FUNCTIONAL OUTCOMES AND STRENGTH MEASURES IN
MINIMALLY INVASIVE TOTAL HIP ARTHROPLASTY UP TO SIX WEEKS POST
SURGERY

A THESIS SUBMITTED TO THE GRADUATE DIVISION OF THE
UNIVERSITY OF HAWAI‘I AT MĀNOA IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF
MASTER OF SCIENCE
IN
KINESIOLOGY AND REHABILITATION SCIENCES
AUGUST 2011

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Keywords: THA; minimally invasive; direct anterior
ACKNOWLEDGEMENTS

I would like to thank everyone at UH who made this thesis possible. I would like to thank Rachele for all of her help reviewing the endless version of my thesis. I would also like to thank Dr. Hetzler and Dr. Stickley being a part of my committee. Most of all I would like to thank Dr. Kimura for that long Friday and Saturday afternoon and evening that made a finished thesis possible. Thank you.

A big thank you also goes out to all of the other grad students that were here with me. I would especially like to thank all of those in my class: Karin, Liz, Eryn, Matt (an honorary member) and of course Reade. There were times that we didn’t think we would make it, but together we made it through!

Finally, thank you to my family. Thanks to my parents, who I think are still coming out of shock from me telling them out of the blue that I was going to Hawai‘i. Your support helped. Thank you, to my sister, Miranda, who is my closest friend and mentor. Here is to the motorcycles built and those to be built. And of course, thank you to Tara. You were always there to support me and understand my frustrations, and to ask me to proof read papers about Supreme Court decisions. You mean more than I can express.

Thank you!
ABSTRACT

Purpose- Total hip arthroplasty (THA) has been crucial in restoring and maintaining quality of life in the active elder and geriatric populations. Traditional THA approaches have been used with great success over the past 70 years. Technical medical advances have allowed new minimally invasive (MI) surgical techniques to be developed to manage THA recovery in a more effective and abbreviated time. These MI surgeries reduce pain and restore function more rapidly by reducing perioperative tissue damage. Therefore the purpose of this study is to assess functional ability in MI-THA patients at pre-operation (PRE) three and six weeks post-operation (POST) compared to a control group.

Methods- A 2x3 repeated measures analysis of variance (ANOVA) design was used to compare 16 participants, 6 direct anterior (DA)-THA procedure participants and 10 controls. Function (Timed Up-and-Go and Trendelenburg test) and strength measures were collected at the following three time periods: pre-operation (PRE), three weeks (POST3) and six weeks (POST6).

Results- Repeated measures ANOVA results revealed no significant differences between groups or across time for either of the functional tests. Significant differences (p<0.05) were revealed between groups on all strength measures. Results revealed a significant difference across data collection periods for three strength measures. All strength measures were no longer significantly different at POST6, except hip external rotation.

Conclusions- Within the limitation of this study and considering the small sample size we conclude that MI DA-THA patients were able to achieve normal hip strength by six weeks post-surgery except for external rotation. Also, functional testing results revealed no significant difference between the MI DA-THA group and controls at any data collection period.

Keywords
THA; minimally invasive; direct anterior
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PART I

INTRODUCTION

Total hip replacement surgery (arthroplasty) has played a vital role in maintaining and restoring function to the active elder and geriatric population by reducing pain and increasing function leading to increases in quality of life activities\(^1\). Traditional Total Hip Arthroplasty (THA) surgical techniques primarily involve the posterior hip approach with incisions between 18-22 cm and incise or transect portions of muscle, specifically the hip abductor and external rotator muscles, to expose the hip joint \(^4,6\). The ever advancing medical field and technical advances have led to the development of minimally invasive (MI) THA techniques which decrease perioperative damage to decrease hip pain and increase return to functional activities \(^1,4,6,10-15\). These MI procedures reduce tissue damage by utilizing smaller incisions, modifying surgical techniques via decreases in incised muscles, and/or elimination of incised muscles via increased muscle retraction. \(^1,4,10,12-14,16\). Some MI Traditional THA procedures continue to utilize the posterior hip approach but involve reduction of incision size only, while others MI modifications involve smaller skin incisions, and techniques where fewer or less of the muscle is actually incised. The MI muscle sparing THA approach utilizes an area of the body not commonly used in a traditional THA, where muscles are retracted and not incised to access the hip joint \(^1,4,10,12-14,16\). One of the MI muscle sparing techniques known as the direct anterior (DA)-THA accesses the hip joint anteriorly via the intermuscular plane and was established by Smith-Peterson to avoid tissue damage \(^1,15\). These MI advances have all improved early post-surgical pain and function \(^1,17\).

Traditional approaches have been shown to be successful at returning function as early as six weeks \(^4,18-20\). Through the use of self-assessment questionnaires and functional tests, studies have reported decreased pain and improved function within the first year \(^4,11,18-20\). However, questionnaire conclusions indicate that they do not adequately assess the full spectrum of surgical recovery \(^21-23\). Minimally Invasive-THA have revealed improvements in quality of life experiences at earlier time periods \(^4,11,12,14,17\). Unfortunately outcome research of these MI THA approaches have not kept up with the number of new MI techniques. This sparse number of studies has been limited to assessment at six weeks and up to one year post-surgery \(^4,11,17\). To our knowledge only Nakata et al. \(^17\) investigated functional outcomes of MI-THAs at less than six weeks post-operation. Nakata compared the MI DA-THA to the MI Posterior THA at three
weeks post operation and found significant improvements in the DA-THA verses the MI posterior-THA in single leg stance, Trendelenburg test, and walking velocity. As noted, little research has focused on the initial six weeks of recovery using functional measures.

Therefore the purpose of this study is to assess functional recovery using the Trendelenburg Test, TUG and isometric hip strength in DA-THA patients at three and six weeks post-surgery compared to a control group.

**METHODS**

**Research Design**

A prospective longitudinal design using eight 2x3 Analysis of Variance (ANOVA) with Repeated Measures (RM) was used to compare the DA-THA and control group at pre-operation (PRE), three weeks (POST3), and six weeks (POST6) post-operation. Functional tests included the Timed Up-and-Go (TUG) and the Trendelenburg. Isometric strength tests included hip extension, hip abduction, hip adduction, hip flexion, hip internal rotation and hip external rotation.

**Participants**

Surgical participants were recruited from a pool of patients selecting to undergo MI DA-THA procedure performed by Cass Nakasone, MD, an experienced surgeon fellowship trained in the DA-THA procedure. All surgical patients were cleared for participation by the surgeon. The control participants were recruited from the greater Honolulu Community (Appendix A), and were cleared for participation using a medical history questionnaire (Appendix B). Exclusionary criteria included a history of lower extremity joint replacement, neurologic or orthopedic conditions that affected walking, or those who used an assistive device while walking. All participants signed informed consent forms, and Health Insurance Portability and Accountability Act authorization forms. The study was approved by the Western Institutional Review Board and the university committee on human subjects (Appendix C and D).

**Minimally Invasive Direct Anterior Total Hip Arthroplasty**

Surgery involved the anterior aspect of the hip with the patient supine on a specialized HANA® hip and knee arthroplasty table (Mizuho OSI, Union City, CA USA). A straight skin incision was made starting 2cm distal and lateral to the anterior superior iliac spine (ASIS) and ending 2cm anterior to the greater trochanter. An intermuscular plane was exposed/enhanced by
separating the fascia of the tensor fascia latae (TFL), which allowed separation from the sartorius muscle. Next, capsular insertions of the rectus femoris and the psoas muscles were elevated and retracted medially. This allowed the interval between the TFL and the rectus femoris to be identified and developed distally. Next, the anterior capsule was incised using two flaps into the joint capsule to expose the femoral head and neck. The neck of the femur was cut, and the head of the femur was removed. The acetabulum was then prepped, and proper alignment was checked under x-ray. Traction was applied using the HANA® table and the femur was externally rotated and extended to expose the femur. After preparation, implants were placed in the femur and acetabulum. The joint was then reduced and inspected for alignment again using x-ray. Finally, the retracted muscles were allowed to return to position, and the TFL fascia was sutured and the wound was closed.

Procedures

All functional and isometric strength data were collected at the University Human Performance and Gait Laboratory by the same group of researchers who were all Board of Certification certified athletic trainers. Height was measured using a wall-mounted stadiometer and body mass was determined using a Befour PS6600-ST scale (Befour, Inc., Saukville, WI, USA). Trendelenburg data were collected using the procedures of Hardcastle and Nade and the rating system of Pai. Three trials were completed for each leg, and the best score for the involved leg was recorded. Timed Up-and-Go data were collected according to Podsiadlo and Richardson. Three trials were conducted, and the fastest time was used for analysis.

