DIRECT ANTERIOR TOTAL HIP ARTHROPLASTY GAIT BIOMECHANICS AT THREE AND SIX MONTHS POST SURGERY

A THESIS SUBMITTED TO THE GRADUATE DIVISION OF THE UNIVERSITY OF HAWAI’I IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

IN

KINESIOLOGY AND REHABILITATION SCIENCE

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Part I

INTRODUCTION

Osteoarthritis (OA) is a degenerative disease that affects the cartilage at the ends of bones, causing joint stiffness and pain with subsequent compensatory gait mechanics [1-5]. Hip OA patients often develop gait adaptations to minimize the pain experienced when performing activities of daily living. These gait adaptations include Trendelenburg gait[6] and decreased: gait velocities, step and stride length [7-13], external hip moments (adduction, extension and internal rotation) [14-16], and internal hip moments (abduction and external rotation) [7, 11]. Lower internal moments of the hip may be attributed to decreased muscular torque in the involved hip abductor and extensor muscle groups[7]. External moments provide a reflection of how an antalgic gait allows compensation for muscle weakness in the stance limb [16]. Lateral trunk lean shifts the center of mass towards the stance limb and decreases the external adduction moment arm decreasing the external joint moments [15]. Conversely, Trendelenburg gait causes hip drop on the non-stance limb increasing the external adduction moment arm on the stance limb causing hip OA patients to walk slower thus producing a lower vertical ground reaction force. Once these compensatory measures become intolerable the most effective treatment is total hip arthroplasty (THA) [17, 18]. The goal of THA is to correct anatomical insufficiencies and to reduce pain and increase function [19-21].

The traditional THA approach involves a large incision on the lateral or posteriolateral aspect of the hip and damage to the hip abductors and external rotators to expose and access the hip joint. This approach results in long recovery times and post operation movement restrictions to prevent posterior dislocation.[20, 22] Consequently,
minimally invasive surgical (MIS) approaches have been developed to decrease internal muscle damage and decrease recovery times. Minimally invasive THA is an umbrella term consisting of several different types of procedures that range from use of the traditional approach with a decrease in the initial incision to differences that include the limitation or elimination of musculature detachment/reflection to minimize post-operative soft tissue damage. One of these MIS approaches, the direct anterior approach (DA), is a muscle sparing technique that involves anterior medial incision via the intramuscular plane where muscles are retracted to access the hip joint. [20, 21, 23, 24] During this procedure, the tensor fascia latae is retracted laterally and the rectus femoris and psoas muscles are retracted medially. The hip is then dislocated and the femoral and/or acetabular components are substituted without damaging to the surrounding soft tissues.[19, 25]

Regardless of the surgical approach kinematic and kinetic gait changes occur following THA surgery[7-9, 11, 12, 16, 22, 23, 26-29]. Minimally invasive THA results show improvements in walking velocity, hip kinematics and kinetics when compared to the traditional THA procedures [8, 9, 22, 27]. Furthermore greater improvements in, walking velocity, single leg support, and hip range of motion were revealed following the MIS DA THA than other MIS THA procedures [8-10, 22].

Gait characteristics that separate THA patients from non-OA sufferers even after THA surgery are external hip adduction and internal rotation moments [7, 11, 16, 23, 26]. These gait asymmetries have been attributed to weakness in the surrounding musculature and learned gait adaptations prior to surgery [11, 16]. Unfortunately, few studies have been conducted to investigate various MIS THA techniques and only four studies
involved the effects the DA THA approach. However, three studies involved three
dimensional gait analysis and two compared DA THA and asymptomatic control groups.

Therefore the purpose of this study was to investigate hip kinematic and kinetic
gait variables of MIS DA THA patients compared to a healthy control group at three time
periods.
METHODS

Research Design

A longitudinal prospective research design was used to analyze three dimensional biomechanical gait characteristics of DA THA and control participants. Fourteen 3 x 2 analyses of variance with repeated measures (RM-ANOVA) were used to analyze walking velocity and kinematic and kinetic variables. Independent variables consisted of group (THA or Control) and time (initial test, 3 months post-test, and 6 months post-test). The initial test for THA participants was performed approximately one to two weeks prior to surgery and all post-tests were performed three or six months after surgery. Similarly the initial test for control group participants was performed 3 months before the three and six month data collection periods. Dependent variables consisted of gait velocity; kinematic measures of hip flexion, extension, abduction, adduction, and internal and external rotation range of motion; kinetic measures of maximum vertical ground reaction force (VGRF), external hip moments in the sagittal, frontal, and transverse planes. (Appendix A). All moment kinetic variables were reported and discussed as external moments in this study.

Participants

Participants were eight DA THA hip OA patients (3 females, 5 males) ranging in age from 43 to 83 (mean age 62.46 ± 11.80) who elected to undergo DA THA surgery and eight non-OA control participants (3 females, 5 males) ranging in age from 55 to 67 (mean age 61.46 ± 4.0) who volunteered for the study. The same board certified orthopedic surgeon trained in minimally invasive THA performed all DA THAs. Direct anterior THA group participants were screened and cleared for study participation by the
study surgeon during their routine pre and post-operative visits. Control group participants also completed a medical history questionnaire (Appendix B) prior to study participation that was screened by a board certified physician. All THA and control group participants signed informed consent forms approved by both the Western Institutional Review Board and the University’s Committee on Human Studies prior to study participation (Appendix C and D). Both DA THA and control participants were excluded from the study if they had a history of previous lower extremity joint replacement, a neurological or orthopedic condition that affected walking, or if they required the use of an assistive device while walking.

**Procedure**

All data, including anthropometric and walking gait were collected bilaterally on the THA and control participants in the University’s Human Performance and Gait Laboratory by the same Board of Certification (BOC) certified athletic trainers. Participants were then fitted with the Knee Alignment Device Alike set of 27 infrared retro-reflective markers (18 mm in diameter) attached to the following anatomical landmarks: clavicle, C7 spinous process, T10 spinous process, right scapula, sternum, bilaterally at the AC joints, ASIS, PSIS, thigh, medial and lateral knee, tibia, medial and lateral ankle, heel, and toe according to the Vicon manual (Vicon, Inc., Centennial, CO) [30]. During testing, participants walked barefoot at a self-selected speed through a four meter data collection field, where walking velocity was determined using infrared timers (Speed Trap II, Brower Timing Systems, Draper, UT). A total of three successful trials were collected for each lower limb. A successful trial was defined as placement of the entire tested foot on the force plate without altering gait or targeting.
A three-dimensional (3D) motion capture system, including six Vicon MX13 motion capture cameras (Vicon, Inc., Centennial, CO) and Vicon software (Nexus and Polygon, Vicon, Inc., Centennial, CO), was used to capture, reduce, and analyze kinematic data. Two force plates (Advanced Mechanical Technology Incorporated, Boston, MA) embedded flush with the floor surface were used to collect kinetic data during walking trials. Kinematic data were collected at 240 Hz and time synchronized with kinetic data collected at 480 Hz then smoothed using a Woltring filter (MSE 10).

**Statistical Analysis**

Descriptive statistics including means, standard deviations and ranges were generated for all demographic characteristics and variables of interest. Inferential statistics were used to analyze walking velocity and kinematic and kinetic variables. All statistical analyses were conducted using SPSS v19 (IBM SPSS Statistics, IBM Corporation, Armonk New York, USA). When significant interactions were revealed subsequent simple effects tests were conducted to identify where the interaction occurred. When significant repeated measures main effects were revealed, Least Significant Differences (LSD) post hoc tests within each group were performed to determine where the differences occurred. Alpha level was set at $p < 0.05$. 
RESULTS

Participant Demographics

The demographic characteristics of the DA THA and control participants included age, height, weight, and body mass index (BMI) (Table 1). There were no statistical differences in age, height, weight, and BMI between groups.

Table 1. Demographic Data: Means and Standard Deviations for DA THA and Control Subjects at Initial Test, and Three and Six Months Post-test.

<table>
<thead>
<tr>
<th></th>
<th>Initial Test</th>
<th>3 months post-test</th>
<th>6 months post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DA-THA</td>
<td>Control</td>
<td>DA-THA</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.25 ± 12.45</td>
<td>61.38 ± 4.17</td>
<td>62.50 ± 12.2</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.67 ± 0.11</td>
<td>1.64 ± 0.10</td>
<td>1.67 ± 0.10</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74.34 ± 7.45</td>
<td>72.21 ± 7.26</td>
<td>73.55 ± 7.28</td>
</tr>
<tr>
<td>BMI</td>
<td>26.80 ± 3.07</td>
<td>26.70 ± 2.56</td>
<td>26.56 ± 2.91</td>
</tr>
</tbody>
</table>

Walking Velocity

Analysis of walking velocity revealed a significant interaction effect for group and time (p = 0.029). Post hoc analysis indicated that the DA THA group’s walking velocity increased between the initial test and three month post-test (p = 0.002) and between the initial test and six month (p = 0.001) post-test but not between three and six month post-test (p = 0.773).
Table 2. Walking Velocity: Means and Standard Deviations DA THA and Control Subjects at Initial Test and Three and Six Months Post-test.

