extension of existing studies to develop criteria for certain groups of critical implants. One might suggest as an example (not to be used literally):

Hip Prosthesis, Femoral Component (example only)

o Maximum vertical and horizontal deflection under load of ___ newtons applied to ball at 0° to axis of stem shall be ___ or less and ___ or less, respectively.

o Design life (analytically determined) by use of Goodman fatigue diagram shall be $_ \times 10^Y$ cycles using $R = _$ and average stress of $_$.

o Surface finish of blade region shall not be greater than ___ RMS.

o Demonstrated ultimate factor of safety on monotonic loading to failure at .005"/"/min shall be $_$.

Basing these criteria on capabilities of existing, proven hardware establishes a performance base for future designs that can take advantage of new concepts or new materials while reducing the probability of structural problems.

It is to be recognized, however, that an experimental and analytical effort is needed to develop the data base required for this approach.

Summary:

To summarize, without unduly regulating the development of implant designs, the establishment of design criteria

applicable to orthopedic implants could serve as an aid to improving the devices by allowing meaningful engineering comparisons between existing designs and new designs taking advantage of improving technology. As voiced by many users of these devices (orthopedic surgeons and researchers), the following is typical:

"In summary, the historical precedent indicates that specifications for surgical implants at the present time should and can be developed based on practical experience, without waiting for a full scientific delineation of the basic underlying phenomenon involved. The development of specifications is, in fact, currently in progress within ASTM F4; however, very little attention is being paid to performance; i.e., what works and what doesn't.

The literature is replete with investigations dealing mainly with the problems of what does not work. It is essential, however, to examine the other side of the coin as well; namely, what does work, and how do the two differ. Definitive results can only be demonstrated through a comprehensive program of implant device retrieval and analysis." (Ref. 18 .)

We agree with this philosophy.

Material Selection and Design

Data Base

General:

As indicated, once the design function and general loads are developed and volumetric or other dimensional limitations are satisfied, a structural shape is defined that can be stress analyzed to develop the material structural requirements. Selection of design data for the material requires that the critical mechanical and physical properties must be identified. For example, mechanical strength (tensile ultimate, tensile or compressive yield, shear, etc.) may be important; fatigue life may be the design parameter. Perhaps modulus of elasticity or some physical property such as coefficient of thermal expansion, relationship in galvanic series to other alloys, or a number of other parameters may be important. Along with the definition of the property, the quality of the design data must be considered. Many of the properties are required to be developed by careful test programs with statistically-derived design values; others are inferred from relationships to other properties and even others are "average" or "typical" values. The needs for reliability and the part criticality determine, to a large extent, how the design values are selected.

Aerospace:

Without doubt, the most widely used reference for alloy design allowables in aerospace designs is MIL-HDBK-5 "Metallic Materials and Elements for Aerospace Vehicle Structures" (Ref. 19). This handbook provides statistically-based design values for all of the major alloys in use in the aerospace industry. Mechanical strength values are reported as "A" allowables (99% nonexceedence with 95% confidence) and "B" allowables (90% nonexceedence with 95% confidence) based on a large experimental data base for the alloys and tempers. In addition to those properties normally used in design, other properties such as shear strength, bearing strength, modulus of elasticity and physical properties such as coefficient of thermal expansion, specific heat, etc., are often also provided.

An example of the sheets provided for the aluminum alloy 6061 is attached for information, Figures 2 , 3 , and Table 3. While properties such as fatigue and fracture are not given statistical treatment, curves and data for these properties are given with discussion that appropriate precautions (design scatter factor, test environment, etc.) must be observed in using these data for design purposes.

The reliance on this document is indicated by the following paragraphs from NASA SP-8057 (Ref. 12) and JSC-SE-R-006 (Ref. 20):

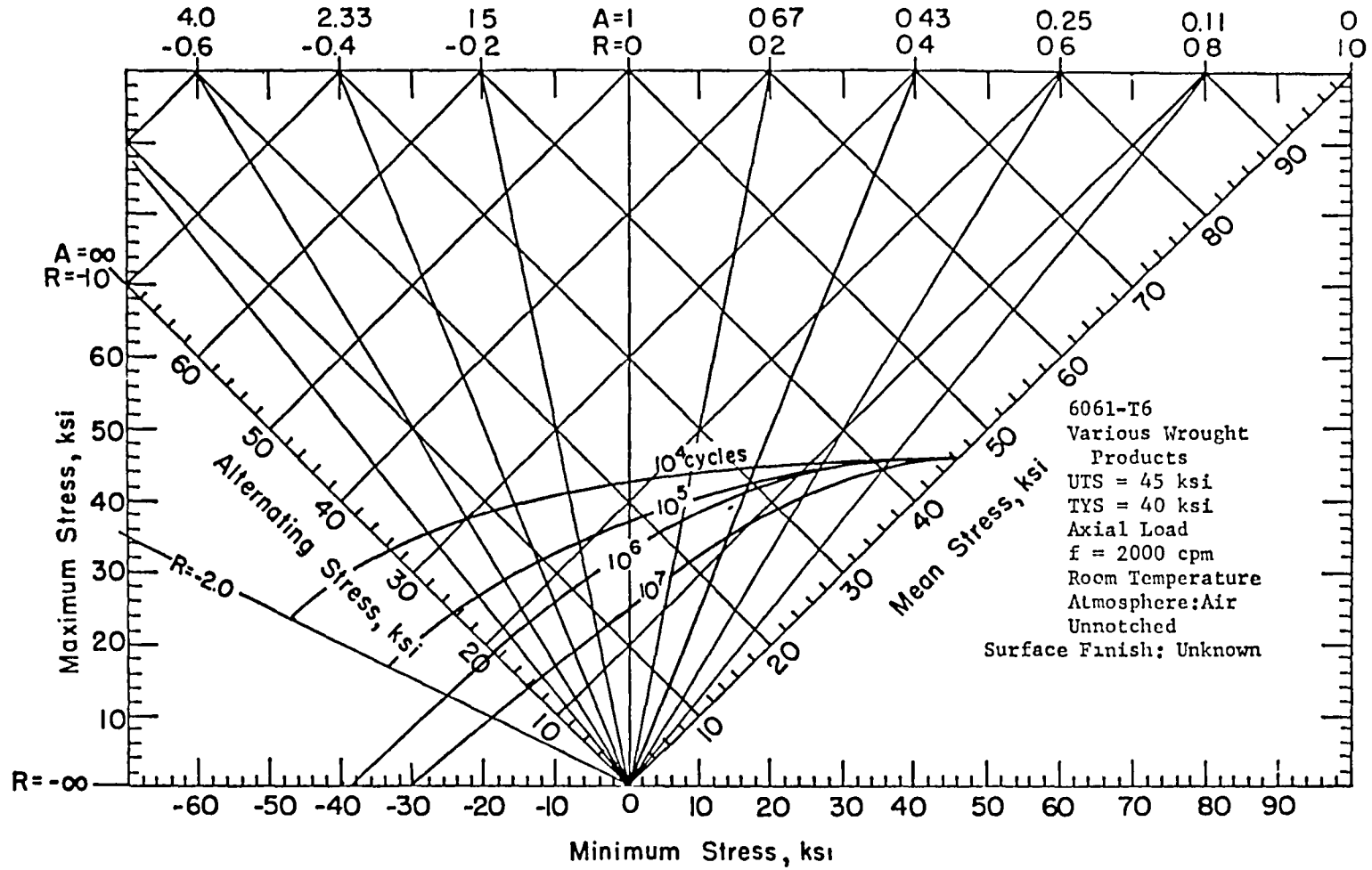


FIGURE 2

EXAMPLE OF MIL-HDBK-5 FATIGUE DATA ON 6061 ALUMINUM ALLOY

Ref: MIL-HDBK-5

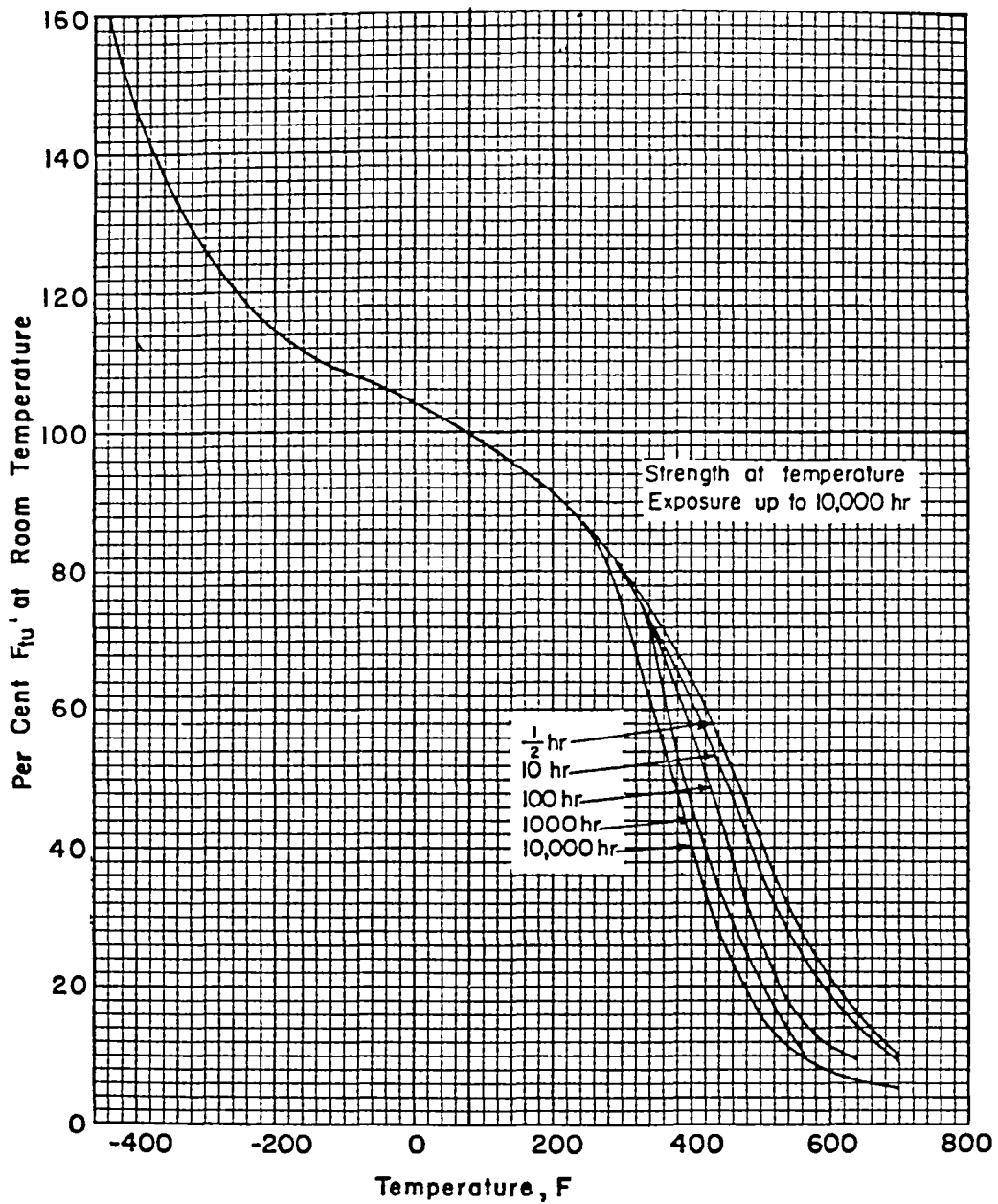


FIGURE 3

EXAMPLE OF MIL-HDBK-5 DESIGN CURVES FOR
6061 ALUMINUM ALLOY

TABLE 3 2 6 0 (d) Design Mechanical and Physical Properties of 6061 Aluminum Alloy (Forgings)

Alloy	MIL-A-22771, Type 6061		
	Die forgings	Hand forgings ^a	
	-T6 and -T652	-T6	
	Thickness, in	≤ 4 000	≤ 4 000
Basis	A	A	A
Mechanical properties			
F_{tu} , ksi			
<i>L</i>	38	38	37
<i>LT</i>		38	37
<i>ST</i>	38	37	35
F_{ty} , ksi			
<i>L</i>	35	35	34
<i>LT</i>		35	34
<i>ST</i>	35	33	32
F_{cu} , ksi			
<i>L</i>	36	36	35
<i>LT</i>		36	35
<i>ST</i>	36	34	33
F_{su} , ksi	25	25	24
F_{bru} , ksi			
(<i>c/D</i> =1.5)	61	61	59
(<i>c/D</i> =2.0)	76	76	74
F_{brv} , ksi			
(<i>e/D</i> =1.5)	54	54	63
(<i>e/D</i> =2.0)	61	61	59
<i>e</i> , per cent			
<i>L</i>	7	10	8
<i>LT</i>		8	6
<i>ST</i>	5	5	4
E , 10 ⁶ psi		99	
E_c , 10 ⁶ psi		101	
G , 10 ⁶ psi		38	
μ		0.33	
Physical Properties:			
ω , lb/in ³		0.098	
C , Btu/(lb) (F)		0.23	(at 212 F)
K , Btu/[(hr) (ft ²) (F) / ft]		96	(at 77F)
α , 10 ⁻⁶ in/in/F		13.0	(68 to 212 F)

^a Maximum cross-sectional area 256 sq in
 *For die forgings the *L* and *ST* values for the directions parallel (within ± 15 degrees) and not parallel (as close as possible to the short transverse direction) respectively to the forging flow lines"

TABLE 3

EXAMPLE OF MIL-HDBK-5 DESIGN DATA ON ALUMINUM ALLOY

" 4.7.2 ALLOWABLE MECHANICAL PROPERTIES

Values for allowable mechanical properties of structure and joints in their design environment (e.g., subjected to single stresses or combined stresses) shall be taken from sources approved by NASA, such as MIL-HDBK-5A, MIL-HDBK-17, and MIL-HDBK-23A. Where values for mechanical properties of new materials or joints and for properties of existing materials or joints in new environments are not available, they shall be determined by analytical or test methods approved by NASA. Where tests are required, they shall be of sufficient number to establish values for the mechanical properties on a statistical basis, and the tests shall conform to procedures in MIL-HDBK-5A and AFML-TR-66-386. Both 'A' (99 percent nonexceedance with 95 percent confidence) and 'B' (90 percent nonexceedance with 95 percent confidence) values for allowable stresses shall be provided.

4.7.2.1 STRUCTURAL COMPONENT ALLOWABLES

Material 'A' allowable values shall be used in all applications where failure of a single load path would result in loss of structural integrity."

2.7 MATERIAL ALLOWABLES

"Structural material 'A' and 'B' allowables shall be determined to the statistical levels of MIL-HDBK-5. 'S' allowables (specification allowables) may be used for materials in lieu of 'A' and 'B' allowables where sufficient industry data do not exist to meet all the requirements of 'A' and 'B' allowables, and lot-to-lot testing is a specification requirement. Programs for the development of new allowables requiring the generation of significant amounts of test data require the review and approval of NASA."

Certainly, companies develop their own design handbooks which may reflect properties negotiated with the supplier but in general, values for aerospace primary structures require the statistical treatment outlined in the referenced document. With the tremendous number of fabricators, machine shops, heat treat facilities, etc., involved in making elements of a modern-day aircraft, the designer must be assured that properties of material procured to a specification, processed in accordance with a specification will yield material in a part with reliable strength meeting the needs of the hardware.

For example, a titanium part design in an aircraft would typically reference the material specification (MIL-T-9046), heat treated per MIL-H-81200, nondestructively evaluated per the requirements of MIL-I-6870 or MIL-I-8950 and further defined by specifications concerning welding, plating, or other processes as applicable. Again, company specifications are recognized alternatives but usually must be approved by the customer or procuring agency before acceptance to insure that these company documents meet or exceed the Government specifications. Conformance to these requirements is usually required by the contract or detailed, negotiated end-item specifications.

Several years ago, the Apollo program encountered a rash of test failures caused by unexpected reactions of alloys with fluids and gases while the alloy was stressed. While

most of the failures were identified as caused by stress corrosion cracking, the ensuing testing led to increased knowledge of environmentally-assisted flaw growth. The data base in this field has expanded significantly through the large test programs conducted by companies, Government, and private research organizations. As an example, it has been demonstrated that many test environments can cause rapid growth of small flaws resident in the material while other fluids or environments can both create and propagate flaws while the alloy is subjected to mechanical loads. The significance of this is that the design allowable or structural capability must be examined in light of the use environment.

Evaluation in the laboratory can be deceptive in that test variables must duplicate use conditions closely. A minor variation in fluid or gas composition, temperature, flow rate, stress level, material strength level, etc., can greatly affect the test results. As a result of this high degree of specificity with some alloys and some environments, drastic steps were often used in the Apollo program. For example, each shipment of propellant (nitrogen tetroxide) flown in the Apollo program not only met the specification but a sample was tested in contact with a stressed, pre-cracked specimen of the flight tank container alloy (6AL-4V titanium alloy) to insure that adverse flaw growth would not occur with that load of propellant. While this represents an extreme, its message is that high reliability structures

cannot be designed using design allowables developed in a "benign" environment and subsequently used in an "aggressive" environment; oft times, the "aggressive" environments are no more than moist, industrial air. Examples of degradation of high efficiency alloys from various "benign" environments are illustrated in the following:

Test Material: 300 M steel

Test Conditions: Precracked samples, stressed to 75,000 psi (84% of air failure strength).

<u>Test Environment</u>	<u>Failure Time, Minutes</u>
Recording Ink	0.5
Distilled Water	6.5
Acetone	120
Lubricating Oil	150
Carbon Tetrachloride	No failure in 1280 minutes
Air	No failure in 6000 minutes
Ref. E. H. Phelps, U.S. Steel, "A Review of the Stress Corrosion Behavior of Steels with High Yield Strengths."	

Test Material: Ti 6Al-4V, solution treated and aged weld areas.

Test Conditions: Tension-tension fatiguing 6 cpm, smooth specimen, 7 to 140 KSI.

<u>Test Environment</u>	<u>Cycles to Failure</u>
Air	1385
Distilled Water	1269
Dry Methyl Alcohol	86-91
Ref. NASA TN D-3868, "Stress Corrosion Cracking of Ti 6Al-4V Alloy in Methanol," February 1967.	

Additional data of this type are found in the "Analysis" discussion of the report.

To illustrate the type of tests performed in the Apollo program, a fatigue-precracked sample of the alloy (Ti 6Al-4V) was stressed while in contact with the fluids. If failure did not occur in less than 100 hours, the metal sample was taken out of test, fatigue tested to deepen the crack and then pulled to failure in tension. By examination of the fracture surface, one could see if sustained load flaw growth had occurred (growth between fatigue bands) or if no growth had occurred (one continuous band of fatigue growth). By varying stress and flaw dimensions to yield various stress intensity levels, a stress intensity value below which flaw growth for that alloy in that fluid will not occur was established and was defined as a KTH. Various fluids and gases were tested and some fluids were found to cause flaw extension in this alloy at very low stress intensities. An example of the type of curves developed is seen in Figure 4 and tabulated data in Table 4.