Isometric strength data were assessed using the MicroFET 2 hand-held dynamometer (HHD) (Hoggan Health Industries, Draper, Utah, USA). Prior to all six isometric strength tests (hip extension, hip abduction, hip adduction, hip flexion, hip internal rotation and hip external rotation) submaximal familiarization trials were administered to THA and control groups. Additionally, 60 second rest periods were administered between all familiarization and strength tests. Following familiarization just prior to specific muscle test two maximal trials were recorded unless the values were greater than ten percent different, then a third trial was recorded. Isometric strength data collection of each movement tested involved three second volitional maximal contractions. Pain level was assessed during each test via a visual analogue scale where zero equaled no pain and ten equaled most pain possible (Appendix E). When pain was reported above an eight, the movement was not repeated. An adjustable Triton® treatment table
(DJO Global, Vista, California, USA) was utilized for patient comfort during all strength tests. Hip extension was tested in a prone position with the dynamometer placed on the posterior of the thigh at 80% the distance from greater trochanter to knee joint line. Hip abduction and adduction were collected in a supine position with the dynamometer placed appropriately on either the lateral or medial thigh at 80% the distance between the greater trochanter and the knee joint line. Hip flexion was tested in a seated position with 110° of hip and 90° of knee flexion. The dynamometer was placed at 80% the distance between the greater trochanter and the knee joint line. Hip internal and external rotation were collected in a seated position with the dynamometer placed appropriately on either the lateral or medial side of the shank at 80% the distance between the knee joint line and the malleolus.

Data Analyses

A 2x3 ANOVA using two groups (MI DA-THA and control) and three data collection measures (PRE, POST3, POST6) with RM was completed for the eight dependent variable data via SPSS 19.0 (IBM, Armonk, NY, USA). Demographic data involved descriptive statistics. The alpha level for all analyses was set at p<0.05.

RESULTS

Participants were 16 volunteers (N=16) divided into MI DA-THA group (4 male 2 female n=6) and an age matched control group (9 male 1 female n=10). The MI DA-THA and control group Means for age, height, and weight, were: 60.67 ± 8.07 years and 60.80 ± 4.21 years; and 1.71 ± 0.08 m and 1.68 ± 0.08m; 72.20 ± 12.43 kg, 72.37 ± 6.98kg, respectively. Participant demographics are presented in Table 1.

<table>
<thead>
<tr>
<th>MI DA-THA</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>60.67 ± 8.07</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.71 ± 0.08</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>72.20 ± 12.43</td>
</tr>
</tbody>
</table>

Analysis of variance with repeated measures results revealed no significance differences in function for the Trendelenburg times or TUG times between groups at all data collection periods (Tables 2 and 3). Significantly lower isometric strength measures were revealed by the MI DA-THA group at PRE data collection time period for hip extension and internal rotation; at
POST3 for hip extension and external rotation; and at POST6 for hip external rotation only. All strength measures were no longer different at six weeks, except external rotation. Significant strength changes were revealed for hip abduction (PRE to POST3) (POST3 to POST6), hip flexion (PRE to POST3) (PRE to POST6), and external rotation (PRE to POST3) (Table 4).

Table 2. Mean and standard deviations of Trendelenburg times at PRE, POST3, and POST6 between a control group and the MI DA-THA group

<table>
<thead>
<tr>
<th>Trendelenburg (s)</th>
<th>N</th>
<th>PRE</th>
<th>POST3</th>
<th>POST6</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI DA-THA</td>
<td>6</td>
<td>17.35 ± 13.94</td>
<td>8.80 ± 12.24</td>
<td>18.32 ± 13.26</td>
</tr>
<tr>
<td>Control</td>
<td>10</td>
<td>16.43 ± 14.75</td>
<td>17.22 ± 11.00</td>
<td>16.17 ± 14.54</td>
</tr>
</tbody>
</table>

Overall model significance for group (p=0.749)

Table 3. Mean and standard deviations of TUG times at PRE, POST3, and POST6 between a control group and the MI DA-THA group

<table>
<thead>
<tr>
<th>TUG (s)</th>
<th>N</th>
<th>PRE</th>
<th>POST3</th>
<th>POST6</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI DA-THA</td>
<td>6</td>
<td>8.81 ± 4.42</td>
<td>9.36 ± 2.18</td>
<td>7.37 ± 1.65</td>
</tr>
<tr>
<td>Control</td>
<td>10</td>
<td>7.50 ± 1.92</td>
<td>7.23 ± 1.68</td>
<td>6.87 ± 1.38</td>
</tr>
</tbody>
</table>

Overall model significance for group (p=0.207)

Table 4. Means and standard deviations of strength measures at PRE, POST3, and POST6 between a control group and the MI DA-THA group.

<table>
<thead>
<tr>
<th></th>
<th>PRE</th>
<th></th>
<th>POST3</th>
<th></th>
<th>POST6</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MI DA-THA</td>
<td>Control</td>
<td>MI DA-THA</td>
<td>Control</td>
<td>MI DA-THA</td>
<td>Control</td>
</tr>
<tr>
<td>Hip Abd (ft-lbs)</td>
<td>24.00 ± 7.44†</td>
<td>32.25 ± 8.09</td>
<td>17.82 ± 7.61†</td>
<td>29.67 ± 9.58</td>
<td>24.40 ± 11.75†</td>
<td>30.25 ± 8.63</td>
</tr>
<tr>
<td>Hip Flx (ft-lbs)</td>
<td>35.50 ± 12.13††</td>
<td>45.55 ± 9.56</td>
<td>18.85 ± 12.91††</td>
<td>42.15 ± 11.02</td>
<td>27.60 ± 16.06††</td>
<td>39.37 ± 14.23</td>
</tr>
<tr>
<td>Hip IR (ft-lbs)</td>
<td>13.80 ± 4.00*</td>
<td>25.25 ± 5.78</td>
<td>16.27 ± 9.51</td>
<td>23.86 ± 6.68</td>
<td>17.27 ± 9.37</td>
<td>22.05 ± 7.30</td>
</tr>
</tbody>
</table>

* Significant difference between groups at time period (p<0.05)
† Significant difference between PRE and POST3 (p<0.05)
‡‡ Significant difference between POST3 and POST6 (p<0.05)
# Significant difference between PRE and POST6 (p<0.05)
DISCUSSION

Strength

Probably the most surprising result of this study was that only hip external rotation of the MI DA-THA group was less strong than the control group at six weeks post-surgery. The strength test results for the control group of the present study are supported by Bohanon\textsuperscript{31} and Andrews\textsuperscript{32} who developed normative values for muscular strength of elders without pathology. At all times periods the MI DA-THA group revealed similar results to the control group except for hip extension PRE (MI DA-THA=19.98 ft-lbs, Control 36.15 ft-lbs), hip extension POST3 (MI DA-THA=18.4 ft-lbs, Control 31.93 ft-lbs), hip flexion POST3 (MI DA-THA=18.85 ft-lbs, Control 42.15 ft-lbs), hip external rotation POST3 (MI DA-THA=10.18 ft-lbs, Control 22.79 ft-lbs), and hip external rotation POST6 (MI DA-THA=14.22 ft-lbs, Control 22.38 ft-lbs) (Figures 1-6). Further, significant changes across time were seen in MI DA-THA strength measures in hip abduction (PRE=24.00 ft-lbs, POST3 17.82 ft-lbs), hip flexion (PRE=35.5 ft-lbs, POST3 18.85 ft-lbs) (POST3=18.85 ft-lbs, POST6 27.60 ft-lbs), and hip external rotation (PRE=18.68 ft-lbs, POST3 10.18 ft-lbs) (Figures 2, 4, and 6). The subsequent decreases in hip abduction, hip flexion, and hip external rotation in POST3 from PRE support the findings of previous research that report associated damage to these muscle areas during the MI DA-THA approach\textsuperscript{13}. Particularly interesting is the fact that at POST6 no significant differences between groups (MI DA-THA=14.22 ft-lbs; Control=22.38 ft-lbs) were revealed except for hip external rotation. These results further demonstrate the fact that while the MI DA-THA is a muscle sparing technique utilizing an anterior hip approach that the mere manipulation of the surrounding musculature and the femoral head during surgical replacement continues to significantly affect external rotator hip strength up to six weeks post-operation\textsuperscript{13}.
Figure 1

*Significant difference between groups (p<0.05)

Figure 2

*Significant difference between groups (p<0.05)
† Significant difference across data collection periods
Figure 3

*Significant difference between groups (p<0.05)

Figure 4

*Significant difference between groups (p<0.05)
† Significant difference across data collection period
Figure 5

**Hip internal rotation strength measures MI DA-THA and control groups at PRE, POST3, and POST6**

*Significant difference between groups (p<0.05)*

Figure 6

**Hip external rotation strength measures MI DA-THA and control groups at PRE, POST3, and POST6**

*Significant difference between groups (p<0.05)*

† Significant difference across data collection periods
The Trendelenburg test was designed to assess hip abductor function, which has been shown to be compromised due to abductor muscle group damage\textsuperscript{13,24,33}. Surprisingly few studies have used the Trendelenburg test to assess hip strength following THA \textsuperscript{9,18,34}. Kiyama\textsuperscript{18} et al compared Traditional THA Trendelenburg results pre surgery and two years post-surgery. Their findings indicated a positive Trendelenburg test prevalence of 84.2% and 82.5% pre-surgery followed by 26.3% and 27.5% two years post-surgery, respectively.\textsuperscript{18} Nakata et al\textsuperscript{17} was the only study that compared MI DA-THA and Traditional THA surgeries and reported a significant difference between the MI DA-THA (29% positive tests) and a minimally invasive posterior approach (67% positive tests) three weeks post operation, but not at pre-surgery, 5 days or 2 months post-surgery. Consequently, Nakata’s results are consistent with the results of the present study (Figure 7). To the best of our knowledge, no other study compared the MI-THA with a control group at multiple time periods within the first six weeks following THA surgery.

