SECTION VIII

REGULATORY CONTROL OF RISKS

Preceding sections of this petition have shown, based on the literature and on unpublished clinical results, that total hip arthroplasty incorporating the use of a constrained liner as part of a total hip system is a highly successful procedure in a properly selected patient group. Neither it, nor any other surgical procedure is free of complications, and this petition has demonstrated that a body of clinical experience has defined those complications. The risks inherent in this procedure are similar to those for total hip replacement surgery utilizing a class II device.

Complications can be distinguished between those that relate to surgery in general, and those that are specific to the device. Separation of the polymer liner from the metal shell is a failure of the device. Loosening may involve device design, but it also depends upon surgical technique as well as uncontrollable patient factors. The complications specific to the device are similar to those specific to class II hip joint replacement devices. Complications such as infection, pulmonary embolism, gastrointestinal and genitourinary problems are not generally device specific, but are risks associated with most major surgical procedures.

The primary difference between the constrained acetabular component (class III) and the semi-constrained acetabular component (class II) is the inherent stability of the device. The constrained liner provides joint stability by the design of mechanical constraint that interlocks the acetabular component onto the femoral component. The semi-constrained liner depends more heavily on the effectiveness of the surgical reconstruction and the soft tissue to provide joint stability, than it does on device design. Due to the mechanical resistance to dislocation, the constrained liner cannot be restored by closed reduction and requires additional surgery in the event it dislocates.

Based upon the above considerations, this petition recommends that the approach to regulatory risk control should be the same for a constrained total hip acetabular liner as for a semi-constrained total hip acetabular liner. Regulatory control of the device can be simple and straightforward. Device risks can be handled through material standards, with substantial equivalence determinations serving to control device design. Patient and surgical risks can be minimized through device labeling, and device quality through good manufacturing practices (GMP). FDA has authority through the 510(k) process, as well as its general authority over misbranding and adulteration to impose controls along these lines. Additionally, guidance documents are commonly used and provide vehicles for specific provisions regarding materials, testing, and labeling. The risks defined by clinical experience are well suited to controls of these types, and this petition's specific recommendation on controls is presented in Table VIII-A.

Warnings and precautions that might be included in labeling are described in Appendix 1 – General labeling Information.

TABLE VIII-A

RISKS AND CONTROLS FOR CONSTRAINED HIP ARTHROPLASTY

Risks/Complications Identified in this Petition	Means to Control/Minimize Risks
Infection	5 1 0(k) requirement – Sterility Adulteration Authority – GMP Sterility Misbranding Authority – Labeling Indications/contraindications/warnings precautions
Loosening of components	5 10(k) Requirement – SE Design Misbranding Authority – Labeling precautions/warnings
Revision of components Dislocation of the hip prosthesis	5 10(k) Requirement – SE Design 5 1 0(k) Requirement – Pre-clinical Testing Femoral head pull-out/acetabular insert dislocation 510(k) Requirement – Conformance to Material Standards Misbranding Authority – Labeling precautions/warnings
Implant failure/fracture/wear Osteolysis Sensitivity to implant materials	5 1 O(k) Requirement – SE Design 5 1 0(k) Requirement – Conformance to Material Standards 5 1 0(k) Requirement – Pre-clinical Testing femoral head pull-out/wear/acetabular insert dislocation/FDA guidance documents Adulteration Authority – GMP Manufacturing and Design
Nerve impingement/damage Pain Vascular disorders Pulmonary embolism Gastrointestinal/genitourinary complications	Misbranding Authority – Labeling warnings/precautions

MECHANICAL TESTING TABLE

TEST PERFORMED	BIOMET 32MM	J & J S-ROM 26,28,29,32MM	OSTEONICS 22,26,28MM
LEVER-OUT RESISTANCE LINER/SHELL	1630 LBS. AVE.		
PUSH-OUT RESISTANCE LINER/SHELL	740 LBS		
PUSH-IN FEMORAL HEAD	40.4 LBS.		
PULL-OUT FEMORAL HEAD/CUP	361.4 LBS.	300 INCH LBS. (28MM HD.)	33 1.5 IN.LBS.
TOGGLE-OUT FEMORAL HEAD/CUP	622 INCH LBS. AVE.	150 INCH LBS. (28MM HD.)	270-410 IN.LBS. (OVER FEM HD SIZE RANGE)

LIST OF SPECIAL CONTROLS

ASTM STANDARDS
FDA GUIDANCE DOCUMENTS
SUGGESTED LABELING FORMAT

000128A

LIST OF SPECIAL CONTROLS

The special controls identified below in this document, in addition to general controls, are adequate to control the identified risks to health for this device. Consensus standards and FDA guidance documents are appropriate special controls to reasonably assure the safety and effectiveness of the device.

Based on available information, we identified the following 10 voluntary standards from the American Society for Testing and Materials (ASTM), and 6 FDA guidance documents as the specific special controls to reasonably assure the safety and effectiveness of the constrained metal/polymer hip prosthesis.

ASTM Standards

1. ASTM F67-95 Standard Specification for Unalloyed Titanium for Surgical Implant Applications. This specification covers the chemical, mechanical, and metallurgical requirements for four grades of unalloyed titanium used for the manufacture of surgical implants.
2. ASTM F75-92 Standard Specification fo. Cast Cobalt-Chromium-Molybdenum alloy for Surgical Implant Applications. This specification covers the requirements for Cast cobalt-chromium molybdenum alloy, shot, bar, or ingot for surgical implant applications.
3. ASTM F136-98 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitual) Alloy (R56401) for Surgical Implant Applications. This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed Titanium-6 Aluminum-4 Vanadium ELI (extra low interstitual alloy (R56401) to be used in the manufacture of surgical implants.
4. ASTM F648-98 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants. This specification covers ultra-high-molecular-weight polyethylene powder (UHMWPE) intended for use in surgical implants.
5. ASTM F1044-95 Standard Test Method for Shear Testing of Porous Metal Coatings. This test method covers “lap shear” testing of porous and non-porous metal coatings adhering to dense metal substrates.
6. ASTM F1147-95 Standard Test Method for Tension Testing of Porous Metal Coatings. This test method covers tension testing of porous and nonporous metal coatings adhering to dense metal substrates at ambient temperatures and determination of the degree of adhesion of coatings to substrates, or the internal cohesion of a coating in tension normal to the surface plane.
7. ASTM F 13 77-98a Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS-R30075). This specification covers requirements for cobalt-chromium-molybdenum alloy powders for use in fabricating coatings on cobalt-chromium-molybdenum alloy orthopedic implants.
8. ASTM F1580-95 Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants. This specification

covers the requirements for unalloyed titanium and Ti-6Al-4V alloy powders for use in fabricating coatings on titanium alloy implants.

9. ASTM F18 14-97a Standard Guide for Evaluating Modular Hip and Knee Joint Components. This guide covers a procedure to assist the developer of a modular joint replacement implant in the choice of appropriate tests and evaluations to determine device safety.
10. ASTM F1820-97 Standard Test Method for Determining the Axial Disassembly force of a Modular Acetabular Device. This test method covers a standard methodology by which to measure the attachment strength between the modular acetabular shell and liner. Although the methodology described does not replicate physiological loading conditions, it has been described as means of comparing integrity of various locking mechanisms.

The ASTM standards define implant material specifications and testing methods applicable to the constrained hip prosthesis. Adherence to these standards and comparison of the results from these standard tests can control the risks to health of adverse tissue reaction, pain and/or loss of function, and revision by having the manufacturer use surgical implant quality materials and assuring that the device has acceptable performance through mechanical testing.

The ASTM standards are FDA recognized consensus standards. ASTM standards may be obtained from ASTM Customer Services, 100 Barr Harbor Dr., West Conshohocken, PA 19428 (Telephone 610-832-9585). ASTM has a site on the World Wide Web at http://www.astm.org/.

FDA Guidance Documents

1. Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement. (Facts-on-Demand #827)
2. Guidance Document for Testing Non-Articulating, "Mechanically Locked' Modular Implant Components (Facts-on-Demand #916)
3. Draft Guidance Document for the Preparation of Premarket Notification 5 1 O(k) Applications for Orthopedic Devices – The Basic Elements (Facts-on-Demand #832)
4. Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices (Call 30 l-443-943 5 flash fax for this document)
5. Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing (Facts-on-Demand #361)
6. 5 1 O(k) Sterility Review Guidance.. . and Revisions of 11/18/94 and ORDB 7/3/97 (K90- 1) (Facts-on-Demand #36 1)

FDA guidance documents provide guidance on how to meet general orthopedic device premarket notification (5 1 O(k)) requirements, including biocompatibility testing, sterility testing, mechanical performance testing, and physician and patient labeling. Use of the preclinical section of the FDA guidance documents can control the risks to health of adverse tissue reaction, infection, pain, and/or loss of function, and revision by having

manufacturers use surgical quality implant materials, adequately test and sterilize their devices, and provide adequate directions for use (and patient information).

Guidance documents can be received via fax machine by telephoning the Center for Devices and Radiological Health's (CDRH) CDRH Facts-on-Demand system at 800-399-0381, or 301-827-0111 from a touch tone telephone. At the first voice prompt, press 1 to access the Division of Small Manufacturers Assistance FAX, at the second voice prompt, press 2, and then enter the document number followed by the pound sign (#). Then follow the remaining voice prompts to complete the request. The guidance documents are also available from CDRH World Wide Web address at http://www.fda.gov/cdrh.

SUGGESTED LABELING FORMAT

INFORMATION FOR PRESCRIBERS

DEVICE DESCRIPTION

The constrained hip is intended for use only in special situations where the patient has a high risk of dislocation due to previous history of dislocation, severe joint laxity, and/or palsy of surrounding musculature.

<insert compatible cup shells and liners>
<insert compatible femoral head sizes/neck lengths>

Material: <insert applicable ASTM standard for polyethylene>
<insert applicable ASTM standard for metal>

<insert a description of the components an how they function>

INDICATION FOR USE

The metal/polymer constrained hip is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS, and POTENTIAL ADVERSE EFFECTS

Relative Contraindications

1. Bone or musculature compromised by disease, infection, or prior implantation that cannot provide adequate support or fixation for the prosthesis.
2. Any active or suspected infection in or about the hip
3. Skeletal immaturity

Warnings

1. Closed reduction of a dislocation of a constrained hip prosthesis is not possible. Patients should be made aware that treatment of device dislocation would require additional surgery.
2. Patients should be warned on the impact of excessive loading that can result if the patient is involved in an occupation or activity that includes substantial walking, running, lifting, or excessive muscle loading due to patient weight causing extreme demands on the constrained hip that can result in the failure of the device. Extreme demands on the device may also cause loosening of the acetabular shell.
3. Alteration of any factory pre-assembled components can result in improper function of the retaining mechanisms, and failure of the device. Discard or return any prosthetic components if the retaining mechanism appears damaged or mishandled.
4. Improper alignment of the acetabular insert within the acetabular shell prior to impaction may result in damage to the locking mechanism, or improper seating of the constrained acetabular insert.
5. Bending, contouring, or modifying the device may adversely affect the implant potentially leading to early implant failure.
6. Do not use steam autoclaving for resterilization of the UHMWPE liner, as it may result in serious deformation and material deterioration.
7. Do not combine components from different manufacturers. This may lead to premature wear or failure of the device.

Precautions

1. Careful selection of components and familiarity with all aspects of the surgical technique are important to the success of the surgery.
2. An implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause failure of the implant.
3. Inspect implants for nicks, scratches, or other defects that may cause failure of the implant.
4. To prevent contamination of the prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surfaces before the final decision to implant has been made.
5. An implant should never be reused. Any implant once assembled and disassembles should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.

6. The wear rate of prosthetic surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.
7. If a metal acetabular shell is affixed without bone cement, an additional method of initial fixation (e.g. bone screws, spikes, screw threads, fins, etc.) should be utilized to assure early stabilization of the cup.

Potential Adverse Effects

1. Infection
2. Pain
3. Loosening, wear, or mechanical failure of prosthetic components
4. Dislocation of the hip prosthesis requiring additional surgery
5. Localized progressive bone resorption (osteolysis)
6. Nerve impingement or damage, vascular disorders (including thrombus)
7. Heterotopic bone formation
8. Sensitivity to implant materials
9. Gastrointestinal and/or genitourinary complications
10. Pulmonary embolism
11. Death
12. Myocardial infarction

ANALYSIS OF PERTINENT CLINICAL STUDIES

<insert bibliography>

PATIENT COUNSELING INFORMATION

In addition to the patient related information contained in the Warnings and Potential Adverse Effects sections, the following information should be conveyed to the patient.

1. Joint prostheses will not restore function to the level expected with a normal healthy joint, and the patient should be instructed as to the limitations of the device. The range of motion achievable with a constrained hip is less than the range of motion with a semi-constrained hip prosthesis. The patient should be told that, although the constrained hip provides resistance to dislocation, it could dislocate if subjected to

excessive loading. Once dislocated, additional surgery will be required to reduce the joint.

2. Wear of the components can occur and potentially lead to future complications, including bone resorption and loosening, necessitating the removal and replacement of the prosthetic components.
3. The patient should be advised that the expected life of the joint replacement components is difficult to estimate, and that many factors may contribute to the longevity of the prosthesis. The patient can expect a restoration of mobility and reduction of pain, however device components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
4. Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.
5. Patients should be instructed that significant reduction in the range of motion is inherent to the design characteristics of a constrained hip prosthesis, and that activities that may force the joint to exceed those range of motion limits should be avoided.

PRODUCTS ARE SUPPLIED STERILE

<insert sterilization method>

Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

000128H

FOLLOWING ARE TESTS AND TEST METHODS

RECOMMENDED TO ESTABLISH THE SUBSTANTIAL EQUIVALENCE OF

Constrained Acetabular Cups

Summary of Laboratory Testing of the Biomet Ringloc Constrained Acetabular Liner:

Testing was conducted on the Ringloc Constrained Acetabular Liner to establish its resistance to potential failure modes. Five potential failure modes were identified and tests were designed to address each of the five modes. Note that all of the implant components used for the testing met the specifications of the implants being produced for commercial sale.