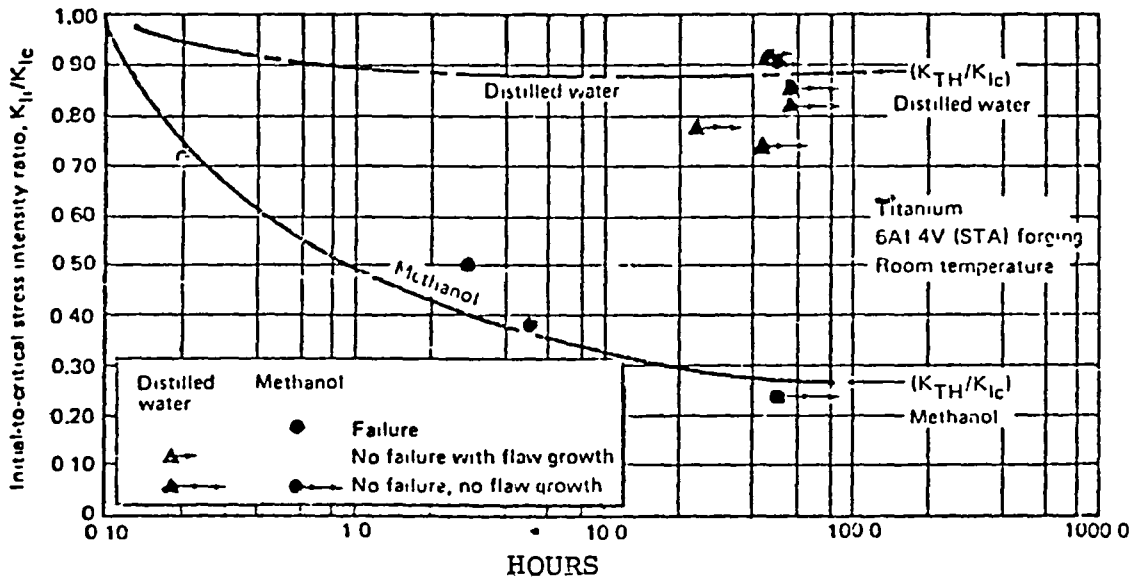


FIGURE 4

EXAMPLE OF DATA USED TO DEVELOP KTH DATA ON 6Al-4V
TITANIUM ALLOY USING PRECRACKED TEST SPECIMENS
(REF. 21)

Material	Temp., °F	σ_{VS} , ksi	Fluid environment	$\frac{K_{IH}}{K_{IC}}$
6Al-4V (STA) titanium forging	RT	160	Methanol	0.24
	RT	160	Iron III	0.58
	RT	160	N ₂ O ₄ (30% NO)	0.74
	RT	160	N ₂ O ₄ (60% NO)	0.83
	RT	160	H ₂ O + sodium chromate	0.82
	RT	160	H ₂ O	0.86
	RT	160	Humid air, or GOX	0.90
	RT	160	Aerozine 50	0.82
	90	160	N ₂ O ₄ (30% NO)	0.71
	90	160	N ₂ O ₄ (60% NO)	0.75
	105	160	Monomethyl- hydrazine	0.75
	110	160	Aerozine 50	0.75

TABLE 4

TYPICAL KTH DATA (RATIOED TO PLANE STRAIN TOUGHNESS, K_{IC})
FOR 6Al-4V TITANIUM ALLOY IN VARIOUS FLUIDS/GASES
(REF. 21.)

These data were used to set a "use" level of fracture mechanics stress intensity based on proof testing or NDT setting an initial flaw size, thereby providing a design stress that would preclude sustained load flaw growth leading to failure in the application.

Similarly, flaw growth data can be developed in fluids or gases and the growth due to sustained load, cyclic load, or combinations can be determined. Such approaches may be found in NASA-SP-8040 (Ref. 21), ASTM-STP-381 (Ref. 22), or numerous references in the literature on fracture mechanics and fracture control.

These approaches, developed for the Apollo program are also used in the Space Shuttle fracture control program. The Department of Defense, many nuclear power plant design groups, and other industries requiring maximum reliability and safety from hardware are developing or are using similar fracture control procedures.

Orthopedic Implants:

As a method of introducing the subject, a brief historical summary of medical metals is cited:

" The History of Medical Metals

What is the best metal to implant into humans? The answer to that problem has changed over the years and will probably continue to change. The earliest written record on the medical use of metal occurred in the year 1546 when Ambroise Par'e described the use of gold in surgical procedures. The first known

case of iron wire being used for bone repair was performed in 1775. In 1829, the first scientific study was conducted to determine which type of metallic wire should be used. It was concluded that of all the known metals and alloys of the day, platinum was the least irritating. Lister, who did much of the pioneering work in developing sterile techniques, also performed operations with silver wire implants. During this period of history, a mistake was occasionally made--that of using one metal for the plate and a quite different one for the screw. One surgeon reported that, during an operation on the upper arm bone, every time he touched a brass screw to an aluminum plate, the hand of the patient contracted. Another surgeon once used a magnesium plate and a steel screw. After several months in a follow-up operation to remove the plate and screw, the doctor found that the implants had completely dissolved." (REF. 23.)

Certainly, much improvement was needed and much has been achieved! Development of test methods to evaluate biocompatibility allowed evaluation of newer materials with improved corrosion resistance and higher mechanical properties that are accepted by the human body.

In 1962, the American Society For Testing and Materials created a committee (F4) to establish standards for medical and surgical materials.

Today, there are standards covering the alloys in use that provide levels of acceptability in terms of physical, mechanical, and chemical characteristics. In addition, there are tentative standards for radiographic inspection and other processes such as liquid penetrant inspection of devices for surface defects. A partial listing of the specifications and compositions of the alloys is found in Table 5.

Emate
11-19-82

ALLOY TYPE	ASTM SPECIFICATION	Cr	Ni	MAJOR CONSTITUENTS (WT. %)						
				Fe'	Co	Mo	W	Ti	Al	V
316L SS	F 55-76, F 138-76) F 621-79, F 56-76,) F 139-76)	17-20	12-14	Bal		2-4				
Cast Co-Cr-Mo	F 75-76	27-30			Bal	5-7				
Ti 6Al-4V	F 136-79							Bal	5.5-6.5	3.5-4.5
Co-Cr-W-Ni	F 90-76	19-21	9-11		Bal		14-16			
Co-Ni-Cr-Mo	F 562-78	19-21	33-37		Bal	9.5-10.5				

TABLE 5

SPECIFICATIONS AND COMPOSITIONS OF THE MAJOR IMPLANT ALLOYS

Methods of fabrication vary with manufacturer but most can be summarized below:

- o Forging of shapes followed by steps such as, machining, heat treatment, and chemical finishing.
- o Casting of shapes followed by steps such as, machining, heat treatment and chemical finishing.
- o Machining from bar, plate, sheet, or strip.
- o Forming from wire, sheet, or strip.

Each of these processes is subject to variations in the industrial manufacturers' plants or in suppliers' processes. In fact, the basic ASTM specifications can really only provide the requirements for the raw material; subsequent operations such as cold-forming, heat treating, or hot forging can affect all of the properties described in the ASTM specifications. The properties and characteristics of the finished parts depend greatly on the steps needed to convert from raw material to finished product. For example, titanium alloys are well known to be imbrittled by the accidental addition of interstitial elements such as carbon, nitrogen, hydrogen, oxygen, etc. Improper thermal or chemical treatments can drastically affect the durability and fracture behavior of these alloys. Having control over the raw material without control over the subsequent manufacturing processes assures only that the starting material is correct--assurance of part processing and subsequent metallurgical characteristics rests with the manufacturers and their subcontractors.

The literature dealing with the materials problems in metallic orthopedic implants is voluminous and controversial. Cahoon and Paxton are quoted as (Ref. 3):

" A number of stainless steel and Vitallium orthopedic implants were purchased from the manufacturers and analyzed to determine their metallurgical soundness. From this sampling of current orthopedic implants over 50% contain metallurgical defects and deficiencies similar to those which have been shown previously to cause failures."

Numerous reports (Ref. 3 , 38 , and 41) cite casting porosity, segregation, excessively large grain size and improper heat treatment as contributing to failures of metallic implants. Most of these citations are for devices made 5-10 years ago and manufacturers are quick to point out that significant improvements have been made in that interim. One recent (1980) paper by Ducheyne, et al., cites the role of casting defects (voids) in limiting part life; however, the source and date of part manufacture are not given.

The use of ASTM specifications to control raw material quality and properties is an excellent approach. However, one must look with critical scrutiny at what is controlled and what is not controlled.

There are no ASTM specifications available, for example, to assure proper heat treatment or restrictions on some chemical processes that could adversely affect performance of the finished orthopedic implant parts; also, all strength levels

being used in hardware are not covered by the existing specifications.

Perhaps one of the biggest concerns in the implant data base for alloys lies in the unavailability of established design allowables for key properties like fatigue or flaw growth thresholds in body fluids.

Without question, the single most predominant failure mechanism cited in the literature for hip implants is fatigue and corrosion-assisted fatigue. Attempts to find uniform or fatigue design allowables used by manufacturers or designers were basically futile. There are numerous articles in the literature that discuss fatigue behavior of implant alloys when tested in air using a variety of test specimen designs and test methods. What is disconcerting is that there appears to be no authoritative fatigue or fracture mechanics values on these alloys to be used in life analyses. One very excellent article by Miller, Rostoker, and Galante (Ref. 24) provides the methodology for such an approach in an article entitled "A Statistical Treatment of Fatigue of the Cast Co-Cr-Mo Prothesis Alloy" but their summary contains the disappointing statement that "These results are valid for substantially sounder material than may be common in commercial use and therefore a more conservative allowable stress probably ought to be used for design purposes."

In addition, fatigue strength can be influenced by the test environment, both mechanical and chemical aspects.

Basically, two classes of fatigue data are reported; data from smooth or notched specimens and crack growth data using precracked fatigue specimens. Both types of data on implant alloys showed evidence of environmental effects.

Using the basic crack growth relationship of Paris, $(da/dN=C(\Delta K)^n)$, Colangelo (Ref. 25) tested and analyzed type 316 SMO stainless steel from implants in air and in 0.9% NaCl solution. The results, illustrated in Figure 5 show the effect of the environment which was to increase the crack growth rate in the salt solution over the rate obtained in air. As noted by Colangelo, the rate of cycling can affect the results and his work was conducted at 30 cycles/second, rather fast for typical frequencies encountered in use.

Similarly, Wheeler and James (Ref. 26) tested type 316 stainless steel in Ringer's solution and in air using a different specimen design and at 50 cycles-per-minute and obtained the data in Figure 6. Again, the effects of the body-type fluid is to increase crack growth rates.

Bowers (Ref. 27) reported the data in Figure 7 showing smooth specimen data on type 316 stainless steel and "titanium" tested in air and in Ringer's solution at 50 cpm and 1700 cpm. The effects of test environment and testing speed are obvious.

Interestingly enough, a recent article by Piehler and Slotter (Ref. 28) on legal and regulatory implications of implant retrieval and analysis cites fatigue data on 316L

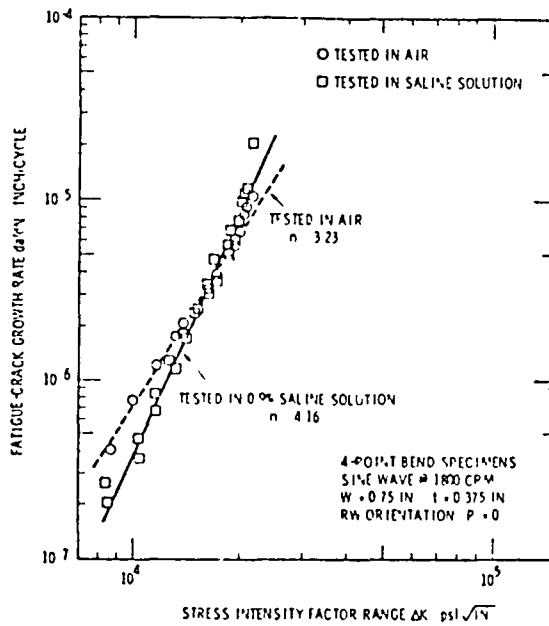


FIGURE 5

da/dn DATA ON TYPE 316 SMO STAINLESS STEEL
 FROM ORTHOPEDIC IMPLANTS
 (REF. 26)

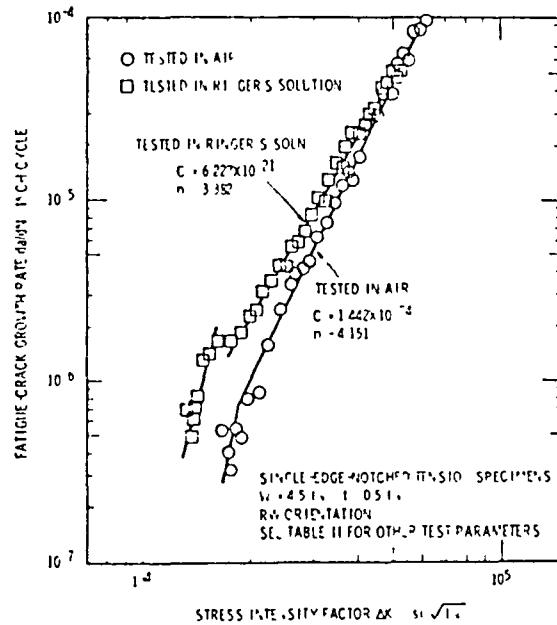


FIGURE 6

da/dn DATA ON TYPE 316 STAINLESS STEEL
 (REF. 27)

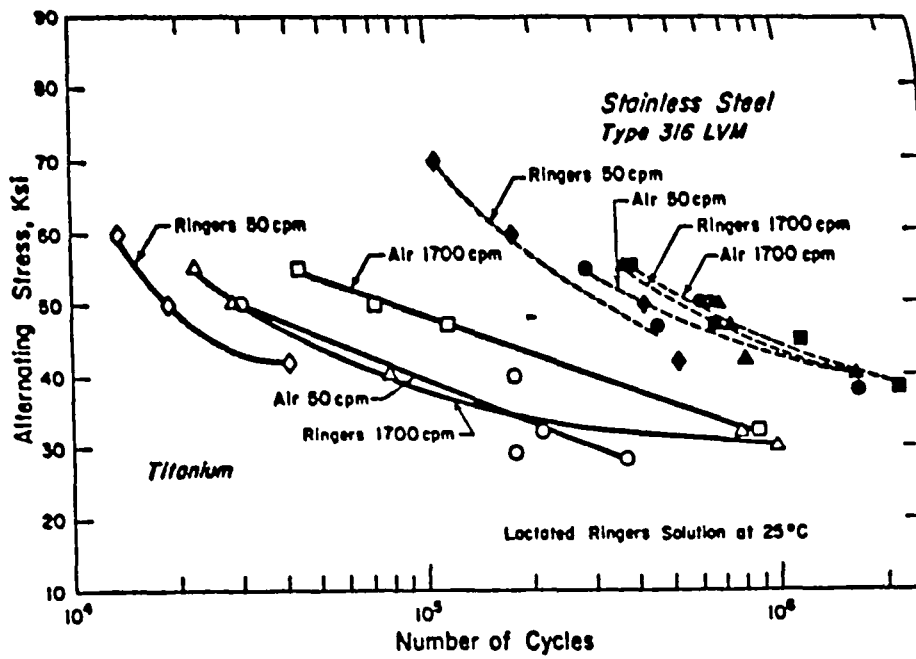


FIGURE 7

TITANIUM AND 316 STAINLESS STEEL FATIGUE DATA IN AIR AND IN RINGER'S SOLUTION AT 50 CPM AND 1700 CPM CYCLE TEST RATE (REF. 28)

stainless and 6 Al-4V Titanium in Ringer's solution (Figure 8) on Jewett Nails. Their observations are:

"The difference in performance of these devices is striking and certainly suggests that Ti 6Al 4V should be given serious attention as an implant material. Since loads applied to retrieved implants are virtually unknown, this superior performance of Ti 6Al 4V, if it translates into improved in vivo performance, would have taken years to observe from analyses of retrieved implants.

Whereas the authors recognize that this corrosion-fatigue performance test does not simulate every aspect of in vivo performance, it nevertheless appears to be a valuable initial step. Since the test is new and not widely proven, its adoption by the BMD as a performance standard is premature, if appropriate at all. However, its adoption as a regulatory guideline seems to make sense to us. In fact, many of the standards already in existence would appear to be prime candidates for recognition as regulatory guidelines. It would appear to us that prudent manufacturers would adhere to these guidelines, and this procedure would circumvent the difficulties involved with the endorsement of standards or mandatory performance-standard development. "

It appears from the preponderance of literature on the subject, that the characterization of materials and the control of material in fabricated hardware is cited as an area for improvement.

The work cited by Wheeler and James on Annealed 316 stainless steel in Ringer's solution represents the NASA-Shuttle approach to developing safe operating stress levels

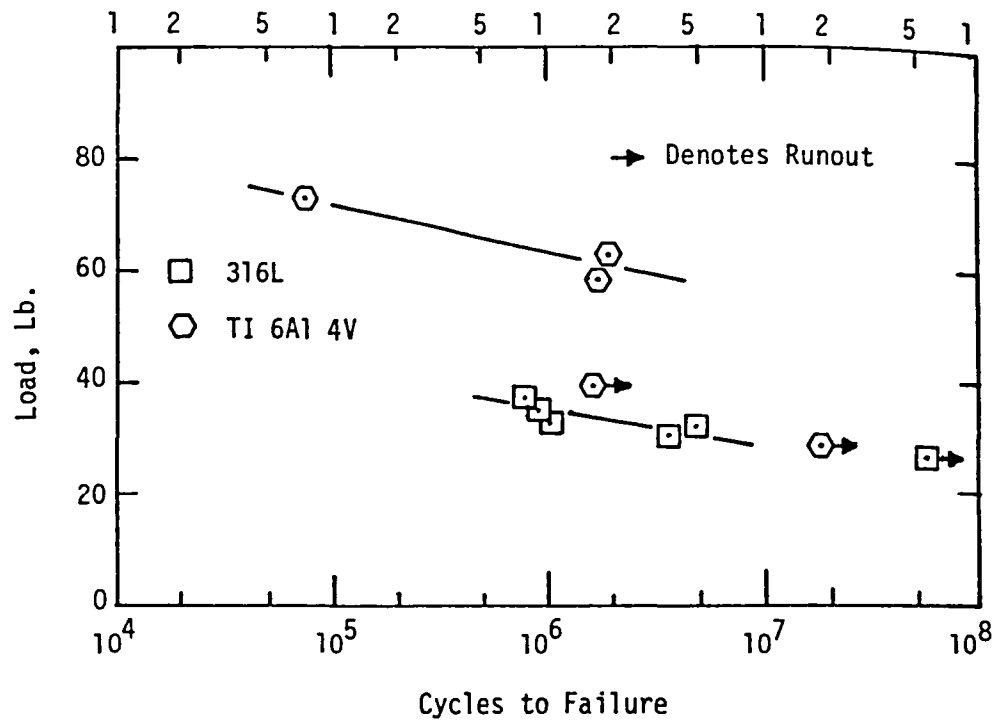


FIGURE 8

FATIGUE DATA ON MATERIAL FROM JEWETT NAILS
(REF. 28)

for critical hardware using pre-cracked specimens tested under load while in contact with the fluids to be encountered in use.

Also, using pre-cracked specimens the flaw growth-per-cycle (da/dN) developed while in contact with the fluid can be developed for life determinations. These approaches have been shown to discriminate between materials performance and strength levels within a material system where smooth or arbitrarily notched specimens do not.

Based on the information in the literature, there are several potential sites in implants for flaws from manufacturing or from installation (nicks or gouges from instruments used to install the implant). These sites can grow under stress or as a result of load cycling until failure occurs. The methods of fracture mechanics can be used to calculate part life if the correct materials data are available and if load conditions can be predicted. Examples of methods and uses of this approach are found in NASA-SP-8040 and in ASTM-STP-384. Development of appropriate materials behavior in body fluids is a necessary element of such an analysis.

If new alloys or strength levels are to be utilized to upgrade the performance of orthopedic implants, proper methods for comparing performance of current alloys with new materials or conditions should be established. Corrosion tests, fatigue strength and flaw growth characteristics in simulated body fluids could be extremely helpful in

comparing performance if uniform tests are used for the materials being evaluated.

Recommendations from ASTM or NASA on standardized test methods would be helpful; many existing standards can be evaluated for applicability to this problem.

Summary:

Use of ASTM specifications can provide adequate control of raw material properties and chemical composition. Thermal or thermo-mechanical processes used in fabricating implants can affect the strength of the products and result in variations in structural capability from different producers even in the same implant design. Control of these processes by ASTM-type specifications could provide more consistency in the finished products.

Establishment of handbook-type data for mechanical properties including fatigue life would introduce additional product consistency and reliability of structural capability.

For those devices operating in body fluids, the allowables should be based on the critical design parameter developed in simulated body fluids. Aerospace-generated test techniques and analytical tools are available for use if required loads and stress analyses are available for the implant designs to use in life calculations.

Analysis Methods

General:

The discussion of methods for analyzing high criticality structures begins with the same point as discussed previously. The methods all require some knowledge of loads and load spectra as an initial input; after that, the methods of handling the loads and lifetime requirements differ greatly from industry-to-industry. Simple, straight-forward stress analysis of structures using formulae from standard references like Roark (Ref. 29) and Timoshenko (Ref. 30) are the methods used in most industries but as part criticality and load complexity increase, the rigor and methodologies lead to the use of automated methods and finite-element computer programs to process the needed data quickly and improve the internal load-determination process.

Aerospace:

In general, loads involved in aerospace components are complex in that many loads from different sources can act on the structure during different time domains in use. As a result, the use of computer programs has become commonly accepted as the method of providing the final loads and stress data. In preliminary design and during the initial vehicle sizing, simplified analyses are performed and several iterations of increasing complexity follow as additional input data justify.