The TUG test results of this study were similar to normative data previously reported from similar age groups revealing no differences in TUG times\textsuperscript{25,35-40}. Bohannon\textsuperscript{37} conducted a meta-analysis that encompassed 4395 subjects similar in age to the present study. One of his final analysis groups included a sample similar in age to those found in the present study; however, the present study times for the TUG were slightly faster than those of Bohannon\textsuperscript{37} or
in various other previously reported populations\textsuperscript{25,35-40}. Once again the results of the present study are supported by the results of other studies that utilized the TUG on patients with various pathologies other than THA. To our knowledge Nankaku\textsuperscript{41} et. al. conducted the only other study that used the TUG to functionally assess THA recovery of patients classified into good (TUG time < 10 seconds) and poor (TUG time > 10 seconds) ambulatory groups, however surgical technique was not reported. The good ambulatory group mean TUG scores at four weeks post-surgery (8.42s) were similar those reported at POST3 (9.35) and POST6 (7.37) weeks in the present study.\textsuperscript{41} The MI DA-THA times in the present were slowest at POST3, but approached times of the controls by POST6 (Figure 8). These changes support earlier reports of rapid return of quality ambulation\textsuperscript{1,17}. The majority of participants in the study completed the TUG in less than ten seconds at all time periods. This was important for three reasons. First, the times produced by the sample in this study classify all the individuals as independently mobile or highly independent based on the categories of previous studies\textsuperscript{25,35-40}. Second, Kristensen et al\textsuperscript{42} suggested a time of 24 seconds as a cutoff for predicting falls following hip fracture surgery. Third, Podsiadlo and Richardson\textsuperscript{25}, the originators of the TUG, in the original article suggested that the TUG may lack the ability to distinguish changes in those with scores less than ten seconds in length. Therefore, this inability to distinguish change in scores less than ten seconds may have affected the value of the TUG in this sample.

\textbf{Figure 8}

\textit{Timed Up-and-Go times MI DA-THA and control groups at PRE, POST3, and POST6}

* Significant difference between groups (p<0.05)
Recommendations

Future research should be considered in the field of early functional return following MI-THA procedures. First, a study using a much larger sample size should be conducted. Second, a functional study should be conducted with an even earlier testing range starting at two weeks and possibly every two weeks post-surgery up to the six weeks mark. Third, research using a similar sample group should look at normalized strength measures and strength measure comparison to the contralateral side. Fourth, further research should also examine the relationship in the TUG test between base height of the chair and the height of the subject and that relationship’s effect on time. Fifth, normative strength values using hand-held dynamometers should be established for various approaches of recovering MI-THA patients.

CONCLUSION

Within the limitation of this study and considering the small sample size we conclude that MI DA-THA patients were able to achieve normal hip strength by six weeks post-surgery except for external rotation. Also, functional testing results revealed no significant difference between the MI DA-THA group and controls at any data collection period. The lack of statistical differences for some measures may be attributed to the small sample size; however, there still may be a clinical difference for these measures.
PART II

REVIEW OF LITERATURE

Intro

Research into the field of total hip arthroplasties (THA) has received growing attention in the last decade. This review of literature encompasses research published in the field in order to provide a thorough understanding of the topic. It examines current and predictive prevalence of THA along with associated costs. Several surgical techniques were explored with an in-depth focus on the Minimally Invasive (MI) Direct Anterior (DA). Next, outcome measures of THAs, with a focus on the MI DA-THA procedure, were considered. Finally, the testing instruments of the Timed Up-and-Go Test, Trendelenburg Test, and hand-held dynamometry were examined.

Total Hip Arthroplasty

Kurtz et al.\textsuperscript{7,43} set out to establish the prevalence and projections in THAs in the United States. In a 2005 study, they looked at the rates of primary and revision THAs in the United States from 1990-2002 using the Nationwide Inpatient Sample (NIS) and National Hospital Discharge Survey (NHDS) and US Census numbers\textsuperscript{7}. They found that the rate of THAs increased steadily during that time period. The rate of primary THA per 100,000 individuals increased 46%. In 1990 there were 119,000 primary THAs performed. This number increased to 193,000 in 2002. In 1990 there were 24,000 revision THAs. This number increased to 43,000 in 2002. These numbers reflected primary and revision rate increases of 62% and 72% respectively. Revision THA burden, defined as the percentage of revision THA cases as a function of all THA cases, was found to be slightly increasing or remaining close to steady. The authors noted that the increase in primary cases will eventually lead to an increase in revisions rates. They suggested that decreasing the revision rate slightly could have a financial affect anywhere from $42.5 million to $112.6 million.\textsuperscript{7} This was a cost that was estimated to have consumed 19% of the Medicare THA expenditures between 1997 and 2003 \textsuperscript{43}. A follow up article in 2007 tried to predict the expected number of primary and revision THAs up through 2030 \textsuperscript{43}. Kurtz et al. \textsuperscript{43} predict the number of primary THA to grow by 174% from 208,600 in 2005 to 572,000 in 2030. THA revisions are predicted to nearly double by 2026 from the 2005 numbers. Revision THAs are expected to grow from 40,800 in 2005 to 96,700 in 2030. These numbers are predictions based on national surveys and US Census numbers. Unlike other
countries the US does not have a national joint replacement registry. These numbers are also not able to predict for any changes in implants, new procedures, or other therapeutic interventions.\textsuperscript{7,43}

Kurtz et al.\textsuperscript{44} continued projection numbers working in 2009 on predictions for primary and revision joint replacements for younger patients. With the baby boomers reaching 65 in 2011 Kurtz predicts an increase in THAs. Typically younger patients are not great candidates for total joint replacements because of their highly active lifestyle. Using NIS and NHDS and the US Census they predicted the amounts of total joint replacements for certain age categories. From 1993 to 2006 32% of THAs were for patients less than 65 years old. In 2006 alone, the younger patient population for total joint replacements accounted for 40-46%. By 2011 individuals under the age of 65 are predicted to account for 50% of all total joint replacements. This number is expected to reach 52% by 2030. By 2030 the demand for THAs for the age category of 45 to 54 years old are expected to increase by a factor of 5.9. This cost of the increase in younger patients receiving THAs should because of the possible need for more durable implants.\textsuperscript{44}

Bozic et al.\textsuperscript{3} examined the epidemiology of THA revisions in the United States. Despite the high success rate of THAs in the United States the revision burden had not decreased over time. They used the NIS reported ICD-9-CM codes related to THA revisions between October 2005 and December 2006 to analyze revision numbers in the U.S. A total of 51,345 revisions were studied in patients with a mean age of 67.1 years. Men made up 42.9% of the sample. The most common causes for revision were instability or dislocation (22.5%), mechanical loosening (19.7%), and infection (14.8%). The most common type of revisions were all component revision (41.1%), femoral component revision (13.2%), acetabular component revision (12.7%), and isolated head and acetabular linear exchange (12.6%). THA revisions were most often reported in the seventy-five to eighty-four age group (27%). The authors feel that more studies need to be done to clarify what revisions are being done and why. Part of the challenge in understanding these rates are accurate reporting. This could be facilitated by new databases, proper measurements, and the use of proper coding.\textsuperscript{3}

**Surgical techniques**

The field of THAs has seen heightened interest in the last few years. New minimally invasive (MI) THAs have been developed. Within the MI-THA family there are three types of
procedures: smaller incision, less invasive, and muscle sparing. During a smaller incision THA, a traditional THA procedure is used with the only difference being a reduced incision size, while the less invasive THA is a modification of a traditional THA that not only uses a smaller skin incision but also modifies the technique so less muscle is damaged. The muscle sparing THA utilizes an area of the body not commonly used in a traditional THA, where muscles are retracted and not incised to access the hip joint.  