<table>
<thead>
<tr>
<th>Walking Velocity (m/sec)</th>
<th>Initial Test</th>
<th>3 Months Post-test</th>
<th>6 Months Post-test</th>
<th>Group</th>
<th>Time p value</th>
<th>Interaction p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DA THA</td>
<td>0.86 ± 0.34</td>
<td>1.30 ± 0.18</td>
<td>1.34 ± 0.22</td>
<td>0.287</td>
<td>0.000*</td>
<td>0.029*</td>
</tr>
<tr>
<td>Control</td>
<td>1.19 ± 0.27</td>
<td>1.32 ± 0.22</td>
<td>1.37 ± 0.23</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

*Statistical significance indicated by two-way repeated measures ANOVA

Significance within group between initial test and 3 months post-test; significance within group between initial test and 6 months post-test

**Hip Kinematics**

Analysis of sagittal plane kinematics revealed a significant interaction effect for group and time for maximum hip extension angle (Wilk’s Lambda, F = 8.897, p = 0.004). Post hoc analysis indicated that the DA THA group’s maximum hip extension increased between the initial test and three month post-test (p = 0.024) and between the initial test and six month post-test (p = 0.012) but not between the three and six month post-tests (p = 0.740). Further analysis of sagittal plane kinematics revealed a significant interaction effect for group and time for hip flexion/extension excursion during the stance phase of gait (Wilk’s Lambda, F = 8.627, p = 0.004). Post hoc analysis indicated that the DA THA group’s flexion/extension excursion increased between the initial test and three month post-test (p = 0.002) and between the initial test and six month post-test (p = 0.001) but not between the three and six month post-tests (p = 0.696).

Analysis of frontal plane kinematics revealed a significant group main effect for maximum hip abduction (F = 6.289, p = 0.025). Analysis of the means indicated that the DA THA group (-3.18) demonstrated lower maximum hip abduction angle than the control group (-7.15) regardless of time.

Analysis of transverse plane kinematics revealed significant group main effect for maximum hip internal rotation (F = 5.078, p = 0.041). Analysis of the means indicated...
that the DA THA group (14.80) demonstrated higher maximum hip internal rotation angle than the control group (7.34) regardless of time.

Table 3. Kinematic Variables: Means and Standard Deviations DA THA and Control Subjects at Initial Test and Three and Six Months Post-test.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Initial Test</th>
<th>3 months post-test</th>
<th>6 months post-test</th>
<th>Group p value</th>
<th>Time p value</th>
<th>Interaction p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Hip Flexion</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>DA THA</td>
<td>36.09 ± 7.69</td>
<td>37.24 ± 10.48</td>
<td>37.17 ± 6.20</td>
<td>0.493</td>
<td>0.946</td>
<td>0.431</td>
</tr>
<tr>
<td>Control</td>
<td>36.00 ± 4.59</td>
<td>33.86 ± 3.83</td>
<td>34.57 ± 4.98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Hip Extension</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DA THA</td>
<td>11.44 ± 10.27</td>
<td>0.03 ± 10.91*</td>
<td>-1.54 ± 6.35b</td>
<td>0.006*</td>
<td>0.000*</td>
<td>0.004*</td>
</tr>
<tr>
<td>Control</td>
<td>-6.02 ± 5.39</td>
<td>-9.63 ± 7.42</td>
<td>-9.18 ± 7.20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip Flexion/Extension Excursion</td>
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<tr>
<td>DA THA</td>
<td>24.12 ± 10.78</td>
<td>37.21 ± 3.54*</td>
<td>38.64 ± 5.23b</td>
<td>0.004*</td>
<td>0.001*</td>
<td>0.004*</td>
</tr>
<tr>
<td>Control</td>
<td>41.99 ± 6.30</td>
<td>43.38 ± 4.78</td>
<td>43.68 ± 5.92</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Hip Adduction</td>
<td></td>
<td></td>
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<tr>
<td>DA THA</td>
<td>4.87 ± 5.20</td>
<td>6.99 ± 4.00</td>
<td>6.45 ± 4.92</td>
<td>0.603</td>
<td>0.881</td>
<td>0.424</td>
</tr>
<tr>
<td>Control</td>
<td>8.17 ± 6.24</td>
<td>6.45 ± 5.54</td>
<td>7.63 ± 7.35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Hip Abduction</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>DA THA</td>
<td>3.11 ± 3.45</td>
<td>4.18 ± 4.49</td>
<td>4.05 ± 3.36</td>
<td>0.025*</td>
<td>0.236</td>
<td>0.215</td>
</tr>
<tr>
<td>Control</td>
<td>7.20 ± 1.46</td>
<td>8.66 ± 3.30</td>
<td>5.59 ± 5.49</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip Adduction/Abduction Excursion</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>DA THA</td>
<td>3.77 ± 1.76</td>
<td>5.40 ± 1.73</td>
<td>3.94 ± 2.14</td>
<td>0.085</td>
<td>0.119</td>
<td>0.088</td>
</tr>
<tr>
<td>Control</td>
<td>8.52 ± 3.50</td>
<td>5.63 ± 7.49</td>
<td>6.09 ± 2.36</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Hip Internal Rotation</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>DA THA</td>
<td>16.21 ± 14.22</td>
<td>13.77 ± 10.06</td>
<td>14.41 ± 6.88</td>
<td>0.041*</td>
<td>0.720</td>
<td>0.675</td>
</tr>
<tr>
<td>Control</td>
<td>6.07 ± 5.38</td>
<td>6.26 ± 9.04</td>
<td>9.68 ± 7.71</td>
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<td></td>
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<tr>
<td>Max Hip External Rotation</td>
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<td></td>
</tr>
<tr>
<td>DA THA</td>
<td>12.35 ± 7.89</td>
<td>9.29 ± 14.14</td>
<td>9.95 ± 12.25</td>
<td>0.449</td>
<td>0.734</td>
<td>0.966</td>
</tr>
<tr>
<td>Control</td>
<td>14.71 ± 9.31</td>
<td>12.73 ± 6.97</td>
<td>13.66 ± 7.64</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip External/Internal Rotation Excursion</td>
<td></td>
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</tr>
<tr>
<td>DA THA</td>
<td>24.35 ± 14.28</td>
<td>22.70 ± 10.79</td>
<td>23.08 ± 13.89</td>
<td>0.479</td>
<td>0.476</td>
<td>0.649</td>
</tr>
<tr>
<td>Control</td>
<td>19.61 ± 9.51</td>
<td>17.41 ± 8.88</td>
<td>23.11 ± 12.20</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

*Statistical significance indicated by two-way repeated measures ANOVA
* Significant within group difference between initial test and 3 month post-test; b, significant within group difference between initial test and 6 month post-test

Hip Kinetics

Analysis of kinetic data at the hip joint revealed a significant interaction effect for group and time for maximum hip extension moment (Wilk’s Lambda F = 5.754, p = 0.004). Post hoc analysis indicated that the DA THA group’s maximum hip extension
moment increased between the initial test and three month post-test (p = 0.003) and between the initial test and six month post-test (p = 0.001) but not between the three and six month post-tests (p = 0.710).

Further kinetic data analysis revealed significant time (Wilk’s Lambda, F = 3.967, p = 0.045) main effects for maximum hip adduction moment. Post hoc tests using the Least Significant Difference (LSD) correction indicated lower maximum hip adduction moments at the initial test than at the six month post-test (p = 0.022) but no difference between initial test and three month post-test (p = 0.403) or between the three and six month post-tests (p = 0.192) regardless of group.