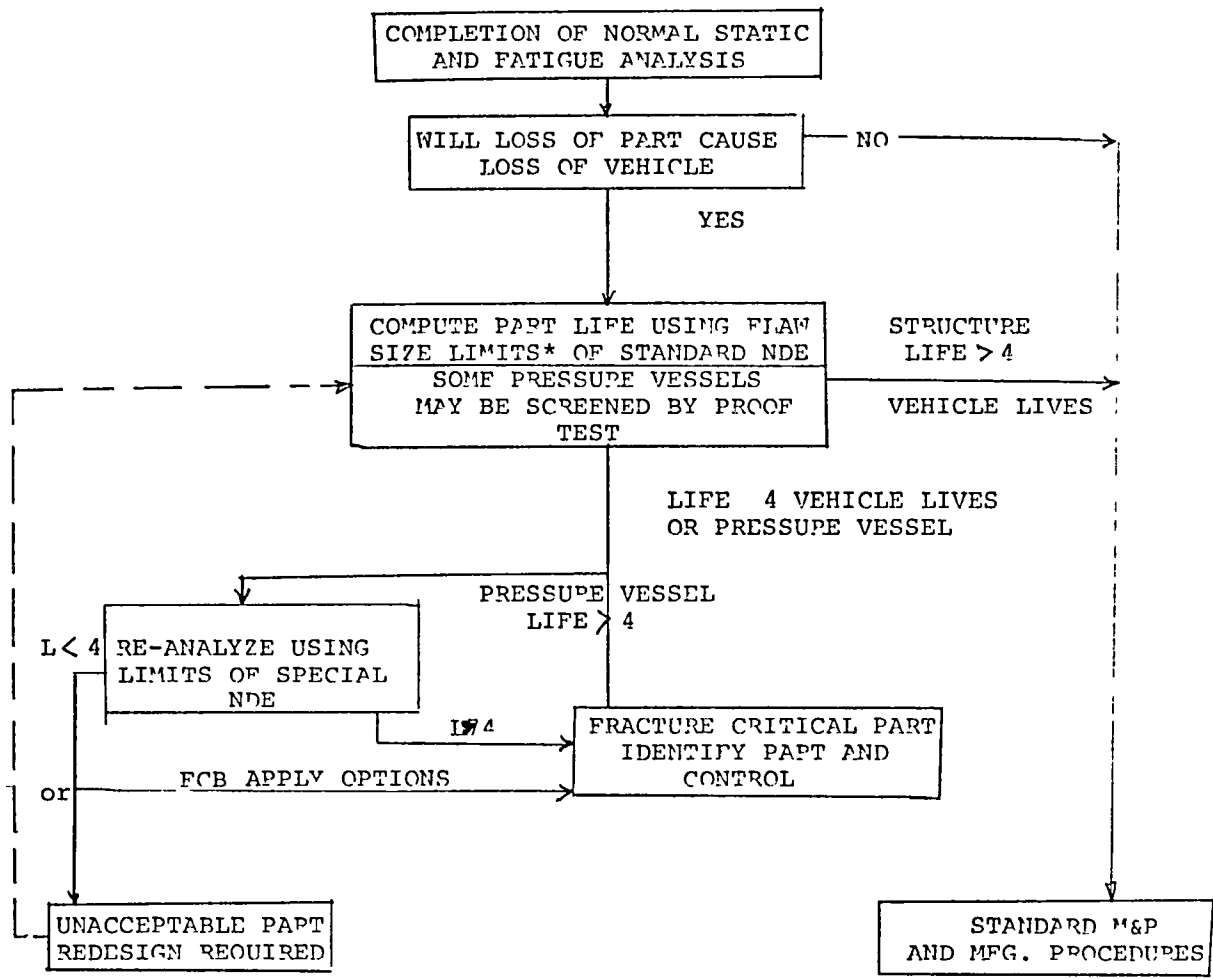
The use of high-speed electronic digital computers allowed the structural engineer to utilize standard matrix structural analysis methods applied to complex problems involving continuous geometries by a set of interconnected finite elements of known characteristics. Analysis of the elements, superimposing element solutions to develop the solution for complex systems, and the overall capability to develop detailed elements of a size consistent with system needs have all led to a very rapidly increasing use of computer programs available to every technical field. Proliferation of these programs, availability of computers (even time-sharing), and the proven value of these methods have led to an extremely popular approach to solving structural mechanics problems.

Aerospace has adopted the use of finite element programs in a routine manner to solve structural, thermal, and combined environment programs. Typical of the general-purpose programs available in most computer centers are listed in Table 6. More complete lists of available programs may be obtained in the literature, from computer centers, or from NASA (see also Ref. 31-36).

Table 6
Partial List of Available
Finite Element Computer Programs

1. NASTRAN (NASA Structural Analysis)
2. STRESS II
3. STRATA (Stress and Thermal Analysis)
4. ANSYS (Engineering Analysis System)
5. STARDYNE
6. SPACE
7. SAP IV

Many aerospace organizations have chosen to develop a fracture control program to apply to those few components that are absolutely required to perform reliably. The fracture control program is both a management and a hardware control system that requires integrated evaluations of stress, materials, manufacturing, and quality assurance. As an example of the selection logic used to determine which parts must conform to this rigor, Figure 9 is taken from the Space Shuttle Orbiter Fracture Control Plan (Ref 47). As seen in the figure, the first "crossroad" identifying a part that can "cause loss of vehicle" screens the large majority of structure so that the additional steps only apply to the



LEGEND: L = LIFE
 NDE = NON-DESTRUCTIVE EVALUATION

FRACTURE CRITICAL PART SELECTION LOGIC

FIGURE 9

(Ref. 47)

most critical elements. The use of highly sensitive and well-monitored nondestructive evaluation (NDE) options or limited life "redlines" can prevent redesign but most parts must show greater than four times the vehicle life when analyzed using fracture mechanics analytical programs.

An integral part of the fracture control program is the fracture mechanics analysis. To perform the analysis, a good stress analysis is needed along with the proper material characteristics (toughness, flaw growth rates, environmental effects, etc.).

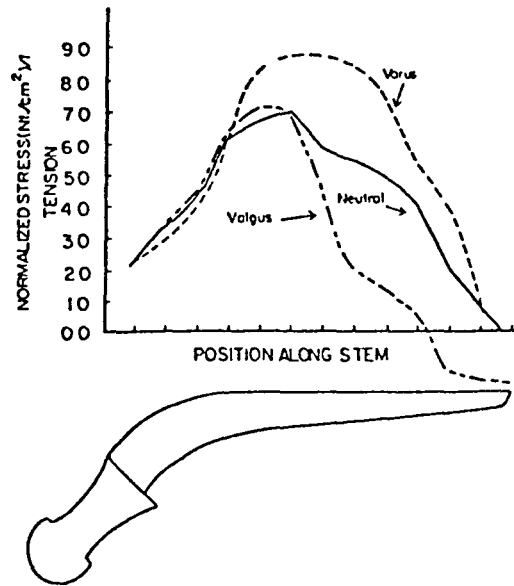
Although the fracture mechanics approach is often criticized for being conservative in assumptions (worst size, orientation of flaw, plane strain toughness for thin material, etc.), analysis showing adequate life has been successful in critical applications. The Department of Defense and NASA have been the most-often cited users of fracture mechanics, but the users of these approaches are rapidly finding applications in diverse industries such as offshore structures, pipelines, nuclear components, rotating machinery, and transportation systems. The techniques (computer models, stress intensity solutions) are available and a single example of life and damage tolerance considerations is included in Appendix A. Interestingly enough, the report from which the material in Appendix A is taken includes case histories of the uses of fracture mechanics in diverse areas such as

railway rail failures, ship hydraulic equipment, and a ski-lift chain failure. Certainly, it is not an exaggeration to say that the application of fracture mechanics is no longer considered "too expensive" or "too complex" for any but aerospace.

Orthopedic Implants:

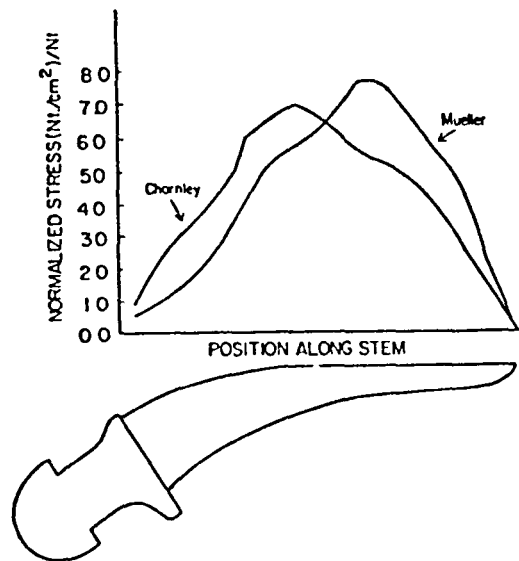
It is encouraging to note that finite element stress models are being used by investigators in the orthopedic implant field. A femoral stem implanted in the femur is a complex structure involving a system composed of bone, adhesive and metal components; loads and load spectra are highly variable. Therefore, these complex conditions preclude simpler methods, and require material properties and load assumptions that may not be entirely available or reliable. Therefore, knowledge of the input data may limit the usability of the output. Nevertheless, work by Andriacchi, et al., using a two-dimensional representation of the femur, implant stem and cement did perform a finite element stress analysis and compared the results with instrumented prosthesis cemented into wet embalmed cadaver femora. The results of analyses and experimental tests as a function of other variables are shown in Figures 10(a) and (b) (Ref. 37).

While three-dimensional models are desired, these simplified results are very enlightening in developing stress



(a)

EXAMPLE OF STRESS vs. POSITION ON STEM



(b)

FIGURE 10

(REF. 37.)

EXAMPLE OF STRESS vs. DESIGN FOR HIP PROSTHESES.

levels along the stem length and relative sensitivities of some of the assumptions of materials properties on the final results.

On the negative side, a recent survey by the Food and Drug Administration asking some of the leading workers in the implant field about needed data on orthopedic implants prior to investigational evaluation in humans resulted in only 22% of the responders stating a desire for "determination of stresses and deformations in the device" and only 11% stating that there is a need for "finite element method of analysis or other numerical techniques." Over 44% felt that empirical determinations were sufficient (Ref. 40).

Indeed, if the general attitude in the industry is to rely on comparison and use history, then developing rigor in other areas of design and development is inconsistent and may be unnecessary. One would hope that the continued broadening of uses of improved analytical methods will illustrate the desirability and simplicity of the methods to this industry. Use of experimental data as methods of improving analytical models will always be desirable but quantitative methods of analyzing designs can lead to greater insights into design improvements with much more hope for understanding and improvement.

Summary:

The analytical methods and procedures in use by aerospace appear to be very applicable to the orthopedic implant design and analysis procedure. Basic loads data would have to be developed for each specific application with sufficient understanding to justify the rigorous analysis, but this should be possible with the existing information from previous and current studies.

The use of fracture mechanics analysis requires a materials data base that is not apparent for the orthopedic implant alloys but the technique of treating flaws in structures emanating from fastener holes, manufacturing defects, raw material defects, or those that develop in use is certainly one that could provide a safe life determination.

Certainly, continued evaluation of finite element stress analyses as a way of examining part stress and strain distribution would provide significant insight into expected use conditions and life calculations. For those orthopedic implants where maximum reliability and performance are needed, the stress analysis is vital in the same way that the stress analysis is the cornerstone of the life calculation in aerospace components.

Inspection/Acceptance Methods

Aerospace:

In addition to the usual dimensional and other visual checks required in parts manufactured to aerospace designs, nondestructive testing (NDT) is also required to an extent specified on the design drawings. Control of the NDT process is effected through manufacturer-written specifications, plans, and design drawings. One widely used Military Specification which establishes such procedures is MIL-I-6870C, a copy of which is included as Appendix C. Much of the present description is taken from this document.

The nondestructive testing plan for each manufacturer is implemented and monitored by a review board comprised of design analysis, manufacturing, and NDT representatives. The selection of this review board is subject to the approval of the Government contracting agency. The functions of these three representatives are as follows:

"Design analysis representative(s).
The design analysis representative shall provide the board information and data on the acceptable limits of defects in the materials and parts under consideration. This shall include part configuration, acceptable defect size, critical locations and orientations, and primary stress conditions and directions.

Manufacturing representative(s).
The manufacturing representative(s) shall provide the board information and data on the stages and limitations of processing, manufacturing and assembly at which non-destructive testing can be achieved. This shall include information and data on accessibility, surface finish, or other conditions which may influence inspectability.

Nondestructive testing representative(s). The nondestructive testing representative(s) shall provide the board information and data on the sensitivity and applicability of NDT techniques for the defect sizes, locations and orientations, part geometries, and materials being considered."

The following classes representing the functional reliability of the material or part have been established:

- Class 1 - Components which are fracture or fatigue critical or components the single failure of which would cause significant danger to operating personnel or would result in an operational penalty. This includes loss of major components, loss of control, unintentional release, inability to release armament stores, or failure of weapon installation components.
- Class 1A - A Class 1 component, the single failure of which would result in the loss of an aircraft or missile system.
- Class 1B - Class 1 components not included in Class 1A.
- Class 2 - All components not classified as Class 1.
- Class 2A - Components having a margin of safety of 200 percent or less.
- Class 2B - Components having a margin of safety greater than 200 percent.

In addition to the above classes, components are often assigned a grade which is defined in terms of defect size, location, type, and frequency which are acceptable.

Note that many of the surgical implants considered in this report would likely fall in Class 1.

" Specific inspection requirements must be made for all Class 1 materials and parts. The action shall include... the design requirements of acceptable defect size, critical locations and orientation, primary stress conditions and directions. The manufacturing recommendation for point of testing, and the specification of NDT technique and sensitivity. " (Para 3.3.3.1)

This information is required on all engineering and production drawings of Class 1 parts. In addition, on

" ...materials and parts in which the grade level varies with location, the drawing shall be zoned and the appropriate information...shall be entered for each zone. (Para 3.3.4.3)"

Test procedures for Class 1 parts shall include:

- a. Specific part number and configuration.
- b. Stage of fabrication.
- c. Surface finish and part preparation.
- d. Manufacturer and model number of all instrumentation to be used.
- e. Fixturing requirements.
- f. Manufacturer and identification of all testing materials.

- g. Detailed procedure steps or reference to company process specification procedure if applicable.
- h. Calibration and standardization procedure.
- i. Acceptance and evaluation procedure.
- j. Precautions in use of test procedure.
- k. Drawings of the part to be tested with identification of areas to be tested and the direction and magnitude of primary stresses.
- l. Physical description of probable defects.
- m. Minimum acceptable defect size and orientation.
- n. Limitations of technique in defect sensitivity.
- o. Sources of noise signals and their identifications.
- p. Procedures for retesting by the same or alternate methods to provide adequate confidence level.

Table 7 lists the common NDT methods currently in use showing the properties being sensed, the flaws detected, their application, advantages, disadvantages (Ref. 43). Note that x-ray radiography, liquid penetrants, eddy current testing, and magnetic particle testing are all capable of detecting surface cracks. Ward D. Rummel, et al., of Martin-Marietta under NASA contract NAS9-14653 performed an investigation to determine the reliability of trained operators, using these techniques, to detect tightly closed cracks of known dimensions and locations. Two alloys were used in this study, 4340 steel and Ti 6Al-4V.

TABLE 7 Comparison of Selected NDE Methods

Method	Chapter	Properties sensed or measured	Typical flaws detected	Representative application	Advantages	Limitations
X ray radiography	4	Inhomogeneities in thickness, density, or composition	Voids, porosity, inclusions and cracks	Castings, forgings, weldments, and assemblies	Detects internal flaws, useful on a wide variety of materials, portable, permanent record	Cost, relative insensitivity to thin laminar flaws such as fatigue cracks and delaminations, health hazard
Neutron radiography	4	Compositional inhomogeneities, selectively sensitive to particular atomic nuclei	Presence, absence, or mislocation of internal components of suitable composition	Inspection of propellant or explosive charge inside closed ammunition or pyrotechnic devices	Good penetration of most structural metals, high sensitivity to favorable materials, permanent record	Cost, relatively unportable, poor definition, health hazard
Liquid penetrants	2	Material separations open to a surface	Cracks, gouges, porosity, laps, and seams	Castings, forgings, weldments, and components subject to fatigue or stress-corrosion cracking	Inexpensive, easy to apply, portable	Flaw must be open to an accessible surface, messy, irrelevant indications often occur, operator dependent
Eddy-current testing	5	Anomalies in electric conductivity and, in cases, magnetic permeability	Cracks, seams, and variations in alloy composition of heat treatment	Wire, tubing, local regions of sheet metal, alloy sorting and thickness gaging	Moderate cost, readily automated, portable, permanent record if needed	Conductive materials only, shallow penetration, geometry sensitive, reference standards often necessary
Microwave testing	7	Anomalies in complex dielectric coefficient, surface anomalies in conductive materials	In dielectrics: disbonds, voids, and large cracks, in metal surfaces: surface cracks	Glass fiber resin structures, plastics, ceramics, moisture content, thickness measurement	Noncontacting, readily automated, rapid inspection	No penetration of metals, comparatively poor definition of flaws
Magnetic particles	8	Anomalies in magnetic field flux at surface of part	Cracks, seams, laps, voids, porosity, and inclusions	Castings, forgings, and extrusions	Simple, inexpensive, senses shallow subsurface flaws as well as surface flaws	Ferromagnetic materials only, messy, careful surface preparation required, irrelevant indications often occur, operator dependent

(Ref. 43)

(Table 7 Concluded)

Magnetic field testing	8	Anomalies in magnetic field flux at surface of part	Cracks, seams laps, voids, porosity, and inclusions	Castings, forgings, and extrusions	Good sensitivity to and discrimination of fatigue cracks, readily automated, moderate depth penetration, permanent record if needed	Ferromagnetic materials only, proper magnetization of part sometimes difficult
Ultrasonic testing	3	Anomalies in acoustic impedance	Cracks, voids, porosity, and delaminations	Castings, forgings, extrusions, thickness gaging	Excellent penetration, readily automated, good sensitivity and resolution, requires access to only one side, permanent record if needed	Requires mechanical coupling to surface, manual inspection is slow, reference standards usually required, operator dependent
Sonic testing	3	Anomalies in low frequency acoustic impedance or natural modes of vibration	Disbonds, delaminations, larger cracks or voids in simple parts	Laminated structures, honeycomb, small parts with characteristic "ring"	Comparatively simple to implement, readily automated, portable	Geometry sensitive, poor definition
Ultrasonic holography	3	Same as ultrasonic testing	Same as ultrasonic testing	Inspection of small, geometrically regular parts	Produces a viewable image of flaws	Cost, limited to small parts, poor definition compared to radiography
Infrared testing	6	Surface temperature, anomalies in thermal conductivity and/or surface emissivity	Voids or disbonds in non-metallies, location of hot or cold spots in thermally active assemblies	Laminated structures, honeycomb, electric and electronic circuits	Produces a viewable thermal map	Cost, difficult to control surface emissivity, poor definition
Strain gages	10	Mechanical strains	Not used for flaw detection	Stress-strain analysis of most materials	Low cost, reliable...	Insensitive to preexisting strains, small area coverage, requires bonding to surface
Brittle coatings	10	Mechanical strains	Not commonly used for flaw detection	Stress-strain analysis of most materials	Low cost, produces large area map of strain field	Insensitive to preexisting strains, messy-limited accuracy
Optical holography	11	Mechanical strains	Disbonds, delaminations, plastic deformation	Honeycomb, composite structures, tires, precision parts such as bearing elements	Extremely sensitive, produces map of strain field, permanent record if needed	Cost, complexity, requires considerable skill
Leak detection	9	Flow of a fluid	Leaks in closed systems	Vacuum systems, gas and liquid storage vessels, pipeage	Good sensitivity, wide range of instrumentation available	Requires internal and external access to system, contaminants may interfere, can be costly

(Ref. 43)

In this study fatigue cracks were intentionally introduced in test samples at known locations. The starter notches were then removed by machining. The samples were cleaned and inspected by the above techniques using three independent, experienced and dependable NDT personnel. There were 176 fatigue cracks in 60 steel specimens and 135 fatigue cracks in 60 titanium alloy specimens. The cracks were randomly located with a range of sizes and shapes using both sides of the test plates. After this first sequence of tests the surfaces were etched to remove about 0.0005-inch of metal from each surface and the liquid penetrant test repeated. Finally, the panels were proof loaded to 80% of the material yield strength except for the thinner of the titanium panels which were proof loaded to 90% of the yield strength. They were then reinspected for cracks using all of the above methods.