The first potential failure mode is the polyethylene liner pulling loose from the well fixed acetabular shell. The Ringloc mechanism must be sufficiently strong to resist the forces that act upon the shell to liner interface.

Tests were designed to simulate a direct pull out condition along the polar axis of the shell as well as the potential levering out of the liner from the shell. (Test# MT0197) The lever out loads could be created if the femoral head partially dislocated from the spherical socket and instead exherted a load on the raised lip of the liner.

From this testing, it was determined that an average push out load of 440lbs. was required to dislodge the polyethylene from the shell. This is well above any loads that are expected to be seen in vivo and is not the primary pull out failure mode of the device. This will be explained further during the discussion of the third potential failure mode.

It was also determined from this testing that an average lever out force required to dislocate the polyethylene liner from the shell was 1630 Ibs. Again, this greatly exceeds any forces that the device is expected to see in vivo.

To validate our in-house testing, we also sent implant samples to Dr. A. Seth Greenwald at the Orthopaedic Research laboratories, Mount Sinai Medical Center. Dr. Greenwald found and reported in his 1996 AAOS Scientific Exhibit that the push out force required to disassemble the polyethylene liner from the acetabular shell was 660 lbs. He also found that in his version of a lever out test, it required more than 660 in-lbs. to lever the polyethylene liner from the shell. These values indicate that our Ringloc design would rank at least #2 when compared to competitive devices as was published by Dr. Greenwald. [1]

The second potential failure mode of the device would be an insufficient area for stress transfer between the polyethylene liner and the titanium shell. The lack of area could cause a stress environment in the polyethylene that might lead to deformation, promote the onset of surface fatigue failures, and generation of particulate debris.

To insure that our product provided an area of support to the polyethylene that was comparable to other clinically successful devices that were currently on the market, we submitted our design to Dr. A. Seth Greenwald of the Orthopaedic Research Laboratories at Mount Sinai Medical Center.

1. Tradonsky et al, "A Comparison of the Disassociation of Strength of Modular Acetabular Components" *CORR*, Number 296, pp. 154-160, 1993.

Dr. Greenwald and his associates determined that our Ringloc shell without holes left only about 16% of the polyethylene unsupported. Our Ringloc shell with 7 screw holes left only 28% of the polyethylene unsupported. The actual contact areas of the shells were approximately $22cm^2$ and $18cm^2$. Overall, our design was second best out of the 10 devices studied by Dr. Greenwald.

The third potential failure mode of the device would be if the femoral head dislocated from the polyethylene liner.

Tests were designed to determine the device's resistance to two loading configurations that could cause dislocation. (Test Numbers MT 1603 and MT789)

The device was subjected to a force attempting to pull the femoral head out of a well fixed cup along the polar axis of the shell. It was determined that a mean force of 361 Ibs. was required to pull the femoral head from the polyethylene liner. This dislocation mode would be a result of the weight of the leg attempting to pull the femoral head from its socket. The 361 lbs. seen in this test far exceed the weight of the human leg and any direct pull out forces that would be expected to be seen in vivo. (Note: the failure mode was always the head pulling out of the liner and never the liner pulling out of the shell.) This mean force of 361 lbs. exceeds that of a comparable test performed on the Johnson & Johnson S-Rom Poly-Dial Constrained liner as reported in their summary of safety and effectiveness included in the P960054 PMA. The J & J device had an average pull out load of 273.6 lbs.

Next a second set of devices were subjected to a force which simulated the neck of a femoral implant moving to a position of impingement against the edge of the polyethylene liner. This could happen in cases of extreme motion or when the acetabular cup is malpositioned.

A load and thus a resulting bending moment were applied to the simulated hip stem until the head levered out of the polyethylene liner. This was always the failure mode for this test and the liner never became dislodged from the shell as a result of this extreme loading configuration.

From this test it was found that a mean torque of 622 inch pounds was required to dislocate the femoral head. This is much greater than the 270 to 410 inch pounds reported for the Osteonics Constrained Acetabular Insert as reported in the summary of safety and efficacy included in their PMA P960047.

These results indicate that the device should survive physiologic loading

A fourth failure made for the device would be the inability to assemble the components at the time of surgery. The surgeon is required to snap the femoral head in to the polyethylene socket without meeting too much resistance.

A test was designed to quantify the force required for this assembly process (Test # MT 0789). It was determined that a mean force of 40.4 lbs was required for assembly. This force can easily be generated in the hands of the surgeon within the surgical arena.

A fifth and final failure mode for the device was identified to be the "wearing out" of the polyethylene due to repeated articulations during the gait cycle. To address this concern, the Ringloc Constrained Acetabular Liners are made of Biomet's ArCom Ultra High Molecular Weight Polyethylene. The ArCom polyethylene is a proven material that was cleared for commercial marketing via K 926 107 on July 28, 1993.

LEVER-OUT AND PUSH-OUT RESISTANCE

OF THE

LINER FROM THE ME AL SHELL

CUP / LINER CONFORMITY TESTING

RING-LOC LINER STABILITY TESTING

DATE: January 21, 1992

PREPARED BY: Kevin Stone

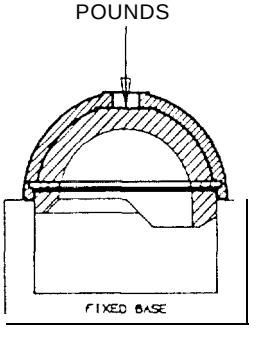
TESTING PERFORMED BY: Kelly Howard

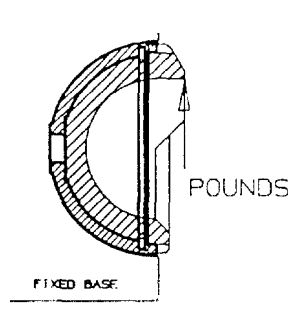
TEST NUMBER: 0197

OBJECTIVE: Determining the push-out and lever-out forces for the Ring-Lot Liner.

SPECIMENS: Specimens prepared in normal manufacturing area conforming to part number 105905 (liner), 105458-03 (ring), and 106058-02 (cup).

PROCEDURE: The liners were tested in push-out as shown in the diagram below. Liner level-out was also performed as indicated below. A single cup was used ^ _ al' tests. The cup was inspected after each test for visible wear an_ none was found.





The following data was gathered for the push-out test.

Specimen	1st Push (lb)	2nd Push (lb)	3rd Push (lb)	4th Push (lb)
1	776	421	*960	329
2	713	619	400	670
3	806	544	683	395
4	702	374	669	384
5	705	673	643	473
x =	740	526	598	450
s.d. =	48	127	133	133
reduction from original		29%	19%	39%

* value excluded from averaging due to error during test

The following data was gathered for the lever-out tests.

Specimen	1st Push (lb)	2nd Push (lb)
6A	1121	1567
7A	1764	930
8A	1883	1406
9A	1518	1378
10A	1866	1708
x =	1630	1398
s.d. =	319	293
reduction from original		14%

CONCLUSION: All failures occurred by shearing of the liner. There was never any damage to the ring or the cup. All tests show adequate stability of the liner in the shell. These values compare favorably with those presented by Tradonsky et al. It is encouraging to note that successive push-puts still maintained over 70% of their original values. Although the practice of reinserting a liner will be warned against, one ignoring these warnings will still have a high degree of stability of the two components. The same conclusions hold true for the lever-out test.

Competitive Push Out Test Results

Product Name	Initial Push Out Force (lbf)	Repeat Push Out Force (lbf)
APR	347	262
Integrity	103	85
PFC	460+	*
Reflection	65	60
Ringloc	660+	*
Trilogy	722+	*

+ NO DISASSEMBLY
* SIGNIFICANT DAMAGE PRECLUDED RETESTING

All data derived from:
Postak PD, Tradonsky S, Froimson AI, Greenwald AS: Performance Characteristics of Two Piece Acetabular Cups: Scientific Exhibit, American Acadamy of Orthopedic Surgeons, Annual Meeting, Atlanta, Georgia, 1996.

This data is the property of the Orthopaedic Research Laboratories of The Mt. Sinai Medical Center, Cleveland, Ohio. The reproduction and distribution of this data are restricted.

Competitive Lever Out Test Results

Product Name	*Initial Lever Out Torque [in-lbf]*	*Repeat Lever Out Torque [in-lbf]*
APR	429	215
Integrity	221	108
PFC	408+	*
Reflection	92	92
Ringloc	660+	*
Trilogy	890+	*

+ NO DISASSEMBLY
* SIGNIFICANT DAMAGE PRECLUDED RETESTING

All data derived from:
Postak PD, Tradonsky S, Froimson AI, Greenwald AS : Performance Characteristics of Two Piece Acetabular Cups: Scientific Exhibit, American Acadamy of Orthopedic Surgeons, Annual Meeting, Atlanta, Georgia, 1996.

This data is the property of the Orthopaedic Research Laboratories of The Mt. Sinai Medical Center, Cleveland, Ohio. The reproduction and distribution of this data are restricted.

CLINICAL ORTHOPAEDICS AND RELATED RESEARCH
Number 296, pp. 154–160
© 1993 J. B. Lippincott Company

A Comparison of the Disassociation Strength of Modular Acetabular Components

STEVEN TRADONSKY, M.D., PAUL D. POSTAK, B.SC., AVRUM I. FROIMSON, M.D AND A. SETH GREENWALD, D. PHIL.(OXON.)

Five short-term in *vivo* disassembly of two-piece acetabular cup designs have been reported. This study evaluates the liner retention strengths of eight contemporary cup systems. Roth push-out (663 ± 65.5 pounds force to 29 ± 1.4 pounds force) and lever-out (684 ± 114 inch-pounds 1.5 inch-pounds) test modes show a wide variation in retention strength. Repeat liner separation testing demonstrates a 26% and 32% respective decrease in locking mechanism integrity. These findings indicate that reseating modular liners at the time of surgery or reassembling a previously separated liner should be avoided

Two-piece acetabular components have gained a wide degree of clinical popularity in total hip arthroplasties (THAs) and have been advocated for cementless and hybrid applications. Their advantages include an ability to maximize stability between the cup and pelvic bony bed, through the adjunctive use of screw fixation. The enhanced stability provided by these constructs serves to facilitate biologic fixation. Additionally, metal backing has been shown to improve stress distribution in the pelvic bed when used in conjunction with cement.[1,2] Secondarily, modular polyethylene liners offer variable head coverage as well as the potential for replacement in situations of clinical difficult!. or material failure.

These modular constructs are not without short-term problems. There are numerous case reports in the literature as well as manufacturer citations to the FDA Medical Devices Register. documenting the early *in vivo* disassembly of modular acetabular components.[1,2,4-6,10-12] These cases are typified by the following one-year retrieval from The Mt. Sinai Medical Center. Cleveland, Ohio. The initial postoperative (Fig. 1A) and ten-month radiographs (Fig. I B) of a 50-year-old woman who experienced left hip pain four months after THA for degenerative joint disease are shown. At revision. liner separation was confirmed. The retrieved components demonstrated polyethylene fracture. and significant galling of the cup interface attributed to six months of continued ambulation after the onset of hip pain (Fig. 2). Similar problems have led to the recall of one system' and a more careful scrutiny oftwo-piece cup performance.

This study investigates the disassociation strength of eight contemporary two-piece acetabular systems and addresses the practice a! liner reinsertion after cup-liner separation.

MATERIALS AND METHODS

Eight contemporary two-piece acetabular cup designs were evaluated in a controlled laboratory investigation at The Mt. Sinai Medical Center. Cleveland. Ohio. These systems included the Dur-

From the Department of Orthopaedic Surgery and the Orthopaedic Research Laboratory The Mt. Sinai Center. Cleveland. Ohio.

Reprint requests to A. Seth Greenwald, D. Phil (Oxon), The Orthopaedic Research Laboratory. The Mt Sinai Medical Center. One Mt. Sinai Dr., Cleveland, OH 44106.

Received: August 4, 1992.
Revised: November 13, 1992.
Accepted: March 25, 1993.

000139

D RELATED RESEARCH

rength of

ts

IMSON, M.D.,

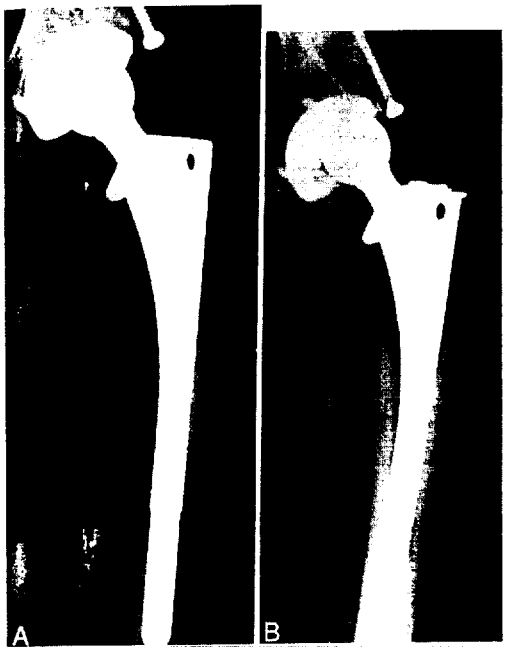
he potential for re-
f clinical difficulty

ts are not without
re are r umerous
re as well as manu-
DA Medical De-
g the early in *vivo*
cetabular compo-
es ... pified by
eval from The Mt.
veland, Ohio. The
A) and ten-month
0-year-old woman
pain four months
joint disease arc
paration was con-
nponents demon-
re, and significant
attributed to six
ulation after the
Similar problems
ne system' and a
)-piece cup perfor-

he disassociation
ary two-piece ace-
ses the practice of
liner separation.