Further kinetic data analysis revealed significant time (Wilk’s Lambda, F = 10.327, p = 0.002) and group (F = 8.764, p = 0.010) main effects for maximum external hip internal rotation moment. Post hoc tests using the LSD correction indicated lower maximum hip internal rotation moments at the initial test than at the three month post-test (p = 0.001) and at the initial test than at the six month post-test (p = 0.001) but no difference between the three and six month post-tests (p = 0.749) regardless of group. Analysis of the group means indicated that there was a lower maximum hip internal rotation moment in the DA THA group (71.07) than in the control group (115.10) regardless of time.
Table 4. Kinetic Variables: Means and Standard Deviations DA THA and Control Subjects at Initial Test and Three and Six Months Post-test. (N/mm)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Initial Test</th>
<th>3 Months Post-test</th>
<th>6 Months Post-test</th>
<th>Group p value</th>
<th>Time p value</th>
<th>Interaction p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Hip Flexion Moment</td>
<td></td>
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</tr>
<tr>
<td>DA THA</td>
<td>498.82 ± 283.39</td>
<td>467.86 ± 195.28</td>
<td>533.55 ± 322.15</td>
<td>0.882</td>
<td>0.756</td>
<td>0.829</td>
</tr>
<tr>
<td>Control</td>
<td>484.27 ± 179.67</td>
<td>515.76 ± 224.05</td>
<td>539.37 ± 110.62</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Hip Extension Moment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DA THA</td>
<td>468.06 ± 205.88</td>
<td>945.48 ± 348.54a</td>
<td>999.42 ± 287.04b</td>
<td>0.011*</td>
<td>0.001*</td>
<td>0.016*</td>
</tr>
<tr>
<td>Control</td>
<td>1158.78 ± 364.29a</td>
<td>1287.63 ± 352.61</td>
<td>1270.18 ± 358.64</td>
<td>0.488</td>
<td>0.045*</td>
<td>0.907</td>
</tr>
<tr>
<td>Max Hip Adduction Moment</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DA THA</td>
<td>916.71 ± 150.32</td>
<td>996.48 ± 191.24</td>
<td>1044.24 ± 396.83b</td>
<td>0.010a</td>
<td>0.002a</td>
<td>0.536</td>
</tr>
<tr>
<td>Control</td>
<td>1002.26 ± 203.18</td>
<td>1027.19 ± 147.20</td>
<td>1096.66 ± 259.78</td>
<td>0.519</td>
<td>0.211</td>
<td>0.537</td>
</tr>
<tr>
<td>Max Hip Abduction Moment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DA THA</td>
<td>80.09 ± 74.02</td>
<td>87.17 ± 78.38</td>
<td>117.59 ± 63.05</td>
<td>0.941</td>
<td>0.941</td>
<td>0.583</td>
</tr>
<tr>
<td>Control</td>
<td>93.01 ± 47.27</td>
<td>138.38 ± 99.47</td>
<td>109.74 ± 88.41</td>
<td>0.544</td>
<td>0.941</td>
<td>0.583</td>
</tr>
<tr>
<td>Max Hip Internal Rotation Moment</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>DA THA</td>
<td>41.48 ± 14.04</td>
<td>91.48 ± 32.58a</td>
<td>81.22 ± 50.23a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>92.68 ± 28.25</td>
<td>123.87 ± 43.92</td>
<td>128.76 ± 50.97</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Max Hip External Rotation Moment</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>DA THA</td>
<td>140.59 ± 58.73</td>
<td>149.62 ± 98.97</td>
<td>139.57 ± 65.00</td>
<td></td>
<td></td>
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<tr>
<td>Control</td>
<td>135.21 ± 62.91</td>
<td>112.95 ± 46.22</td>
<td>128.15 ± 52.77</td>
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</tbody>
</table>

*Statistical significance indicated by two-way repeated measures ANOVA
* Significant within group difference between initial test and 3 month post-test; b, significant within group difference between initial test and 6 month post-test

Maximum Vertical Ground Reaction Force (VGRF)

Analysis of maximum VGRF revealed a significant main effect for time regardless of group (p = 0.032). Post hoc tests using the LSD correction revealed lower maximum VGRF between the initial test and three months post-test (p = 0.015) and between the initial test and six months post-test (p = 0.003) but not between three and six months post-test (p = 0.086) regardless of group.

Table 5. Maximum VGRF: Means and Standard Deviations DA THA and Control Subjects at Initial Test and Three and Six Months Post-test.

<table>
<thead>
<tr>
<th>Maximum VGRF (N/kg)</th>
<th>Initial Visit</th>
<th>3 months post-test</th>
<th>6 months post-test</th>
<th>Group p value</th>
<th>Time p value</th>
<th>Interaction p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DA THA</td>
<td>9.69 ± 1.19</td>
<td>10.72 ± 0.34a</td>
<td>11.06 ± 0.54b</td>
<td>0.17</td>
<td>0.007*</td>
<td>0.089</td>
</tr>
<tr>
<td>Control</td>
<td>10.64 ± 0.68</td>
<td>11.11 ± 0.96</td>
<td>11.11 ± 0.54</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Statistical significance indicated by two-way repeated measures ANOVA
* Significant within group difference between initial test and 3 month post-test; b, significant within group difference between initial test and 6 month post-test
DISCUSSION

The most significant findings in this study was that the DA THA group showed significant improvements in walking gait velocity, maximum VGRF, flexion/extension excursion, extension moment, internal rotation moment following surgery as early as three months post-op and continued to improve at the 6-month post-op data collection period. The THA participants presented with habitual antalgic gait characteristics including: Trendelenburg gait, and lateral trunk lean toward the involved hip. As expected the control group data remained constant with slight non-significant differences at the initial data collection and throughout the six month study duration.

In the present study the DA THA group walked at slower velocities resulting in lower maximum hip flexion/extension and abduction range of motion prior to surgery. Similar findings have been reported in the literature showing lower hip ROM, shorter stride length and slower walking velocities [9, 13, 16, 22, 26, 27]. By reducing hip extension and abduction during gait, hip OA patients in the present study were able to reduce pain by avoiding the closed pack position of the hip, which consists of full extension, abduction and internal rotation[31]. Following THA, the results of the present study are supported by several other minimally invasive studies[9, 22, 24, 27] that also revealed that hip OA patients walked faster with resultant increased hip extension ROM by three and six months post-surgery (Figure 1 & 2). Despite these improvements post-surgery, the DA THA group continued to demonstrate lower gait characteristics than the control group six months post-surgery. Similarly, Klausmeier et al [22] reported that THA patients increased sagittal plane ROM (i.e. hip flexion and extension) but did not match the control values at 16 weeks following surgery. It is unclear why decreased
ROM exists in the absence of pain, due to OA, after surgical realignment, they concluded that impaired gait is an adaptation learned prior to surgery that may never change [22]. Differences in post-surgical ROM may also be due other factors such as ectopic-bone formation or femoral position and offset during the THA procedure [32, 33].

Mean Values for Walking Velocities for DA THA and Controls Subjects at Initial Test, and Three and Six Months Post-Test During Walking Gait.
Similar to Meneghini et al [23] prior to surgery, maximum VGRF and maximum hip extension and internal rotation moments were found to be significantly lower before surgery in the DA THA group than in the control group (Figure 3 & 4). This can be explained by slower walking velocities, decreased sagittal plan ROM, and possible strength deficits in hip flexion found in the DA THA group in the present study. Similarly, Foucher et al[16] found hip OA patients to have lower hip moments than healthy subjects. They concluded that external moments reflect antagonist muscle activity. Therefore, weak hip flexors may have contributed to the lower hip extension moment. Although not reported in the present study, the DA THA group demonstrated lower average hip flexion strength than the control group prior to surgery. In the present study maximum VGRF and hip extension moment in the THA group improved post-surgery and approached control levels at the three and six month post-test period. This increase in THA group walking gait produced greater maximum VGRF, consequently all
THA group hip moments increased during the data collection period in the present study[34]. Conversely, Perron et al[11] found that THA patients still produced lower hip extension moments compared to healthy controls following surgery unfortunately no pre-surgery data were collected in this study prior to surgery for comparison.

Figure 3. Mean Values for Maximum VGRF for DA THA and Controls Subjects at Initial Test, and Three and Six Months Post-Test During Walking Gait.
Traditional THA procedures involve incision or damage to the hip abductor and external rotator muscle groups resulting in decreased strength and decreased hip moments [16, 20, 21]. Currently, there are differences among the literature when reporting hip moments because they are expressed as either internal or external hip moments (i.e. external hip adduction moment reflects an internal hip abduction moment). These frontal plane decreases in internal hip abduction or external hip adduction moments are a common concern of researcher following traditional THA surgery [7, 9, 11, 16, 22]. However, the DA THA procedure minimizes hip musculature damage therefore having the potential to promote normal function sooner than other non-MI THA surgery[25]. In the present study, hip adduction moment deficits were only revealed at the six month data collection time period. (Figure 5) Conversely, Klausmeier et al [22], was the only researcher who investigated moments and found internal hip abduction moment deficits in the DA THA at pre surgery, six and 16 weeks post-surgery. Comparative research on
MIDATHA is limited via: limited control data collection points, sparse comparison to traditional THA procedures and outcomes extending beyond six months. The present study is also limited by the small sample size. Future research should be conducted at further post operation time periods to identify if THA patients ever reach healthy population values.

**Figure 5. Mean Values for Hip Adduction Moment for DA THA and Controls Subjects at Initial Test, and Three and Six Months Post-Test During Walking Gait.**

Gait parameters for hip OA patients are typically altered by, muscle weakness, and pain-avoidance gait prior to surgery. However, many of these negative characteristics continue to exist after surgery even when the pain has subsided. Clinically, it is important to manage these patients with gait re-training in the rehabilitation process correcting pre-surgical habits and post-surgical impairments. Therefore it may also be important to concentrate on hip strengthening in the rehabilitation protocol following surgery to offset the low hip moments.
Conclusions

Within the limitations of the present study, DA THA participants demonstrated improvements in gait at three and six months post-surgery. Although gait differences between DA THA and control participants persisted six months post-surgery, the DA THA group started to approach the control values.
Part II

REVIEW OF LITERATURE

Total hip arthroplasty (THA) procedures have been successful in helping patients suffering from hip osteoarthritis (OA) return to their pre-OA activities of daily living. However, there seems to be a large percentage of revision procedures performed following the first (initial) THA procedure. The majority of these studies involved investigation of biomechanical characteristics before and after different types of THA procedures. Many of these studies had several limitations in their research design that do not allow all research questions to be answered. A major limiting factor in several studies was the lack of longer post-operative data collection periods. Only one study involved greater than a two year evaluation post-surgery. Due the varying post-operative time periods, there are conflicting results in regards to kinematic and kinetic variables following a THA procedure.