At the conclusion of all the NDT inspections the cracks were broken open in bending and measured. Finally, statistical correlations were performed to determine the probability of finding cracks of various dimensions.

The most reliable method for Ti 6Al-4V was the liquid-penetrant test and the least reliable was the x-radiographic method. Figures 11 and 12 show the results of these two methods. For the liquid-penetrant method note that etching the machined surface improved the sensitivity but that proof loading had little effect. Note also that the probability

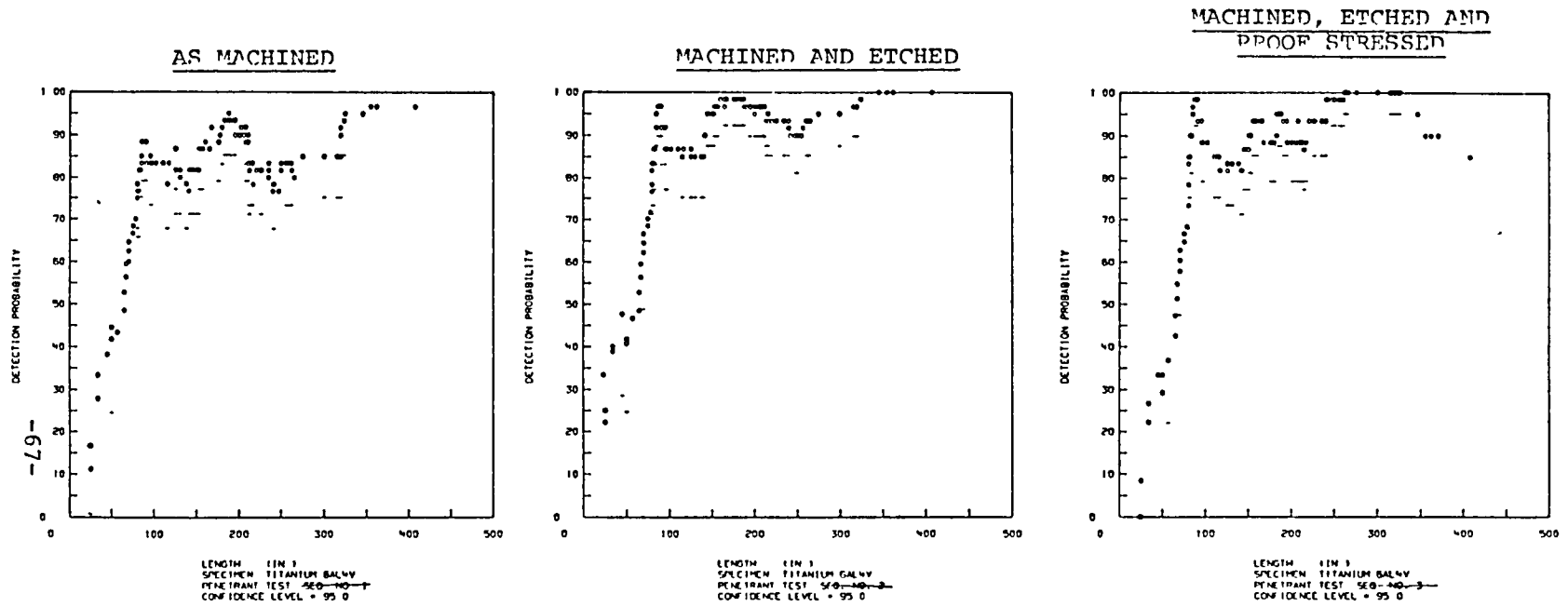


FIGURE 11
CRACK DETECTION PROBABILITY OF THE PENETRANT
INSPECTION METHOD FOR TITANIUM SPECIMENS
PLOTTED BY ACTUAL CRACK LENGTH AT 95% CONFIDENCE
(REF. 44.)

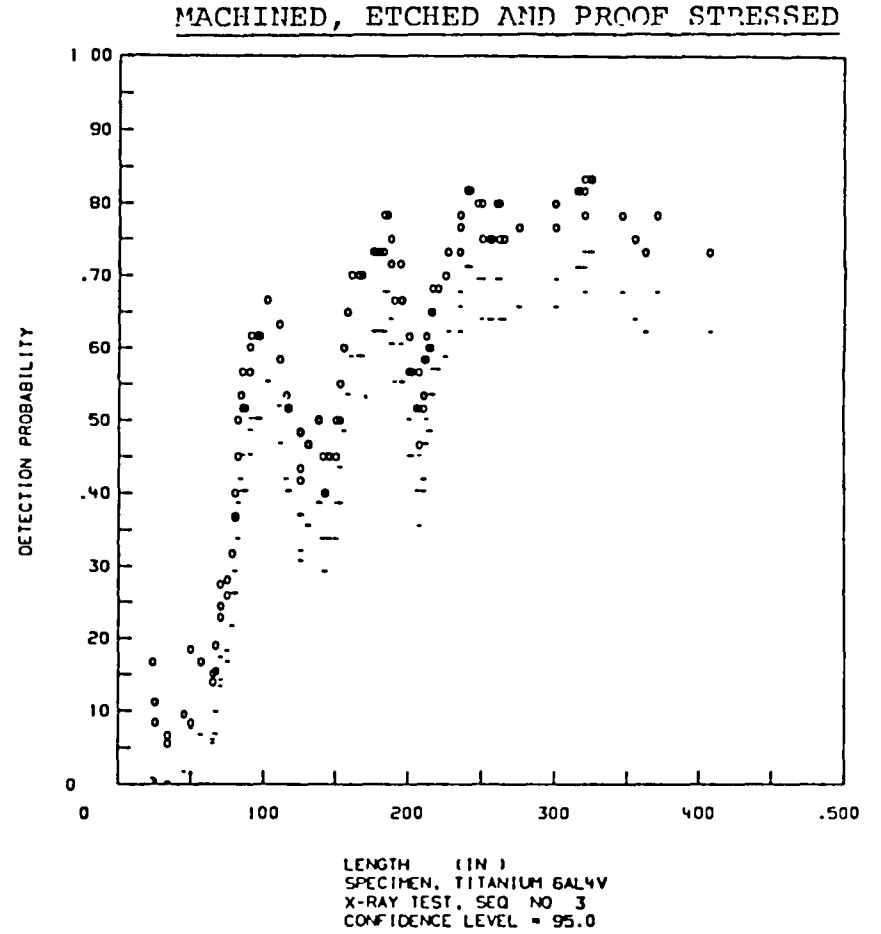
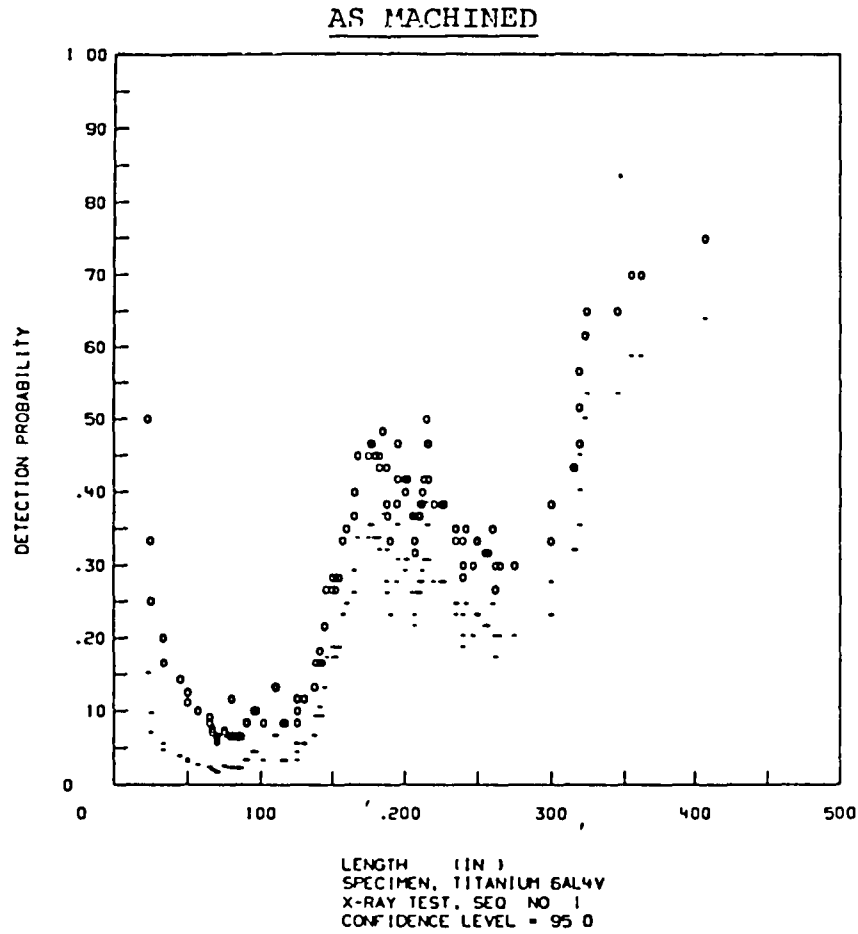


FIGURE 12

CRACK DETECTION PROBABILITY OF THE X-RADIOGRAPHIC
INSPECTION METHOD FOR TITANIUM SPECIMENS PLOTTED BY
ACTUAL CRACK LENGTH AT 95% CONFIDENCE
(REF. 44.)

of finding cracks shorter than 0.1 inch decreases dramatically as crack length decreases. In other words, the best available inspection technique is likely to miss any crack shorter than 0.10 inch in T1 6Al-4V.

For the steel specimens liquid penetrant and magnetic particle methods were about equally effective, with the other techniques showing lower sensitivity. The final conclusion is similar to that for titanium, i.e., that after inspection and elimination of all parts in which defects are detected the best that one can say is that the remaining parts have no defects longer than about 0.1 inch.

Orthopedic Implants:

From our questions and site visits, it appears that there is no uniform authority governing inspection of orthopedic implants equivalent to MIL-I-6870C. The implant manufacturers questioned either used the ASTM Standards directly as specifications or wrote their own internal specifications based upon the ASTM Standards and on aerospace/military documents. Only two specifications are currently published, ASTM F 601-78 dealing with fluorescent penetrant inspection and F 629-79 dealing with radiography.

With the larger manufacturers, inspection begins at the receiving dock where each batch of incoming parts or material is inspected. This inspection generally consists of mass-spectrographic analysis to verify the alloy composition,

and metallography to verify the microstructure. Smaller manufacturers do not perform such tests on site. Visual inspection is performed throughout manufacture. In the case of total hip prostheses and presumably nail plates and bone plates a dye penetrant test is performed to check for cracks. One manufacturer performed proof tests on hip prostheses for a period of a year but quit this test because it did not screen any flaws. Final inspection is visual. Dimensions are checked, surface finish is observed for evidence of pitting, scratches, undetected cracks, etc.

From a fracture mechanics viewpoint the ability or inability of an inspection method to find flaws of a given nature is significant information to the design and analysis of a device. The size, shape, and location of undetected flaws combined with the load spectra on the device are used to predict the flaw growth rates and hence the life of the device. Thus it is important to know the sensitivity of any method being used to inspect for flaws. The only way that this can be done with confidence is by the use of standards similar to those used in the Rummel, et al., study cited above. In the case of castings where porosity or inclusions are likely to promote crack initiation, standards must be prepared with these type of defects of varying sizes, shapes, and orientations in material of similar size and shape to the part to be inspected. Only by the use of such

standards can a manufacturer know that the method of inspection which is being used is capable of screening out those flaws which his design and analysis say will degrade the performance of the device. If it turns out that the methods being used are incapable of screening flaws with the required sensitivity then other methods of NDT should be investigated.

Referring again to the Rummel, et al., study, note in Figure 11 that the dye penetrant test was made more reliable by an etch procedure. Whether the same is true after an electrolytic polish is not known. Buffing or mechanical polishing operations are commonly employed in making implants. Whether and to what extent these operations influence the sensitivity of a dye-penetrant test could easily be determined with a series of samples similar to those used by Rummel, et al.

The only methods of NDT in use by orthopedic manufacturers to our knowledge are x-radiography and dye penetrant. As was shown in Table 6 many other techniques exist with their own advantages and limitations. The use of these should be investigated using the appropriate standards to make sure that the optimum technique for each device is indeed being used.

As noted above, the Rummel, et al., study showed that no technique could reveal tightly closed cracks smaller than 0.1 inch long. Another difficult NDT task is to find small

subsurface porosity and inclusions by x-radiography. A method which should be investigated as a solution to these problems is the combined use of acoustic emission and a proof test. It is known that propagating cracks emit high frequency sound pulses as they move, and these can be detected with the proper equipment. By applying this equipment to a device being loaded with forces similar to those to be encountered in service, it has been shown that one can locate any flaws which are of the necessary orientation and dimensions to propagate under such loading. This test thus shows promise of screening precisely those flaws which would be of concern to the functioning of the device.

In any manufacturing effort, failure analysis is a potentially valuable tool for identifying trouble spots whether they be in inspection, design, manufacture, or operation. The implant companies questioned are all engaged in failure analyses. Many other groups have collected data on performance, in some instances looking for metallurgical problems (Ref. 4, 8, 18), sometimes looking for biomedical problems (Ref. 44), sometimes looking for a variety of problems (Ref. 45). It would appear that such efforts would all profit from coordination among each other. Because of the large number of these devices being implanted continually, because of the variety of manufacturers, designs, and materials being used, because of the large number of surgeons using them, and because of the importance of each device

to the patient in which it is implanted early warning of any problem would appear to be of great importance. Therefore, it appears worth recommending that a continuing retrieval program of removed devices be established with all the necessary data being collected on each retrieval. The development of this program should include the entire spectrum of users of such information.

Summary:

The contrast, as noted before in this report, between a central large-customer-oriented inspection requirement and an individual manufacturer-oriented-inspection requirement is obvious. Considering that customers for implants are individual surgeons with little or no interest in or access to NDT specialists and quality control personnel, this contrast is not surprising. Furthermore, the ultimate consumer, the orthopedic patient, can be considered to be totally ignorant of these considerations.

The question, "Would more uniform and detailed inspection requirements result in a better quality implant?" can only be answered on a company-by-company basis. Furthermore it would require substantially more information than is available to the authors. The findings of Cahoon and Paxton (Ref.

3) cited earlier seems to suggest that in some instances it would.

As noted above the limitations of inspection need to be known by all key elements of the production endeavor, and also the inspection requirements "built into" each device need to be known by the inspection elements of the organization. For this reason it appears worth recommending that orthopedic manufacturers investigate a coordination method similar to that required in the aerospace industry (MIL-I-6870).

As far as specific inspection techniques are concerned, the development and use of realistic standards to qualify each inspection technique is recommended. Other methods, such as ultrasonic, eddy current, etc., should be evaluated for their potential. Finally, newer inspection devices like acoustic emission should not be overlooked for their potential to detect flaws not revealed by the conventional methods.

CONCLUSIONS AND RECOMMENDATIONS

Design

The basic design principles to be followed by industries including aerospace and biomedical, are established, understood, and generally accepted. Examples of failures to adhere to these principles are also common to all industries, and aerospace has had its share of improper designs leading to early failures caused for example, by improper attention to stress concentrations (edge distance from holes, bend radii, sharp corners, engraved markings, etc.). This bad experience in NASA and the aerospace industry has led to a number of corrective measures such as a more deliberate, interdisciplinary review of designs before drawing release supplemented by special analyses or tests where required.

Although "paper requirements" won't improve part design quality, per se, the establishment of design requirements based on service experience, tests, analyses will help insure that bad experiences will not be repeated in the industry or within an organization. For example, the designer often expects that higher material strengths yield stronger parts; an example of the fallacy of this notion in high strength steels is illustrated schematically in Figure 13 where the higher strength conditions are more susceptible to notches than the lower strength levels. Providing cautions like this to the designer can be a valuable input that can only come from proper communication of good information.

Table 8

Effect of Notch Acuity on StressConcentration Factor(All other notch variables constant)

<u>Notch Radius</u>	<u>K_T</u>
.001"	17
.004"	9.4
.007"	7.3
.025"	4.1
.050"	3.1

Certainly, the orthopedic implant industry is not the only one plagued with design and manufacturing problems like tool marks or engraved identification stamps that have initiated failure. Current statements in specifications that these marks should be located in low stress regions are only useful if a stress analysis exists and the low stress region is so identified on the drawing. Many people show the frustration expressed by Hughes and Jordan (Ref. 38):

"The failure of the titanium upper femoral replacement was undoubtedly due to the loads imposed by a fall. However, it is incredible that the identifying 'T' should have been spark etched at a position of maximum stress. Titanium implants have been seen to be susceptible to sharp notches and BS3531: 1962 specifically advises that identifying marks should be made at a site of minimal stress. "

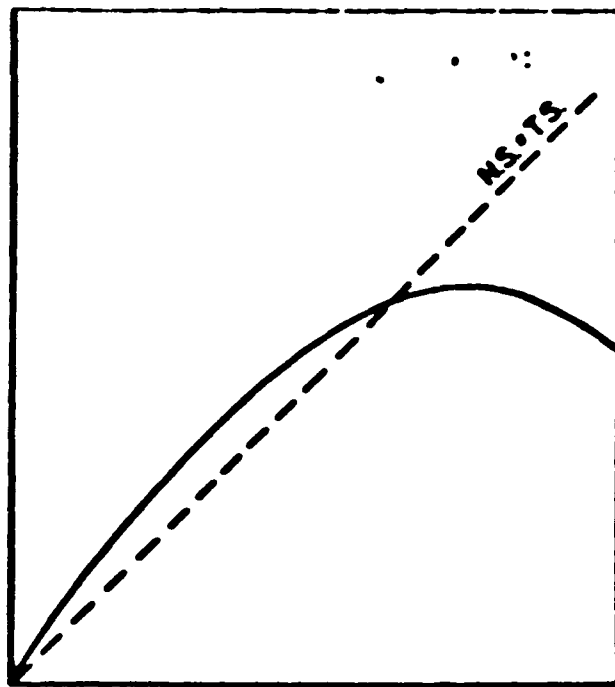
and by Cahoon and Paxton (Ref. 39):

"The violation of elementary design principles of implants such as the presence of sharp corners, insufficient metal between screw holes and plate edges, and screw holes in fixation plates too close to the bone fracture have caused failures of the implants. These violations must be avoided. "

A simple example of the effects of holes on stress concentration is shown in Figure 14 for a hole in an infinite plate; a crack growing from a fastener hole is acted on by a very high stress level; see Table 8 for the effect of notch acuity on stress concentration factor. For these reasons, NASA has chosen to establish rigorous controls over design practices and design review systems. Whether or not these practices and systematic reviews are useful or needed in the orthopedic implant industry is best answered by the industry, participating technical societies, and involved Government agencies.

From another view, this limited study did not uncover any structural design criteria that are used consistently within the industry for metallic implants. Without some degree of uniformity, it is difficult to see how a level of performance of an implant design can be expected if different materials and strength levels are used resulting in a different percentage of operating stress level to ultimate or fatigue limit and therefore likely, large variations in fatigue life. By consistent use of a static factor-of-safety for example, or a specified endurance strength combined with

NOTCH
TENSILE
STRENGTH



SMOOTH TENSILE STRENGTH

FIGURE 13

SCHEMATIC OF RELATIONSHIP OF NOTCH/UNNOTCH
PROPERTIES FOR HIGH STRENGTH STEEL
(REF. 47.)