METHODS

ece acetabular cup
ntrolled laboratory
ti Medical Center,
... the Dur-



FIGS. IA AND 1 B. (A) The initial postoperative and (B) ten-month radiographs of a 50-year-old woman who experienced left hip pain four months after THA for degenerative joint disease are shown. Liner separation is suggested from the proximal-lateral apposition of the head and cup surfaces.

aloc (DePuy, Warsaw, Indiana), Triloc (DePuy, Warsaw, Indiana), Omnifit (Osteonics Corp., Allendale, New Jersey), S-ROM (Joint Medical Products Corp., Stamford, Connecticut), PCA (Howmedica, Inc., Rutherford, New Jersey), Optifix (Richards, Memphis, Tennessee), APR (Intermedics Orthopedics, Austin, Texas), and HGP 11 (Zimmer, Inc., Warsaw, Indiana). Two tests designed to measure the integrity of the locking mechanism were performed on each system. These tests consisted of polyethylene liner separation by push out and lever out. Three components from each system were evaluated for each test mode.

All tests were performed using a customized apparatus mounted on an Instron Testing Machine (Model 1115, Instron Corp., Canton, Massachusetts). Cups and liners were of implantable quality and equivalent size, (-52 mm cup outer diameter and 32 mm liner inner diameter).

A diagrammatic representation of the push-out test apparatus is shown in Figure 3. Once the liner was fully seated, a 0.25inch diameter metal pin was advanced through the apical hole of the metal cup. A loading rate of 0.2 inches per minute was employed to fully dislodge the liner from the cup.

The lever-out test was designed to model the potential physiologic loading conditions present in the extremes of hip flexion and extension as well as situations of variable head coverage. *In vivo*, the kinematics of these disassociations are assumed to be a [rotation of the liner about some point on the tip of the cup. The lever-out test assembly is shown in Figure 3. A 0.25-inch diameter metal rod, serving as a lever, was inserted into a hole drilled into the side wall of the polyethylene liner 0.375 inches below the lip. For each system, the fulcrum was positioned directly adjacent to the metal cup. The rod was loaded until liner separation, at 1.33 radians per minute about the fulcrum. The lever arm length was defined as the distance from the fixed fulcrum to the midpoint of the liner thickness. In this model, liner thickness is a contributing factor to lever-out strength. For the eight de-

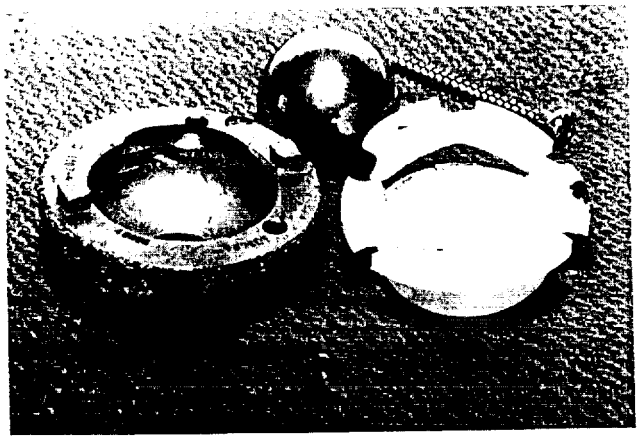
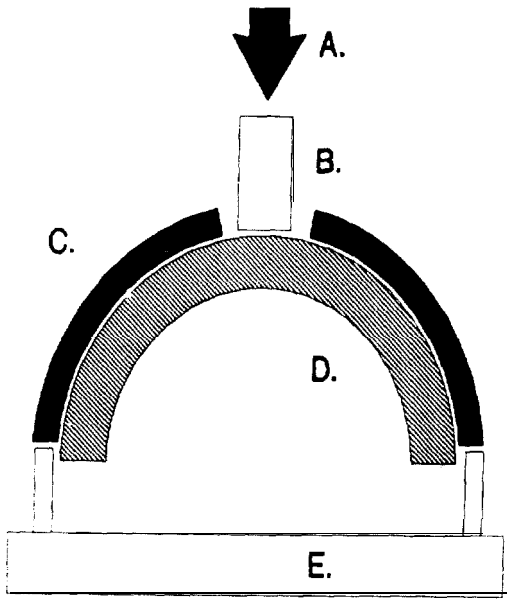


FIG. 2. At revision, liner separation was confirmed. The retrieved components describe polyethylene fracture with significant galling of the cup interface attributed to six months of continued ambulation after the onset of hip pain.



FIGS. 3A–3E. Push-out test apparatus: (A) the direction of applied displacement and location of the load measuring device. (B) 0.25-inch cylindrical metal loading pin. (C) sectioned view of ~52-mm outer diameter metal acetabular cup. (D) sectioned view of 32-mm. inner diameter polyethylene liner. (E) rigid. circumferential support for metal cup.

signs tested, the lever arm length varied from 2.1 to 2.3 inches.

For the push-out tests, the maximum force required to fully dislodge the liner from its cup was obtained from the force/displacement plot recorded on the Instron strip chart. The dislocation torque in the lever-out test was calculated as the product of the applied maximum force and the length of the lever arm. The average strength of three identical components for each design in both test modes were reported to assess the consistency of the locking mechanism.

To evaluate the reduction in the effectiveness of the locking mechanism after separation, the polyethylene liners were reinserted and the tests repeated.

Failure analysis was conducted on all systems after initial and repeat testing to determine the type and extent of the damage to the locking mechanism.

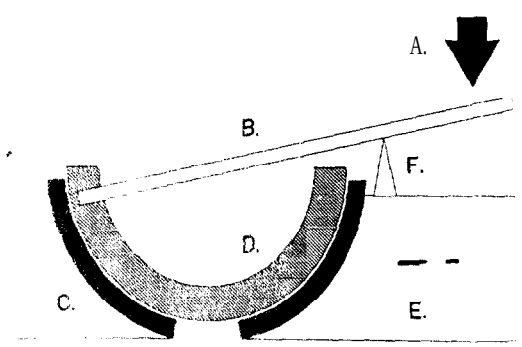
RESULTS

For both push-out and lever-out tests, all cup–liner assemblies failed by disassociation of the liner from the cup, reflecting a failure of the liner retention mechanism.

The results demonstrate a wide variation in the push-out strength measurements between systems (Fig. 5). The force required to dislodge the liners varied from 663 ± 65.5 pounds force in the Duraloc to 29 ± 1.4 pounds force in the Triloc (Table I).

For the repeat testing, the forces required for liner separation were consistently lower than those measured in the initial tests. The average reduction in repeat push-out force for all systems combined was 26%. This was found to be significantly different from zero at an alpha level of $p = 0.0005$ using a two-tailed Student's i-distribution analysis. In two systems, damage to the locking mechanism during initial separation was so extensive that repeat testing was not possible. These systems are excluded from the average.

The results of the initial and repeat lever out tests are presented in Figure 6. Considerable variation in the locking mechanism strength of the different systems was noted. The torque required to dislodge a liner varied from 684 ± 114 inch-pounds in the Duraloc



FIGS. 3A–4F. Lever-out test assembly: (A) the direction of applied displacement and location of the load measuring device. (B) US-inch cylindrical metal loading rod inserted into a hole in the liner 0.375 inch below the cup lip. (C) sectioned view of ~52-mm outer diameter metal acetabular cup. (D) sectioned view of 32-mm inner diameter polyethylene liner modified with a 0.25-inch hole in the side wall. (E) rigid mounting for the metal cup. (F) fixed fulcrum located directly adjacent to the metal cup.

000141

PUSH OUT TESTS

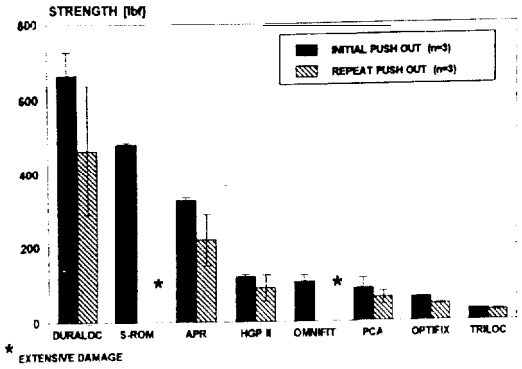


FIG. 5. The bar graph demonstrates the variation in push-out strengths between acetabular cup designs. For six systems, the combined mean repeat push-out strength was significantly less than the initial strength. (p = 0.0005). In two designs. repeat testing was not possible because of extensive damage during initial testing. Error bars represent plus or minus one standard deviation.

to 33 ± 1 .5 inch-pounds in the Triloc (Table 2). Lever-out strength was only minimally influenced by the variations in liner thickness that contributed no more than 8% to the lever arm length.

For the repeat testing, the torques required for liner separation were consistently lower than those measured in the initial tests. The average reduction in repeat torque-out strength for all systems combined was 32%. This was found to be significantly different from zero at an alpha-level of p = 0.0 17 using a two-tailed Student's I-distribution analysis. In three systems. damage to the locking mechanism during initial separation was so extensive that repeat testing was not possible. These systems were excluded from the average.

To determine the extent to which the results evaluate the locking mechanism, the test methods were compared for each design. Using linear regression analysis, a significant correlation was found between the initial push-out and lever-out test method, r^2 = 0.889 (n = 8).

Visual inspection of the systems suggests five general types of locking mechanism. Three systems. the PCA, the Optifix, and the APR. employ a circumferential polyethylene flange on the liner that locks into a circumferential retaining slot in the cup. During liner insertion. the flange initially compresses and then expands into the retaining slot. The retention strength of this method is directly related to the geometry of the flange and its engagement in the slot. After initial testing,

TABLE 1. Retention Strengths of Two Piece Acetabular Cups: Initial and Repeat Push Out Test

	Push Out [lbf] Mean SD	Repeat Push Out [lbf] Mean SD	Percent Reduction of Initial Strength	Failure Analysis
Duraloc	663 ± 65.5	463 ± 174.6	30%	Cup retaining wire bent and liner damaged
S-ROM	482 ± 4 . 7	*		Extensive damage to liner flange
APR	325 ± 10.8	219 ± 69.3	33%	Liner flange deformed
HGP II	119 ± 6.7	89 ± 34.7	25%	Cup retention prongs bent and liner damage
Omnifit	103 ± 19.8	*		Extensive damage to liner and liner retaining wire
PCA	85 ± 29.6	61 ± 17.7	28%	Liner flange tip deformed
Optifix	61 ± 2.6	44 ± 2.2	27%	Liner flange deformed
Triloc	39 ± 1.4	26 ± 3.3	9%	Material loss from liner cutouts
n = 3 for all tests			mean 26%	p = 0.0005

lbf, pounds force; SD, standard deviation.
* Initial damage precluded repeat testing.

000142

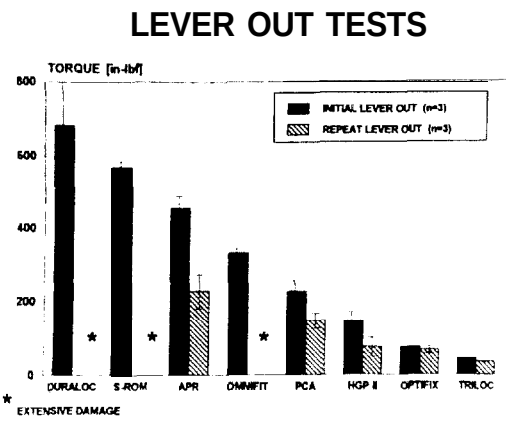


FIG. 6. The bar graph demonstrates the variation in lever-out strengths between acetabular cup designs. For five systems. the combined mean repeat lever-out strength was significantly less than the initial strength. (p 0.017). In three designs. repeat testing was not possible because of extensive damage during initial testing. Error bars represen: plus or minus one standard deviation

these flanges were markedly deformed. accounting for the observed strength reduction in subsequent separation. No deformation of the cups for these designs occurred.

A second locking mechanism. seen in the S-ROM design. is similar to the tirst. The liner flange is interrupted, however, facilitating its insertion into intermittent gaps in the retaining slot of the cup. The liner then is rotated so that the flanges are completely engaged within the slot. Further rotation is limited by secondary. peripheral pins or screws. The S-ROM has the advantage that no damage is done to the liner or cup during assembly. thus allowing multiple liners to be inserted without concern. The damage to the liner after forcible separation was considerable, however, and prohibited subsequent testing of that liner.

A third locking mechanism is present in the Triloc design. Two protrusions on the rim of the cup engage two of six undersized cutouts in the lip of the liner at their mid-thickness. After separation, the liners exhibited evidence of material shaving in the cutout'; aused by the sharp locking edges of the protrusions. A reduction in retention strength tbr this device was demonstrated when the same two slots were reused.

A fourth locking mechanism. used in the HGP II design, employs five pairs of spring-loaded prongs on the rim of the cup that loch into a circumferential slot in the liner. After separation. scoring of the liner in the region

TABLE 2. Retention Strengths of Two Piece Acetabular Cups: Initial and Repeat Lever Out Test

	Initial Lever Out [in-lb]	*Repeat Lever Out [in-lb]*	*Percent Reduction of Initial Strength*	*Failure Analysis*
	Mean SD	*Mean SD*		
Duraloc	684 ± 113.9	*		Extensive damage to cup retaining wire and liner
S-ROM	569 ± 15.3	*		Extensive damage to liner flange
APR	456 ± 34.0	229 ± 46.5	50%	Liner flange deformed
Omnifit	332 ± 13.0	*		Extensive damage to liner and liner retaining wire
PCA	228 ± 29.2	148 ± 20.6	35%	Liner flange tip deformed
HGP II	145 ± 26.0	75 ± 10.9	48%	Cup retention prongs bent with liner damage
Optifix	73 ± 2.6	67 ± 10.0	8%	Liner flange deformed
Triloc	43 ± 1.5	35 ± 1.5	17%	Material loss from liner cutouts
n = 3 for all tests			mean 32%	p = 0.017

in-lb, inch-pounds; SD, standard deviation.
* Initial damage precluded repeat testing.

of the prongs was observed. Repeat testing of new liners in the same cup resulted in continually decreasing retention strengths. This can only be explained by the permanent deformation of the metal prongs. The results reported represent the initial and repeat retention strengths for six new cup-liner assemblies. three for each test mode.

