Stability of Modular Acetabular Components Depends on the Lacking Mechanism Design, Temperature, and Axial Load

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Appendix D - UNIVERSITY HONORS PROGRAM
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PROJECT TITLE: Stability of Modular Acetabular Components Depends on Locking Mechanism Design, Temperature, and Axial Load

I have reviewed this completed senior honors thesis with this student and certify that it is a project commensurate with honors level undergraduate research in this field.

Signed: Jack Wasserman, Ph.D.  Faculty Mentor

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Comments (Optional):
Stability of Modular Acetabular Components Depends on the Locking Mechanism Design, Temperature, and Axial Load

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Abstract

The goal of this study was to investigate the rotational stability of modular press-fit acetabular components with four different locking mechanism designs by measuring the micromotion occurring at the liner/shell interface during torsional loading at either room (21 degrees C) or body temperature (37 degrees C), and at either high (2943 N) or low (490 N) compressive loads. Torsional loads (±2.5 N-m at 3 Hz for 50 cycles) with superimposed axial loads were applied to four liner/shell constructs of each of the four locking mechanism designs with a servohydraulic loading frame. Rotational micromotion was measured with an LVDT arranged tangentially to the liner/shell construct. It was found that different locking mechanisms responded differently to liner temperature and compressive load. These findings support the hypothesis that the effect of temperature and compressive load on the stability of the liner/shell interface depends upon the design of the locking mechanism between the liner and metal shell.
**Introduction**

Because of the suspected causative role of particulate material in osteolysis, the generation of wear debris is an important concern in total hip arthroplasty (THA). In particular, high density polyethylene particles produced by wear of an acetabular liner are thought to be a main cause of osteolysis in cementless THA.\(^3,5,9,12,13,16,17\) In addition to the more well-studied primary articulation between the metal head of the femoral component and the acetabular liner, another potentially significant source of polyethylene debris is the articulation between the back side of the polyethylene liner with the inner surface of the adjacent metal acetabular shell.\(^4,8\)

Although modular press-fit acetabular components have significantly increased the availability of surgical options in THA, the torsional stability of the modular components has come under scrutiny. A stable fit between a liner and its shell could reduce the production of debris by limiting the micromotion occurring at the liner/shell interface.\(^4,8\) There are several possible factors which might affect the stability of this interface, one of which is the design of the locking mechanism between the polyethylene liner and metal shell.\(^4,14\) A more secure locking mechanism should reduce the relative motion between the liner and shell. It is also reasonable to expect liner temperature to have a significant effect on the interface stability, due to polyethylene’s high coefficient of expansion. It has been shown that the cooling of a polyethylene liner produces a size contraction which significantly reduces the force necessary to seat the liner in its metal shell.\(^15\) Expansion of a liner due to increased temperature could, for some locking
mechanism designs, increase component congruency and stability. Also, subjecting the acetabular component to a physiologic compressive load could increase the degree of contact between the liner and shell surfaces, reducing their relative motion.4

In the present study, rotational stability of modular press-fit acetabular components has been investigated by measuring the micromotion occurring at the liner/shell interface during torsional loading at either room or body temperature, and at either high or low compressive loads. Four locking mechanism designs were tested to determine if different types of locking mechanisms were similarly affected by temperature and load. The proposed hypothesis was that the effects of temperature and compressive load on the stability of the liner/shell interface depend upon the design of the locking mechanism between the liner and metal shell.

Materials and Methods

Locking Mechanisms:

Four polyethylene liner samples were tested for each of four designs of liner/shell locking mechanisms. All shells had a 56 mm outer diameter, and all liners had a 28 mm inner diameter. The liners and shells were labeled as cups A, B, C, and D according to their locking mechanism design. Cups A and C used a spline locking mechanism with 24 and 12 spline elements, respectively. The locking mechanism in cup B was based on locking lugs and a constraining ring on the inner rim of the metal shell, while Cup D used four radial spurs around the rim of the shell.
Method of Loading:

Cyclical torsional loads were applied with a servohydraulic rotational loading frame. The acetabular shell with its seated liner was clamped to a torsional load cell on the base of the loading frame (Figure 1). A 28 millimeter diameter stainless steel ball representing the prosthetic femoral head was attached to the torsional actuator. The femoral head was cemented to the concave surface of the liner with epoxy so that torsional loads were transmitted to the liner/shell interface. Static compressive loads were superimposed through the vertical movement of the base of the loading frame with attached load cell. The acetabular components and fixtures were maintained at a prescribed temperature during testing by submersion in a water bath which was incorporated into the servohydraulic loading frame.