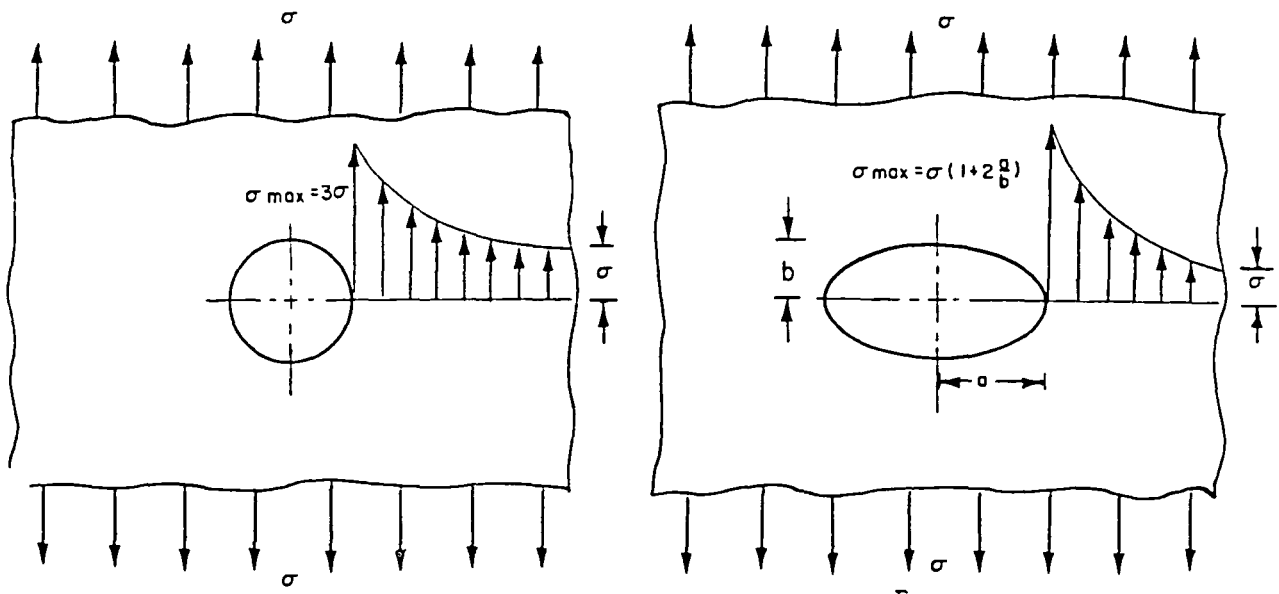


FIGURE 14

ILLUSTRATION OF EFFECT OF HOLES
ON STRESS LEVEL

a load scatter factor for an application, the manufacturer can modify design, change materials, etc., and yet the customers can expect some consistent performance, all other variables constant.

There appear to be adequate mechanisms and organizations to develop such criteria for specific designs like bone plates or hip prostheses. In addition to ASTM, an industry group, OSMA (Orthopedic Surgical Manufacturers Association), the conferences arranged by NBS, and the Bureau of Medical Devices, FDA, offer forums to develop criteria in much the same way NASA developed the Space Vehicle Design Criteria series, using Government and industry representatives working together to arrive at mutually satisfactory, technically sound criteria. The competition within the orthopedic industry should not be damaged any more than was Boeing's working with Lockheed, working with McDonnell-Douglas, Grumman, General Dynamics, Bell Aerospace, and Rockwell in developing NASA's criteria. There are ways to develop understandings for mutual industry benefit without sacrificing company position in the industry.

The data base from which to build these criteria is largely empirical, but at least it is extensive. Such groundwork provides a definite insight into areas where productive improvements can be made.

As cited earlier by one reference, the need to develop knowledge from what has worked is likely to be more important than to examine what has failed.

Therefore, the recommendation for design consideration is to use aerospace design criteria documents as models on which to develop mutually agreeable criteria for a device or class of devices in orthopedic implants. Examination of fatigue life, static strength, strain-to-failure, or other appropriate criteria based on existing, successful applications provides a benchmark for future work. It is recognized that this will require cooperation within the industry, additional analysis, and much coordination before a usable document can be finalized but aerospace experience has shown the worth of the effort.

Materials

The limited number of alloy compositions approved for use in orthopedic implants should indicate that the characteristics and control of the important material parameters is a reasonable task. Indeed, much impressive work on corrosion behavior, biocompatibility, and to some extent, effects of manufacturing processes on properties has been published. As a comparison, MIL-HDBK-5 reports design data on about 50 alloys (many strength levels) representing hundreds of thousands of test points that have been statistically analyzed for use by the aerospace industry. As was pointed out, the use of these data is not a matter of choice for the Space Shuttle contractors but is required or properties of equal statistical validity are required.

It would seem to be very beneficial to assimilate the available data on orthopedic alloys into a handbook that establishes the mechanical data from the ASTM specifications as well as data illustrating the fatigue life (S-N curves, Goodman diagrams, etc.), environmental effects (simulated body fluids), and effects of notches of various acuties on mechanical strength. As fracture toughness data and cyclic flaw growth rate data are developed for these alloys, this information should also be incorporated into the materials guide. Corrosion and data on galvanic series compatibility are also of general interest to the industry.

Another recommendation is to initiate a well-designed test program using a single laboratory and common test specimen designs, test procedures and data analysis methods to evaluate the behavior of these alloys and various strength levels without introducing the data scatter that undoubtedly exists because of the experimental variations from laboratory-to-laboratory. Additionally, environmental effects on mechanical strength and fatigue properties should be developed along with fracture characteristics.

In addition to aerospace precedents for this type of joint activity, one can look to the American Petroleum Institute, Electric Power Research Institute, and other organizations who have collectively supported test activities of this type to provide upgrading in the data bases for the mutual benefit of the industry at large.

Analysis

It is not possible to properly assess the rigor of the analytical steps used in the implant industry because very little is described in the literature and even less was available from the limited industry contact. It is fair to say, based on discussions, that there is an underlying confidence in experiment and empiricism as the basis of design. It is also fair to say that stress analysis and math modeling is the cornerstone of design verification and approval in the aerospace industry so that there appears to be a significant difference of approach in this technical area.

The use of fracture mechanics analysis in aerospace to establish safe life of critical components is correctly limited to only that criticality of hardware that requires it. It is to be determined by others in the implant industry if the cost and time required to develop the needed data base and load spectra data warrant the use of these approaches. As one industry representative stated, the development of a metal implant that doesn't fail may drive the fatigue mode to the bone itself which may be a more catastrophic failure location. The conclusion of this study is that there is no inherent obstacle to the use of this method if the industry or the regulatory bodies feel it is desirable. In any event, the use of standardized fracture mechanics data to evaluate alloys, advances in strengthening mechanisms, effects of

environments, effects of load spectra could represent a significant improvement over the "single-point data" often reported in the implant literature involving a wide range of test techniques, test environments, and data analyses.

The recommendation is for additional work in developing stress analysis models to be verified by experiment and/or use data to support life calculations, develop static margins-of-safety, etc. In addition, the use of fracture mechanics analyses can provide additional lifetime information using a large, available technology and should be evaluated.

Inspection and Approval

The last point of control in the manufacture of a prosthesis is the inspection process. Adequate inspection is implied in the design, analysis, and materials phases of production of each article. The dimensions and surface finish, the microstructure, the strength and toughness, the non-existence of critical cracks all must be assured in order for the actual performance of each product to match its intended performance. Thus it is vital that all elements of the production sequence participate in the development and operation of the inspection criteria and procedures.

Because of the vital role of inspection to product quality, the same remarks made above concerning product uniformity from manufacturer to manufacturer apply to the inspection process. No set of inspection criteria could be found within the implant industry. Although certain manufacturers are known to be using inspection methods which go beyond the two published ASTM standards, it appears certain that manufacturers exist which do not approach inspection with the rigor required by MIL-I-6870C. Thus it is suggested that one of the forums mentioned above (OSMA, FDA, NBS) develop an industry-wide inspection specification which would insure that:

- (1) All key elements in the design, development, manufacture, and certification of each device participate in the final inspection requirements.

(2) Critical components and high stress regions requiring special attention are identified.

(3) Capabilities and limitations of inspection are adequately fed back into the design and analysis parts of the organization.

(4) The best and most appropriate inspection techniques are being used.

Such a specification if used uniformly throughout the industry would go a long way toward providing uniformity of product capabilities from manufacturer to manufacturer.

The final test of any device is its performance. From this standpoint failure analyses and retrieval analyses serve a valuable function to all elements from the patient and surgeon back to the original designer. This is apparently recognized because every manufacturer questioned is performing failure analyses, ASTM has developed a device retrieval standard (F561) as have a number of other organizations (cf. NBS Special Publication 601, for example). Such efforts tend to pinpoint problems sometimes with embarrassing clarity. For example, the following quotation was taken from a survey done at Stanford University (Ref. 45):

" A second surgeon operated on 12 of the 13 joints which became loose on a delayed basis and one of the two which was initially loose. "

This clearly indicates where one should focus his attention to reduce the incidence of loosening. Similarly with new designs and processes being introduced and with manufacturers

continually changing their products the potential always exists for an undetected problem to occur. The only way to spot such problems often is by means of performance analyses on the final product. Therefore, it is recommended that an industry-wide retrieval analysis be considered as a means of obtaining performance data as rapidly and as inexpensively as possible to be continually fed back into the device development cycle.

It is also recommended that flaws of known character be developed and used as standards to appraise the inspection methods being used or considered for use. The optimum location in the production sequence for dye penetrant inspection should be established by experiment. Methods of NDT not currently in use should be considered for potential application where x-radiography and dye-penetrant are not satisfactory. Acoustic emission combined with proof testing is recommended as a possibly useful NDT method for critical part inspection.

SUMMARY OF
RECOMMENDATIONS

- o Through ASTM or other appropriate organizations, continue to develop test methods and material allowables on orthopedic implant alloys under simulated use conditions. Both static and cyclic data will be needed to support designs and analyses.
- o By examining the existing implant use data base, develop general design factors and good practices to serve as aids for improving devices through meaningful engineering comparisons of hardware.
- o Continue to evaluate the use of analytical approaches such as finite element analysis and fracture mechanics analysis to develop analytical models for future improvements.
- o Continue to evaluate new inspection and flaw detection methods to improve raw material and part quality as an input to fracture mechanics analyses and as a means of improving reliability and performance.

ACKNOWLEDGEMENTS

The following organizations are acknowledged for providing information and help during the conduct of this study:

Bureau of Medical Devices, Food and Drug Administration
National Aeronautics and Space Administration

NASA - Johnson Space Center
NASA - Langley Research Center
NASA - Lewis Research Center

Zimmer - USA
Dow Corning - Wright Mfg. Co.
Richards Manufacturing Co.
Case Western Reserve
University of Florida
NET Systems, Inc.
Battelle - Northwest
Dr. Lynn Pearson

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APPENDIX A

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DAMAGE TOLERANCE DESIGN AND ANALYSIS OF A TYPICAL AIRCRAFT WING STRUCTURE (NEW OR EXISTING)

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HISTORICAL BACKGROUND

Damage tolerance design has become a necessity in the design of modern aircraft although its importance was recognized as long as four centuries ago. Around the end of the fifteenth century the first technical notes were written on what must have been the first requirements for damage tolerant design. These were in notebooks of Leonardo da Vinci in which he discussed the physics of flight and the design of flying machines. He wrote:

"In constructing wings one should make one cord to bear the strain and a looser one in the same position so that if the one breaks under strain the other is in position to serve the same function."

About two decades ago (1954), after the disastrous failure [1] of Comet aircraft in the air near Italy, structural design engineers and research workers saw the need of applying damage tolerance concepts to the design of aircraft structure. The United States Civil Aeronautics Board has defined the damage tolerant structure as one in which:

"Catastrophic failure or excessive structural deformation, which could adversely affect the flight characteristics of the airplane, are not probable after damage or obvious partial damage of a single principal structural element."

In 1969, after the F-111 failures [2], the United States Air Force initiated the Air Force Structural Integrity Program with the coordination of the Aerospace Industry Association (AIA). Damage tolerance structure (structural safety and durability) is described in MIL-STD-1530A [3] and associated Military Specifications [4, 5]. The basic criterion is:

"The assurance that safety of flight structure of each aircraft will achieve and maintain a specified residual strength level throughout the anticipated service life. Further assurance that the fleet can operate effectively with a minimum of structural maintenance, inspection and downtime, etc."

However, the essence of damage tolerance design is to ensure that the structure will continue to sustain a high proportion of its design load even after damage has occurred. The basic philosophy of damage tolerant design is based on:

- 1 The acceptance that damage will occur for one reason or another despite all precautions taken
- 2 An adequate system of inspection prescribed so that the damage (cracks) may be detected and repairs made at a proper time.
- 3 An adequate residual strength maintained in the damaged structure so that, during the period between inspections when the damage is undetected, ultimate failure of the structure is not possible.

In the early fifties, due to a lack of comprehensive damage tolerance methodology, large-scale component test results were used to develop empirical damage tolerance methods. Although in 1913 Inglis [6] attempted the elastic stress analysis of cracks in an infinite plate under various degrees of biaxial tension, it is only recently [7] that linear elastic fracture mechanics (LEFM) has been used to predict residual strength and crack growth rates in damaged structure.

The objective of this study case is a systematic investigation of the damage tolerance design capability (residual strength and crack growth) of a typical aircraft wing structure (new or existing) using linear elastic fracture mechanics. The assumptions made and the limitations applied are discussed in detail at each step of the development and analysis of the case study. A specific example in this case study is to establish inspection intervals for a typical aircraft wing structure lower surface rear span cap.

TECHNICAL BACKGROUND

A first approach toward minimizing the risk of catastrophic or rapid fracture in structures is to use materials with as high a fracture toughness as possible. This should be consistent with strength, environment, etc., involved in the specific application. In aircraft structures, weight-to-strength ratio is the most pertinent factor. Usually, weight considerations dictate relatively high stress levels so that the fracture toughness available is limited even on a very carefully selected material. Hence a trade-off is required and generally materials are used at lower than maximum strength. This results in a weight sacrifice.

Another way to ensure damage tolerant design is to employ ingenious design innovations rather than material specifications. In general, in a damage tolerant design concept the following points must be considered skillfully:

- a Material selection or control (material should be as flaw tolerant as possible).
- b Design concepts (multiple load paths).
- c Stress level selection and control (fatigue cracks should not propagate rapidly during the service life).

- d Inspection procedures - cracks must be detected prior to any impairment of the load carrying capacity of the structure.
- e Process control - control during manufacturing and processing to ensure that the initial flaws are small and the basic fracture properties are not impaired by manufacturing processing.
- f Environment effect - resistance to stress corrosion cracking must be evaluated and controlled.
- g Fracture toughness control - variation of fracture toughness and other associated parameters within the heat-treatment range must be thoroughly characterized.
- h Static and fatigue design allowables must be evaluated carefully.

STRESS INTENSITY FACTOR

The basic development of linear elastic fracture mechanics is well documented [8 - 14]. However, in order to systematically use fracture mechanics in the design and analysis of a structure, the stress intensity factor K and the influence of various parameters on it must be completely understood as the cracking rate is dependent upon it. The stress intensity factor K in the ideal case of an infinite plate containing a central straight crack of length $2a$ and subjected to plane stress σ acting uniformly and perpendicularly to the crack is expressed as:

$$K = \sigma \sqrt{\pi a} \tag{1}$$

where

K is the stress intensity factor (KSI $\sqrt{\text{IN}}$)

σ is the remote stress (KSI)

a is the half crack length (in)

THICKNESS EFFECT

The critical stress intensity factor is very much dependent on material thickness B . In real structure there is a large variation in thickness at various sections, therefore variation of K_C with thickness must be evaluated. Figure 1 displays the variation of K_C versus B for 7075-T6511. There are three distinct regions which exhibit three characteristic type of failure modes, namely, plane stress, mixed mode and plane strain. This curve is devel-

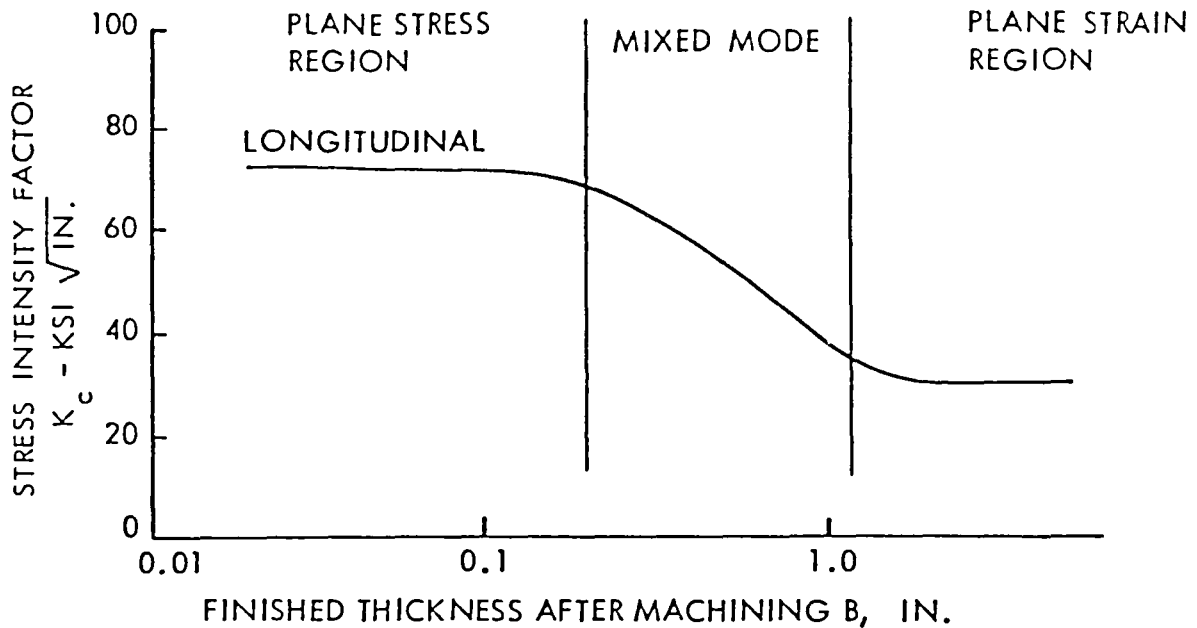


FIG. 1 STRESS INTENSITY FACTOR AS A FUNCTION OF THICKNESS FOR 7075-T6511 EXTRUSION

oped using a limited number of test specimens. The right hand side of the curve can be accurately established using the ASTM standard E-399 specimen, but currently there is no standard specimen for the mixed mode and plane stress regions.

PLASTICITY EFFECT

As discussed previously, linear elastic fracture mechanics is based on linear elasticity. Virtually all materials exhibit some ability to deform plastically without fracture. If the size of the plastic zone around the crack tip is very much smaller than all other significant dimensions of the structure and the crack length, the value of K elastically calculated is not very much changed. However, when the plastic zone becomes larger, as in a relatively ductile material, the value of K becomes questionable, and the effects of plasticity can be formulated as follows:

$$r_p = \frac{1}{2\pi} \left(\frac{K}{\sigma_y} \right)^2 \quad \text{for plane stress} \quad (2a)$$

$$r_p = \frac{1}{4\sqrt{2}\pi} \left(\frac{K}{\sigma_y} \right)^2 \quad \text{for plane strain} \quad (2b)$$

where r_p is the plastic zone radius at the tip of the crack, K is the fracture toughness stress intensity factor, σ_y is the material yield stress.

CRACK GROWTH EQUATION

The use of the concept of fracture mechanics in the design and analysis of structure assumes the existence of initial flaws or cracks. These cracks under repeated service loading conditions propagate and become unstable (fast fracture) when critical length is attained. The rate of crack propagation depends on many factors, such as material, environment, service load spectrum, crack geometry and local structural configuration. It is shown [16] that for a particular material the crack growth rate (da/dN) can be described as a function of stress intensity range ΔK as shown in Fig. 2. At present, there are large numbers of crack growth equations. The Forman crack growth equation [17], given below will be used in the present case study

$$da/dN = \frac{c (\Delta K)^n}{(1 - R) K_f - \Delta K} \quad (3)$$

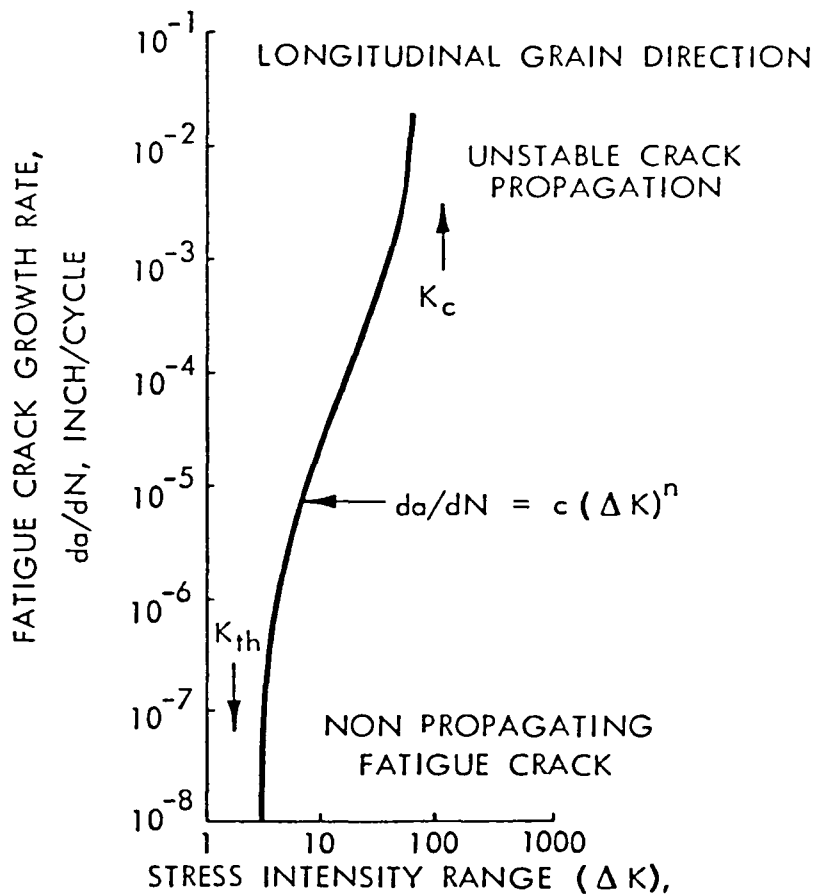


FIG. 2 CRACK GROWTH RATE AS A FUNCTION OF STRESS INTENSITY FACTOR RANGE FOR 7075-T6511 EXTRUSION

where, da/dN is the rate of crack growth, c and n are material constants, ΔK is the stress intensity range, R is the stress ratio defined as minimum stress divided by maximum stress and K_f is a critical stress intensity factor. The stress intensity range $\Delta K = \Delta\sigma\sqrt{\pi a} \cdot \beta_T$ where $\Delta\sigma$ is the stress range, a is the crack length and β_T is the product of various boundary condition correction factors.