Epidemiology of Hip Osteoarthritis

A number of studies[2, 4] have involved possible risk factors for patients suffering from hip OA. Cooper et al [2] performed a case-control study of surgically treated hip OA patients and reported the non-occupational risk factors. The risk of hip OA significantly increased with body mass index. Previous hip injury was associated with an increase in the risk of hip osteoarthritis, which was greater in men than women. Physical activity levels early and throughout life was associated with an increased risk for hip OA, which was higher in women than men. Overall, the main findings of this study suggest that obesity, previous hip injury, and a tendency to polyarticular involvement were independent risk factors of hip OA.[2] Similarly, Flugsrud et al [4] investigated the
possible risk factors in both men and women for total hip replacement (THR) due to primary OA. Similar to another study[2], the overall finding of this study was that body mass index and physical activity were considered risk factors for total hip replacement due to primary OA. This analysis controlled for sex, age at screening, body height, marital status, and smoking habits.[4] In contrary to Cooper et al[2], results indicated a lack of relationship between physical activity during leisure time and later OA development and THR. Due to the aforementioned intrinsic risk factors and the onset of hip OA, several pathological gait characteristics have been found in hip OA patients.

**Hip Osteoarthritis Gait Characteristics**

Hip OA patients often develop gait adaptations to minimize the pain experienced in the hip while performing activities of daily living such as walking. These gait adaptations include slower gait speed, decreased velocities, and shorter step and stride length [7-13]. Reducing hip pain is accomplished by decreasing the percentage of time the involved limb is in the stance phase and increasing the time spent in the swing phase[12]. Because of the shorter stance phase on the involved limb, hip OA patients walk with decreased sagittal range of motion on the involved limb in order to decrease pain [12, 14-16]. Most commonly, peak hip extension angles have been shown to be reduced for pain avoidance during the stance phase [15].

Compared to the healthy population, hip OA patients walk with reduced peak external hip adduction, extension, and internal and external rotation moments prior to surgery [7, 11, 14-16]. Researchers concluded that the reduction in external moments may represent decreased loads on the joint as well as decreased demands on the hip muscles.[15] The primary hip abductors are responsible for balancing the external
Adduction moment and weakness of these muscles can lead to a decreased moments.[14] Also, discoveries have been made that the lower hip moments of the hip are due to lack of muscular strength especially within the hip abductor and extensor muscle groups[7]. Due to the shortened stance time on the involved limb, hip OA patients produce less power at the hip, knee and ankle joints during the stance phase[13]. The lack of power absorption by the involved limb causes an antalgic gait.[13]

Another gait abnormality commonly seen in hip OA patients is a Trendelenburg gait. The Trendelenburg gait, typically involves dropping the contralateral hip (uninvolved) and laterally leaning the thorax toward their involved limb when that leg is in the stance phase. This occurs due to inadequate hip abductor muscle torque which reduces force applied to the involved hip joint. The center of mass in the thorax moves closer to the involved hip joint thus decreasing the external hip adduction moment typically found in hip OA patients.[6] For many of these individuals, conservative treatment is unsuccessful and surgical intervention is needed.

**Total Hip Arthroplasty (THA)**

There are several different THA procedures used to correct anatomical deficiencies caused by hip OA. The traditional approach involves a large incision on the lateral or posteriolateral aspect of the hip. This type of procedure is very invasive and results in damage to a large portion of hip musculature including the hip abductors and external rotators. The traditional THA procedure results in long recovery times and post operation movement restrictions to prevent dislocation.[20, 22]

Several different types of minimally invasive (MIS) THA procedures have become popular under the theory they decrease internal muscle damage compared to the
traditional THA and provide faster recovery times. Minimally invasive THA can be considered an umbrella term consisting of several different types of procedures. There are several MIS procedures where the main difference from the traditional THA is the size of the incision. Other differences found in MIS procedures from the traditional approach include the limitation of musculature cut to minimize post-operation soft tissue damage/impairments. A more advanced technique involves this idea of muscle sparing through the direct anterior aspect of the hip. [20, 21, 23, 24] An example of a muscle sparing technique is the direct anterior (DA) THA.

Minimally Invasive Direct Anterior Surgical Technique

Bal et al [19] conducted a study discuss key technical steps, potential pitfalls, and early outcomes of the MIS direct anterior (DA) surgical approach for hip OA. First, a specific orthopedic table that facilitates retraction and allows optimal leg positioning in the supine position is needed for this particular procedure. A straight incision is made obliquely on the antero-lateral thigh, beginning 2 cm distal and lateral to the anterior superior iliac spine (ASIS) and ending 2 cm anterior to the greater trochanter. Blunt dissection of the subcutaneous fat is utilized to uncover the tensor fascia latae muscle to minimize the risk of injury to the lateral femoral cutaneous nerve. The tensor fascia latae is then separated from the sartorius muscle by an incision. The tensor fascia latae is then retracted laterally and the capsular insertions of the rectus femoris and psoas muscles are retracted medially exposing the lateral femoral circumflex vessels, which are ligated to avoid bleeding. Once the anterior hip capsule is visible, a few millimeters of the anterior acetabular wall is excised to facilitate the procedure. Slight traction and external rotation the femoral head exposes and dislocates the hip joint. Once dislocated, the vastus
lateralis is retracted and the lesser trochanter is exposed. Using retractors with slight external rotation and traction of the femur, the acetabulum is exposed. After acetabular screw fixation, osteophyte removal and acetabular bearing insertion, attention is directed to the femoral stem insertion. The femur is elevated laterally by the surgeon, while the patient’s foot is externally rotated to about 90 degrees and dropped toward the floor.

Preparation of the femoral canal is performed by a quick release of the thick hip capsule off the greater trochanter from anterior to posterior while protecting the abductors. The canal is opened and then stem inserters are mounted. Leg lengths are measured followed by hip stability by externally rotating the femur and checking for impingement or subluxation of the femoral head. No adverse outcomes in a series of 100 consecutive patients who underwent the procedure were revealed. An advantage to this procedure is that the lateral incision which lessens the chance of injury to the lateral femoral cutaneous nerve. Second, there is no blind femoral canal preparation which prevents muscle damage and intramuscular hematoma. Also, this procedure is less traumatic to the external rotators of the hip and it has been shown to have less intraoperative blood loss.

The only disadvantages discussed were the special orthopedic table needed and the lack of familiarization of the procedure by the surgeon.[19] Clinical Outcomes Nakata et al.[10] compared short-term clinical and radiographic outcomes of MIS posterior and DA THA. There were 99 hips in the MIS DA group and 96 hips in the MIS posterior group. Both groups received the same post-surgical treatment as required by the institution. Anteroposterior pelvic radiographs were obtained on post-operative on day 1, then at 3 weeks, 2 months, 6 months, 12 months, and at 1 year. Several tests for hip functional recovery were used to evaluate the outcome of each surgery. Such tests included single-
leg stance, Trendelenburg sign, a timed 50-m walk to assess walking velocity, the Merle d’Aubigne and Postel score, etc. Statistical analysis was performed by using the Mann-Whitney U test and data were stratified into specific categories. The MIS DA group was able to perform a single leg stance longer than the MIS posterior approach, 16.6 days to 22.9 days post-surgery, respectively. Significant differences in walking velocity were revealed 3 weeks post-operatively between the groups. Thirty-four percent of the MIS DA group was able to walk without an aid and only 19% of the MIS posterior group was able to walk without the use of an aid at 3 weeks post-operatively. The MIS DA group’s ability to walk was superior to the MIS posterior group 2 months post-operatively. They proved that the MIS DA group’s hip function and stability returned more rapidly than the MIS posterior approach group. One commonality in both procedures was that neither the gluteus medius nor minimus were detached in either surgical approach. However, the gluteus maximus and tensor fascia were incised in the MIS posterior approach and not in the MIS DA approach. They concluded that the more rapid functional recovery in the MIS DA group occurred secondary to the difference in involvement of the gluteus maximus, hip abductors and short external rotators. One notable weakness of this study was the retrospective nature, bias in patient selection, and the lack of randomization.

The MIS DA THA has been shown to be effective in reducing recovery time; however there is limited research on the biomechanical factors associated with this procedure. The number of THA procedures performed continues and is expected to grow due to higher incidences of individual risk factors. Kurtz et al [1] stated that by the year 2030, primary total hip arthroplasties are expected to grow by about 174%. Additionally, the number of total hip revisions is expected to double by the year 2026. Therefore, it is
important to continue to conduct research relative to the clinical and biomechanical outcomes of the DA THA procedure.