A fifth locking mechanism. employed in the Duraloc and Omnifit designs, is characterized by the use of a metal wire retaining ring. In the case of the Duraloc, this wire is configured into a multiple series of bends and inserted into a slot in the cup. During assembly, the wire expands into a circumferential slot in the liner. After separation. the liners exhibited considerable deformation in the region of the slot. Deformation of the metal retaining ring was also observed, requiring a new wire ring for each test. In the case of the Omnifit, the metal wire ring is integral to the liner and engages four hooks located on the interior edge of the cup. After separation. deformation of the nirc prohibited subsequent testing.

DISCUSSION

This study addresses the short-term disassociation of two-piece acetabular cups w how failure mechanism is attributed to design and material deficiency. Although it is reasonable that polyethylene creep and wear may increase the occurrence of liner disassociation over time, this mode of failure has not, as yet, been reported clinically nor demonstrated experimentally. Because the *in vivo* failure of these systems is complex and the mechanism of liner separation is not completely understood. the results do not infer the clinical superiority of one system over another. These results do provide a basis for comparison of liner locking mechanisms. It is not known how much force a cup-liner assembly should be able to withstand *in vivo*. It is reasonable, however, that those designs with a stronger locking mechanism. if appropriately assembled, are less likely to disassociate.

Although it is unlikely that pure push-out forces represent a component of *in vivo* hip loading, they do by comparison provide a measure of system integrity. By contrast, the lever-out test does simulate the torque acting on the liner during the extremes of hip flexion and extension. These orientations as well as liners that offer variable head coverage have been implicated as possible causes of liner disassociation.' The significant correlation between the push-out and lever-out tests in the current study supports the contention that both tests in fact measure the integrity of the retention mechanism.

The repeat push-out and lever-out tests for all systems evaluated indicate a significant reduction in retention strength. This is indicative of permanent material degradation of the cup–li. locking mechanism. In two designs. specifically the HGP II and Duraloc. failures in retention structures integral to the metal cup were observed. For the Duraloc. deformation of the retention wire necessitated its replacement in subsequent testing. This requires routine wire exchange in clinical situation5 where liner replacement is necessary and suggests that additional wires be available in the operating theater. For the HGP II, deformation of the retention prongs in successive testing resulted in continually decreasing retention strengths. This necessitated that new cups be used for all initial testing. Although it is possible in the clinical setting to forcibly bend the prongs in an attempt to improve the retention strength. this practice is neither recommended nor proven effective, and is potential]? dangerous because of the risk of long-term prong fracture caused by metal fatigue. In clinical practice, the potential for subsequent liner disassociation arising from damage to the prongs must be weighed against the difficulty of cup replacement.

Given the significant decrease in retention strength in both push-out and lever-out tests, the practice of reseating modular liners at the time of surgery or reassembling a previously separated liner is strongly discouraged.

REFERENCES

1. Beaver, R. J., Schemitsch, E. H.. and Gross, A. E.: Disassembly of a one-piece metal-backed acetabular component: A case report. J. Bone Joint Surg. 73B:908, 1991.
2. Bueche, M. J.. Herzenberg, J. E., and Stubbs. B. T.: Dissociation of a metal-backed polyethylene acetabular component: A case report. J. Arthroplasty 4:39, 1989.
3. Carter, D. R., Vasu, R., and Harris, W. H.: Stress distributions in the acetabular region: II. Effects of cement thickness and metal backing of the total hip acetabular component. J. Biomech. 15:165, 1982.
4. Ferenz, C. C.: Polyethylene insert dislocation in a screw-in acetabular cup: A case report. J. Arthroplasty 3:201, 1988.
5. Kitziger K. J.. DeLee, J. C.. and Evans, J. A.: Disassembly of a modular acetabular component of a total hip-replacement arthroplasty. J Bone Joint Surg. 72A:621, 1990.
6. Medical device reporting program for two piece acetabular cup components. Department of Health and Human Services. Public Health Service. Food and Drug Administration. Center for Device and Radiological Health: Freedom of Information Act, April 1991.
7. Medical Device Reports: FDA recall #Z-505/538-0. Commerce Clearing House, 1990.
8. Morrey, B. F.: The hip: Dislocation. *In* Morrey B. F. (rd.): Joint Replacement Arthroplasty. New York, Churchill Livingstone, 1991, pp. 851–865.
9. Pedersen, D R., Crowninshield, R. D.. Brand, R. A., and Johnston. R. C.: An axisymmetric model of acetabular component? in total hip arthroplasty. J. Biomech. 15:305, 1982.
10. Schmalzried, T. P., and Harris, W. H.: The Harris-Galante porous-coated acetabular component with screw fixation: Radiographic analysis of eighty-three primary hip replacements at a minimum of five years. J. Bone Joint Surg. 74A:1130, 1992.
11. Star M. J.. Colwell C. W., Jr., Donaldson W. F. III. and Walker, R. 11.. Dissociation of modular hip arthroplasty components after dislocation: A report of three cases at differing dissociation levels. Clin. Orthop. 278: 111, 1992.
12. Wilson, A. J., Monsees, B., Blair, V. P. III: Acetabular cup dislocation: A new complication of total joint arthroplasty. AJR 151:133, 1988.

CUP/LINER CONFORMITY OF MODULAR ACETABULAR DESIGNS

Orthopaedic Research Laboratories
The Mt. Sinai Medical Center
Cleveland, Ohio 44106

Benjamin I. Rosner, B.S.
Paul D. Postak, B.S.
A. Seth Creenwald, D.Phil.(Oxon)

INTRODUCTION

Two piece acetabular cups have gained widespread use in total hip arthroplasty. As the optimizations of mechanical design and surgical technique have c'fered solutions to short term failure, considerable attention has turned towards long-term survivorship. ı ı particular, debris generated from polyethylene has been implicated in prompting progressive osteolysis, resulting in long-term implant instability[1,2].

While the incorporation of metal backings with polyethylene components was intended to distribute loads more evenly to the pelvic bed, the subsequent compromise in the thickness of the polyethylene posed the risk of increasing contact stresses[3]. Moreover, the presence of holes for fixation screws, and lack of conformity at the polyethylene/metal interface compromised the area available for stress transfer between the polymer and metal[4]. This combination of holes and nonconformity provides a stress environment in the polyethylene that not only may lead to deformation, but may promote the onset of surface fatigue failures and the generation of debris.

This study examines the degree of conformity between the polyethylene liners and metal shells of ten modular acetabular designs, and discusses the relationship between conformity and polyethylene wear.

MATERIALS AND METHODS

Ten acetabular cup systems were analyzed for metal-cup/polyethylene-liner conformity. The dimensions for each system studied were approximately 52mm OD/32mm ID. Cups representing all available hole configurations for each system were obtained for analysis. Regions of nonconformity were attributed to holes, gaps, or both. According to the following protocol, three cups representing the minimum hole configuration for each system were analyzed for gap information.

A self curing acrylic was poured into each metal cup immediately prior to cup/liner assembly. After curing for 24 hours under a 10 lbf. compressive load, each assembly was sectioned with a diamond wire saw and digital images were obtained with a Hewlett Packard digital scanner. Macroscopic dimensions and geometric information were obtained from both the digital images and vernier caliper measurements. Using an ocular micrometer and dissecting microscope, gap dimensions between the polyethylene liners and metal shells were determined. Based on reasonable machining tolerances, regions of contact were characterized by gaps less than 0.20 ± 0.01 mm.

METHODS (cont.)

As shown in Figure 1 A, gap dimensions were recorded at +θ and -θ degrees from the central axis of the section. A solid of 180 degree revolution about this axis was assumed to have gap characteristics similar to those measured at the section face. When the polyethylene was supported at both ±θ from the axis, the revolution was considered entirely supported at that angle. Conversely, when the polyethylene was unsupported at both ±θ from the axis, the revolution was considered entirely unsupported at that angle. If supported polyethylene was indicated at any θ and unsupported polyethylene indicated at the opposite angle, the polyethylene and metal surfaces of revolution were assumed to resemble a semicircle of radius rl offset within a semicircle of radius r2, where rl <r2, as shown in Figure 1 B. The supported portion of this surface was determined from the calculated location of 0.20mm separation. Gap information obtained from the minimum ho. configuration for each system was applied directly to analogous designs with more numerous holes. Surface maps of gaps and holes were constructed separately, assembled, and duplicate data was removed. Areas of polyethylene/metal contact were similarly determined for each system.

Figure 1A

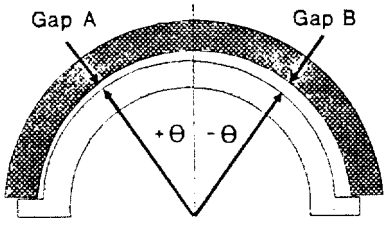


Figure 1B

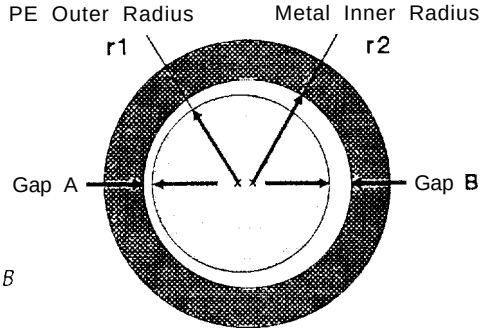
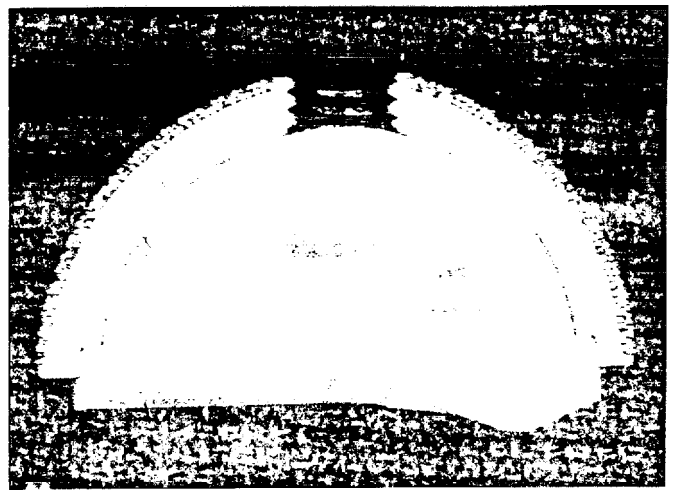


Figure 1A. Cup section indicating locations for gap measurements. 1B. Section through cup in a plane parallel to the rim, indicating assumption of polyethylene offset within the metal shell.