**Minimally Invasive Direct Anterior**

Several good articles exist regarding the actual technique of minimally invasive total hip replacements. The direct anterior approach was first described as the Smith-Petersen approach in a paper by authors of the same name. This technique was first published in 1949. The technique involves a small anterior incision to expose the joint field. This procedure takes care to minimize the amount of damage that occurs to the surrounding musculature. Instead of transecting or removing muscle attachments the approach creates fields of vision by retracting muscles to the side in various directions. The technique also allows for visualization and sparing of important vascular and nervous structures. Some other current techniques are variations upon this original procedure. The newer procedures may create other fields of view, or they may involve mild detachment of certain portions of accessory muscles. Either way the direct anterior approach provides a technique for decreasing the amount of internal derangement along with a smaller incision point. The direct anterior approach does have a few additional requirements. The procedure is more easily accomplished when using a specifically designed HANA® table. The table allows the surgeon to properly secure the lower extremities and apply traction allowing the surgeon to easily manipulate the leg to expose the femoral head anteriorly. This allows the surgeon to easily accomplish the surgery with only one assistant. The surgery can be performed without the use of a specifically designed table, but the procedure is drastically simpler with the specified table. Without the table the surgeon requires more assistants to properly perform the procedure. A drawback of the direct anterior approach is its ability to visualize the posterior acetabulum. Therefore, the direct anterior approach is not used with patients that have posterior acetabular complications.

Minimally invasive surgeries are of interest because of early functional recovery, reduced dependence on pain meds, reduced hip precautions post-surgery, no required outpatient therapy, and early weight bearing. In a study by Bal et al of 100 patients undergoing a DA-THA
(Mean patient age 61 (range 33-91), mean patient BMI 29.8 (range 18.1-51.8) they examined several perioperative measures and outcomes for a minimum of ten months. The mean time of surgery was 53 minutes (range 34-87 min), mean blood loss was 185 cc (range 65-630cc), mean incision length was 10.4cm (range 7.8-13.7), and mean hospital stay was 2.4 days (range 1-5 days). All patients were discharged home, and all resumed normal activities by week four with satisfaction. The authors felt that the procedure was beneficial in sparing the lateral femoral cutaneous nerve because of the more lateral placement of the incision. The authors reported decrease blood loss likely due to the positioning of the patient.  

Siguier et al. looked at dislocation rates in the minimally invasive anterior approach using a Heuter approach which is a modification of the Smith-Petersen. They examined 1027 primary THAs between June 1993 and June 2000. They performed the THA on 926 patients (336 men 590 women) with a mean age of 67.8 years (range 23-93). A skin incision of less than 10cm was used for all of the surgeries. Fifteen cases were excluded from the study because the incision was extended beyond the 10cm. Eight other patients were also excluded because their muscular build required sectioning of the piriformis to allow for proper femoral exposure. None of the excluded patients suffered dislocations. Both seated and standing positions were allowed starting the day following surgery, and simple, active movements were encouraged from day two. Patients were allowed full weight bearing when they were comfortable after day two, with all patients in the study achieving full weight bearing within the first two days. The use of walking aids was discontinued by all patients by day eight. All patients were given an at home six week physical therapy protocol. Clinical and radiographic follow-ups were done at three months, one year, and yearly after the first year. Forty-five patients were lost after the first follow up, but no dislocations had occurred in this group at that time. Out of the 1037 THAs performed there were no incidences of limping, and only ten dislocations occurred. Eight of the ten dislocation occurred within the first two months. Of the ten dislocations, seven incidences were limited to one occasion. The authors reported an overall dislocation rate of 0.96%. Siguier et al. suggests that this low incidence of dislocation could be attributed to a minimal amount of muscle damage and good hip joint exposure during surgery. They suggest that these conditionals are favorable for better functional outcomes.

Matta et al. also explored the Heuter approach examining implant placement measures and dislocation rates. Between September 1996 and September 2004 they examined 494
anterior THAs with a mean patient age of 64 (range 27-91). The mean hospital stay for unilateral procedures was three days, while bilateral hospital stay averaged 5 days. The mean abduction angle was $42^\circ \pm 4^\circ$ (range 34-54$^\circ$). Ninety-six percent were placed in the target range of 35$^\circ$ to 50$^\circ$. The average anteversion was $19.4^\circ \pm 5.2^\circ$ (range 0-30$^\circ$). Ninety-three percent were within the target range of 10$^\circ$ to 25$^\circ$. Leg length accuracy was accurate with an average post-op leg-length discrepancy of 3mm $\pm$2mm. Three patients suffered dislocations (3 of 494) for a dislocation rate of 0.61%. There were two anterior dislocations and one posterior; all of which were one time occurrences. Seventeen other complications were reported ranging from infection to iatrogenic fractures. All of these cases were successfully resolved. The authors felt that minimally invasive anterior approach to THA was a viable surgery for proper implant placement, and that the approach leads to a small number of post-surgical dislocations.12

One of the beneficial components to a minimally invasive THA is the proposed decrease in the amount of internal muscle derangement. Meneghini et al.13 set out to test the modified Smith-Petersen approach and a mini-incision posterior approach through a cadaveric study of muscle damage from the two procedures. Six fresh frozen cadavers (12hips) with a mean age at death of 81 years (range 77-87), a mean height of 178.7 cm (range 170-183cm), a mean weight of 72.7 kg (range 67-82 kg), and a BMI of 22.8 (range 20.6-25.2) were thawed at room temperature and the left and right hips were randomly assigned one of the THA procedures. After completion of the procedures, three independent surgeons evaluated the amount of muscle damage as a function of percent of the muscle belly and tendon derangement. Both approaches found similar damage to the gluteus medius. The anterior approach had a mean damage of 2.62% (range 0-7.94%), while the posterior approach damaged 2.85% (range 0-8.9%) of the muscle. Damage from the anterior approach occurred mainly along the anterior aspect of the medius muscle belly, while the posterior approach damaged an area mainly along the posterior muscle border. Damage to the gluteus minimus was found to be the greatest difference in the two approaches. The anterior approach had a mean damage of 8.48% (range 0-28.6%) to the muscle while the posterior approach damaged 18% (range 10.1-33.3%). Tendon damage to the gluteus minimus was 4.63% (range 0-16.7%) in the anterior approach, while the tendon damage was 22.81% (range 0-56.8%) in the posterior approach. The short external rotators were released in the posterior approaches which lead to 100% derangement in the posterior approach. There was a need to release the external rotators in three of the six anterior procedures. Damage to the
tensor fascia latae (TFL) in all the anterior approaches lead to a disruption rate of 31.31% (18.31-58.38%) to the muscular area. There was no discernable damage to the TFL in the posterior approach. The direct head of the rectus femoris in the anterior approach accounted for 12.24% (range 0-24%) damage in the muscular area. No damage to the direct head was reported in the posterior approach. The authors admit that the sample size is limited, and that further testing should be conducted. They also suggest that cadaveric tissue may not react the same as in vivo tissue. It should also be kept in mind that there are several different minimally invasive anterior and posterior approaches to THA, and that this study only addressed two of those techniques.

**Outcomes**

Dislocation post-surgery is one of the biggest complications with total hip replacement surgeries\(^1\),\(^2\),\(^6\). The dislocation is thought to be a complication of the muscle damage. This is especially true in the posterior and lateral approaches to the surgery where the glutes and/or external rotators are either transected or removed from insertion points. The posterior approach also causes a remarkable amount of damage to the posterior hip capsule. The combinations of these factors are thought to be the leading culprit to post-surgical dislocation.\(^1\),\(^2\),\(^6\) Several studies examined the dislocation rates of the direct anterior approach and compared them with findings from other studies that looked at the post-surgery dislocation rates of the lateral and posterior surgeries from other surgeons\(^1\),\(^2\),\(^3\),\(^6\),\(^45\). A study by Siguier et al\(^6\) had a dislocation rate of 0.96% (10 out of 1037 patients), which is significantly lower than researched dislocation rate of nearly 2% in other techniques. Most of the dislocations were one time dislocations.\(^6\) A study by Matta\(^2\) found similar results. They had a dislocation rate of 0.61% (3 out of 494 patients). All of these dislocations were one time dislocations.\(^2\) They compared this to researched dislocation rates of 3.23% and 2.03% when there were no repairs of external rotator muscles and when there was repair attempted respectively. This study also reported the incidence of 3 femoral head fractures.\(^2\)

The muscle sparing of the direct anterior approach is also thought to be the reason why there is a reduced hospital stay, and why there is a quicker return to functionality. Studies show consistent reduction in hospital stays to one or two days with the direct anterior approach\(^1\),\(^6\). The patient is allowed to be full weight bearing as soon as tolerated which has been reported as early as day one, and a reported return to activities around four weeks post operatively\(^1\). A reduced incidence of limp after surgery is also apparent in the direct anterior approach\(^45\).
The direct anterior approach allows for good visualization of the joint field, which allows for better implant placement. The better placement leads to a reduction in post-surgical complications. There have been reported reductions in dislocations, leg length discrepancies, unequal joint angulations, as well as other complications. A further advantage of the direct anterior approach is the decrease in pain postoperatively. The pain often associated with total hip replacements is often derived from the derangement of muscle tissue. Meneghini points out that a smaller incision alone does not reduce pain or improve outcomes. The decreased amount of damage to musculature leads to a reduced dependence on narcotics, and can lead to quicker return to activity.