**Gait Characteristics following Total Hip Arthroplasty**

Kinematic and kinetic gait changes have been reported following different THA procedures. Many researchers have attempted to compare hip OA subjects to "healthy" control groups consisting of individuals free of lower extremity OA. Study results have shown increases in specific biomechanical gait variables following THA; however these patients do not seem to attain values similar to those of the control subjects. The following studies identify conflicting results and limitations found among these gait studies. Tanaka et al [12] investigated the factors influencing the improvement of gait following a THA procedure. Spatio-temporal gait parameters during the recovery time of THA patients were investigated. Forty-three women with severe hip OA were assessed prior to THA surgery and post-surgically at 2, 6, and 12 months. Twenty-six healthy elderly women were used as the control group. All THA procedures were performed by the same surgeon using the posterolateral THA approach. All patients and controls were analyzed during self-selected velocity walking trials along a five meter walkway. Three successful trials were used for statistical analysis. Gait analysis involved the use of two force plates collecting data at a sampling rate of 60 Hz. The gait variables analyzed included step-length ratio, stride length, single-support duration, cadence, and velocity. Analysis of variance (ANOVA) was used to assess the mean values and standard deviations for the gait parameters collected. Student $t$-test were used to detect differences between involved and uninvolved limbs and differences between the control and experimental groups ($p<0.05$). Linear-regression analysis was performed to evaluate
factors influencing post-THA gait improvement. Significant differences between the control group values and the preoperative values of the THA patients were found in mean stride length, cadence and velocity. Regardless of the increase compared to preoperative values, the values of all measured variables at 12 month post-surgery did not reach that of the control group. At 2 to 6 months post-surgery, stride length, single-support duration of involved limb, single-support duration ratio, cadence and velocity increased significantly when compared to preoperative levels of the THA group. After performing linear regression analysis, patient age, stage of hip OA, and changes in the leg-length discrepancy were identified as significant variables that influenced gait improvement. The greatest improvements in the spatio-temporal parameters were noted between 2 and 6 months post-surgery. Other researchers[11] have reported the largest improvements 1 to 3 years post-surgery. Spatio-temporal improvements in the THA population have been seen in other studies [23, 26]. However, the researchers in this study found that certain gait variables like cadence and velocity were lower when compared to other studies[11, 23, 26] which could have been due to hip OA severity of patients in this study.

Through different methodological procedures and research questions, Perron et al [11] compared gait patterns between subjects with THA and a healthy control population using three-dimensional gait analysis. The primary purpose of this study was to identify primary and secondary impairments during gait in patients with THA. The THA subjects included 18 women between the ages 50-75 who had THA 6-18 months prior to analysis. The healthy control group was matched for age, height and weight. Three-dimensional kinematic data were collected at a sampling rate of 100 Hz and ground reaction forces were collected at a sampling rate of 1000 Hz. Three pressure sensitive footswitches were
placed under the sole of the foot to detect spatiotemporal characteristics of gait. The subjects were instructed to walk at a self-selected velocity for a total of five successful trials that were used for analysis. The Mann-Whitney U-test was used for inter-group comparison. In order to control for velocity, a second analysis was used to compare subgroups of subjects matched for gait velocity (p=0.05). Spearman correlation coefficients were used to assess comparisons between kinetic and kinematic variables. The average time since surgery was 46.5 weeks. The THA group walked slower with fewer steps per min and shorter stride length, which led to a shorter single leg support phase. Peak extensor moment of force in the THA group was lower by 20% which is related to the slower gait velocity. Comparable findings were reported by Tanaka et al[12]. Peak hip extension in THA patients decreased 59% during early push-off compared to the control group. These findings indicate that the strength of hip extensors may have been an important factor in the rehabilitation program. Two main impairments found in the frontal plane were: a 15% lower peak abduction moment at the end of the weight acceptance period, implying weakness among the hip abductor muscle group, and a decrease of 31% in peak lateral force rate under the stance foot during the weight acceptance period and THA patients. This difference was attributed to the need for a longer recovery period to allow hip abductor strengthening. In the transverse plane, there was a 66% decrease in the peak external rotation moment during mid-stance, which was related to the decrease in gait velocity. However, this study did not involve investigation of the change in gait before and after THA surgery in the experimental group.

Miki et al [27] conducted a study to determine the recovery of walking velocity and symmetrical movement of the hip, knee, ankle, and pelvis after an unilateral THA.
The purpose of this study was to investigate hip kinematic and kinetic gait variables of MIS DA THA patients compared to a healthy control group at three time periods. Seventeen subjects with unilateral posterior THA were used for gait analysis at the following time periods: pre-operation, 1, 3, 6, and 12 months. Three dimensional gait analyses was conducted with a 3D-optical analyzer sampling at 60 Hz and two force plates sampling at 600 Hz. Each subject performed three trials for each limb at each data collection session. Comparisons between the operated and non-operated limbs were performed via the Student t-Tests. Comparison of data between different time periods was performed using repeated measures ANOVA and paired Student t-Tests (p<0.05). Walking velocity, cadence, stride length, and step length all increased in comparison to the pre-operative levels and remained stable six months post- surgically. Decreases in involved hip flexion range of motion was reported pre-operatively and despite a gradual increase over time, was still significantly different at the 12 month post-surgery data collection period. Prior to surgery, hip OA patients had lower hip abduction and extension moments in the involved limb. Conversely,[7, 9, 11, 16, 22], hip abduction and extension moments resolved shortly after surgery in several other studies. Similar to Watelain et al[13], pelvic asymmetries (pelvic tilt and obliquity) were found prior to THA surgery due to restricted hip range of motion in these patients. In conclusion, THA patients gained some symmetry between limbs at the 12 month time period while other kinematic and kinetic variables were still different. However, no comparison to a healthy control population was assessed in this study.

Bennett et al [26] conducted a study to compare pre-operative and early post-operative temporal-spatial and gait kinematics between patients who received MIS THA
and standard traditional hip replacements. Twenty-five patients (mini-invasive = 9, standard = 8, control group = 10) were used for the three-dimensional gait analysis at 1 day pre-operatively, 2 days post-operatively and 6 weeks post-operatively. A six camera motion analysis system with a sampling rate of 120 Hz was used to collect gait kinematics. Kolmogorov-Smirnov test was used to compare differences between the temporal-spatial and gait kinematic variables. Students’ t-Test was used to detect differences between groups and for variable differences that were normally distributed and the Mann-Whitney test was used for variable differences not normally distributed. Findings indicated that both groups tended to hold the affected hip in external rotation pre-operatively, but this measure was reduced after either procedure. At two days post-operation, the investigators’ measures indicated that the standard incision approach achieved more normal hip joint kinematics post-operatively than the MIS THA group. The MIS THA group did not show any significant improvements in any of the kinematic or temporal-spatial variables compared to the standard incision group. At six weeks post-operation, the measured variables did improve for each group but never matched the control group.[26] These results agree with previous research[11] that showed gait kinematic improvements following THA but once again the measures did not near those of the control population. Similarly, Bennett et al [28] performed a study to assess the kinematic changes of THA in patients up to ten years following surgery. The researchers found residual = kinematic gait differences between the THA OA patients and the healthy control group [28]. Two limitations of this study included the short period of time tested after THA and a small sample size for each procedure tested. Similarly, Foucher et al [16] performed a study to determine if normal function can be attained
following a THA procedure by analyzing gait characteristics. The researchers hypothesized that dynamic range of motion and peak external moments (flexion and extension, abduction and adduction, internal and external rotation) during walking improved and returned to normal after surgery. The experimental group consisted of 28 individuals with end-stage osteoarthritis (13 = lateral approach, 15 = posterior approach) and the control group consisted of 25 healthy matched individuals. Data were collected approximately two weeks prior to surgery and one year post surgery in the experimental group. Gait analysis was assessed using four optoelectronic cameras and one force plate. Six trials were collected for each limb at self-selected slow walking velocity (2), self-selected normal velocity (2) and self-selected fast velocity (2) however only data from the involved limb was used for analysis. Statistical analysis was performed using Friedman tests for differences between pre-operative and post-operative gait. Spearman correlations were used to determine whether pre and post-operative gait parameters were linearly related. Mann-Whitney tests were used to determine differences in kinematic and kinetic variables (p<0.05). Osteoarthritic patients walked with different kinematics and kinetics compared to the normal subjects. Similar to previous research [11, 26, 28], THA patients did not return to a normal gait patterns as compared to a normal population. The abduction, adduction, and external rotation moments did not change significantly after the surgery. The pre and post-operative values of dynamic range of motion, external flexion, abduction and external rotation moments were all correlated. Range of motion, adduction and internal rotation moments were significantly different from the normal group. Similar to Perron et al[11], suggested that patients with hip OA tend to have weakness in the hip abductor group that is demonstrated via decreased internal and
external moments. This weakness may be due to learned patterns of gait to reduce forces on the hip before and after surgery. This study only involved investigation of two different traditional THA procedures.

Meneghini et al [23] compared early recovery and return of function between three different MIS THA surgical approaches. Twenty three hips from 21 patients were randomly assigned to one of the three surgical procedures (2-incision = 8, mini-posterior = 8, mini-anterolateral = 7). No control group was used for comparisons to a “normal” population in this study. Gait was analyzed during two different time periods, pre-operatively and 6 weeks post-operatively. Patients were asked to walk ten meters at a self-selected velocity and five successful trials were averaged. Data were collected with four motion capture cameras at a sampling rate of 40 Hz and two force plates at a sampling rate at 500 Hz. Kinematic variables assessed included gait velocity and single leg stance time. Kinetic data assessment included vertical ground reaction force, limb loading rate and hip abduction moment. Two-way mixed ANOVA was used to detect differences between pre and post-operative variables of the three study groups (p=0.05). All three surgical groups experienced an increase in mean gait velocity at the six week post-operative data collection trials. All three surgical groups experienced a decrease in mean single leg stance time but statistical significance was not reached. The MIS mini-anterolateral approach was the only group that showed a decrease in all kinetic variables six weeks post-operatively. No statistical significances were found in the vertical ground reaction force when comparing the percent decrease 6 weeks post-operative values with the pre-operative values. Similarly, Bennett et al[26] found no differences between surgical groups at six weeks after surgery in spatio-temporal gait variables, however they
did not investigate gait kinetics, or abductor torque measures between the three MIS THA procedures. The researchers concluded that there were no noticeable advantages for any of the MIS THA approaches they investigated. They also found that the MIS mini-anterolateral approach patients demonstrated a gait patterns consistent with abductor injury or weakness despite the minimally invasive nature of the surgeries.