CUP SECTIONS

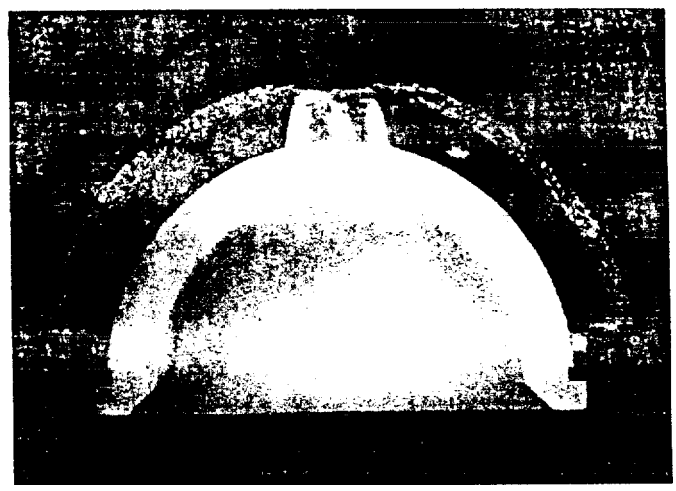
Reflection



Minimum Hole Geometry:
(1) 1 Apical Hole

Other Hole Geometries:
(6) 1 Apical Hole + 5 Dome Holes

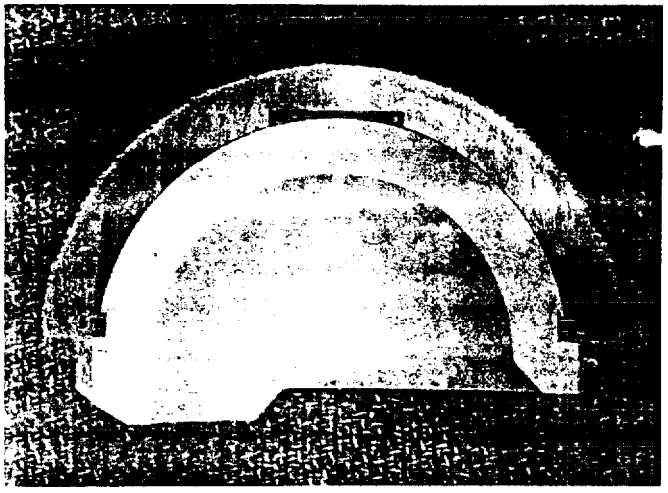
HGP II



Minimum Hole Geometry:
(12) 1 Apical Hole + 11 Dome Holes

Other Hole Geometries:
None

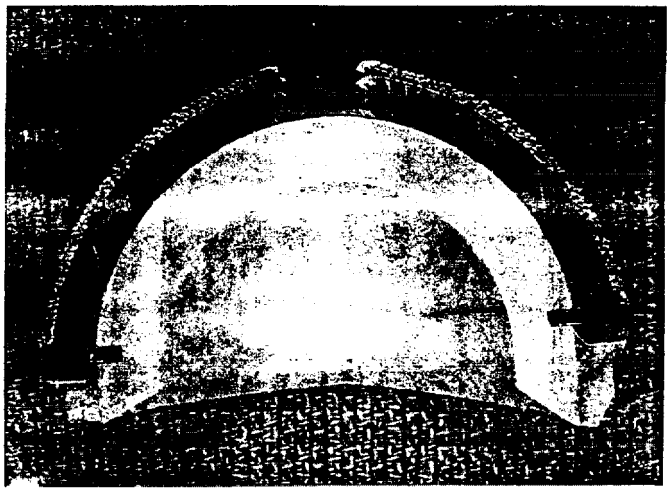
RingLoc



Minimum Hole Geometry:
(0) 0 Apical Holes

Other Hole Geometries:
(7) 1 Apical Hole + 6 Dome Holes

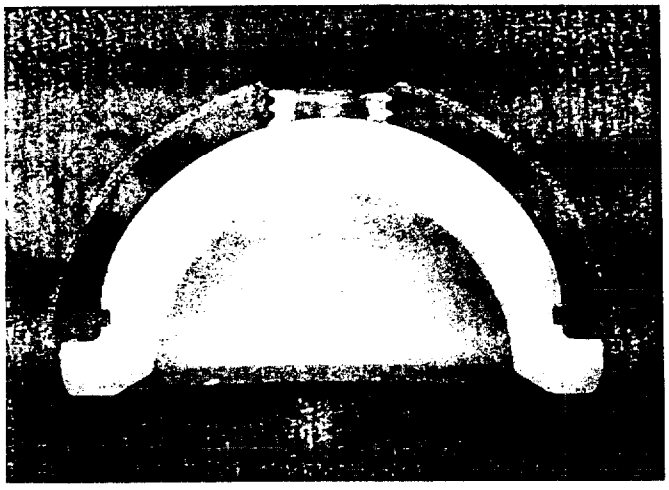
PFC



Minimum Hole Geometry:
(1) 1 Apical Hole

Other Hole Geometries:
(9) 1 Apical Hole + 8 Dome Holes

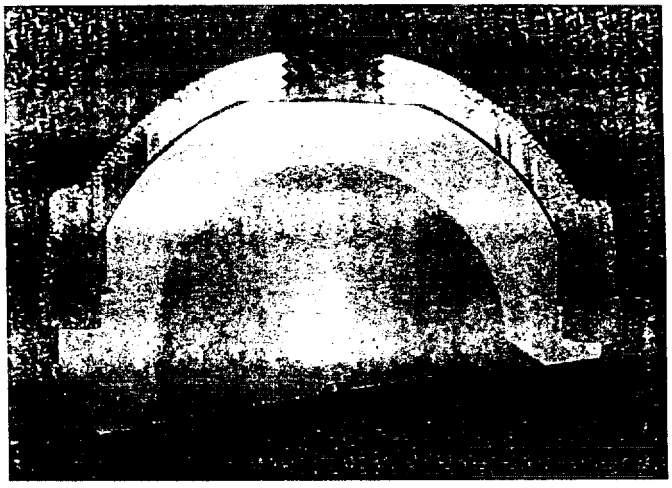
Duraloc



Minimum Hole Geometry:
(1) 1 Apical Hole

Other Hole Geometries:
(8) 1 Apical Hole + 7 Dome Holes
(11) 1 Apical Hole + 10 Dome Holes

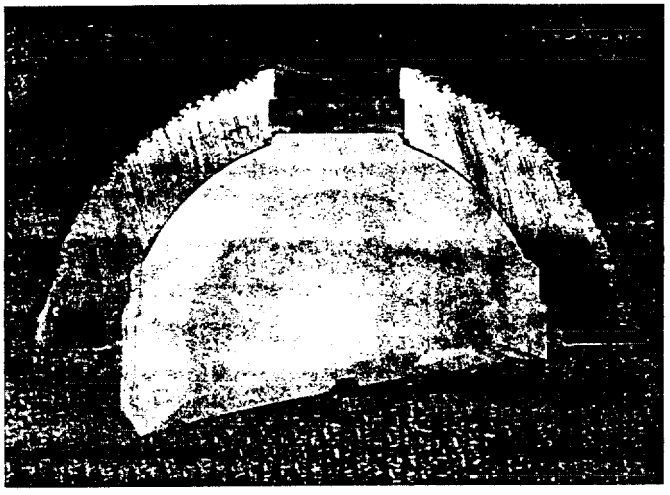
Omnifit



Minimum Hole Geometry:
(1) 1 Apical Hole

Other Hole Geometries:
(9) 1 Apical Hole + 8 Dome Holes

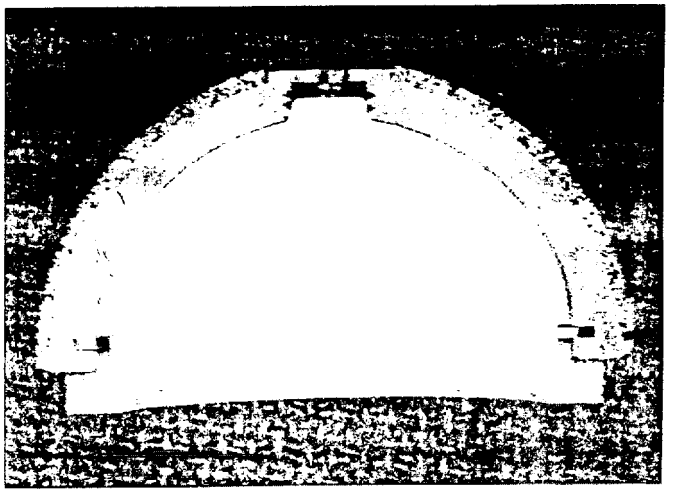
S-ROM



Minimum Hole Geometry:
(1) 1 Apical Hole

Other Hole Geometries:
(4) 1 Apical Hole + 3 Dome Holes

Trilogy



Minimum Hole Geometry:
(0) 0 Apical Holes

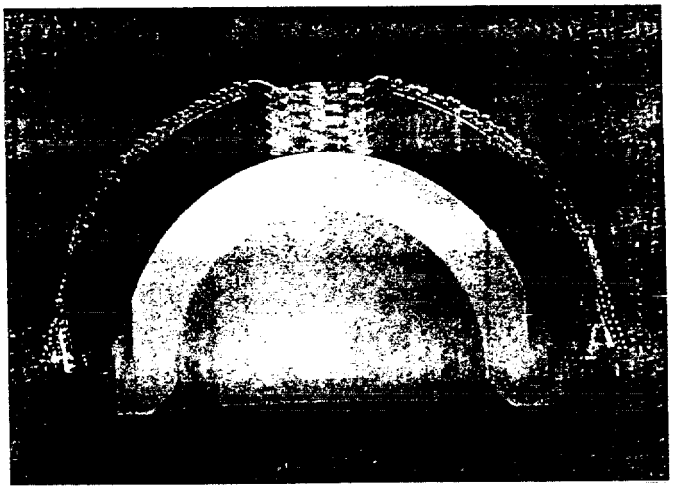
Other Hole Geometries:
(3) 0 Apical Holes + 3 Dome Holes
(11) 0 Apical Holes + 11 Dome Holes

Osteolock

Minimum Hole Geometry:
(7) 1 Apical Hole + 6 Dome Holes

Other Hole Geometries:
None

Integrity



Minimum Hole Geometry:
(1) 1 Apical Hole

Other Hole Geometries:
(7) 1 Apical Hole + 6 Dome Holes

RESULTS

The cup sections presented are of the minimum hole configuration for each system. Figure. 2 describes the percent of unsupported polyethylene in each cup, covering the outer polyethylene surface up to, but not including the rim. Hole, gap, and hole/gap overlap information are graphed for the cup whose total percentage is the median for that system. Range values for total percentages are also presented. Unsupported polyethylene in cups containing only apical holes varied from 10.3% to 96.9% as evidenced in Figure 2. Note the relatively small contribution to non-contact in the cups of minimum hole configuration by comparison to the large contribution evident in the multiple hole systems. The percent of unsupported polyethylene in cups containing multiple holes ranged from 20.7% to 96.9%.

Supported regions of polyethylene were characterized by the area of conformity up to, but not including the rim. Figure 3 demonstrates median areas of contact for each system, including indications of the ranges observed. Areas of contact varied from 25.0cm² to 0.7cm² for apical hole cups, and from 22.1 cm² to 0.7cm² for multiple hole cups.

Percent of Unsupported Polyethylene

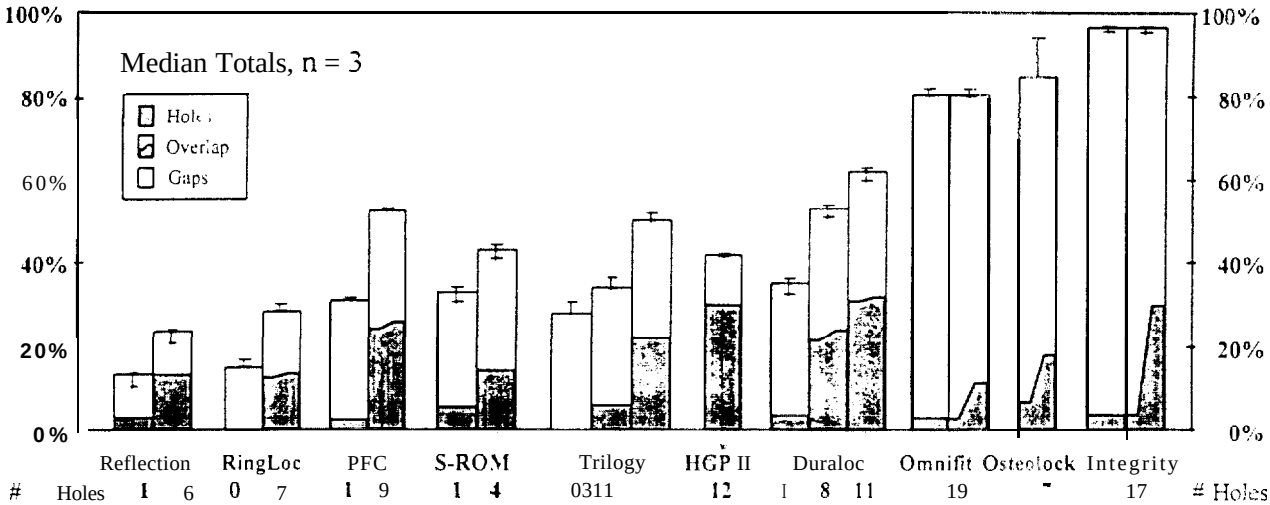


Figure 2. Percent of unsupported polyethylene over outer surface of liner up to, but not including the rim. Overlap regions are defined as locales where a calculated gap coincides spatially with a hole.

Contact Area of Supported Polyethylene

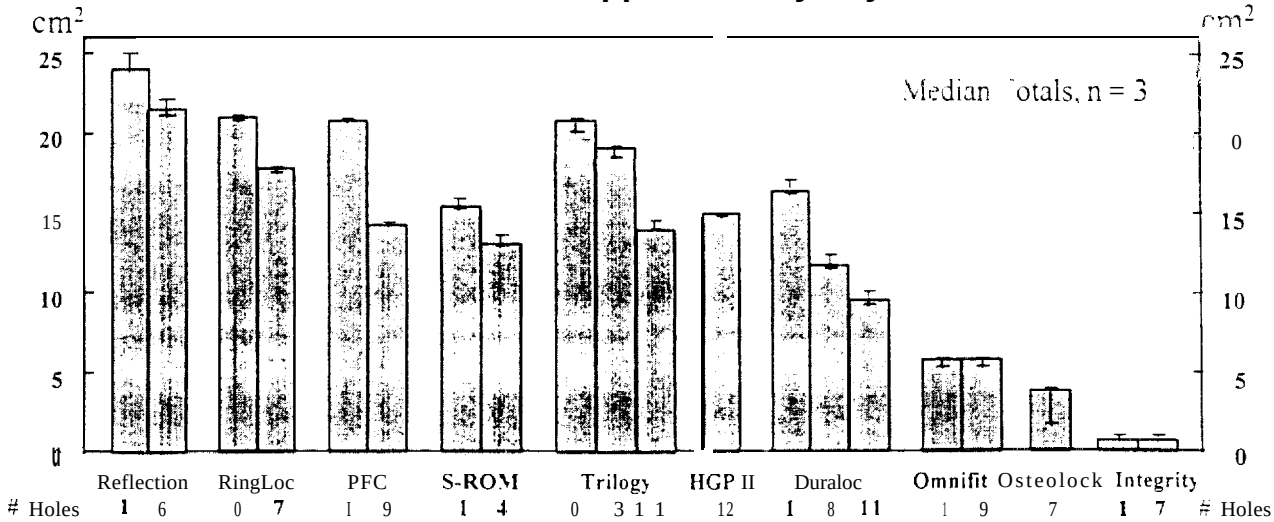


Figure 3. Contact area of supported polyethylene over [illegible] up to, but not including the rim.

-- DISCUSSION

The significance of polyethylene/metal conformity rests in the understanding that high contact and subsurface stresses in polyethylene lead to wear and debris formation. It has been suggested that the most active mechanisms in polyethylene wear are pitting and delamination[5]. These mechanisms are more appropriately referred to as forms of surface fatigue failure. Dynamic tensile and compressive stresses, often reaching greatest magnitudes near the outer and inner surfaces of the polyethylene, drive crack propagation, eventually resulting in pitting and delamination[6]. Moreover, as unsupported polyethylene is cyclically loaded, any plastic deformation that takes place, may incur residual stresses in the polymer. Although such residual stresses typically increase material strength for future loads applied in the same direction, load distributions in the polyethylene not only vary in direction, but in amplitude as well.

The presence of gaps and holes adjacent to the polyethylene prevent the transfer of stresses directly to the underlying metal, concentrating these stresses in regions of conformity. Based on this premise, the ideal stress transl'erconfiguration, as suggested by the following models, would be an assembly where maximum conformity is assured throughout the dome of the metal shell. The first model assures full conformity throughout the dome providing a large area of contact directly beneath the loaded polyethylene. The second model assures full conformity initially on the rim with full conformity throughout the dome occurring only after elastic deformation. In the latter model, initial stresses are taken up at the rim, followed by a load sharing scenario between the rim and the dome. If plastic deformation results, however, residual stresses may remain within the polyethylene which could weaken the polymer's resistance to surface fatigue failure. Because it seems unlikely that all deformation throughout the lifetime of the implant will be of an elastic nature, the first model is believed to be most realistic as an optimum clesign configuration. Alternative interface configurations with incompl conformity and a lower potential for wear may exist as a result of specific design. The extent to which any design presented fits this description is unknown, and the issue remains undocumented in the literature.