The direct anterior approach to total hip arthroplasty has been around for many years. Only recently has the technique been subject of renewed interest. All of the techniques focus on decreasing muscle damage while improving the field of vision for implantation. These advantages are thought to be the reasons why there have been small amounts of complications reported, and why the time to return to activity has been reduced. In all the studies cited the authors reported lower incidences complications from surgery; however, they do state that there is an increased learning curve associated with the direct anterior approach.

Functional Assessment

The Role of Functional Assessment

Clinicians have often assessed their patients function in one of two ways. Clinicians have either used self-report assessment scores, or they have used functional tests. Some authors in published works and some physicians anecdotally hold that there may be some concern with using self-report assessments to consider functional ability. In a study in 2003 authors investigated the modest correlations often seen between timed functional tests and self-report tests. The authors examined the Lower Extremity Functional Scale (LEFS), the Timed Up-and-Go Test (TUG), Self-Paced Walk (SPW), and the Stair Test (ST). The authors stated that, despite the theory by others that measurement reliability in the functional tests plays a large role in arriving at the moderate correlation, there is a high reliability in the functional tests. Therefore, measurement reliability did not play a large role in the moderate correlation. Further, the authors suggested that in their study the functional tests had an underlying theme of ambulation and did not adequately cover the breadth of the self-assessment tool. They did suggest that adding a measurement of pain and exertion to the
performance measure more adequately correlated with the LEFS. This study proposed three main points. First, time to complete a performance test may not adequately account for the breadth of a self-assessment tool. Second, phrasing of the self-assessment tool may affect the breadth of the domains perceived relevant by the patient. Third, a battery of tests with the same underlying concept does not result in appreciable gain in correlation with a self-assessment measure. Finally, the authors support the use of either self-assessment scores or functional timing tests based on the preferred outcome to be examined. 

In another study authors examined the ability of a self-assessment tool to detect change in functional status. Similar to above studies, the authors used performance tests such as the TUG, SPW, and ST to compare to an adapted WOMAC test in osteoarthritic patients that underwent total hip or knee arthroplasty. The authors constructed two shorter versions derived from the WOMAC Pain and Function subscale to test validity. The first version, SIMILAR-8, included activities on both the pain and function subscales, while the other version, DISIMILAR-8, avoided activities common to the pain and function subscales. "The SIMILAR-8 was unable to detect a change in physical function in the presence of discordant changes in pain and function; however, the DISSIMILAR-8 did detect change in the presence of discordance changes in pain and function." Therefore, the authors concluded that the overlap present on the WOMAC pain and function scales hindered the "measure’s ability to detect change."

Expanding upon the ideas of the low correlation between often misinterpreted self-assessment tools and functional performance tests, Stratford and Kennedy proposed that performance scores were necessary to obtain a complete picture of function. They studied total hip and knee replacement patients using the SPW, ST, TUG, and 6-minute walk compared to the WOMAC Physical Function Scale and the LEFS to examine stability of the association between the self-report tools and the functional performance tools over three time periods ranging from pre-operatively to approximately 36 days post-operatively. They reported varied amounts of association between parts of the self-assessment scores and performance measures across the different time periods. Expanding, the authors state that similar to others they found a significant improvement in self-assessment scores post-operatively at approximately two months post-arthroplasty despite significant deterioration in the scores of performance measures. Despite the conflicting results of performance tests and self-assessment tests, the authors expressed the
importance of both sets of tests. “We proposed that self-report measures comment on the experience associated with the physical activities and that time or distance provides information concerning the ability to perform the activity.” The authors suggest that this distinction between the results of the testing methods provide complementary information to the clinicians.

Concerning the use of performance tests, one study examined the stability and change of four performance measures in a longitudinal study. The authors examined the usefulness of the SPW, ST, TUG, and 6-minute walk test to determine physical function in osteoarthritic patients following total hip and knee arthroplasty. The authors collected data on several occasion both pre-operatively and post-operatively. Pre-operatively three measurements were taken spanning an average time period of 178 days, while the two post-operative measurements were taken over a span of approximately 46 days. The authors suggested that the test-retest reliability estimates of the SPW, ST and 6-minute walk test were good for making decisions at the patient level, and that all the test, including the TUG, were able to detect change in the early post-operative time period.

Considering the information presented, the role of the functional performance test is important. While self-assessment tests were not highly reliable in assessing physical performance, they still held a purpose. Self-assessment test presented complimentary information, but physical function was best assessed by implementing functional performance tests.

**Timed Up-and-Go Test**

The Timed Up-and-Go Test (TUG) was first introduced by Podsiadlo and Richardson in 1991 as a clinical tool to assess basic mobility skills in frail community-dwelling elderly. This new test was proposed as a more efficient and reproducible test than its predecessor the Get Up-and-Go test which used a subjective grading scale to measure performance. The test was designed to test mobility by asking an individual to stand from a seated position with the back against the backrest in a chair that had a seat height of 45cm and arm height of 65cm, walk as quickly and safely as possible to a mark three meters away, turn around, walk back, and return to a seated position with their back supported by the chair backrest. The authors concluded that the TUG was valid test for mobility because of its correlation with scores on the Berg Balance Test \( r = -0.72 \), gait speed during a 20m walk \( r = -0.55 \), and the Barthel Index of Activities of Daily
Living \( r = -0.51 \). They determined that the TUG was also a reliable measure when considering inter-rater scores and intra-rater scores on consecutive days with a variation in scores being less than five seconds from day to day. The authors did suggest a limitation of the test was the inability of the test to discriminate changes in those with scores less than ten seconds in length and those who require help to stand from the seated position in a chair. Further, they suggested that a score of 20 seconds or less be considered independently mobile, while scores of less than ten seconds be considered freely independent. Taking their findings into consideration, Podsiadlo and Richardson suggested the test was a good objective measurement of improvement or deterioration in a simple, quick, and practical test.\(^{25}\)

Years later, an attempt to establish a normal TUG score for an elderly population was made. Authors examined 491 mobile elderly women and 78 institutionalized women in Switzerland. They categorized the women into three groups: 1. independently living and mobile, 2. able to walk without aid in the institution, and 3. Uses a cane or walker. They discovered that the TUG was able to give a global appraisal of impairment, and that the test was able to successfully differentiate the groups.\(^{36}\) They also concluded that a normal TUG score for that population was 12 seconds or less, which is in agreement with the times of ten seconds and 20 seconds suggested by Podsiadlo and Richardson\(^{25}\) of identifying freely independent and independently mobile individuals.\(^{36}\)

Further study of normative data for the TUG was commenced in 2004. In this study TUG scores were collected on 613 women age 20-80 that could ambulate freely. These data were collected as a part of a whole battery of balance tests to establish normative data for the test. The authors reported normative times for six age categories: 20-29 years old 5.31s±0.25, 30-39yo 5.39s±0.23, 40-49yo 6.24s±0.67, 50-59yo 6.44s±0.17, 60-69yo 7.24s±0.17, 70-79yo 8.54s±0.17.\(^{39}\) These scores reflect slightly faster times than those suggested by earlier authors \(^{25,36}\).

All of these times were within a small deviation of the times that would be eventually suggested by Bohannon\(^{37}\) in a 2006 meta-analysis. This analysis included published literature that reported TUG scores in various populations which included 21 different studies and 49 total groups. Groups with conditions common with ageing such as arthritis were included, but subsets of abnormalities such as those using assistive devices or frequent fallers were excluded. Bohannon specifically reported scores for three categories: 60-60yo 8.1s (8.9-9.9 95%
confidence limit), 70-79yo 9.2s (8.2-10.2), and 80-99 11.3s (10.0-12.7). The total sample size for the analysis was 4395 subjects. The age group sample size ranged from 176 (60-69yo) to 798 (70-79yo) and 1102 (80-99yo). A mean of all the gathered subjects’ scores was 9.4s with a 95% confidence limit of 8.9-9.9s.\textsuperscript{37}

Shortly following the 2006 meta-analysis, a study in 2008 was implemented to establish normative data for the TUG in a population based sample of elderly without gait disturbances.\textsuperscript{40} This varied from some of the previous studies because of their exclusion of any subject with gait disturbances such as arthritis. Three hundred and eight (171 males, 137) elderly Spanish with normal gait completed the TUG. An overall mean TUG score of 10.2s±3.1 was reported. These data were further stratified into age groups and gender. Mean scores for groups were 71-75yo 9.58s (8.6s male, 10.7s female), 76-80yo 9.93s (9.42s male, 10.71s female), 81-85yo 11.28s (10.34s male, 12.36s female), and 86-99yo 12.03s (11.13s male, 13.15s female).\textsuperscript{40} These data support earlier suggestions for normative TUG scores for independently mobile individuals\textsuperscript{25,36,37,39}