Mayr et al [9] investigated the hypothesis that patients undergoing a MIS DA approach return to normal function earlier than patients undergoing the traditional anterolateral approach as evaluated by gait analysis. Gait analysis was measured pre-operatively, six weeks, and twelve weeks post-operatively. There were 16 patients in the MIDA THA group and 17 patients in the traditional anterolateral group. No control group was used for comparisons. Both groups received the same standard rehabilitation program and patients were asked to complete the WOMAC questionnaire prior to each gait analysis session. Three-dimensional gait kinematic data were collected using a 15 marker set with a six camera motion analysis system collecting at a sampling rate of 60 Hz. Patients were asked to walk a 9m walkway at a self-selected velocity. Nonparametric tests were used because all variables were not normally distributed. Friedman’s analysis of variance was used to indicate changes over time (p<0.05). At the 12 week follow-up, the MIS DA group showed a significant improvement in cadence, stride length, and walking velocity. However, no significant changes were found in the traditional anterolateral group during the two follow-up periods. Conversely significant improvements in the hip range of motion were revealed in the MIS DA group post-operatively at six and twelve weeks. Results of this study support the theory that MIS DA patients revealed significant improvements in a larger number of gait parameters than
patients treated with the standard anterolateral approach. Unlike other studies, there was no control groups used for this study for a “normal gait” comparison.

Lugade et al [8] conducted a study to determine which surgical procedure (anterior lateral or anterior) minimized short-term limping in THA patients. Twenty-three patients receiving either anterior THA (12) or anterolateral THA (11) procedures were studied. Ten healthy aged-matched controls were used for comparison. All patients performed the same rehabilitation protocols following the surgical procedure to control for cofounding variables. Gait analysis was performed at pre-surgery, 6 weeks and 16 weeks post-surgery. The controls were only tested two times within the same month. Gait kinematic and kinetic data were collected with an eight camera motion analysis system collecting at a sampling rate of 60 Hz and two force plates collecting at 960 Hz.. Pelvic obliquity was calculated throughout gait via the frontal plane angle of the pelvis in relation to the global coordinate system. The effect of surgical approach and pelvic obliquity was determined using two-way ANOVA with repeated measures with group as between subject factor and time as within factor. Prior to surgery both THA groups displayed greater limb asymmetry in step length and single limb support time but no differences between the two surgical groups were identified. Greater gait asymmetry was found in the anterolateral patients six weeks post-operation than the anterior group. The anterior THA group demonstrated improvements in single limb support time six weeks post-operatively while the anterior lateral group did not. By 16 weeks, both groups revealed increases in single limb support and gait velocity but did not demonstrate changes in pelvic obliquity or step width. Similar to other researchers [23], greater ground reaction forces were found in the uninvolved limb compared to the involved limb,
which indicated an altered loading pattern adapted by individuals with hip osteoarthritis to reduce pain. Shorter stride length was found in the THA patients, which is supported by Perron et al[11], who described abductor weakness as a possible cause. By 16 weeks, both experimental groups approached the levels of the control group.[8]

Beaulieu et al [7] investigated the effect of THA on mobility by comparing hip, knee and ankle joint moments and powers of both operated and non-operated limbs. Twenty THA patients (10 male and 10 female) were used for comparisons against a group of 20 healthy individuals. All patients were operated on by the one of three surgeons who all used the traditional lateral approach. A nine camera digital optical motion capture was used to collect kinematic data at a sampling rate of 200 Hz and a single force plate was used to collect kinetic data at 1000 Hz. Ground reaction forces were collected at the stance phase of gait and six successful trials (3 left foot contact and 3 right foot contact) were used for analysis. One-way ANOVA was used between both the THA operated limb and control group as well as the THA non-operated limb and control group. One-way ANCOVA was used for analysis with walking velocity and stride length as covariates. No significant findings were found between the THA patients and the control group in the kinematics of the pelvis and knee and kinetics of the knee joint during walking gait. The THA group displayed significantly lower peak flexion angle, peak extension angle, total sagittal plane range of motion, peak adduction angle and peak external rotation angle in comparison with the control group. In accordance with other research data [9, 11, 16], the researchers found that THA patients walked with a smaller hip abduction moment on the operated hip following surgery. This occurs because the hip is in a less adducted position compared to healthy individuals. In
agreement with other research[11], the results indicated that the THA patients walked with a smaller hip range of motion of the operated limb regardless of stride length and walking velocity. Gait adaptations were observed in the non-operated limb that included a smaller hip adduction ROM during the transition of single to double limb support. In conclusion, gait mechanics did not return to normal following surgery. A limitation of this study was that there were no pre-operation assessments performed for the THA patients.

Klausmeier et al[22] examined the gait mechanics for two different THA procedures (anterior and anterolateral). Subjects included 23 hip OA patients (anterior group=11 and anterolateral group=12) and 10 healthy matched control subjects. All THA subjects were tested at pre surgery, 6 weeks and 16 weeks post-operative time periods. Control subjects were only tested twice in one month for comparisons. Gait mechanics were analyzed using a 29 marker set, an eight camera motion analysis system and two force plates. Kinematic data were collected at a sampling rate of 60 Hz while kinetic data were collected at a sampling rate of 960 Hz. Kinetic variables analyzed included hip abduction, internal and external rotation, and flexion and extension moments. Gait temporal spatial variables analyzed included stride length and gait velocity. A mixed model ANOVA with repeated measures was used to determine differences between and within groups. At 6 weeks post- operatively anterior THA subjects walked with increased gait velocities and stride length and demonstrated a greater peak flexor moment during late stance compared to the other procedure. Additionally, the anterior THA group showed an increase return to “normal” levels at the 6 week post-operative time period. At the 16 week post-operative time period, the only variable that showed any
significance difference between the two surgical groups was peak external rotator moment. Contrary to other studies [9, 11, 16, 26], the second peak hip abductor moment of the anterior group reached the level of the control group at the 16 week time period. However, no such improvement was found in the anterolateral group which may due to the style of the procedure as discussed by other researchers.[11, 16, 26]

Gait analysis has been widely used to determine differences between patients with hip OA and a healthy matched population. Throughout the literature, it can be seen that there are biomechanical differences following THA procedures. Following THA, patients walk with better hip ROM but never seem to reach normative values. Similarly, patients walked with reduced external hip adduction, extension and internal and external moments. These differences can be due to learned behaviors and types of surgeries performed. However, differences exist between studies as far as which procedure is the best and what variables are more often involved. Further investigation is needed in the external moments of the hip. There is limited research on the direct effects of the DA THA and this field needs continued research especially at further post operation time periods.
APPENDIX A

DATA COLLECTION FORMS
Anthropometric Data

Subject ID#: ________________ Date__________
Age______________ Gender: F / M

Data Collection Period  0 1 2 3 4 5 6 7 8
Center: Control / Straub / Queens

Patient’s Operated leg: L / R Dominant Leg: L / R

Date of Surgery______________
Weeks after Surgery______________

Vicon/Nexus Measurements

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Height (mm)</th>
<th>Age (yrs)</th>
<th>Left leg length (mm)</th>
<th>Left knee width (mm)</th>
<th>Left ankle width (mm)</th>
<th>Right leg length (mm)</th>
<th>Right knee width (mm)</th>
<th>Right ankle width (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Data Collection Form

Subject ID#: ________________

Data Collection Period 0 1 2 3 4 5 6 7 8

Patient’s Operated leg: L / R Dominant leg: L / R

Center: Control / Straub / Queens

Total Trials: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

<table>
<thead>
<tr>
<th>Trial</th>
<th>Which foot hit the plate</th>
<th>Walking Pace (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R / L</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>R / L</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>R / L</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>R / L</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>R / L</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>R / L</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX B

HEALTH HISTORY FORM
**Instructions:** Please complete each question to the best of your knowledge/ability. If you have any questions, please ask the investigators.

**Part 1. Participant Information**

Participant’s Name: ___________________________

Date of Birth: ________________ Age (years) ____________ Sex: M / F

Home Address: _______________________________________

City/State/Zip: ______________________________________ Email: ___________________________

Home/Cell Phone (_ ) __________________________ Emergency Phone (_ ) __________________________

Emergency Contact Person/Relationship: ____________________________

Hospital Preference: ____________________________

Doctor Preference: ____________________________ Phone __________________________

**Part 2. Medical History**

Instruction: Please identify any condition that you have or had that might restrict your participation in physical activity. If you answer yes to any of the following, please describe the proper aid requirements on the next page.