Measurement Methods:

Two 1.6 mm diameter holes were pre-drilled into the rim of each polyethylene insert, perpendicular to the equatorial plane of the insert. A thermocouple was inserted into one of the holes to monitor the temperature of the liner during testing. A metal rod was placed into the second pre-drilled hole. A linear variable differential transformer or LVDT was fixed to the loading frame, and arranged tangentially to the acetabular component so that it contacted the metal rod (Figure 1). Motion of the polyethylene liner during testing caused the metal rod to move the LVDT and, thus, generated output. The measured linear LVDT output in microns and the distance from the LVDT to the center of rotation of the construct were used to approximated the amount of rotation. The error
due to this approximation was found to be 0.0001 degree for a 50 micron movement of the LVDT, which was a typical measured value.

Testing Protocol:

With the monitoring devices and each liner/shell assembly properly secured in the loading frame, a sinusoidal torsional load of ±2.5 N-m was applied at 3 Hz for 50 cycles, with the last 5 cycles used for micromotion measurement. Each liner was tested at the four combinations of room (21°C) or body (37°C) temperature, and low (490 N) or high (2943 N) static compressive load. This entire sequence was repeated twice for each liner.

To avoid bias due to possible wear of the liners introduced by a particular order of the temperature/axial load test states, the test sequence was alternated so that the initial test state was different for each of the four liners of a particular locking mechanism design.

The temperature of the liner was maintained to within ± 1 degree C of the target temperature. The peak applied torsional loads were controlled to within ± 0.1 N-m. The applied static compressive loads were controlled to within ± 25 N.

Statistical Analysis:

The data collected from this study were the rotations for two repetitions of the four temperature/axial load test states applied to each of the four liners, for each of the four locking mechanism designs. Data were analyzed using a repeated measures analysis of variance with two “within subjects” trial factors, temperature and compressive load, and two “between subjects” factors, the liners and repetitions. “Liners” refers to the effect of the variation in micromotion among the four liners for each locking mechanism design.
“Repetitions” refers to the effect of the variation due to the two repetitions of testing of each liner.

Results

Figure 2 shows the rotational micromotion in degrees for the four liners of Cup A as a function of the four test combinations of temperature and compression. For Cup A, whose locking mechanism is based on 24 splines, there were no significant effects on the measured rotational micromotion due to temperature, compressive load, liner, or repetition.

The locking mechanism for Cup B is based on lugs with a constraining ring. Both temperature and compressive load significantly affected the rotational micromotion, while liner and repetition did not (Figure 3).

For Cup C, whose locking mechanism is based on 12 splines, there were no significant effects on the measured rotational micromotion due to temperature, compressive load, or repetition. However, variation in micromotion due to the liner was significant, meaning that there was significant variation in measured micromotion over the four liners tested with this locking mechanism (Figure 4).

The locking mechanism for Cup D is based on four radial spurs on the inside of the metal backing. Both compressive load and liner significantly affected the rotational micromotion, while temperature and repetition did not. There was also a significant interaction between the liner and compressive load, meaning that some of the four liners
with this type of locking mechanism reacted differently to compressive load than did others (Figure 5).

Discussion

The articulation between the back side of the polyethylene liner and the adjacent metal shell of modular acetabular components has been recognized as a potential source of polyethylene wear debris, which has in turn been implicated as a cause of osteolysis and arthroplasty failure. A stable fit between the liner and its shell, due to either the high coefficient of expansion of polyethylene or to a superior locking mechanism, could reduce the production of debris by limiting the magnitude of the micromotion occurring at the liner/shell interface. Other factors such as the surface roughness of the inner surface of the metal shell, the presence of screw holes in the shell, or the degree of congruency between the mating liner and shell components under load, will also influence the amount of debris generated. Additionally, femoral component head size and surface finish, liner thickness, articulating materials, and patient age and gender may also influence wear.