Recently the TUG has started to receive more attention as an effective assessment and prediction tool\textsuperscript{35,50-53}, which has led to an increased investigation into the construct of the test itself\textsuperscript{38,42,54,55}. One set of authors set out to associated TUG scores with a history of falls or near falls in participants with hip osteoarthritis\textsuperscript{35}. They found that participants with hip osteoarthritis reported a higher prevalence of falls, but that the TUG was not useful in classifying people into fall categories. However, the authors suggested that the TUG was useful in classifying mobility that may lead to near falls.\textsuperscript{35} Similarly, authors used the TUG as a possible predictor of falls within six months after hip fracture surgery. Contrary to the previously mentioned study, the authors found that that, when using walking aids, the TUG can significantly classify someone as a faller or non-faller. The authors suggested that a TUG score of 24s be used as a cutoff time to predict falls within the first six months following fracture surgery.\textsuperscript{50} Further, the authors of another study used a prospective cross sectional cohort study to use the TUG as a predictor for falls in community dwelling elderly. The authors reported that they could successfully use the TUG to predict “stumbles” and to differentiate between recurrent fallers and non or one time fallers. Contrary to earlier reported literature, the authors were not able to use the TUG to easily discriminate between one time fallers and non-fallers.\textsuperscript{52} These authors all comment of the TUG
as a useful tool to predict falls, however, the TUG has been shown to be a useful tool in other formats.

Several authors have used the TUG as either an outcome descriptor or predictor. One set of authors used the TUG as an outcome measure of a six week home-based exercise program in frail older adults. The authors used the TUG as a functional fitness test before and after an implemented at home program. They found that this program was used to improve functional ability as they suggest by an average 26% improvement in TUG scores in the post exercise program testing period. Another set of authors used the TUG to possibly correlate a pre-operative TUG score with the incidence of DVT following total hip arthroplasty surgery in female patients. The authors reviewed five preoperative measures: duration of hip OA before surgery, body mass index, serum total cholesterol, visual analog scale pain scores, and TUG times. Comparing those with post-surgical DVTs versus the non-DVT group presented only one preoperative variable of difference. Those with DVTs took longer to complete the TUG tests (18.4±4.0 sec vs. 15.0±3.2 sec, p<0.01). Authors suggested a cut-off point of 15.3 seconds before surgery as a risk for DVT post-surgery (sensitivity 83.3%, specificity 61.1%). They refute other suggestions that inactivity plays a role in both slow TUG times and DVT presence. The authors compared JOA hip scores, which are daily ability scores, between the two groups, and they found no difference.

Recently, several investigators have examined the TUG and its properties. Herman et al in 2010 compared the TUG with several other tasks in a group of 265 men and women 70-90 years old. They found, similar to earlier research, good correlations between balance and gait tasks. The TUG demanded multiple subtasks that, while common and basic, may be complicated and require some level of planning, orientation in space and organization. They state that the TUG mildly correlated with cognitive function with r values ranging from -0.18 to -0.21. Authors suggested that the TUG does not suffer from ceiling or floor effects in healthy older adults, and that the test is sensitive to early changes in functional status. Considering this, the authors suggested a cut-off time of 13.5 seconds as an indicator of poor mobility, but they caution this may not be an ideal value for providing an early marker for fall risks.

Two studies by Kristensen et al investigated the properties of the TUG test with repaired hip fracture patients. In 2009, Kristensen demonstrated that when controlling for cognitive function the TUG has the ability to reflect pre-fracture functional levels at early
rehabilitation stages. They also comment on the necessity to use age specific reference values for TUG scores. A similar study investigated the number of trials necessary to attain performance stability on the TUG. They showed that TUG performance improved up to and including the third trial (p<0.001), while test scores for trials three through six maintained performance stability. Further, they suggest that the fastest of the three timed TUG trials be used instead of an average because the data over blocks of trials can mask the nature of the change that is actually evident in the data when considered on an individual basis.

Authors recently investigated the influence on outcomes in the TUG based on chair type. A need to have a more portable testing instrument for the field led the authors to compare TUG times in 118 individuals age 62-99 using two different chair types. The first chair was a “standard” chair with solid frame, firm cushions, backrest, and armrest as previously described in the literature. The second chair was a “collapsible” chair with aluminum frame, firmly fitted canvas seat and back, low back rest, and padded armrests. Both chairs had a 46 cm seat height. The authors concluded that older frail individuals may show hesitancy to using a portable canvas chair, but, more importantly, a portable chair with firm seat, back, and armrests can be reliably used at field locations. Time taken to complete the TUG using the two chair conditions did not differ [median (interquartile range, IQR) =12.3 (9.53-15.9) and 12.6 (9.7-16.6) seconds for “standard” and “collapsible” chairs respectively, p=0.87].

Literature concerning the TUG test shows that it is both a valid and reliable test. The test demands multiple task completion within one test which are correlated with other functional tests such as the Berg Balance test and Dynamic Gait Index. Further, the TUG has been used for several unique populations including the frail, osteoarthritic, hip fractures, and total hip arthroplasty patients to name a few. Times for the TUG have been shown to accurately predict several objectives such has changes in mobility and falls, but some controversy still exists on its reliability in some instances. Several studies have suggested normal TUG times, but advise the use of age specific norms. Despite a range of different suggested normal times, all times fall within reasonable numbers reported for those categories. Overall, the TUG is a useful clinical test for a range of populations when considering factors related to mobility.

**Trendelenburg Test**

The Trendelenburg Test is a test of abductor function that was first described by Friedrich Trendelenburg in 1897 as a test for hip abductor function. His original description of the test
focused mainly on the role of the hip abductors as concerned with congenital hip dislocations and the resultant muscle atrophy\textsuperscript{24}. Today the test is often used as a general test for hip abductor function\textsuperscript{33}. The Trendelenburg Test requires the individual to stand on one leg while controlling the elevation of the contralateral hip.

The most recent in-depth analysis of the Trendelenburg Test was conducted in 1985 by Hardcastle and Nade\textsuperscript{24}. Their study had a two part purpose. They first wanted to define a standard Trendelenburg Test because of the wide array of style that had been developed over the years. Second, they studied the Trendelenburg test in individuals with abnormalities in order to assess the value of the test and pitfalls that may be associated with the test in standard orthopedic practice.\textsuperscript{24} They defined a standard test as having an individual stand on one leg while flexing the contralateral hip to about thirty degrees, then the individual elevates the level of the contralateral hip \textsuperscript{24}. The authors point out that the elevation of the hip is a vital part of the test to ensure that the hip abductors are being fully taxed as demonstrated by the research of Inman\textsuperscript{56}. Simply noting the final position of the trans-iliac line of the pelvis will not give an accurate account of the hip abductor function. Rather, elevation, and maintaining this elevation, examines the abductor function. As the pelvis rises there is an increase in the abductor activity.\textsuperscript{24,56} The authors further established a rating system for a “positive” and “negative” Trendelenburg. They noted a “negative” Trendelenburg as the individual being able to raise the pelvis. A “positive” Trendelenburg is seen when the individual’s pelvis remains level or drops. The authors also go on to state that time is a crucial element of the Trendelenburg. The elevation of the pelvis should be maintained for 30 seconds in a negative Trendelenburg. They point out that the rating system accompanied with the time element gives the clinician an objective measure that can be performed in a small area.\textsuperscript{24}

In 1996 Pai\textsuperscript{9} examined the usefulness of the Trendelenburg in assessing patients following three THA approaches. The author based his approach to conducting the Trendelenburg off of the work of Hardcastle\textsuperscript{24}. Pai, however, adapted the classification system to a more specific scale than that proposed by Hardcastle. Pai suggested a six point scale: “1. Normal: if the pelvis on the non-stance side can be elevated high up and is maintained for 30 seconds, 2. Elevation of the pelvis is present but not maximal, 3. Pelvis is elevated but not maintained for 30 seconds, 4. No elevation of the pelvis on the non-stance side, 5. Drooping of the pelvis, 6. Non-valid response: presence of hip pain, uncooperative patient.”\textsuperscript{9} They noted that
both the ratings of “1” and “2” were considered normal, or negative, but that ratings of “3”, “4”, “5” were consider positive indicating abductor weakness. Applying this grading system to the subject pool Pai found no significant difference between the Transtrochanteric, Hardinge, and Liverpool THA approaches on Trendelenburg scores at one year post surgery. The author in agreement with Hardcastle and Nade noted that the Trendelenburg should also include a timed element with a max of 30 seconds in association with the rankings that allows the clinician to objectively measure hip abductor function in a small area.9