<table>
<thead>
<tr>
<th>A. General Conditions</th>
<th>B. Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Fainting Spells</td>
<td>1. Toes</td>
</tr>
<tr>
<td>2. Headaches</td>
<td>2. Feet</td>
</tr>
<tr>
<td>3. Convulsions/epilepsy</td>
<td>3. Ankles</td>
</tr>
<tr>
<td>4. Asthma</td>
<td>4. Lower Legs</td>
</tr>
<tr>
<td>5. High Blood Pressure</td>
<td>5. Knees</td>
</tr>
<tr>
<td>7. Intestinal Disorder</td>
<td>7. Hips</td>
</tr>
<tr>
<td>8. Hernia</td>
<td>8. Lower Back</td>
</tr>
<tr>
<td>10. Heart Disease/Disorder</td>
<td>10. Ribs</td>
</tr>
<tr>
<td>11. Dental plate</td>
<td>11. Abdomen</td>
</tr>
<tr>
<td>15. Allergies</td>
<td>15. Hands</td>
</tr>
<tr>
<td>Specific</td>
<td>16. Wrists</td>
</tr>
<tr>
<td></td>
<td>17. Forearms</td>
</tr>
<tr>
<td></td>
<td>18. Elbows</td>
</tr>
<tr>
<td>16. Joint Dislocation Or separations Yes No</td>
<td>19. Upper Arms</td>
</tr>
<tr>
<td>Specify Past Present</td>
<td>20. Shoulders</td>
</tr>
<tr>
<td></td>
<td>21. Head</td>
</tr>
<tr>
<td></td>
<td>Specify Past Present</td>
</tr>
<tr>
<td>17. Allergies</td>
<td>22. Others</td>
</tr>
<tr>
<td>Specify Past Present</td>
<td>Past Present</td>
</tr>
<tr>
<td>18. Other</td>
<td>Past Present</td>
</tr>
</tbody>
</table>
APPENDIX C

WIRB THA INFORMED CONSENT FORM
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A PROSPECTIVE COMPARISON OF THE BIOMECHANICAL AND FUNCTIONAL GAIT CHARACTERISTICS OF INDIVIDUALS UNDERGOING EITHER A DIRECT ANTERIOR OR MINI-INVASIVE POSTERIOR TOTAL HIP ARTHROPLASTY: A LONGITUDINAL, MULTI CENTERED STUDY.

PROTOCOL NO.: None
WIRB® Protocol #20100778

SPONSOR: University of Hawaii
Honolulu, Hawaii
United States

INVESTIGATOR: Cass Nakasone, M.D.
888 South King Street
Honolulu, Hawaii 96813
United States

SITE(S): Straub Clinic and Hospital Bone and Joint Center
888 South King Street
Honolulu, Hawaii 96813
United States

University of Hawaii, Manoa
PE/A Complex Room 231
1337 Lower Campus Road
Honolulu, Hawaii 96822
United States

Queens Medical Center
Suite 608
1380 Lusitana Street
Honolulu, Hawaii 96813
United States

STUDY-RELATED PHONE NUMBER(S): Cass Nakasone, M.D.
808-522-4232
This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study you must give your informed consent. “Informed consent” includes:

- Reading this consent form
- Having the study doctor or study staff explain the research study to you
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

After reading and discussing the information in this consent form you should know:
• Why this research study is being done;
• What will happen during the research;
• Any possible benefits to you;
• The possible risks to you;
• How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

The purpose of this research study is to analyze the walking biomechanical and functional characteristics following a total hip replacement to determine when patients return to normal.

PROCEDURES

If you decide to take part in this study:

You will be asked to complete 9 data collection sessions over the next three years: 1.) before surgery, 2.) 2 weeks, 3.) 4 weeks, 4.) 6 weeks, 5.) 3 months, 6.) 6 months, 7.) 1 year, 8.) 2 years, and 9.) 3 years following your total hip replacement.

Data Collection Time Line

<table>
<thead>
<tr>
<th>HIP Patients (n=100)</th>
<th>Before surgery</th>
<th>2 Weeks After surgery</th>
<th>4 weeks After surgery</th>
<th>6 Weeks After surgery</th>
<th>3 Months After surgery</th>
<th>6 Month After surgery</th>
<th>1 year After Surgery</th>
<th>2 Years After Surgery</th>
<th>3 Af Su</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Analysis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Trendelenburg</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Up and Go Test</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Isometric Strength</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
At each data collection session you will be asked to:

1. Complete 3 questionnaires about your osteoarthritis and your state of mind. These questionnaires include: the Harris Hip Function Score, the Western Ontario and McMaster Universities Osteoarthritis Index, and the Short Form Health Survey.
2. Push as hard as you can into a non-moving strength measuring device in 8 different leg motions: hip flexion, extension, abduction, adduction, internal rotation, external rotation, knee flexion, and extension. This will be done on both legs.
3. Walk 6 meters (about 20 feet) 6 to 10 times at a self-selected (natural) walking speed.
4. Balance on one leg 3 times, and then repeat on the opposite leg.
5. Perform the Timed Up and Go test. This test is a timed test where you will be asked to sit in a chair, then stand, walk 3 meters (about 10 feet), turn around, and return to a seated position in the chair.
6. One data collection session will take approximately 60 minutes.

Information will also be collected from your medical records and stored on the secured database at Straub Clinic and Hospital. The following items will be reviewed and entered into a data collection spreadsheet:

1. History of total hip replacement surgery and other leg surgeries
2. Age, height, weight, and body mass index at the date of total hip replacement surgery
3. Pre-operative diagnosis
4. Hospital length of stay
5. Discharge disposition
6. Anesthesia physical status and analgesic medications used before and following surgery
7. Arthroscopy component characteristics
8. Tourniquet time
9. Anesthesia type
10. Hip radiographs
11. Pre-discharge blood transfusions, hematocrit and hemoglobin levels
12. Peri-operative physical therapy outcomes
13. Surgical complications
14. Date of discharge from physical therapy
RISKS AND DISCOMFORTS

Due to the level of physical activity involved, there is a risk of injury. You may have pain in your affected joint during testing. You may also have some discomfort, muscle cramping or soreness during or after test sessions. Although we have a fall prevention system, there is a chance of falling during the gait trials, the balancing test, and the Up and Go test. There is a very remote chance of cardiac arrest and/or death. These risks are comparable to your routine rehabilitation and activities of daily living, and will not affect your recovery from the surgery.

You cannot participate in this study if you are pregnant because the walking biomechanics collected may not accurately represent your normal walking characteristics. If you are unaware that you are pregnant, participation in this study will result in no more danger to the mother or fetus than normal activities of daily living. However, if you become pregnant or think you might be pregnant during the course of this study, you must inform the researchers, and you will be taken out of the study.

NEW INFORMATION

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

BENEFITS

You will not receive direct/immediate benefits from participating in this study. However, you will obtain information regarding your walking gait, functional activity capacity, hip and knee muscular strength, and behavioral characteristics. Results of this study may assist physicians, physical therapists, and athletic trainers to ensure the optimal clinical outcomes following total hip replacement surgery.

PAYMENT FOR PARTICIPATION

You will receive $5 for each data collection session. This money can be applied to your parking and transportation to and from the University of Hawaii Gait Laboratory. You will be paid only for the visits you have completed.

COSTS

You will be responsible for parking and transportation to and from the University of Hawaii, Manoa, Kinesiology and Rehabilitation Science, Human Performance and Gait Laboratory (Sherriff 100). You will be given $5 per data collection session that can be applied toward the parking fee or transportation; however, the money will be given after you arrive at the facility, so it is a reimbursement. The fee for parking at the University of Hawaii, Manoa parking structure is $4 during the week and $5 on the weekends. Any
other cost associated with parking/transportation over and above the $5 provided will be your responsibility.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

ALTERNATIVE TREATMENT

This is not a treatment study. Your alternative is not to participate in this study. Your follow-up care is the same whether or not you are in this study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about your study visits.
- Information gathered for this research about:
  - Data collection sessions
  - Questionnaires

Who may use and give out information about you?

- The study doctor and research assistant that will be reviewing your medical records at Straub Clinic and Hospital.

Who might get this information?

- The research team at the University of Hawaii, Manoa, Department of Kinesiology and Rehabilitation Science
- Representatives of outside groups hired by Straub Clinic and Hospital or the Western Institutional Review Board for audits to make sure studies are done as required.

Your information may be given to:

- The University of Hawaii, Committee on Human Studies
- Hawaii Pacific Health
- Western Institutional Review Board® (WIRB®)
Why will this information be used and/or given to others?

- To do the research
- To study the results, and
- To see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

- Then you will not be able to be in this research study.

May I review or copy my information?

- Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

- Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.
COMPENSATION FOR INJURY

The study doctors are National Athletic Trainers’ Association/Board of Certification certified athletic trainers and First Aid/CPR/Automated External Defibrillator (AED) trained. In the event of any physical injury from the research, only immediate and essential medical treatment will be available including an AED. First Aid/CPR and a referral to a medical emergency room will be provided. In the event of any emergency incidence outside the gait lab as a result of this research, contact your medical doctor and inform the study doctor: Dr. Cass Nakasone at 808-522-4232. You should understand that if you are injured in the course of this research process that you alone will be billed for the costs of treating your injuries.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY

This research study is sponsored by the University of Hawaii, Manoa.