The present study supports the hypothesis that the effect of temperature and compressive load on the stability of the liner/shell interface depends upon the design of the locking mechanism between the liner and metal shell. It should be noted, however, that the statistical significance of the differences between the locking mechanism designs in this study will not necessarily result in significant clinical differences. Each locking mechanism achieves its rotational stability by different means. The behavior of each type
of locking mechanism will probably depend, to differing degrees, on the relative amount of locking that can be achieved by radial expansion of the polyethylene due to temperature effects, and on the deformation produced from the compressive loading of the cup. For example, the rotational micromotion of Cup A, with its 24 spline locking mechanism, was least sensitive to changes in temperature and load, while the stability of Cup B, with its lugs and constraining ring, was significantly affected by temperature and compressive load. In addition, some locking mechanisms may achieve their stability by direct engagement of the polyethylene by some other means, where temperature and compression would have little or no effect.

For locking mechanisms in which rotational stability was significantly affected by temperature, greater stability was achieved at body temperature conditions, compared to room temperature. For locking mechanisms in which compressive load significantly affected the rotational stability, greater stability was achieved with a high compressive load, compared to low compressive loads. In Cups C and D, there was a significant variation in measured micromotion among the four liners tested for each locking mechanism. One possible contribution to this variation might be a lack of consistency in the manufacturing of the locking mechanism between the liner and shell.

This study has several limitations. The components in this study were subjected to only dynamic torsional loading with a low number of cycles, and with a superimposed static compressive load representing body weight, a loading condition that does not perfectly simulate in vivo hip loads. More importantly, the locking mechanism will probably behave differently in high cycle fatigue testing, compared to the low cycle loading reported here. Finally, it is known that the wear process is multifactorial. This
study only considered the effect of micromotion, not surface roughness, conformity, or contact stresses. With these limitations in mind, the present results should not be used to compare locking mechanism designs; rather, locking mechanism comparisons should be based on high cycle fatigue tests. The results of the present study are, however, important for establishing appropriate test conditions for high cycle fatigue testing.

Conclusions

It is concluded that the locking mechanism between a polyethylene liner and its metal shell is an important design feature which may have a considerable impact on the micromotion and wear at the liner/shell interface. The use of body temperature and dynamic superimposed body weight may more realistically portray functional condition and may be recommended for future testing of locking mechanisms. Further study of the high cycle fatigue characteristics of each locking mechanism design under body temperature and physiologic loading conditions is necessary before more definitive comparisons can be made regarding the benefit of different design features of the locking mechanisms.
References


15. Roland GP, McAllister RW, Bourgeault C, et al: Does cooling an acetabular liner make its insertion into a metal shell easier? (need to get complete reference for this)

Figure Legends

Figure 1. Schematic of the liner/shell construct fixed to the loading frame. The thermocouple measured the temperature of the liner, and the LVDT arrangement detected the rotational motion of the liner within the shell during loading.

Figure 2. Scatter plot representing the rotational micromotion in degrees for the four liners of Cup A. “R” refers to room temperature, “B” to body temperature, “L” to low compressive load, and “H” to high compressive load.

Figure 3. Scatter plot representing the rotational micromotion in degrees for the four liners of Cup B.

Figure 4. Scatter plot representing the rotational micromotion in degrees for the four liners of Cup C.

Figure 5. Scatter plot representing the rotational micromotion in degrees for the four liners of Cup D.
Locking Mechanism A
Spline Locking (24 elements)

CONDITIONS (Temperature, Load)
Locking Mechanism B
Lugs with Constraining Ring

ROTATION (degrees)

R, L    R, H    B, L    B, H

CONDITIONS (Temperature, Load)
Locking Mechanism C
Spline Locking (12 elements)

CONDITIONS (Temperature, Load)
Locking Mechanism D

4 Radial Spurs around rim

ROTATION (degrees)

CONDITIONS (Temperature, Load)