The value of c and n (material constants) in Eq. 3 can be calculated from constant amplitude test data by applying the following rectification technique to the Forman equation

$$\log \left\{ (1 - R) K_f - \Delta K \right\} + \log \left(\frac{da}{dN} \right) = \log c + n \log \Delta K. \quad (4)$$

For any two coordinate points, say $\Delta K_i, (da/dN)_i$ and $\Delta K_{(i+1)}, da/dN_{(i+1)}$, which represent a segment of the crack growth rate curve, one can solve two simultaneous equations for c and n .

LOAD INTERACTION

The crack growth analysis under constant amplitude cycling is fairly straightforward. On in-service structure the load conditions are quite complex. High and low loads are mixed. Therefore, to calculate the crack growth the load interaction must be taken into account. There are quite a few load interaction or retardation models to account for the load sequence effects. In this case study, only the Willenborg model [18] will be discussed and used. A peak load in the spectrum creates a plastic zone ahead of the crack tip. This plastic zone can cause retardation in the crack growth because there are compressive stresses in the plastic zone caused by tension stresses in the surrounding elastic material. In other words, the crack is operating at an effectively smaller alternating stress until the crack grows through the peak stress plastic zone.

The Willenborg retardation model accounts for the retardation effects by modifying the stress intensity range ΔK and the stress ratio R in the constant amplitude da/dN data to an effective stress intensity range ΔK_{eff} and an effective stress ratio R_{eff} . The effective stress intensity range and stress ratio are calculated as a function of the size and location of the current yield zone and the yield zone produced by the peak load. After the application of a peak overload the plastic zone can be calculated using Eq. 2a or 2b. If a peak stress σ_1 is encountered in the spectrum followed by another stress cycle σ_2 such that $\sigma_2 \ll \sigma_1$, the peak stress σ_1 will produce a plastic zone ahead of the crack tip.

Following the overload, the crack will continue to grow under a cyclic loading $\Delta\sigma_2 = \sigma_{2Max} - \sigma_{2Min}$. The growth rate, however, is delayed as long as no subsequent maximum stress greater than σ_1 is applied and as long as the growth remains within the zone of plasticity caused by the overload σ_1 . Assume that a third stress level $\sigma_3 = \sigma_{ap}$ (less than σ_1) occurs following the last cycle of σ_2 and that growth has not completely progressed

through the yield zone caused by the first overload. The retardation will be terminated when the value of applied stress is large enough compared to the first overload ($\sigma_{ap} < \sigma_1$) and the current crack length is of such an extent that the following condition exists.

$$a_c + r_{yap} = a_{p1} \quad (5)$$

where r_{yap} is the yield zone caused by σ_{ap} at current crack length, a_c . Using Eq. 2 for plane stress, the applied stress required to reach a_{p1} can be calculated as:

$$r_{yap} = \frac{1}{2\pi} \left(\frac{K_{ap}}{\sigma_y} \right)^2 = \frac{1}{2} \left(\frac{\sigma_{ap}}{\sigma_y} \right)^2 a_c$$

or

$$\sigma_{ap} = \sigma_y \sqrt{\frac{2 r_{yap}}{a_c}}$$

now inserting the value of r_{yap} from Eq 5 in the above equation, we get:

$$\sigma_{ap} = \sigma_y \sqrt{\frac{2(a_{p1} - a_c)}{a_c}} \quad (6)$$

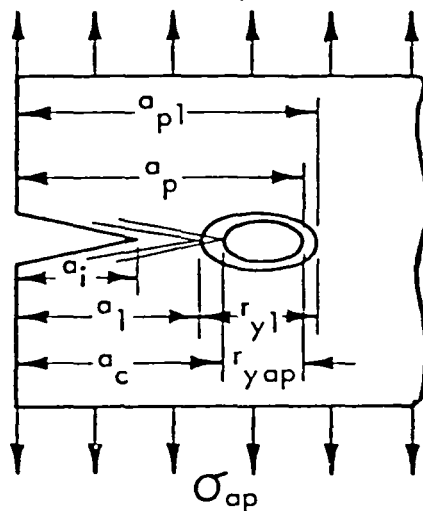


FIG. 3 YIELD ZONES FOLLOWING OVERLOAD σ_1 FOR ANY APPLIED STRESS σ_{ap}

σ_{ap} may be thought of as the effective portion of σ_1 remaining following the application of σ_1 . As retardation is a function of the differences in applied stresses, the amount that σ_2 is reduced is the difference $\sigma_{ap} - \sigma_2$ (Max) at any crack length, i.e.,

$$\sigma_{red} = \sigma_{ap} - \sigma_2 \text{ (Max)} \quad (7)$$

The effective reduced stress is dependent on σ_2 and variable with current crack length. Thus, following the overload, σ_2 (Max), σ_2 (Min) are reduced by the amount σ_{red} . These values are used to compute the reduced crack growth rate.

The limitations of this model are:

- 1 It does not take into account the negative stresses (compression stresses).
- 2 It cannot handle the negative overload effects.
- 3 It does not differentiate between single or multiple overloads.

DESIGN

For an efficient damage tolerant design structure, the designer must select a material as a compromise with strength and weight. Ideally, a material with high yield strength and high fracture toughness is desired. However, in reality this is not possible, as it is generally known [19] that fracture toughness K_{Ic} decreases with increasing yield strength for aluminum and many other materials. This variation is in part due to the inherent characteristics of impurities associated with the manufacturing processes of the material.

Another important parameter in the design of a structure is the establishment of an acceptable operating stress level so that critical length cracks do not occur for a specified number of flight hours. Generally, for 7000 series aluminum aircraft wing structure, the designer chooses 50 to 65 percent of the yield strength of the material as a design limit stress.

Using linear elastic fracture mechanics, and the available nondestructive inspection (NDI) capability for detecting flaws the designer can screen for the suitability of a particular material. Using the criterion that the structure will be inspected and crack lengths must be stable up to limit load stress and neglecting plasticity effects, the following relationship can be established between applied stress and critical crack length.

$$\sigma = \frac{K}{\sqrt{\pi a}} \quad \text{for very wide plate}$$

$$a_c = \frac{1}{\pi} \left(\frac{K_c}{.5\sigma_y} \right)^2 \quad (8)$$

Comparing the critical crack length a_c to the crack detection capabilities of the NDI techniques available for a particular design, the material can be accepted or rejected, i e., if the crack becomes critical before it can be detected, another material will need to be selected, stress levels lowered, or design for the "non-inspectable category" as defined in MIL 83444 [4].

ANALYSIS PROCEDURE

The analysis of crack propagation requires a working knowledge of the stress intensity factor and the various other parameters in influencing it. Therefore, it is appropriate at this stage to discuss the "boundary condition" correction factors needed in the case study to modify the stress intensity factor. The majority of cracks in a typical wing structure emanate from fastener holes as corner cracks, where the influence of the hole and the fastener load transfer become important. There are no exact classical solutions for load transfer effect on the crack growth, however through recent application of detailed finite element models excellent two-dimensional approximations of load transfer correction factors have been derived. Assuming no load transfer, the modified stress intensity factor for a quarter circular corner crack emanating from the fastener hole can be written as follows:

$$K = \sigma \sqrt{\pi a} \cdot \beta_f \cdot \beta_b \cdot \beta_h \cdot \beta_w \cdot \frac{M}{\phi} \quad (9)$$

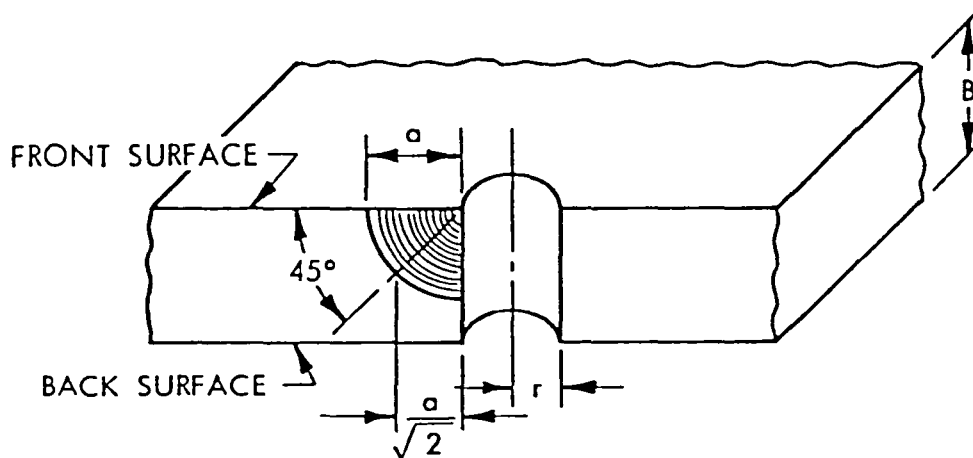


FIG. 4 CIRCULAR CORNER CRACK AT THE FASTENER HOLE

where β_f is the front surface (the free surface coincident with the initiation location of the crack) correction factor. This factor is [20] 1.12. β_b is a factor accounting the influence of the back surface [21] of the panel on a part-through corner crack. β_h accounts for the influence of hole and is a function of a/r where a is the crack length and r is the radius of the hole. β_h may be modified to account for the influence of a fastener filled hole and load transfer. For a corner crack emanating from the fastener hole, crack growth predictions are more correct if β_b is considered a function of $a/\sqrt{2r}$, where $1/\sqrt{2}$ comes from the location of a point at 45° on the quarter circular corner crack [22].

β_p and β_w are the plasticity and width correction factors given by [23] and [24], respectively.

$$M = \left[(a/c)^2 \sin^2 \theta + \cos^2 \theta \right]$$

where c is the visible crack length and θ is the angle locating a specific point on the crack front with respect to the axis of symmetry. For a quarter circle crack, $M = 1$.

$$\phi = \int_0^{\pi/2} \left[1 - \left(\frac{c^2 - a^2}{c^2} \right) \sin^2 \theta \right]^{\frac{1}{2}} d\theta = \pi/2 \text{ for } a = c$$

Assuming a wide panel where finite width correction is not necessary and considering the plasticity effect minimum so that this correction can also be ignored, by using the quoted values of β_f and M/ϕ , Eq. 9 for a quarter circular crack becomes:

$$\begin{aligned} K &= \sigma \sqrt{\pi a} \cdot 1.12 \beta_b \beta_h \cdot 2/\pi \\ &= .712 \sigma \sqrt{\pi a} \beta_b \cdot \beta_h \end{aligned} \quad (10)$$

Further geometric correction factors needed for a specific problem are given in the next section.

CRACK GROWTH ANALYSIS

The damage tolerant design of an aircraft wing structure requires a reliable method of predicting the crack growth from some defined initial crack length to the size where unstable crack growth is imminent. In order to perform the crack growth analysis using linear elastic fracture mechanics, the following information is required.

- 1 Structural geometry
- 2 Crack geometry
- 3 Spectrum stresses
- 4 Material crack growth and crack stability data
- 5 Initial crack size

The accuracy of the crack growth predictions depends upon accurate da/dN versus ΔK data and the modified stress intensity factors discussed previously. da/dN versus ΔK for a typical material is shown in Figure 2. It can be observed that the log-log curve has three characteristic regions; lower, middle, and upper. The lower region corresponds to the limiting stress intensity factor value K_{th} , known as the threshold stress intensity factor, below which value crack growth does not seem to propagate for that particular material. The middle region of the curve corresponds to the stable crack growth region, where the rate of the crack growth seems to be linear. The upper region is near to the unstable crack growth point and the limiting value is the critical intensity factor K_c .

The stress ratio R and the environment have a significant effect on this curve. In addition the scatter in the basic crack growth data must be taken into account by repeating a realistic number of tests. The initial test crack length should be within the nondestructive inspection (NDI) capability [25]

For analysis the number of cycles or flight hours required for growth of the initial flaw to critical dimensions are calculated by a process of integration using Eq. 3. The stress intensity range ΔK corresponding to the initial crack length a_i and crack geometry is calculated using Eq. 9, assuming that the crack starts from the fastener hole. This value of stress intensity range ΔK is used with constant amplitude laboratory test data to determine the crack growth rate, da/dN . The crack extension increment Δa_i during a period, ΔN , can be calculated by integrating Eq. 3. This value of crack extension Δa_i is added to the initial crack length a_i to determine the new stress intensity range and a new crack growth rate. Eq. 3 is again used for another period to give further crack extension and iteration process is repeated until the critical crack length is achieved.

In order to take into account the retardation effect discussed previously, the stress intensity range and R value must be modified using Eq. 7, and the same iteration process applied.

DAMAGE TOLERANCE DESIGN CRITERIA

Fracture mechanics analysis is carried out on two types of structures: (1) new design and (2) existing structure. These currently have different criteria. On existing structure, analysis is carried out to determine inspection requirements, or safe operating life, while

analysis of new design is carried out to meet a specific set of criteria

General requirements and detail criteria are defined in Refs [3 - 5] for both types of structures. The example problem described in this case study consists of existing structure operating under a defined spectrum. The pertinent features of the criteria applicable to existing structure are:

- a What locations should be analyzed? The locations are chosen by reviewing test article failures, particularly the fatigue test articles. If no test article information is available, the analysis points must be selected by using static and/or fatigue analysis, by study of service or fatigue failures on similar structures, or by examination of drawings.
- b What size flaws should be assumed in the analysis? The size and configuration of the initial flaw is a very pertinent parameter in the fracture analysis. Some rationale, analytical or arbitrary must be used to select an initial flaw size and shape. A great deal of guidance, particularly for military aircraft, can be found in [4] where the size and configuration of the initial flaws are specified as a function of the category/slow crack growth, fail-safe multi-element, or fail-safe crack arrest). For example, in the "slow crack growth category," the specified initial flaw in a hole is an .05 inch crack. For thickness greater than .05 inch, the assumed flaw is a .05 inch radius corner flaw, and for thickness less than or equal to .05 inch, the flaw is a .05 inch through-the-thickness flaw. Various other flaw sizes are similarly defined. The criteria allows reduction of the assumed initial flaw by taking into account special fastener and inspection procedures. The criteria also differentiates between the assumed initial flaw and the detectable flaw. An assumed initial flaw, a_i , or equivalent initial flaw, is the result of manufacturing and fabrication processes and a regression analysis of test results. The detectable flaw, a_{det} , is a flaw that a particular inspection technique can be expected to detect. The time to the first inspection is calculated using the assumed initial flaw established by specification or by agreement while the second and the subsequent inspection intervals are determined using the detectable flaw, a_{det} , corresponding to the applicable NDI inspection technique.

In the example problem shown later the assumed initial flaw is an .001 in radius corner flaw in a hole. In this instance, the small flaw is chosen just to generate the crack growth curve over the small flaw range and does not represent a realistic initial flaw for establishment of the inspection interval.

- c What maximum load level will crack instability be checked against? The maximum expected load level may or may not be in the crack growth spectrum. If crack arrest due to peak loads (retardation) is considered, it can be unconservative to include maximum expected peak loads or limit load, since the peak loads may not actually occur on a specific airplane. MIL-A-83444 [4] defines the load levels for which crack instability must be analyzed. The maximum expected load level

is defined as a function of "degree of inspectability and inspection interval," i.e., the shorter the inspection the less likely a limit load will be encountered during the interval.

In the example problem, limit load is used to determine the first (initial), the second and subsequent inspection intervals.

- d Crack metamorphosis? Since there is a large number of possible crack growth paths, the most critical (fastest growing) should be analyzed. Test data and/or finite element models and analysis must be used to determine the most critical crack path. As expected, cracks start at peak stress points and propagate in a direction perpendicular to the maximum principal stress. MIL-A-83444 lends significant guidance on determining crack path through specific requirements on continuing damage.
- e What safety factors, and/or test will be used to verify accuracy analysis? Obviously, safety factors and verification level are related. If a high level of confidence can be established in the analysis technique, a lower safety factor can be used than if a low or questionable level of verification exist.

Safety factors should also be related to inspection technique; for example, if a complex NDI inspection technique is required to detect relatively small flaws, a higher safety factor should be used than if a simple NDI technique is used to detect large flaws. Crack growth rate is more accurately predicted if load sequencing effect (retardation) is accounted for in the analysis; however, some form of spectrum test should be performed to verify the ability of the retardation model to predict the crack behavior. In the example problem a safety factor of 2 is used on the inspection intervals.

EXAMPLE APPLICATION

The example given below displays the use of fracture mechanics in analyzing an existing structural element. The crack growth analysis procedure is equally applicable to new or existing structure. The only difference is the damage tolerant design criteria which is briefly discussed in the last section.

EXAMPLE: Using fracture mechanics procedures described in the previous sections, perform residual strength and crack growth analysis for the given existing structural element of a front beam cap on the lower surface of a typical aircraft wing. The analysis will consist of deriving stability curves (critical stress σ_{cr} versus critical crack length a_{cr}) and growth curves (crack length versus flight hours). Using the stability curves, establish critical crack lengths for limit load stress (33 KSI) and establish the flight hours associated with crack lengths at this stress.

- Structural element. As shown in Figure 5, the grain directions are perpendicular to crack and parallel to load direction
- Material: 7075-T6511 extrusion
Yield stress = 70 KSI
Fracture toughness K_{Ic} for .2 inch thickness from Figure 1 is equal to $64 \text{ KSI} \sqrt{\text{in}}$
Plain strain fracture toughness K_{Ic} from Figure 1 = $23.0 \text{ KSI} \sqrt{\text{in}}$
 da/dN versus ΔK is given in Figure 2, constant amplitude data for $R = 0$
- Spectrum Stresses: Shown in Table I, adjusted to represent stresses perpendicular to crack growth and the sequence of missions is shown in Table III.

Assume four phases of crack growth analysis, start with Phase I part-through quarter circular corner crack from the wall of the hole and terminating at the back surface of the element. For Phase II, the initial crack is a 0.2 inch single edge through crack from the edge of the hole and terminating at the edge of the element. Initial crack length for Phase III is a 0.005 part-through quarter circular corner crack from the second wall of the hole and terminating at the back surface of the element. The beginning crack length for Phase IV is 1.356 inch edge crack which is composed of edge distance, hole diameter and the element thickness.