The role of the Trendelenburg traditionally is used as test of abductor strength, however, Youdas et al57 examined the role of the Trendelenburg as a possible diagnostic tool for hip osteoarthritis (OA). The study ran a battery of tests on a group of 20 controls (10 male 10 female) and 20 individuals (10 male 10 female) diagnosed with hip OA. The battery included several tests including muscle strength as measured by a hand held dynamometer and a Trendelenburg Test in which the hip elevation was measured with a goniometer. They found that the sensitivity for identifying subjects with diagnosed hip OA with the Trendelenburg was 0.55 while the specificity was 0.70, which yielded a likelihood ratio of 1.83. In contrast, the strength testing yielded a sensitivity of 0.35 and a specificity of 0.90, which yielded a likelihood ratio of 3.5. Therefore, the authors concluded that the Trendelenburg Test was not useful in identifying individuals with early stage OA. 57

Despite its lack of usefulness in identifying hip OA, the Trendelenburg has still been used to assess functional ability with THA. In 2010 a study used the Trendelenburg to examine functional ability for patients undergoing THA using the direct lateral approach (76 limbs) and the posterolateral approach (80 limbs)18. The patients were tested pre-operation and at a minimum of two years post-operation. Pre-operatively the two procedures showed similar numbers of positive Trendelenburg Tests. There were 32/38 (84.2%) positive tests in the direct lateral group and 33/40 (82.5%) in the posterolateral group. Two years postoperatively similar results were once again found. There were 10/38 (26.3%) positive Trendelenburg Tests in the direct lateral and 11/40 (27.5%) in the posterolateral group. The authors further stated when considering strength ratios and Trendelenburg, “strength ratio was significantly higher in THA limbs with a negative delayed Trendelenburg sign (mean 91.7%) than in the THA limbs with a positive delayed Trendelenburg sign (mean 73.0%) (p<0.0001).” 18 Once again agreeing with the theory of Inman of the role of the hip abductors in a level or elevated pelvis during single leg
The authors therefore conclude that the Trendelenburg is a reliable and useful test that was used to demonstrate no significant difference in abductor function two years post-operation following direct lateral and posterolateral THAs.

**Strength testing using Hand-Held Dynamometers**

Strength testing using portable dynamometers has a long history of use and study. The assessment of strength has been considered an integral part of a physical examination. Traditionally, clinical assessment of muscle strength was performed by the use of graded manual muscle testing, which has been considered a less than ideal method. Therefore, many researchers have investigated the usefulness and reliability of dynamometry in clinical practice.

In 1987 authors investigated the intrarater reliability of both manual muscle testing (MMT) and hand-held dynamometry (HHD). The investigators tested several sets of muscles from both the upper and lower extremity measuring outcomes using a 12 point MMT grading system and the Chatillon dynamometer. They reported r values ranging from 0.63-0.98 for both MMT and HHD. The authors supported both MMT and HHD as useful clinical tools with both having pros and cons; however, the authors determined that MMT was less discriminating in identifying small differences in muscle strength than HHD.

Also in 1987, researchers examined the reliability of a portable dynamometer for muscles in the upper and lower extremity. They examined the intrarater and interrater reliability on two separate occasions separated by at least two days. They established intrarater correlations ranging from 0.88-0.97 and interrater correlations ranging from 0.79-0.99 for the upper extremity. Additionally, the lower extremity correlations observed were lower ranging from 0.49-0.81 for both intra- and interrater correlations. They determined that upper extremity testing was reliable, but hypothesized that the lower reliability in the lower extremity may have been due to methodological error with the positioning of their dynamometer.

Bohannon examined the test-retest reliability of hand dynamometry during a single strength assessment session. He recorded three readings for 30 patients with varying pathologies during a single assessment period. Pearson product moment correlations for test-retest reliability ranged from 0.84-0.99. He stated that the retest reliability of HHD was more accurately described by a testing method that occurs within a short period of time as opposed to a protocol of testing separated by days or weeks. The reasoning behind this was that patients’ physical
status may change from day to day therefore affecting reliability levels. The researcher concluded that HHD is reliable when executed by an experienced clinician, but he cautions that “stabilizing and meeting muscle force production may be particularly difficult for clinicians who are not physically strong.”

The effect on strength measures by a tester’s characteristics was the focus of authors in a 1992 study. The authors examined the effects of rater gender, body weight, and grip strength on interrater reliability. Twenty (10 male, 10 female) healthy, trained raters were asked to take three trials of strength measures on five groups of muscles on two separate subjects. Two (1 male, 1 female) healthy young subjects were used to provide a high intrarater reliability. The authors then investigated the effects of the characteristics on outcomes. The authors reported that both male and female raters had a good interrater reliability on the female subject. Further, the male raters had high interrater reliability for the male subject, but the female raters exhibited a low interrater reliability for the strong muscle groups of elbow flexion and knee extension on the male subject. The authors reported that weight and grip strength did have an influence on the raters ability; therefore, the males, who typically have more weight and higher grip strengths, were able to leverage their weight better and properly stabilize the dynamometer with their grip strength which led to the more reliable interrater numbers.

The authors of another study of reliability of HHD questioned the strength of the examiner in recording strength measures. The authors investigated the reliability of HHD and its relationship with osteoarthritic knee patients. They reported ICC levels ranging from 0.89-0.98 with an overall test-retest reliability of 0.92. They reported that the HHD measurements were “less subjective than the MMT grades, especially in stronger subjects.” The authors concluded that HHD was a reliable for strength measurement in knee osteoarthritis patients, but caution that, “if the tester is weak, the measurement will be lower than the patient’s actual capability. Subjects may not have been exhibiting full strength if they perceived that the tester could not match their efforts.” Hand-held dynamometry was again shown to be a reliable clinical measure.

In order to investigate the concept of the clinicians ability to stabilize and meet muscle force production, researchers examined the reliability of hip abductor measures using both examiner and belt resisted protocols in young and old subjects. The researchers examined two groups of 20 women each. The first group’s mean age was 24, while the second group’s mean
age was 68. Identical protocols where used for all testing methods except for the variation of the resistance by either an examiner or a 5cm wide belt. The investigators published ICCs for belt-resisted measures of 0.92 for the young population and 0.98 for the old population. Examiner resisted ICCs were slightly lower at 0.84-0.93 for the young population and 0.96-0.97 in the old population. They further stated that both methods were reliable, but that 55% higher torques were recorded with the belt-resisted method. They reasoned that patients may have a greater tendency to trust their own resistance, over which they have control, and are less hesitant to perform strong contractions in this manner. This may have also pointed to the reason why 95% of patients preferred the belt-resisted method. The authors conclude that both methods are reliable protocols for HHD, but that comparisons cannot be made across the two methods.62

Schaubert and Bohannon61 again set out to test the test-retest reliability of HHD in 2005 using the MicroFET 2. This study also included a validity measure of HHD by comparing the strength measures to performance tests. The authors measured strength in a small group of seniors between 65-85 years old at a baseline, six weeks, and twelve weeks. These measures were compared to a sit to stand test, timed up-and-go test, and gait speed. The authors reported ICC levels for the MicroFET 2 to be 0.92. This high ICC level was obtained despite the researchers only collecting one measurement and a lack of familiarization trials. The authors felt that this showed that multiple measurements are not essential if there is a limitation in time. They reported that the timed up-and-go test and gait speed were significantly correlated with dynamometrically measured knee extension strength. In defense of the reliability and validity drawn from the study the authors state, “if a measure is to be advocated, it must be not only reliable but also valid. Of particular importance, if strength is to be a measured, is the relevance of the measure to function. This aspect of validity was supported by the correlation.”61

The reliability and validity of HHD having been proven, authors set out to established normative data using HHD31,32. The first set of data established in 1996 was drawn from a group of 150 healthy subjects32. The authors used the Chatillon CSD400C, and they established ICC intrarater values ranging from 0.932 to 0.984 for their study. They reported force scores in both pounds of force and Newtons. They further reported a normalized score based on body weight because of the relationship between force production and body weight. They also established a relationship between force production and other factors such as gender, age, and side dominance.32 The second set of reference values were established in 1997 using an Ametek
digital hand-held dynamometer on 106 men and 125 women with no known pathology. This set of data includes two limitations. First, the force measurement was capped at 650N, and second, all measurements except knee extension were measured in gravity neutral positions. The authors reported ICCs of 0.940. In addition to reporting strength measures, the authors reported error estimates expressed in measurement of the HHD which would give the clinician a change in measurement that would assume a real difference.

Hand-held dynamometry has a robust history of clinical use supported by numerous investigations from several authors. Repeatedly the use of HHD to measure strength outcomes have been proven to reliable and valid. Some authors have cautioned to use of HHD to obtain reliable numbers when the rater may not be able to match the force of the subject. Overall, the use of the hand dynamometer as a clinical measure was considered a good choice.
Appendix A: Flyer for Control Volunteers
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 Mānoa is seeking volunteers to participate in a research study: *Functional Recovery and Gait Biomechanics following Total Hip Arthroplasty: a Longitudinal Study*

**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
- Hip muscle strength
- Questionnaires

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

**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 both the functional and biomechanical differences between the two THR procedures.