The degree to which actual cups appear to approximate the first model is apparent qualitatively in the cross sections, and quantitatively in Figures 2-3. Note in Figure 2, that in general, gaps account for the majority of nonconformity, even in cups with multiple holes. Other than rim contact preventing the liner from fully seating in the dome, large gap nonconformity may be attributable to locking mechanism geometries, poor machining tolerances, or simply design of the interface. In many of the multiple hole cups, lack of support attributable to the holes themselves is considerable. Thus, selective placement of a minimal number of holes is strongly recommended as an effective means of achieving greater conformity.

While it is valuable to understand the causes oi nonconformity, the areas of conformity as shown in Figure 3 suggest an absolute context by which average contact stresses may be inierrecl. The goal to increase conformity is synonymous with the goal to increase contact area. Although certain locales ot'contsct will be of much greater relevance than others for stress transfer in any single loading condition, dynamic loading in common activities such as gait, suggest the necessity for contact over a relatively wide range. Not only is it likely that an increase in contact area may reduce stress-induced redefinition of the polyethylene surface, but as a result it may inhibit catalysis of wear mechanisms. Thus, to decrease polyethylene wear and increase implant longevity, it is recommended that areas of unsupported polyethylene should be minimized by increasing cup/liner conformity and by eliminating unnecessary holes.

These ongoing laboratory evaluations assist an understanding of the anticipated performance of contemporary acetabular cup designs. The results are intended to aid the surgeon in device selection when considering patient factors. Further, they provide the manufacturer with design criteria and assist regulator) agencies in determining the safety and efficacy of specific cup designs.

REFERENCES

1. Howie, D.W., Vernon-Roberts, B., Oakeshott, R., Manthey, B.: A Rat Model of Resorption of Bone at the Cement-Bone Interface in the Presence of Polyethylene Wear Particles, Journal of Bone and Joint Surgery, Vol. 70-A, No. 2:257-263, 1988.
2. Marra, J.M., Marder, R.A., Amstutz, H.C.: The Pathology of Failed Total Joint Arthroplasty, Clinical Orthopaedics and Related Research, No. 170: 175-83, 1982.
3. Bartel, D.L., Burstein, A.H., Toda, M.D., Edwards, D.L.: The Effect of Conformity and Plastic Thickness on Contact Stresses in Metal-Backed Plastic Implants, Journal of Biomechanical Engineering, Vol. 107:193-199, 1985.
4. Kurtz, S.M., Gabriel, S.M., Bartel, D.L.: The Effect of Non-Conformity between Metal Backing and Polyethylene Inserts in Acetabular Components for Total Hip Arthroplasty, Transactions of the Orthopaedic Research Society, Vol. 18, Sec. 2:434, 1993.
5. Wright, T.M., Bartel, D.L., Rimnac, C.M.: Surface Damage in Polyethylene Joint Components, *in* The Changing Role of Engineering in Orthopaedics, Mechanical Engineering Publication Ltd., London, 187-192, 1989.
6. Connelly, G.M., Rimnac, C.M., Wright, T.M., Hertzberg, R.W., Manson, J.A.: Fatigue Crack Propagation Behavior of Ultrahigh Molecular Weight Polyethylene, Journal of Orthopaedic Research, Vol. 2, No. 2:119-125, 1984.

© 1995 Orthopaedic Research Laboratories
The Mt. Sinai Medical Center

PUSH-IN, PULL-OUT, AND TOGGLE-OUT OF FEMORAL HEAD IN ASSEMBLED CUP

March 1, 1999

Testing of Ring-Lot 32mm
Constrained 10" One-Piece Liner

Test Conducted by: Troy Hershberger
Director of Product Development

Dan Williamson
Development Engineer

Kelly Howard
Laboratory Technician

Test Conducted at: Biomet, Inc.
P.O. Box 587
Warsaw, IN 46580

Report Prepared by: Troy Hershberger

Test Numbers: MT 1603 – Completed 3/1/99 and MT 0789 – Completed 2/23/95

Objective: Determine head push-in. pull-out and toggle-out strength for new one-piece constrained 10" liner design.

Materials: Size 23 constrained liners (1 I-105833) and RD 114570 (identical design to 1 l-105833)
Constrained liner lock bands (RD 11 4576 1
Appropriate acetabular components
Custom test fixtures
Interlaken testing apparatus
All componenets were off-the-shelf components representing standard production procedures.

Methods: Push-in tests were performed on 3 Size 23 constrained liner test samples as shown in Figure 1. The femoral head was pushed into the liner and the corresponding load was recorded.

Pull-out tests were performed on 3 Size 23 liners as shown in Figure 2. These pull-out tests were done following the push-in test for each specific sample.

Lever-out tests were performed on 6 Size 23 liners as shown in Figure 3. Toggling of the head was allowed until there was contact between the shaft on the head and the wall of the liner opposite the 10° raised side. The shaft of the test head was the same diameter as an implant neck taper. The load was then increased until the head levered out of the constrained liner.

For each test a rate of .008"/second was used. Load versus displacement was recorded for each test.

Results:

Push-In Tests

Test Sample	Max. Load (1 lbs)	
Size 23 Liner	**38.4**	
Size 23 Liner	**44.7**	Mean 40.4
Size 23 Liner	**38.2**	S.D. ± 3.7

Pull-Out Test

Test Sample	Max. Load (lbs)	
Size 23 Liner	361.2	
Size 23 Liner	371.0	Mean 361.4
Size 23 Liner	351.9	S.D. ± 9.5

Lever-Out Tests

Test Sample	Max. Load (lbs.)	Resulting Torque (inch lbs.)	
Size 23 Liner	164	656	
Size 23 Liner	154	616	
Size 23 Liner	147	588	Mean 422
Size 23 Liner	149	596	S.D. ± 33
Size 23 Liner	152	608	
Size 23 Liner	167	668	

Figures 4-7 show a graphical representation of the 'test results.

Discussion/Conclusion:

The 32mm constrained liner will be offered in sizes ranging from 23 to 28. The Size 23 liner was used for the tests because it has the least amount of polyethylene that would resist the head from distracting from the liner.

Push-in was achieved when the head component snapped into the liner. Pull-out and toggle-out tests were performed until the head distracted from the liner. This would be considered failure of the device.

Push-in tests indicate that assembly by the surgeon during surgery will be possible.

Head distraction force for the constrained liner yielded results similar to those reported in the literature for a competitive constrained liner (Joint Medical Products, head pull-out 300 lbs[1]).

The failure mode for the Lever-out test was as expected. The 32mm diameter ball levered out of the liner leaving the liner in the shell and the locking band in place. The average torque to failure of 622 inch pounds was significantly greater than Osteonics' 270-4 10 inch lbs., as reported in their FDA submission, and 150 inch lbs. for the Joint Medical Products device. [1]

These results indicate that dislocation of the femoral head component from the acetabular component is unlikely to occur at a rate greater than what is currently accepted as state-of-the-art technology.

[1] Anderson, MJ. Murray, WR, Skinner. HB; Constrained Acetabular Components, *J. Arthroplasty*, Vol. 9. No. 1:17, 1994.