SOLUTIONS

Crack configurations and stress intensity factors for each phase are given below, using Eq. 8 with appropriate geometric correction factors:

Phase I Quarter circular, part-through corner crack from the edge of a hole of initial crack length $a_i = .001$ inch.

$$K = .712 \sigma \sqrt{\pi a} \cdot \beta_b \cdot \beta_h \cdot \beta_{sg}$$

Phase II Through single crack from the edge of a hole - initial crack length for this phase is .2 inch equal to the thickness of the part, $a_i = .2$ inch.

$$K = \sigma \sqrt{\pi a} \cdot \beta_h \cdot \beta_{sg} \cdot \beta_w$$

Phase III Quarter circular, part-through corner crack from the opposite edge of the hole wall of initial length $a_i = .005$ inch.

$$K = .712 \sigma \sqrt{\pi a} \cdot \beta_b \cdot \beta_s \cdot \beta_{sg}$$

Phase IV An equivalent edge crack of initial crack length of $a_i = 1.356$ inch.

$$K = \sigma \sqrt{\pi a} \cdot \beta_s \cdot \beta_{sg}$$

TABLE I CRACK GROWTH SPECTRUM

	MAX STRESS KSI	MIN STRESS KSI	CYCLES FLIGHT		MAX STRESS KSI	MIN STRESS KSI	CYCLES FLIGHT		MAX STRESS KSI	MIN STRESS KSI	CYCLES FLIGHT
MIS 0	20 327	-3 949	1 00	MIS 7	16 302	-1 630	1 00	MIS 11	8 758	000	1 00
MIS 1	9 974	- 997	1 00		9 282	7 282	335 00		5 373	3 373	1032 00
	4,816	2 816	219 00		10 294	6 294	72 00		6 626	2 626	155 00
	6 002	2 002	29 00		11 282	5 282	16 00		7 769	1 769	26 00
	7 057	1 057	4 00		12 236	4 236	4 00		8 758	758	5 00
	8 224	- 129	1 00		13 827	2 452	1 00		10 889	-1 257	1 00
	9 974	-2 214	10		16 302	- 342	10		13 828	-3 994	10
MIS 2	11 586	-1 159	1 00	MIS 9	18 717	-1 872	1 00	MIS 12	7 697	-1 367	1 00
	6 049	4 049	293 00		10 424	8 424	478 00		7 697	000	1 00
	7 359	3 359	40 00		11 731	7 731	107 00		7 697	000	1 00
	8 345	2 345	6 00		12 742	6 742	25 00		7 697	000	1 00
	9 726	885	1 00		13 751	5 751	6 00		13 605	-1 367	1 00
	11 586	-1 314	10		14 699	4 699	1 00		8 690	000	1 00
MIS 3	10 670	-1 067	1 00		15 942	3 392	1 00		8 690	000	1 00
	7 030	5 030	420 00		18 717	271	10		8 690	000	1 00
	8 030	4 030	60 00	MIS 9	18 541	-1 854	1 00		8 690	000	1 00
	8 988	2 988	10 00		10 479	8 479	383 00		5 332	3 332	1008 00
	10 670	1 257	1 00		11 706	7 706	91 00		6 565	2 565	153 00
MIS 4	13 288	-1 329	1 00		12 670	6 670	22 00		7 697	1 697	26 00
	8 573	6 573	473 00		13 643	5 643	6 00		8 690	690	1 00
	9 860	5 860	85 00		14 578	4 578	1 00		10 791	-1 305	1 00
	10 906	4 906	16 00		15 759	3 309	1 00		13 665	-4 030	10
	11 916	3 916	3 00		18 541	273	10				
	13 288	2 265	1 00	MIS 10	16 556	-1 656	1 00				
MIS 5	13 735	-1 373	1 00		11 170	9 170	321 00				
	7 449	5 449	314 00		12 171	8 171	86 00				
	8 592	4 592	55 00		13 155	7 155	24 00				
	9 621	3 621	10 00		14 130	6 130	7 00				
	10 551	2 551	2 00		15 067	5 067	2 00				
	11 576	1 411	1 00		16 556	3 475	1 00				
	13 735	-1 205	10	MIS 11	7 769	-1 383	1 00				
MIS 6	15 767	-1 577	1 00		7 769	000	1 00				
	10 206	8 206	567 00		7 769	000	1 00				
	11 561	7 561	116 00		7 769	000	1 00				
	12 607	6 607	25 00		13 828	000	1 00				
	13 629	5 629	6 00		8 758	000	1 00				
	14 591	4 591	1 00		8 758	000	1 00				
	15 767	3 329	1 00		8 758	000	1 00				

TABLE II GEOMETRIC CORRECTION FACTOR FOR VARIOUS PHASES

PHASE I $\beta_T = \beta_c, \beta_b, \beta_c, \beta_c$		PHASE II $\beta_T = \beta_s, \beta_h, \beta_c$		PHASE III $\beta_T = \beta_c, \beta_b, \beta_c, \beta_b$		PHASE IV $\beta_T = \beta_c, \beta_f$	
α	β_T	α	β_T	α	β_T	α	β_T
001	4 01	200	1 80	005	10 23	1 356	1 63
003	3 85	250	1 75	007	10 04	1 40	1 63
005	3 70	300	1 70	009	9 86	1 50	1 54
007	3 56	350	1 69	020	8 83	1 60	1 45
009	3 42	400	1 70	040	7 53	1 70	1 39
020	2 86	450	1 76	050	6 51	1 80	1 36
040	2 33	500	1.84	080	5 79	1 90	1 35
060	2 06	550	1 93	100	5 24	2 00	1 47
080	1 88	600	2 06	120	4 88	2 10	1 65
100	1 75	650	2 27	140	4 70	2 20	1 63
120	1 67	700	2 54	160	4 54	2 30	1 63
140	1 61	750	2 84	180	4 53	2 40	1 62
160	1 58	800	3 22	200	4 89	2 50	1 58
180	1 62	850	3 82			2 60	1 57
200	1 78	900	4 80			2 70	1 56
		950	7 10			2 80	1 54
		1 000				2 90	1 53
						3 00	1 53

TABLE III SEQUENCE OF MISSIONS IN 500 HRS PASS

SEQUENCE MISSION	SEQUENCE MISSION	SEQUENCE MISSION	SEQUENCE MISSION	SEQUENCE MISSION	SEQUENCE MISSION	SEQUENCE MISSION	SEQUENCE MISSION	SEQUENCE MISSION	
1	7	25	8	49	4	73	12	97	2
2	8	26	6	50	7	74	8	98	1
3	1	27	11	51	12	75	7	99	12
4	2	28	1	52	8	76	5	100	5
5	12	29	12	53	11	77	2	101	7
6	7	30	7	54	5	78	4	102	8
7	5	31	8	55	7	79	1	103	9
8	11	32	2	56	1	80	8	104	2
9	8	33	5	57	2	81	7	105	7
10	9	34	7	58	12	82	12	106	11
11	7	35	1	59	8	83	11	107	12
12	1	36	9	60	7	84	9	108	1
13	12	37	12	61	0	85	7	109	8
14	2	38	8	62	3	86	8	110	5
15	7	39	11	63	5	87	2	111	7
16	8	40	7	64	1	88	5	112	2
17	11	41	2	65	7	89	1	113	12
18	5	42	5	66	12	90	12	114	8
19	1	43	12	67	8	91	7	115	7
20	7	44	7	68	2	92	10	116	9
21	12	45	2	69	11	93	8	117	1
22	4	46	8	70	9	94	11	118	11
23	2	47	1	71	7	95	3	119	4
24	7	48	9	72	1	96	7	120	12

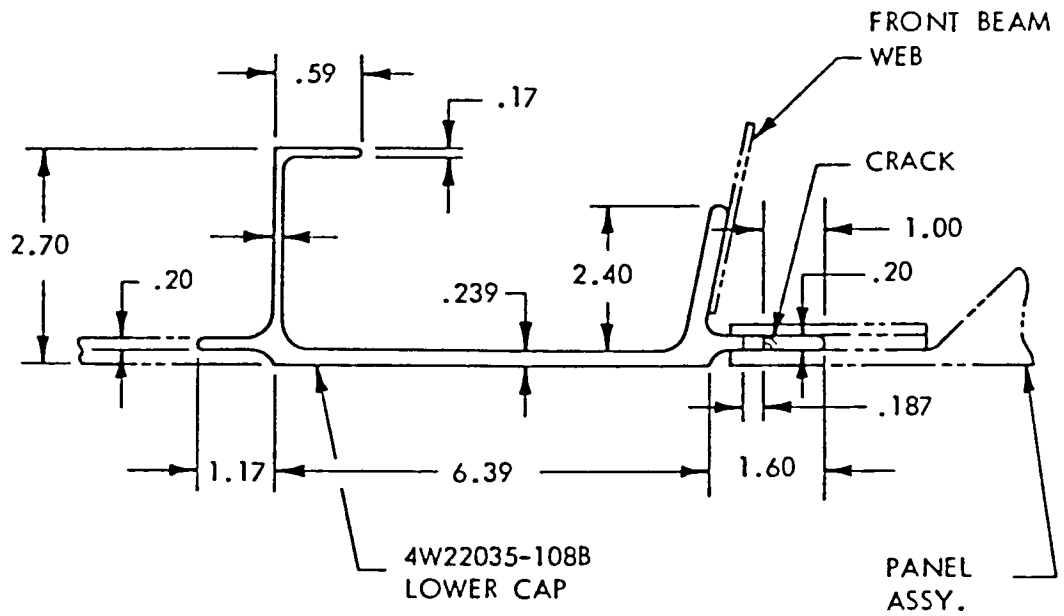


FIG. 5 STRUCTURAL DETAILS AT THE LOCATION OF ANALYSIS

β_b and β_h are as discussed before, β_s is the geometric correction factors for the slot effect (edge crack plus the hole) and is calculated using a cracked finite element model [26]. Note that $a/\sqrt{2}$ should be used for β_h and β_s for part-through Phases I and III for an equivalent crack length at 45° or at the mid point of the quarter circle. β_{sg} is the stress gradient correction factor due to the adjacent structural changes and it is calculated using the finite element model. β_w is the secant width correction factor. The various Beta factors (geometric boundary correction factors) are given in Table II.

The above stress intensity factors are modified to take into account the load interaction effect (variable amplitude spectrum) by using Eq. 7. The Forman equation and the Willenborg retardation model described in the previous section are used to evaluate the crack growth. A computer program [27] is used on a 500 hour repeating block spectrum to analytically generate a crack growth curve. The computer program "crack growth" uses a numerical integration technique [28-29] to generate a da/dF versus a curve where dF is an increment of the 500 hour block. Using Eq. 10 and making appropriate geometric correction factors for each phase, the critical stress for critical crack length can be calculated. The results are plotted in Figure 6. For limit load stress (33 KSI), the critical crack length is 1.3. The crack length versus flight hours is plotted in Figure 7. The critical crack length for limit stress is shown on the graph.

The primary objective of this analysis is to ensure the safety of the structure. Hence, the inspection of the structure in an economical way plays an important role. Economy of the inspection procedure depends on the procedure used and upon the criticality of the structure. The inspection intervals are established using a detectable crack length (based on the particular inspection procedure used) and the critical crack length. Assume for the present case study the initial flaw, a_i , is .05 and a_{det} is .15 inch and the critical crack length, a_c , at limit load is 1.3 inches.

Based on the above assumptions, the required inspections, including a safety factor of 2, and protecting the aircraft for limit load, the intervals are as follows:

$$\begin{aligned}
 \text{Initial inspection} &= \frac{\text{Time @ } a_c = 1.30 - \text{Time @ } a_i = .05}{2} \\
 &= \frac{23450 - 19000}{2} = \frac{4450}{2} = 2225 \text{ Hrs} \\
 \\
 \text{2nd and subsequent inspections} &= \frac{\text{Time @ } a_c = 1.30 - \text{Time @ } a_{det} = .15}{2} \\
 &= \frac{23450 - 21500}{2} = 975 \text{ Hrs.}
 \end{aligned}$$

Note: Inspection interval calculated as an example only, not to represent any specific aircraft.

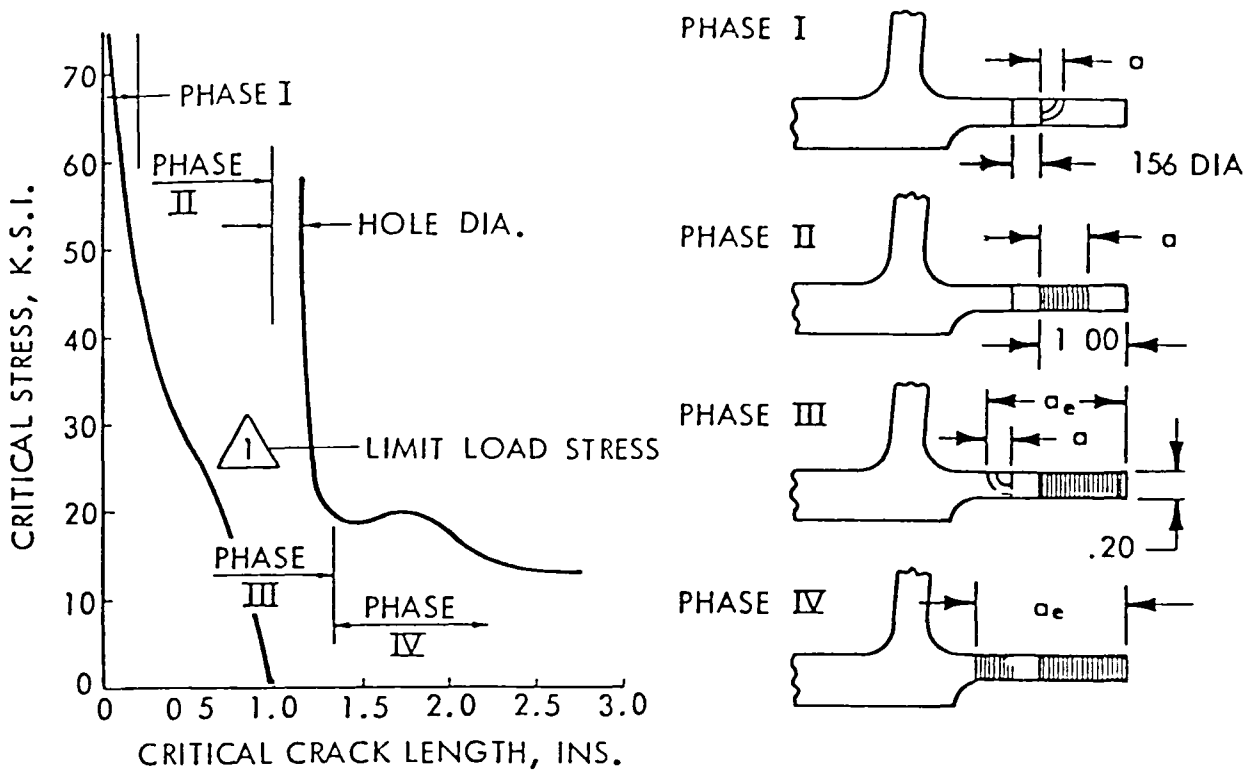


FIG. 6 CRITICAL STRESS AS A FUNCTION OF CRITICAL CRACK LENGTH

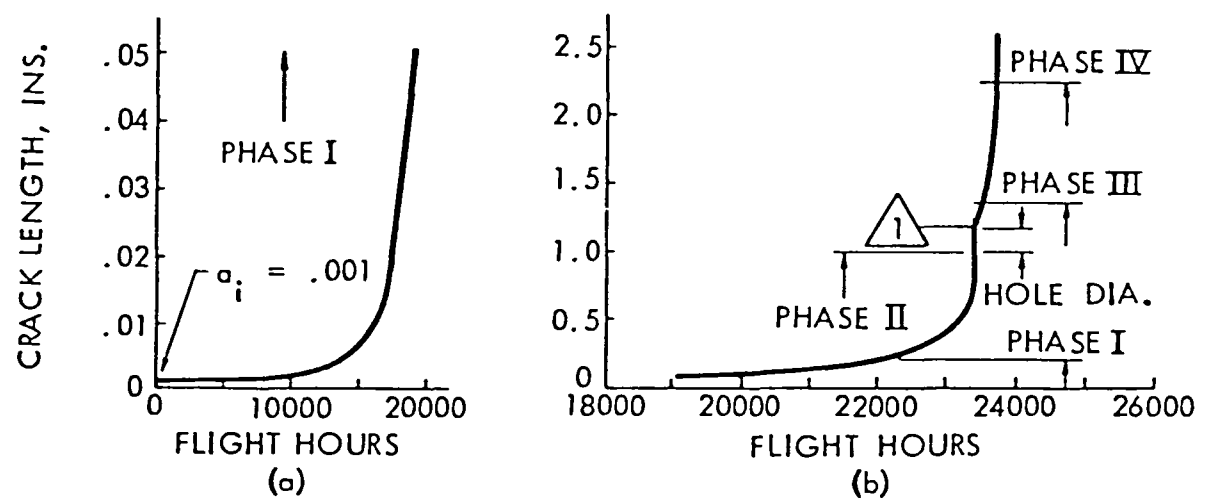


FIG. 7 CRACK LENGTH AS A FUNCTION OF FLIGHT HOURS

CONCLUSIONS

- 1 Basic fracture mechanics concepts and a sample analysis is described to establish inspection intervals that will ensure the safety of an existing aircraft structure. Longer inspection intervals can be realized by lowering the operating stress levels (aircraft restrictions) or if the short inspection intervals are confined to a few "hot spots" a "local beefup" may effectively be used to locally lower the stress. Any reduction in operating stress level has a very significant effect on crack growth since the minimum value of n for an aluminum alloy in the Forman equation is approximately 3, which is to say that the "time to grow" will increase as the cube of the stress reduction.
- 2 Parameters such as load transfer, spectrum derivation, load sequence effects (retardation) and special boundary conditions which effect crack growth characteristics are discussed only briefly in the text. There are a number of sophisticated techniques currently being developed and used to handle these parameters and are available in the "literature" but are considered outside the scope of this case study.
- 3 Fundamental fracture mechanics methodology that more accurately predicts the behavior of crack growth is developing at a very rapid rate. Therefore, the analyst should be aware of the current "state of the art" on such things as retardation models, effects of cyclic rate, threshold K 's and other parameters effecting crack growth behavior.

ACKNOWLEDGMENTS

This work was carried out at Lockheed-Georgia Company. The authors would like to thank Messrs. F. M. Conley, A. P. Shewmaker, S. C. Rogers, J. A. Neilson, and N. C. Appold for their encouragement in preparing this paper. The authors are also indebted to Mrs. Ruth Bowman for typing this document.

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APPENDIX B

U.S. DEPARTMENT OF COMMERCE
National Technical Information Service

AD-762 832

FATIGUE EVALUATION OF WING AND ASSOCIATED
STRUCTURE ON SMALL AIRPLANES

Airframe Branch, Engineering and Manufacturing
Division
Washington, D. C.

May 1973

- (1) Full scale spectrum testing - 3 to 4.
For the usual case, a scatter factor of four should be used for full scale spectrum testing. The factor may be reduced to three if equivalent safety is provided by determining crack location and growth rate and prescribing an inspection program based on this information that will assure that catastrophic failure will not result from initiation and growth of fatigue cracks. The specified inspection program should include specific information on when, where, and how to inspect the critical portions of the structure. The inspection openings and techniques should be adequate and appropriate to the inspection capability for the category of airplane involved.
- (2) Component testing -5 to 7.
The factor will depend on the experience level of the applicant adjudged on the degree to which he develops a test loading and a specimen which accurately simulates operational loading and stress distributions and the full scale structure. This should include consideration of spectrum loading, realism of the spectrum, and the degree to which the test structure support and loading simulates that of the full-scale structure. The upper value would apply to the usual S-N test, while the lower value would apply to an exceptional realistic spectrum test of components.
- (3) Analysis alone -7 to 8.
For the usual case a scatter factor of eight should be used for analysis alone. Where the designer presents data which shows that his knowledge of the stresses and fatigue properties of his structure is comprehensive based on flight measurements and on previous test and use of the type of construction in similar designs, a scatter factor as low as seven may be used.

- b. If additional specimens are tested, the above test factors may be reduced by dividing by the following factor:

$$\text{antilog} (3.511 \times 0.14 (1+1/N_S)^{\frac{1}{2}} - 3.511 \sigma (1+1/N_T)^{\frac{1}{2}})$$

where -

N_S = number of specimens specified

N_T = number of specimens tested

σ = standard deviation of log of test life = 0.14 unless sufficient specimens tested to conclusively establish standard deviation.

- c. Should an airplane that has previously been evaluated with a safe life be subjected to a mission change, gross weight increase, or gross weight increase with structural material added (without changing existing stress concentrations), to decrease the operating stress level, the scatter factor used in original evaluation would be applicable to adjust the previously established safe life.

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APPENDIX C

MIL-I-6870C

27 March 1973

SUPERSEDING

MIL-I-6870B (ASG)

25 February 1965

MILITARY SPECIFICATION

INSPECTION PROGRAM REQUIREMENTS, NONDESTRUCTIVE TESTING: FOR AIRCRAFT AND MISSILE MATERIALS AND PARTS

This specification is approved for use by all
Departments and Agencies of the Department of Defense.

1. SCOPE

1.1 Scope. This specification covers requirements for establishing the nondestructive testing (NDT) program for the procurement of all supplies or services when referenced in the item specification, contract, or order.

1.2 Applicability. This specification shall apply to all materials and parts for aircraft and missiles and their propulsion systems when nondestructive testing is required for acceptance.