QUESTIONS

Contact Dr. Cass Nakasone at 808-522-4232 for any of the following reasons:

- if you have any questions about this study or your part in it
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research
If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights

______________________________
Subject Name (printed)

CONSENT SIGNATURE:
Signature of Subject

Date

Signature of Person Conducting Informed Consent Discussion

Date
APPENDIX D

WIRB CONTROL INFORMED CONSENT
TITLE: A PROSPECTIVE COMPARISON OF THE BIOMECHANICAL AND FUNCTIONAL GAIT CHARACTERISTICS OF INDIVIDUALS UNDERGOING EITHER A DIRECT ANTERIOR OR MINI-INVASIVE POSTERIOR TOTAL HIP ARTHROPLASTY: A LONGITUDINAL, MULTI CENTERED STUDY.

PROTOCOL NO.: None
WIRB® Protocol #20100778

SPONSOR: University of Hawaii
Honolulu, Hawaii
United States

INVESTIGATOR: Cass Nakasone, M.D.
888 South King Street
Honolulu, Hawaii 96813
United States

SITE(S): Straub Clinic and Hospital Bone and Joint Center
888 South King Street
Honolulu, Hawaii 96813
United States

University of Hawaii, Manoa
PE/A Complex Room 231
1337 Lower Campus Road
Honolulu, Hawaii 96822
United States

Queens Medical Center
Suite 608
1380 Lusitana Street
Honolulu, Hawaii 96813
United States

STUDY-RELATED PHONE NUMBER(S): Cass Nakasone, M.D.
INTRODUCTION

You are being asked to participate in this research study as a “control subject” because you are around the same age as the population that we are studying, you do not have arthritis (osteoarthritis) or a joint replacement, and you are able to walk normally. The following information is being provided to help you decide if you would like to participate in this study. This consent form may have words that you do not understand. If you have questions, please ask us. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. The purpose of this study is to look at the biomechanical and functional gait (walking) characteristics of subjects who have received a total hip replacement, and compare them to “normal” gait of individuals (control subjects) who do not have a hip or knee replacement.

DESCRIPTION OF PROCEDURES

You will be asked to fill out a medical history questionnaire and four other questionnaires regarding your physical and mental health relative to your ability to participate in this arthritis (osteoarthritis) study as a “control subject” before the first day of data collection. Your responses to the above questionnaires will be screened (reviewed) by a medical doctor. If you are cleared for participation and you choose to participate in this study, you will then be asked to report to the University of Hawaii at Manoa, Kinesiology and Rehabilitation Science Laboratory (Gait Lab) (Sherriff 100) for all testing sessions. When you arrive at the Gait Lab, you will be asked to perform the following four tasks: (1) walk for 6 m (20 feet) at a comfortable speed 6-10 times (Gait Analysis); (2) balance on one leg at a time, 1-3 times each (Trendelenburg); (3) stand up from a seated position in a chair, walk 3m (10 feet), then return to the chair, 1-3 times (Up and Go Test); (4) push your leg into the researcher’s hand and/or muscle testing device (dynamometer) for 3 sec for 8 different leg movements (Isometric Strength). The entire procedure will take approximately 60 minutes. You will be asked to return to the Gait Lab for seven more data collection sessions over the next three years to repeat this procedure (please see Table 1 below).
Table 1. Data Collection Time Line

<table>
<thead>
<tr>
<th>Control Subjects (n=50)</th>
<th></th>
<th>Initial Visit</th>
<th>3 Weeks</th>
<th>6 Weeks</th>
<th>3 Months</th>
<th>6 Months</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Analysis (test)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Trendelenburg</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Up and Go Test</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Isometric Strength</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Paper/Pencil Tests</td>
<td>X</td>
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<td>X</td>
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<td>X</td>
</tr>
</tbody>
</table>

**RISKS**

Due to the level of physical activity involved, there is a risk of injury. You may also have some discomfort, muscle cramping or soreness during or after test sessions. Although we have a fall prevention system, there is a chance of falling during the walking test. There is a very remote chance of cardiac arrest (heart attack) and/or death.

**NEW FINDINGS**

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

**BENEFITS**

You will not receive direct/immediate benefits. However, you will obtain information regarding your walking gait, functional activity capacity, hip and knee muscular strength, and behavioral characteristics. Results of this study may assist physicians, physical therapists, and athletic trainers to ensure the optimal clinical outcomes (results) following total hip replacement surgery.

**PAYMENT FOR PARTICIPATION**
You will receive $5 for each data collection session. This money can be applied to your parking and transportation to and from the University of Hawaii Gait Laboratory. You will be paid only for the visits you have completed.

COSTS

You will be responsible for your parking and transportation to and from the University of Hawaii, Manoa, Kinesiology and Rehabilitation Science, Human Performance and Gait Laboratory (Sheriff 100). You will be given $5 per data collection session that can be applied toward the parking fee or transportation; however, the money will be given after you arrive at the facility, so it is a reimbursement. The fee for parking at the University of Hawaii, Manoa parking structure is $4 during the week and $5 on the weekends. Any other cost associated with parking/transportation over and above the $5 provided will be your responsibility.

ALTERNATIVES

This is not a treatment study. Your alternative is to not be in this study.

COMPENSATION FOR INJURY

The study staff are National Athletic Trainers’ Association, Board of Certification certified athletic trainers and First Aid/CPR/AED trained. In the event of any physical injury from the research, only immediate and essential medical treatment is available including an AED. First Aid/CPR and a referral to a medical emergency room will be provided. In the event of any emergency incidence outside the lab as a result of this research, contact your medical doctor and inform the study doctor: Dr. Cass Nakasone at 808-522-4232. You should understand that if you are injured in the course of this research process that you alone will be billed for the costs of treating your injuries.

SOURCE OF FUNDING

Funding for this research study will be provided by University of Hawaii, Manoa.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:
• if it is in your best interest;
• you do not consent to continue in the study after being told of changes in the research that may affect you;
• or for any other reason.

CONFIDENTIALITY

Your research records will be confidential to the extent permitted by law. Agencies with research oversight, such as the University of Hawaii Committee on Human Studies and Western Institutional Review Board® (WIRB®), have the right to review research records.

An identification number will be used to identify you during the study, which will be known only to you and study personnel. In addition, all data and subject (identity) information will be kept under lock and key in the Department of Kinesiology and Rehabilitation Science at the University of Hawaii at Manoa. These materials will be permanently disposed of in a period not longer than 5 years. You will not be personally identified in any publication arising from this study. Personal information about your test results will not be given to anyone without your written permission.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

• Research records
• Records about phone calls made as part of this research
• Records about your study visits.
• Information gathered for this research about:
  Gait lab data collection sessions
  Questionnaires

Who may use and give out information about you?

The study doctor and the study staff.

Who might get this information?

The sponsor of this research. “Sponsor” means any persons or companies that are:

• working for or with the sponsor, or
• owned by the sponsor.
Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Hawaii Pacific Health, and
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.
QUESTIONS

If you have any questions, concerns or complaints related to this study or if at any time you feel you have had a research-related injury, please contact: Dr. Cass Nakasone at 808-522-4232.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

If you cannot obtain satisfactory answers to your questions, or have complaints about your treatment in this study, please contact: Committee on Human Subjects, University of Hawai’i at Manoa, 1960 East-West Rd., Biomed Bldg. Ste. B-104, Honolulu, Hawaii 96822, Phone 808-956-5007.
Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your record

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

I attest that I do not believe that I am currently pregnant and that should I become pregnant during participation in this study that I will voluntarily withdraw from further participation.

________________________________________
Subject Name (printed)

________________________________________
Signature of Subject Date

________________________________________
Person Conducting Informed Consent Discussion Name (print)

________________________________________
Signature of Person Conducting Informed Consent Discussion Date
APPENDIX E

CONTROL FLYER
Do you have healthy knees and hips?
Are you interested in assessing your walking gait, functionality, and muscle strength?

The Department of Kinesiology and Rehabilitation Science at the University of Hawai‘i Manoa is seeking volunteers to participate in a research study: Functional Recovery and Gait Biomechan following Total Hip Arthroplasty: a Longitudinal Study

**Background Information**

The number of total hip replacement (THR) surgeries has been increasing dramatically over the past 10 years. While the posterior THR is a very successful surgical procedure for hip arthritis, the procedure that accesses the hip joint from the front of the body has shown a quicker functional recovery, however neither approach has demonstrated a biomechanical return to normal gait. The purpose of this research is to investigate the both the functional and biomechanical differences between the two THR procedures.

**What is involved in the study?**

3 year follow up after initial session
- Total of 8 data collection sessions over 3 years
- 60 min for each data collection session

Data to be collected:
- Walking gait
- Functional capacity

**What are the benefits for participants?**

You may not receive direct/immediate benefits. However, you will obtain information regarding your walking gait, functional activity capacity, hip muscular strength, and behavioral characteristics. The results of this study will help to maintain and optimize the beneficial effect of THR.

**Inclusionary criteria:**
- Free from Knee and hip osteoarthritis
- No previous THR or Total Knee Replacement
- No other injuries
- Adult under 85 years of age

For more information contact:
Ryan Molzon, ATC - rmolzon@hawaii.edu (808) 956-3815

Department of Kinesiology and Rehabilitation Science