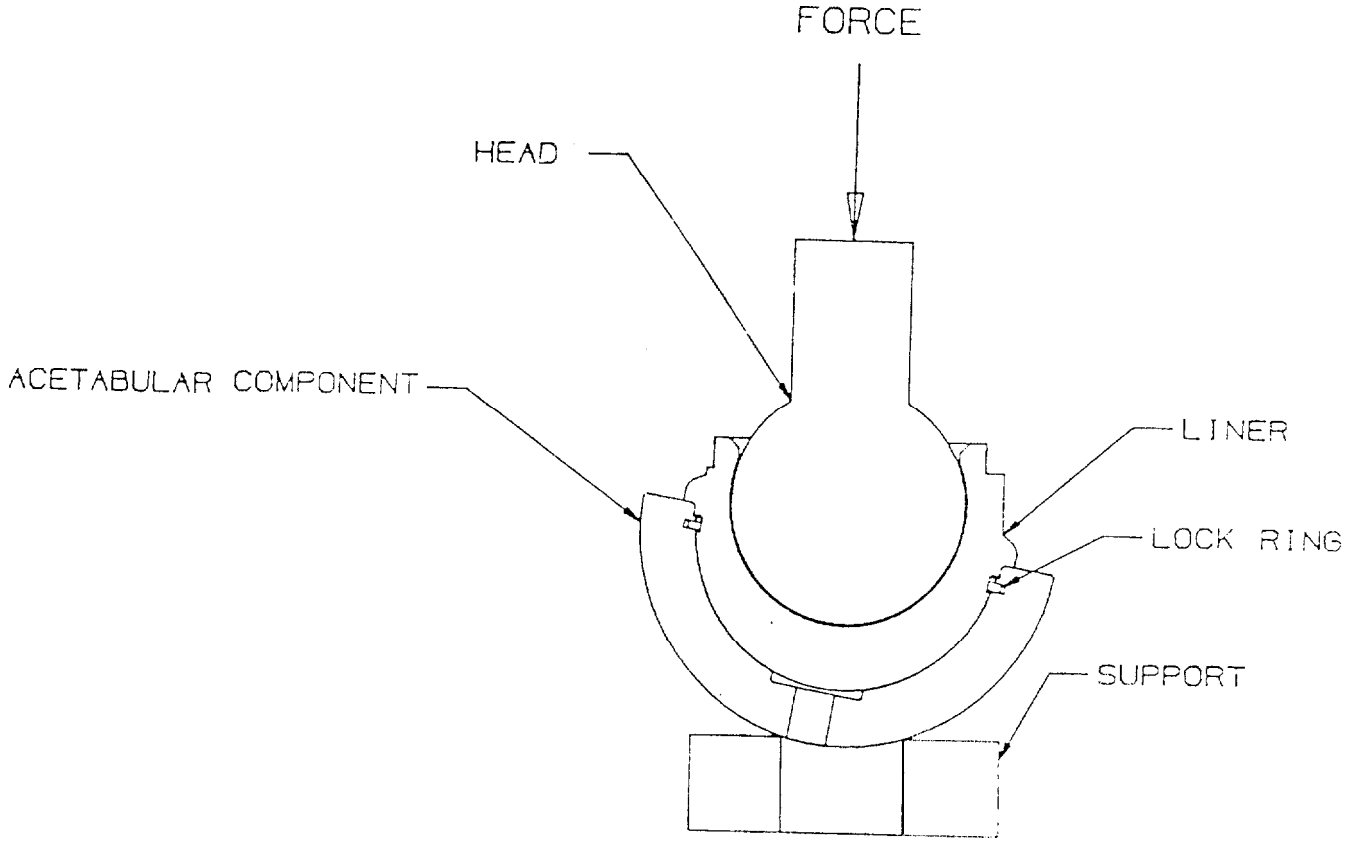


FIGURE 1

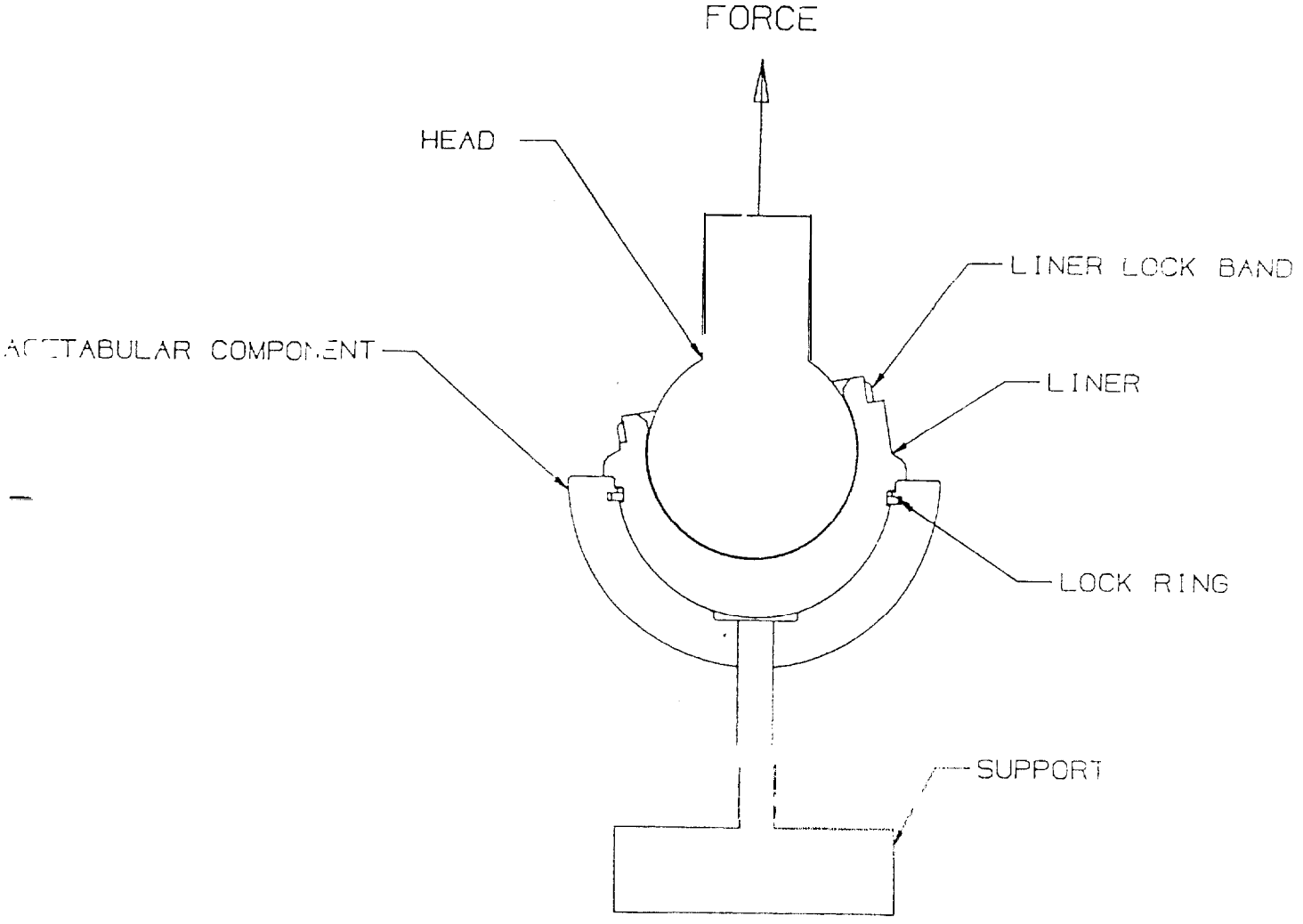

FORCE
HEAD
LINER LOCK BAND
ACETABULAR COMPONENT
LINER
LOCK RING
SUPPORT

FIGURE 2

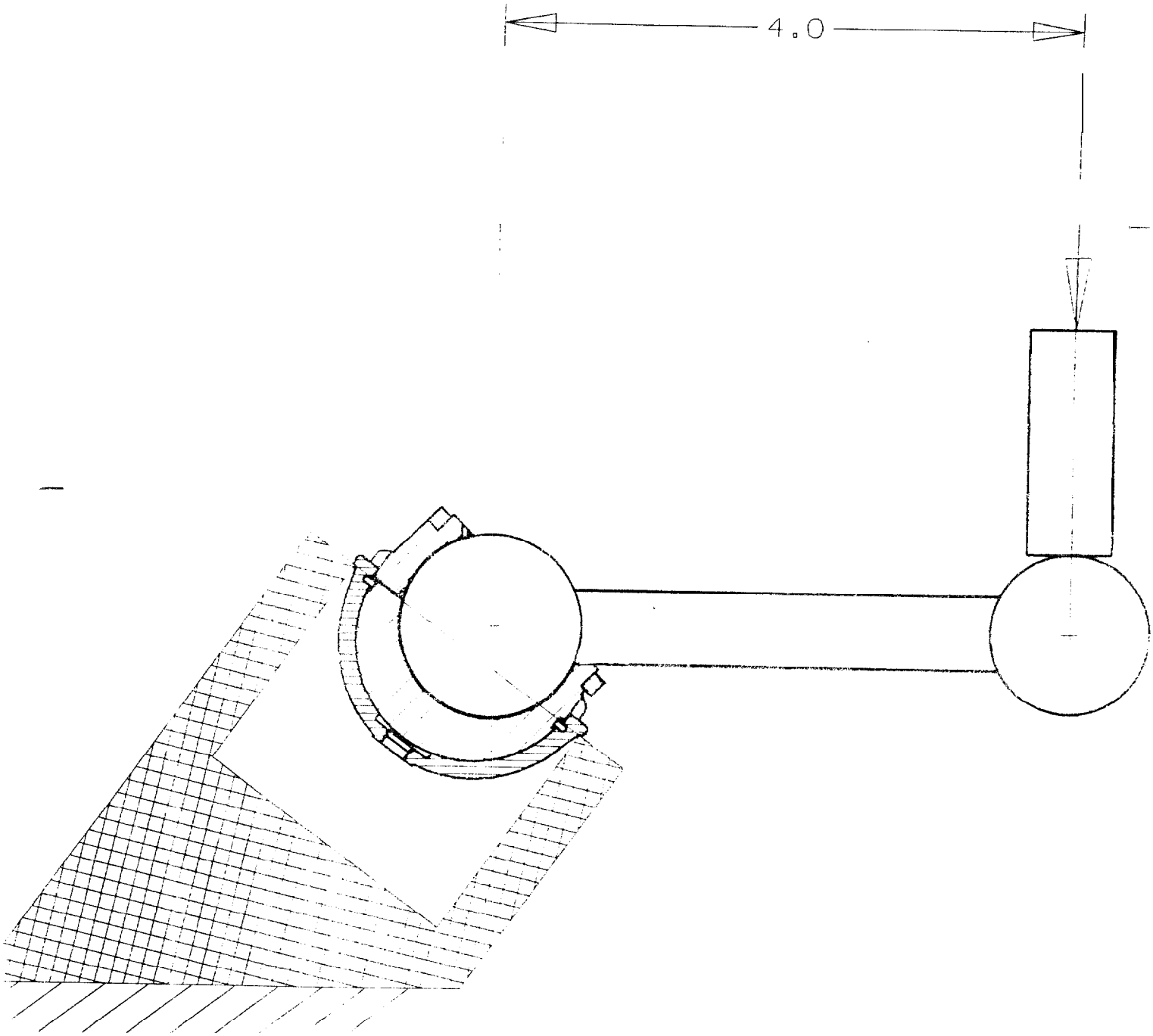


FIGURE 3

Graph Title

MT1603 CONSTRAINED LINER PEAD LEVER OUT #

Peak Load 164.2

Print

Invert Disp

ON

Invert Load

ON

Start Point

27

# of Points

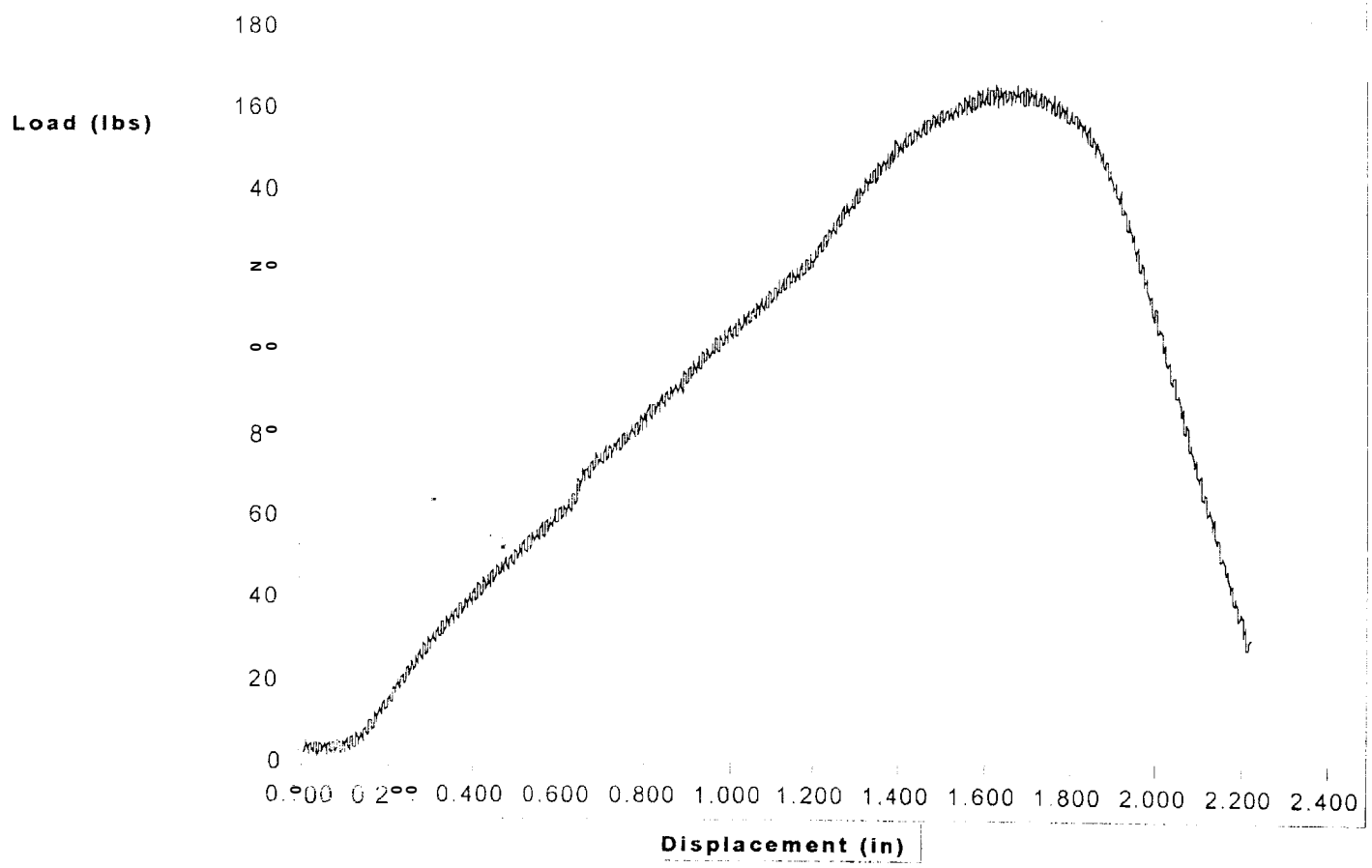
1300

Disp Offset

-0.087

Load Offset

1.0



000159

Graph Title

MT1603 CONSTRAINED LINER HEAD LEVER OUT #2

Peak Load 153.6

Print

Invert Disp

ON

Invert Load

ON

Start Point

49

# of Points

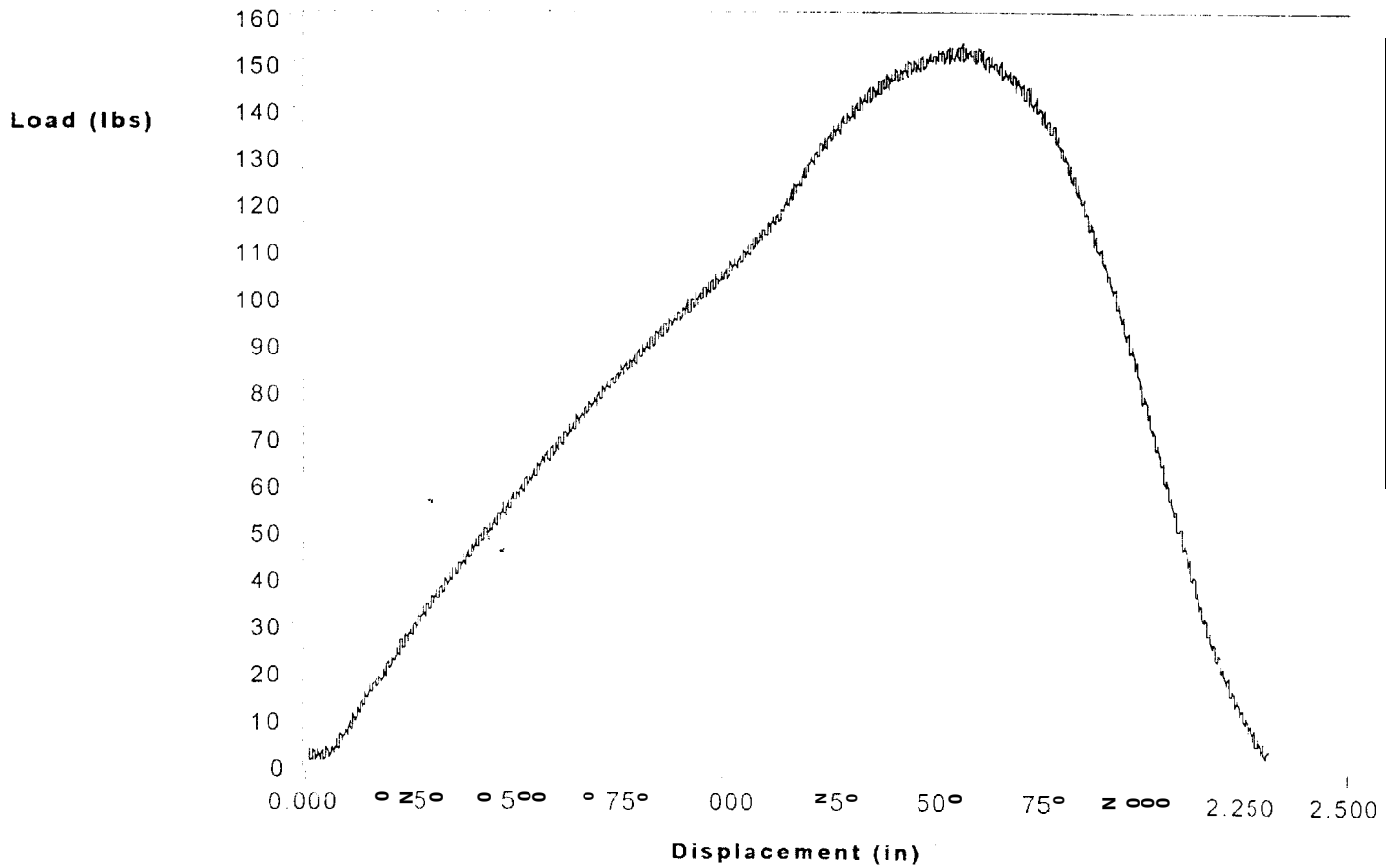
1354

Disp Offset

-0.243

Load Offset

1.0



0001600

Graph Title

MT1603 CONSTRAINED LINER HEAD LEVER OUT #3

Peak Load 147.0

Print

Invert Disp
ON