2. REFERENCE DOCUMENTS

2.1 Government documents. The issues of the following documents in effect on the date of invitation for bids or request for proposals form a part of this specification to the extent specified herein:

SPECIFICATIONS

Military

MIL-I-6866	Inspection, Penetrant Method of
MIL-I-6868	Inspection Process, Magnetic Particle
MIL-I-8950	Inspection Ultrasonic, Wrought Metals, Process for
MIL-I-83387	Inspection Process, Magnetic Rubber

STANDARDS

Federal

Federal Test Method	
Std. No. 151	Metals; Test Methods

FSC MISC

MIL-I-6870C

Military

MIL-STD-143	Standards and Specifications, Order of Precedence for the Selection of
MIL-STD-410	Qualification of Inspection Personnel (Magnetic Particle and Penetrant)
MIL-STD-453	Inspection, Radiographic
MIL-STD-860	Fokker ^(R) Ultrasonic Adhesive Bond Test
MIL-STD-1530	Aircraft Structural Integrity Program Requirements
MIL-STD-1537	Electrical Conductivity Test for Measurement of Heat Treatment of Aluminum Alloys, Eddy Current Method

PAMPHLETS

AMCP 702-10	Guidance to Nondestructive Testing Techniques
AMCP 702-11	Guide to Specifying NDT in Materiel Life Cycle Applications

(Copies of specifications, standards, drawings, and publications required by suppliers in connection with specific procurement functions should be obtained from the procuring activity as directed by the contracting officer.)

2.2 Other publications. The following documents form a part of this specification to the extent specified herein. Unless otherwise indicated, the issue in effect on date of invitation for bids or request for proposal shall apply.

AMERICAN SOCIETY FOR TESTING AND MATERIALS

ASTM B-244	Measuring Thickness of Anodic Coatings on Aluminum with Eddy Current Instruments
ASTM B-342	Electrical Conductivity by Use of Eddy Currents
ASTM E-113	Recommended Practice for Ultrasonic Testing by the Resonance Method
ASTM E-164	Standard Method for Ultrasonic Contact Inspection of Weldments
ASTM E-215	Recommended Practice for Standardizing Equipment for Electromagnetic Testing of Seamless Aluminum Alloy Tubing

- ASTM E-309 Recommended Practice for Eddy Current Testing of Steel Tubular Products with Magnetic Saturation
- ASTM E-376 Recommended Practice for Measuring Coating Thickness by Magnetic Field or Eddy Current (Electromagnetic) Test Methods
- ASTM E-426 Recommended Practice for Electromagnetic (Eddy Current) Testing of Seamless and Welded Tubular Products, Austenite Stainless Steel and Similar Alloys
- ASTM E-427 Recommended Practice for Testing of Leaks Using the Halogen Detector (Alkali-Ion Diode)

(Application for copies should be addressed to the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103.)

AMERICAN SOCIETY FOR NONDESTRUCTIVE TESTING

- SNT-TC-1A Recommended Practice, Supplement A Radiographic Testing Method, Supplement C, Ultrasonic Testing Method, Supplement E, Eddy Current Testing Method, Nondestructive Testing Personnel Qualification and Certification

(Applications for copies of the above publications should be addressed to the American Society for Nondestructive Testing, 914 Chicago Avenue, Evanston, Illinois 60202.)

AMERICAN WELDING SOCIETY

- AWS-A.2.2 Nondestructive Testing Symbols

(Copies of the above publication may be obtained from the Naval Publications and Forms Center (Code 1051), 5801 Tabor Avenue, Philadelphia, Pennsylvania 19120.)

(Non-Government requests should be addressed to the American Welding Society, 3690 N.W. 50th Street, Miami, Florida 33142.)

3. REQUIREMENTS

3.1 Preparation of NDT plan. The contractor (5.6) shall establish in writing an overall systems plan to assure adequate nondestructive testing of all materials and applicable safety of flight components in an aircraft or missile system. The objective of this plan is to achieve a level of nondestructive testing consistent with design requirements.

MIL-I-6870C

3.1.1 Applicability. This plan shall include and be applicable to materials, safety of flight, structures and guidance control components produced by the contractor, subcontractors (5.8), and suppliers (5.9).

3.1.2 Elements. This plan shall present the scheme for establishing the NDT requirements and implementing procedures to meet these requirements. It shall include the means of:

- a. Conducting a materials and parts classification.
- b. Coordination of design requirements and NDT procedures.
- c. Preparing NDT procedures.
- d. Implementing NDT procedures.
- e. Staging or scheduling of testing during processing, fabrication, and assembly.

3.1.3 Coordination. This plan shall be coordinated with the Aircraft Structural Integrity Plan (ASIP) when MIL-STD-1530 is a contractual requirement.

3.2 Materials and parts classification. The contractor shall classify all materials and parts in an aircraft or missile system on the basis of function and quality according to the structural integrity requirements.

3.2.1 Class. Class refers to functional reliability requirements of the material or part and implies a confidence level requirement for NDT. A high-reliability class may require redundant testing to assure adequate NDT confidence level.

Class 1 - Components which are fracture or fatigue critical (5.4) or components the single failure of which would cause significant danger to operating personnel or would result in an operational penalty. This includes loss of major components, loss of control, unintentional release, inability to release armament stores, or failure of weapon installation components.

Class 1A - A Class 1 component, the single failure of which would result in the loss of an aircraft or missile system.

Class 1B - Class 1 components not included in Class 1A.

Class 2 - All components not classified as Class 1.

Class 2A - Components having a margin of safety of 200 percent or less.

Class 2B - Components having a margin of safety greater than 200 percent.

3.2.2 Grade. The grade of a component is a measure of quality level and implies a defect sensitivity requirement for NDT. The grade is defined in terms of defect size, location, type, and frequency which are acceptable. High and low stress areas on the same component can have different grade levels. The grade level shall be based on the acceptable defect limits.

3.3 NDT requirement review board. The contractor shall appoint an NDT requirement review board made up of technical personnel to implement and monitor the nondestructive testing plan.

3.3.1 Personnel. The NDT requirement review board shall be selected from the contractor's experienced design analysis, manufacturing and NDT personnel as defined below. The selection of this board shall be subject to the approval of the Government contracting agency (5.2).

3.3.1.1 Design analysis representative(s). The design analysis personnel shall be familiar with the overall design requirements of the aircraft or missile system. In particular they shall be knowledgeable of the service life criteria and the damage tolerance analysis for the materials and parts for which inspection requirements are to be established.

3.3.1.2 Manufacturing representative(s). The manufacturing personnel shall be familiar with all process, manufacturing, and assembly operations associated with the aircraft or missile system. They shall be knowledgeable of the influence of these operations on subsequent inspectability of materials and parts.

3.3.1.3 Nondestructive inspection representative(s). The NDT personnel shall be knowledgeable of the capabilities and limitations of the NDT techniques used in examining and testing materials and parts for the aircraft or missile system.

3.3.2 Function. The NDT requirements review board shall review the nondestructive testing requirements for all materials and parts in an aircraft or missile system to assure that the most effective and complete testing technique(s) have been selected for the materials and parts being tested, and that the level and scheduling of inspection is commensurate with the quality required. The representative(s) of design

analysis, manufacturing, and nondestructive testing shall interact to certify that the testing requirements are compatible with the design requirements as expressed by the class and grade of the materials and parts classification. This certification, or lack thereof, shall be documented as described later in this specification. The NDT requirements review board shall have available from its participants information and data according to the following responsibilities. Non NDT personnel of the board needing a basic understanding of NDT should refer to AMCP702-10 and AMCP702-11.

3.3.2.1 Design analysis representative(s). The design analysis representative shall provide the board information and data on the acceptable limits of defects in the materials and parts under consideration. This shall include part configuration, acceptable defect size, critical locations and orientations, and primary stress conditions and directions

3.3.2.2 Manufacturing representative(s). The manufacturing representative(s) shall provide the board information and data on the stages and limitations of processing, manufacturing and assembly at which nondestructive testing can be achieved. This shall include information and data on accessibility, surface finish, or other conditions which may influence inspectability.

3.3.2.3 Nondestructive testing representative(s). The nondestructive testing representative(s) shall provide the board information and data on the sensitivity and applicability of NDT techniques for the defect sizes, locations and orientations, part geometries, and materials being considered.

3.3.3 Action of the board. The action of the NDT requirements review board on all materials and parts shall be documented on the drawing. The degree and nature of documentation is dependent on the material and part classification as described below. In all cases, the action will be signature approved by the authorized design analysis, manufacturing, and nondestructive testing representatives of the NDT requirements review board.

3.3.3.1 Class 1 materials and parts. Specific inspection requirements must be made for all Class 1 materials and parts. The action shall include the part identification and configuration, the design requirements of acceptable defect size, critical locations and orientations, primary stress conditions and directions, the manufacturing recommendations for point of testing, and the specification of NDT technique and sensitivity.

3.3.3.2 Class 2 materials and parts. The action of the testing requirements board on Class 2 materials and parts shall include the part identification and the selection of the NDT technique(s) and quality level required.

3.3.3.3 Discrepancy reports. In the event that the NDT requirements review board cannot achieve conformance with the objectives of the NDT plan for a given material or part, a discrepancy report shall be issued for that material or part. This report shall identify the material or part, and describe the nature of the discrepancy. This report shall be returned to the design analysis group for reconsideration in terms of design requirements.

3.3.4 Drawings. The NDT board action shall be the basis for specification of NDT requirements on engineering production drawings. The board action may require a special drawing to reflect the NDT requirements.

3.3.4.1 Class 1. On all engineering and production drawings related to Class 1 materials and parts, the testing requirements shall be specified in summary form as follows:

- a. Acceptable defect size.
- b. Critical locations and orientations.
- c. Primary stress conditions and directions.

The NDT symbols, if used, shall be in accordance with the symbol convention of AWS A.2.2.

3.3.4.2 Class 2. On all engineering and production drawings related to Class 2 materials and parts, the quality level shall be specified.

3.3.4.3 Zones. On all engineering and production drawings related to materials and parts in which the grade level varies with location, the drawing shall be zoned and the appropriate information as required in 3.3.4.1 and 3.3.4.2 shall be entered for each zone.

3.4 Preparation of NDT procedures and process specifications

3.4.1 Use of general NDT process specifications. The use of process specifications such as those listed in 2.1 and 2.2 as sole controlling documents is not permitted. These specifications reflect minimum quality requirements and, of necessity, are broad in scope.

3.4.2 Company process specifications. Company process specifications shall be prepared incorporating the requirements of the referenced process specifications and in addition supplying detailed information necessary to meet or exceed these specifications using the particular equipment, personnel, and test facilities required to meet the reliability requirements of the product. If no general process specification exists for a particular method a company process specification shall incorporate sufficient information and criteria to adequately describe the NDT method and control the process.

3.4.2.1 Standard procedures. Standard procedures to obtain various grade level tests and various confidence levels for the particular product(s) may be a part of these company process specifications. These standard procedures may be referenced to meet the detailed procedure requirements for Class 2 parts (3.4.3.1).

3.4.2.2 Standardization. The company process specification shall reflect procedures and records to assure adequate quality assurance measures are being enforced to keep the NDT process in control. Basic process, equipment, materials, and technique variables shall be monitored and controlled to assure adequate control of the testing process.

3.4.2.3 Approval. Company process specifications to be applied on aircraft and missile components must be approved by an authorized representative of the contractor and, the Government as specified by the contract.

3.4.3 Testing processes. The following methods of nondestructive testing are acceptable.

- a. Magnetic particle, in accordance with MIL-I-6868 as supplemented by an approved company process specification.
- b. Penetrant, in accordance with MIL-I-6866 as supplemented by an approved company process specification.
- c. Radiographic, in accordance with MIL-STD-453 as supplemented by an approved company process specification.
- d. Ultrasonic, in accordance with MIL-I-8950 and ASTM E-113 or E-164, if applicable, as supplemented by an approved company process specification.
- e. Eddy current, in accordance with MIL-STD-1537 and ASTM B-244, B-342, E-215, E-309, E-376, or E-426 as applicable and as supplemented by an approved company process specification.

- f. Thermal, in accordance with an approved company process specification.
- g. Magnetic rubber in accordance with MIL-I-83387 as supplemented by an approved company process specification.
- h. Leak testing, in accordance with Federal Test Method Std. No. 151 and an approved company process specification.
- i. Adhesive bond strength testing in accordance with MIL-STD-860 as supplemented by an approved company process specification.
- j. Other methods, in accordance with an approved company process specification or other industry document.

3.4.4 Test procedures. Test procedures will be provided for each part to be tested. These procedures shall be in accordance with the requirements of the component drawing, the company process specification, and shall contain the information listed below.

3.4.4.1 Class 2 parts. Test procedures for parts shall include:

- a. Specific part number and configuration.
- b. Stage of fabrication.
- c. Surface finish and part preparation.
- d. Manufacturer and model number of all instrumentation to be used.
- e. Fixturing requirements.
- f. Manufacturer and identification of all testing materials.
- g. Detailed procedure steps or reference to company process specification procedure if applicable.
- h. Calibration and standardization procedure.
- i. Acceptance and evaluation procedure.
- j. Precautions in use of test procedure.

3.4.4.2 Class 1 parts. Test procedures for Class 1 parts shall contain all of the items listed in 3.4.3.1 and in addition:

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- a. Drawings of the part to be tested with identification of areas to be tested and the direction and magnitude of primary stresses.
- b. Physical description of probable defects.
- c. Minimum acceptable defect size and orientation.
- d. Limitations of technique in defect sensitivity.
- e. Sources of noise signals and their identifications.
- f. Procedures for retesting by the same or alternate methods to provide adequate confidence level.

3.4.4.3 Common product forms. General procedures are acceptable for common product forms such as plate and bar stock. The general procedures shall cover as a minimum all of the items listed for the class of the components for which the material is to be used.

3.5 Implementation of NDT procedures

3.5.1 Personnel. The NDT facility shall have available records of certification (5.1) for personnel conducting, directing and interpreting nondestructive tests in accordance with the following:

- a. Magnetic particle, in accordance with MIL-STD-410.
- b. Penetrant, in accordance with MIL-STD-410.
- c. Radiographic, in accordance with MIL-STD-453.
- d. Ultrasonic, in accordance with MIL-I-8950.
- e. Eddy current, in accordance with SNT-TC-1A, Supplement E.
- f. Others in accordance with the specific requirements of the contracting agency.

3.5.2 Test reports. Test reports with data records shall be kept on file by the NDT facility unless otherwise specified. Reports shall be signed by an authorized representative of the testing facility and the individual conducting and interpreting the test.

3.5.3 Equipment and materials. The equipment and materials used for testing shall be in accordance with the applicable approved company process specification.

3.5.4 Facilities. The physical plant used for NDT shall be such that it creates no unnecessary restrictions to the attainment of satisfactory testing. Housekeeping shall be maintained to assure equipment and materials are kept in good operating condition. Equipment should be marked to show adequate maintenance is being performed and that only operational and satisfactory equipment will be used to conduct a test.

3.5.5 Procedure verification. All procedures shall be verified to assure adequate defect sensitivity and confidence level to meet the requirements for which it is intended.

3.5.5.1 Class 2 parts. Procedures for parts may be verified on test pieces simulating the actual part providing the essential features of the part with regard to important application variables which may affect defect sensitivity and confidence level.

3.5.5.2 Class 1 parts. Procedures for class 1 parts shall be verified on test pieces as in 3.5.5.1 with additional verification by further tests on first items. Verification of adequate redundant testing to achieve the required confidence level of the testing shall be provided during first item tests.

3.5.6 Removal of discontinuities. When nondestructive testing reveals discontinuities in excess of the level permitted by applicable drawings or specifications, such discontinuities may be removed if permitted by applicable drawings and specifications. Evidence of removal shall be shown by reinspection. If the defect is merely removed by grinding and surface blending, the retesting shall be conducted at a higher sensitivity level to assure complete removal.

3.5.6.1 Retesting. Retesting for removal of discontinuities shall be conducted using an approved procedure. If a new procedure is to be used, an addendum to the original procedure shall be prepared showing the essential features of the repair test. This addendum must be approved by an authorized representative of the contractor.

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3.5.7 Inspection scheduling

3.5.7.1 Receiving inspections. On materials, parts, or assemblies suspected to have wide variations in quality from piece to piece, the contractor should establish an NDT sampling program to help assure that incoming materials, parts, or assemblies meet the engineering requirements.

3.5.7.2 Manufacturing and assembly. Testing shall be performed as necessary during manufacture and assembly of components to insure freedom from harmful discontinuities in the final part or assembly.

- a. When processing operations are involved which may in any way adversely affect the quality of material or part, such as heat treating, forging, or cold forging, NDT shall be performed subsequent to such operations.
- b. When processing operations are involved which may in any way interfere with the kind(s) of inspection to be used, inspection shall be performed prior to such operations.

3.5.8 Data and documentation. Requirements expressed as implied herein concerning preparation, submittal, approval, availability, retention, or delivery of data or documentation shall be applicable only to the extent provided in a DD Form 1423 in the contract.

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for NDT. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all testing requirements as specified in the NDT program. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the testing requirements unless disapproved by the Government. The Government reserves the right to perform any test set forth in the specifications where such tests are deemed necessary to assure supplies and services conform to prescribed requirements.

5. DEFINITIONS

5.1 Certification. Certification shall mean written testimony of qualification. The certifying agency must be the employer of the inspection personnel.

5.2 Contracting agency. A contractor, subcontractor, or Government agency procuring parts or services.

5.3 Final inspection. The last inspection of a part or component, usually just prior to shipping. This may occur during manufacturing if the component becomes uninspectable at some later stage of fabrication or if it is inspected just after some processing step and is not subject to reinspection after further processing.

5.4 Fracture or fatigue critical component. Components which are susceptible to crack initiation and propagation mechanism as established in MIL-STD-1530.

5.5 NDT facility. NDT facility shall mean that organization responsible to the contractor and the subcontractor for nondestructive testing services.

5.6 Contractor. Contractor shall mean that organization having contractual responsibility to the Government.

5.7 Qualification. The ability of personnel to meet the minimum requirements for a specified level of capability.

5.8 Subcontractor. Subcontractor (supplier) shall mean that organization responsible to the contractor for a portion of the weapons system.

5.9 Supplier. The organization directly responsible for delivering a material, part, or service to the Government, a contractor, or a subcontractor.

5.10 Nondestructive testing. Inspection processes or techniques intended to reveal conditions at or beneath the external surface of a part or material which cannot be evaluated solely by visual examination with or without magnification or by dimensional measurement.

6. NOTES

6.1 Certification of personnel

6.1.1 Radiographic personnel not working on Air Force Contracts may be certified in accordance with SNT-TC-1A.

Custodians:

Army - MR

Navy - AS

Air Force - 11

Preparing activity:

Air Force - 11

PROJECT NUMBER: MISC-0670

1 Report No NASA CR-165868		2 Government Accession No		3 Recipient's Catalog No	
4 Title and Subtitle "STUDY ON APPLICATION OF AEROSPACE TECHNOLOGY TO IMPROVE SURGICAL IMPLANTS"				5 Report Date March 1982	
				6 Performing Organization Code	
7 Author(s) R.E. JOHNSON AND J.L. YOUNGBLOOD				8 Performing Organization Report No	
9 Performing Organization Name and Address EAGLE ENGINEERING, INC. 17629 EL CAMINO REAL, #125 HOUSTON, TX 77058				10 Work Unit No	
				11 Contract or Grant No NAS1-16567	
12 Sponsoring Agency Name and Address NATIONAL AERONAUTICS AND SPACE ADMIN. WASHINGTON, DC 20546				13 Type of Report and Period Covered Contractor Report	
				14 Sponsoring Agency Code	
15 Supplementary Notes LANGLEY TECHNICAL MONITOR: SHEILA ANN T. LONG FINAL REPORT					
16 Abstract A study was conducted to assess the areas where aerospace technology could be used to improve the reliability and performance of metallic, orthopedic implants. Specifically, comparisons were made of material controls, design approaches, analytical methods and inspection approaches being used in the implant industry with hardware for the aerospace industries. While the overall assessment of the implant industry approach is very complimentary, several areas for possible improvement were noted such as the future, increased use of finite element stress analysis and fracture control programs on devices where the needs exist for maximum reliability and high structural performance.					
17 Key Words (Suggested by Author(s)) Orthopedic Implants, Fracture Control, Material Control, Design Approaches			18 Distribution Statement Unclassified - Unlimited Subject Category 26		
19 Security Classif (of this report) Unclassified		20 Security Classif (of this page) Unclassified		21 No of Pages 138	22 Price A07

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