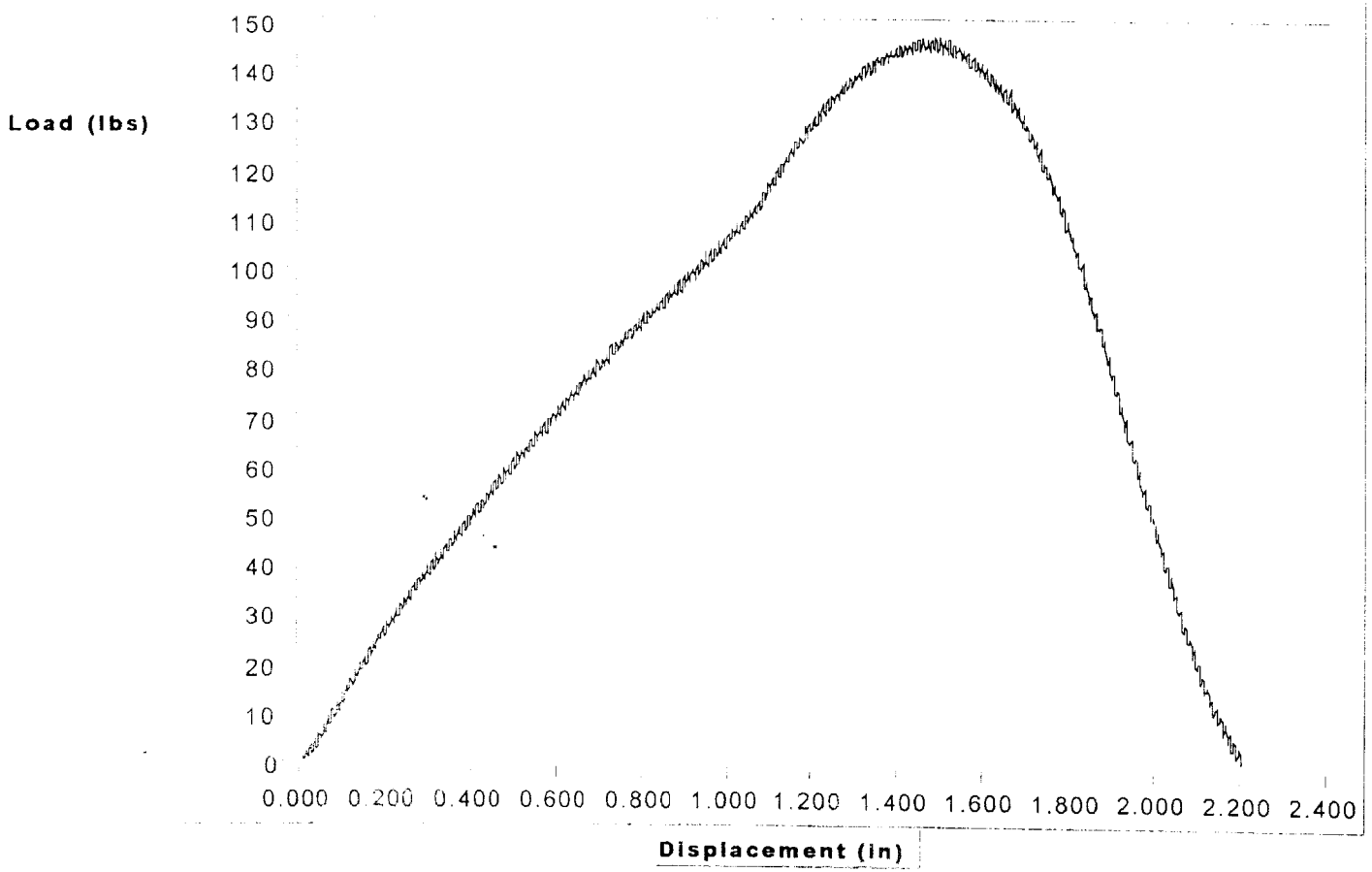
Invert Load
ON

Start Point
112

# of Points
1292

Disp Offset
-0.266

Load Offset
0.0



0001161

Graph Title

MT1603 CONSTRAINED LINER HEAD LEVER OUT #4

Peak Load 149.4

Print

Invert Disp

ON

Invert Load

ON

Start Point

80

# of Points

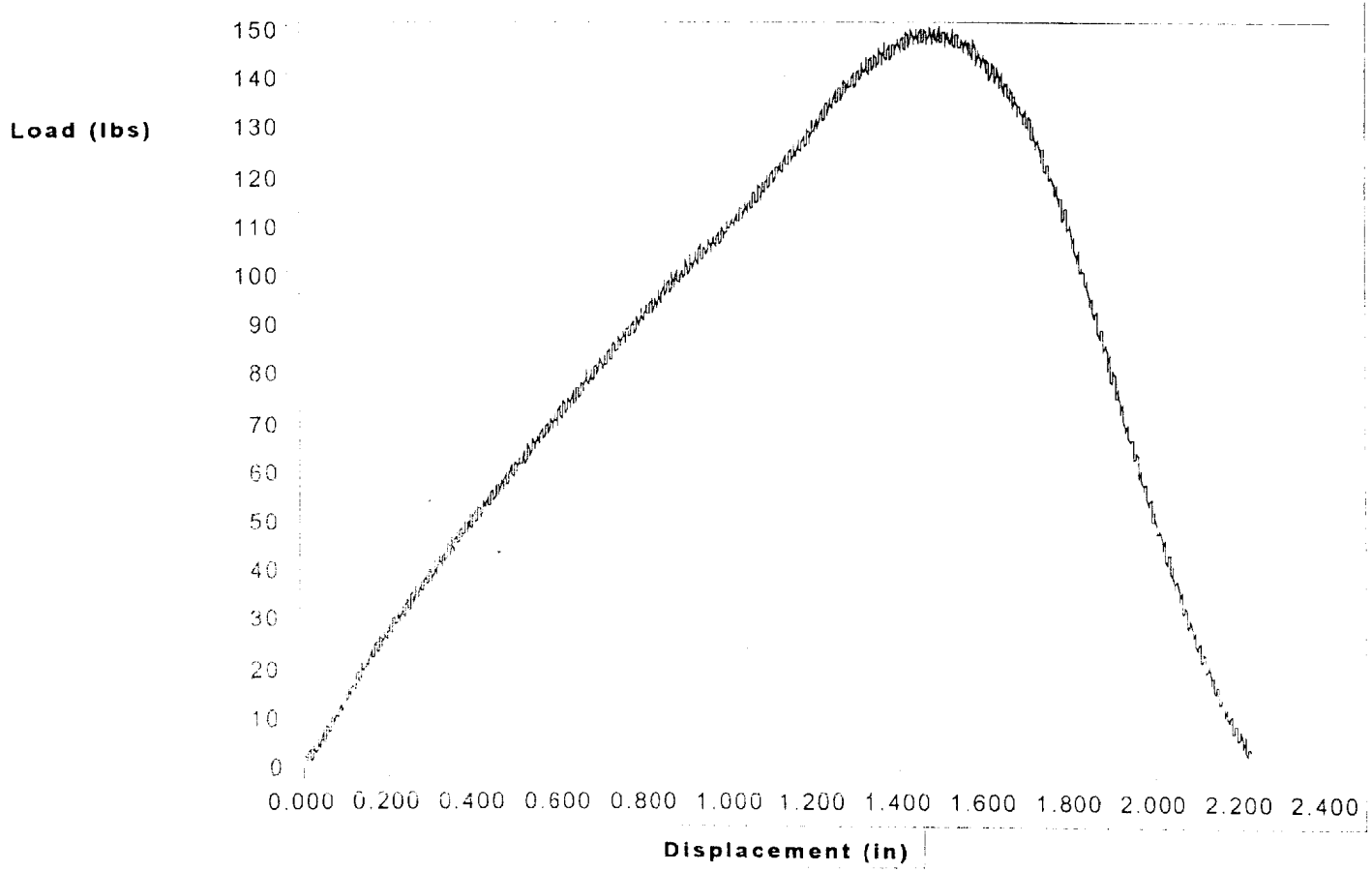
1302

Disp Offset

-0.318

Load Offset

0.0



000162

G ph

MT1603 CONSTRAINED LINER HEAD LEVER OUT #5

Peak Load 152.3

Print

Invert Disp

ON

Invert Load

ON

Start Point

135

# of Points

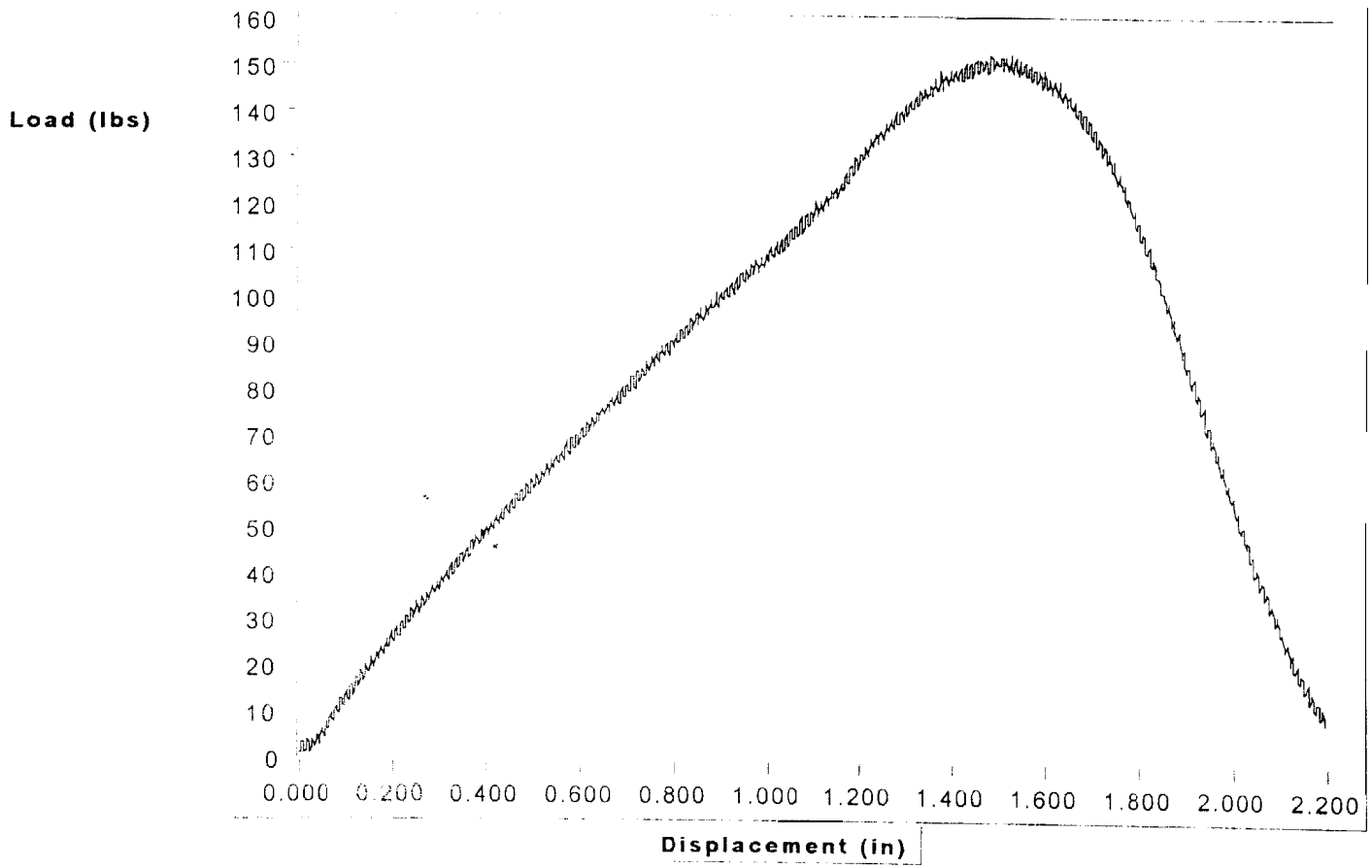
1289

Disp Offset

-0.177

Load Offset

1.0



000163

Graph Title

MT1603 CONSTRAINED LINER HEAD LEVER OUT #5

Peak l

Print

Invert Disp

ON

Invert Load

ON

Start Point

135

# of Points

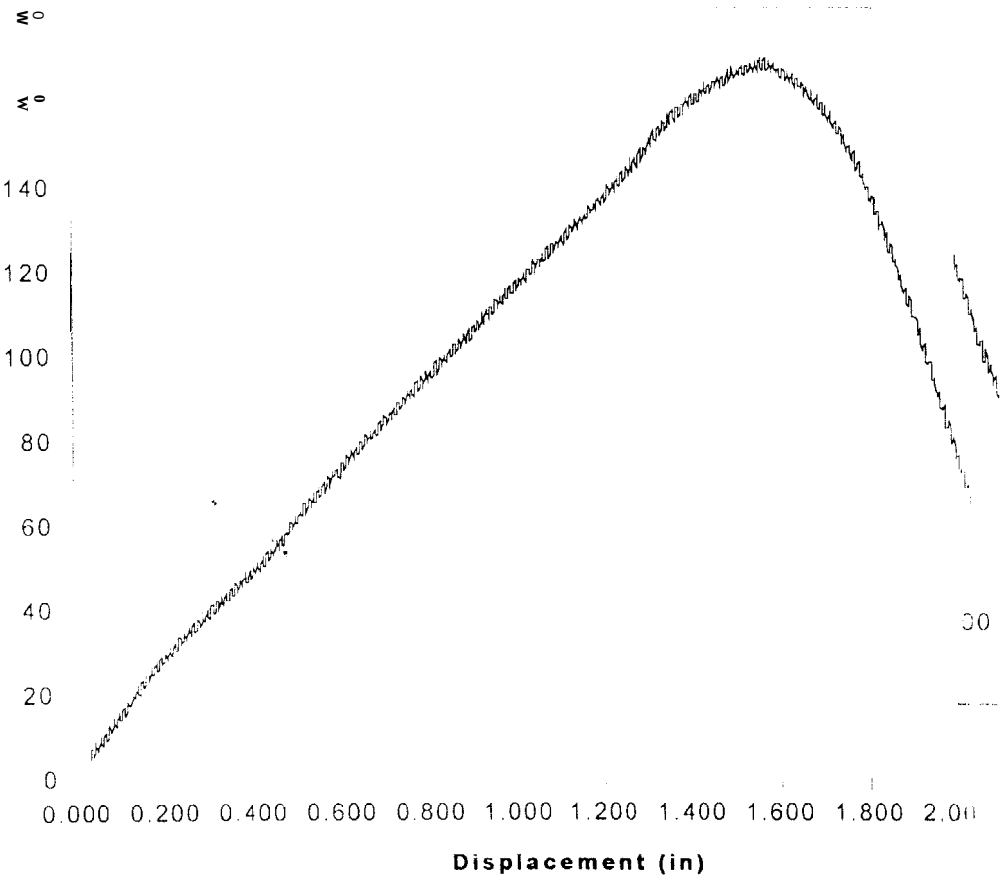
1289

Disp Offset

-0.177

Load Offset

1.0



0001164