**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.

For more information contact:
Rachele Vogelpohl, MS, ATC - rachelev@Hawai‘i.edu (808) 956-3801
Kaori Tamura, MS, ATC – ktamura@Hawai‘i.edu (808) 956-3801

Department of Kinesiology and Rehabilitation Science
1337 Lower Campus Road, Room 231, Honolulu, HI
Appendix B: Medical History Questionnaire
**UNIVERSITY OF HAWAI‘I AT MĀNOA**  
DEPARTMENT OF KINESIOLOGY AND REHABILITATION SCIENCE  
MEDICAL 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 _______________________________________________________

**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.*

**A. General Conditions**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Past</th>
<th>Present</th>
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</thead>
<tbody>
<tr>
<td>1. Fainting Spells</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2. Headaches</td>
<td></td>
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<tr>
<td>3. Convulsions/epilepsy</td>
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<tr>
<td>4. Asthma</td>
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<tr>
<td>5. High Blood Pressure</td>
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<tr>
<td>6. Kidney Problems</td>
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<tr>
<td>7. Intestinal Disorder</td>
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<tr>
<td>8. Hernia</td>
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<tr>
<td>9. Diabetes</td>
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<tr>
<td>10. Heart Disease/Disorder</td>
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<tr>
<td>11. Dental plate</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>12. Poor Vision</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>13. Poor Hearing</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>14. Skin Disorder</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
</tbody>
</table>

**B. Injuries**

<table>
<thead>
<tr>
<th>Location</th>
<th>Yes</th>
<th>No</th>
<th>Past</th>
<th>Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Toes</td>
<td></td>
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<td></td>
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<tr>
<td>2. Feet</td>
<td></td>
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<tr>
<td>3. Ankles</td>
<td></td>
<td></td>
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<tr>
<td>4. Lower Legs</td>
<td></td>
<td></td>
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<tr>
<td>5. Knees</td>
<td></td>
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<tr>
<td>6. Thighs</td>
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<tr>
<td>7. Hips</td>
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<tr>
<td>8. Lower Back</td>
<td></td>
<td></td>
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<tr>
<td>9. Upper Back</td>
<td></td>
<td></td>
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<tr>
<td>10. Ribs</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>11. Abdomen</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>12. Chest</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>13. Neck</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>14. Fingers</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>15. Hands</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>16. Wrist</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>17. Forearms</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>18. Elbows</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>19. Upper Arms</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>20. Shoulders</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>21. Head</td>
<td>Yes</td>
<td>No</td>
<td>Past</td>
<td>Present</td>
</tr>
<tr>
<td>22. Others</td>
<td></td>
<td></td>
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</tbody>
</table>
Appendix C: WIRB Informed Consent Form for Straub Clinic and Hospital Patients
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
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Honolulu, Hawaii 96822
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Queens Medical Center
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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 Months After surgery</th>
<th>1 Year After Surgery</th>
<th>2 Years After Surgery</th>
<th>3 Years After Surgery</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>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>
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</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>
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<tr>
<td>Functional Scores</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</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.

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. Arthrootomy 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: University of Hawai‘i Informed Consent Form for Control Participants
### RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**“CONTROL PARTICIPANT”**

**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
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>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>
</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>
</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>
</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>
</tr>
<tr>
<td>Paper/Pencil Tests</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>
</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 (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.

**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 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.

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)

________________________________________
Subject Name (print)

________________________________________
Signature of Subject Date

________________________________________
Person Conducting Informed Consent Discussion Name (print)

________________________________________
Signature of Person Conducting Informed Consent Discussion Date
Appendix E: Visual Analog Scale
Several times during the test, we will ask you to rate your pain, according to the pain rating scale. You will be asked to choose a number that describes how much pain you are experiencing. A rating of “0” corresponds to no pain and a rating of “10” corresponds to the worst pain you could possibly experience.

At the end of every functional test, we will ask you to give local muscular ratings for perceived pain in your legs and joints.
Appendix F: Data Collection Forms
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 Tester: ________________

<table>
<thead>
<tr>
<th></th>
<th>Left Leg</th>
<th></th>
<th>Right Leg</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trial 1 Score (ft-lb)</td>
<td>Pain Score (HHD/Jt)</td>
<td>Trial 2 Score (ft-lb)</td>
<td>Pain Score (HHD/Jt)</td>
</tr>
<tr>
<td>Hip extension</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Knee flexion</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Hip abduction</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Hip adduction</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Hip flexion</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Hip internal rotation</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Hip external rotation</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>Knee extension</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

<table>
<thead>
<tr>
<th>Trendelenburg Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>6</td>
</tr>
</tbody>
</table>

Response Classification:
1. Normal: if the pelvis on the non-stance side can be elevated high up and is maintained for 30 seconds.
2. Elevation of the pelvis is present but not maximal
3. Pelvis is elevated but not maintained for 30 seconds
4. No elevation of the pelvis on the non-stance side
5. Drooping of the pelvis

<table>
<thead>
<tr>
<th>Timed Up &amp; Go Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>
# 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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td></td>
</tr>
<tr>
<td>Height (mm)</td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td></td>
</tr>
<tr>
<td>Left leg length (mm)</td>
<td></td>
</tr>
<tr>
<td>Left knee width (mm)</td>
<td></td>
</tr>
<tr>
<td>Left ankle width (mm)</td>
<td></td>
</tr>
<tr>
<td>Right leg length (mm)</td>
<td></td>
</tr>
<tr>
<td>Right knee width (mm)</td>
<td></td>
</tr>
<tr>
<td>Right ankle width (mm)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix G: Anthropometric Data
## Anthropometric Data for control and MI DA-THA groups at PRE, POST3, and POST6

| Subject ID | Surgery Group | Operated Leg | Gender | Dominant Leg | Age PRE | Age POST3 | Age POST6 | Height (m) PRE | Height (m) POST3 | Height (m) POST6 | Weight (kg) PRE | Weight (kg) POST3 | Weight (kg) POST6 |
|------------|---------------|--------------|--------|--------------|---------|-----------|-----------|---------------|----------------|----------------|----------------|----------------|----------------|----------------|
| C-001      | 0 N/A         | m            | R      | R            | 67      | 67        | 67        | 1.685         | 1.682          | 1.686          | 73.1           | 71.8           | 71.9           |
| C-002      | 0 N/A         | M            | R      | R            | 63      | 63        | 63        | 1.764         | 1.76           | 1.695          | 85.7           | 84.3           | 83             |
| C-003      | 0 N/A         | M            | R      | R            | 63      | 63        | 63        | 1.634         | 1.647          | 1.637          | 71.8           | 71.2           | 71.1           |
| C-004      | 0 N/A         | M            | R      | R            | 55      | 55        | 55        | 1.738         | 1.736          | 1.733          | 76.2           | 76.4           | 76.6           |
| C-005      | 0 N/A         | F            | R      | R            | 58      | 59        | 59        | 1.544         | 1.546          | 1.542          | 60             | 59.9           | 62.4           |
| C-006      | 0 N/A         | M            | R      | R            | 64      | 64        | 64        | 1.725         | 1.721          | 1.722          | 68.7           | 67.8           | 69.2           |
| C-007      | 0 N/A         | M            | R      | R            | 64      | 64        | 64        | 1.686         | 1.69           | 1.684          | 79             | 78.7           | 79.1           |
| C-009      | 0 N/A         | M            | R      | R            | 57      | 57        | 57        | 1.561         | 1.562          | 1.559          | 69.3           | 67.9           | 68.5           |
| C-010      | 0 N/A         | M            | R      | R            | 62      | 62        | 62        | 1.733         | 1.723          | 1.714          | 67.3           | 67.2           | 67.2           |
| C-011      | 0 N/A         | M            | R      | R            | 55      | 56        | 56        | 1.752         | 1.744          | 1.744          | 72.6           | 73.4           | 73.7           |
| THA-S-001  | 1 L           | F            | R      | R            | 68      | 68        | 68        | 1.695         | 1.7             | 1.69           | 73.7           | 73.2           | 72             |
| THA-S-002  | 1 R           | M            | R      | R            | 49      | 49        | 49        | 1.715         | 1.712           | 1.712          | 62.7           | 61             | 60.1           |
| THA-S-003  | 1 R           | F            | R      | R            | 57      | 57        | 57        | 1.616         | 1.624           | 1.623          | 53.2           | 54.6           | 54.4           |
| THA-S-004  | 1 L           | M            | R      | R            | 71      | 71        | 71        | 1.664         | 1.666           | 1.667          | 75.1           | 74.8           | 75.2           |
| THA-S-005  | 1 L           | M            | R      | R            | 62      | 62        | 62        | 1.784         | 1.85            | 1.8            | 81.1           | 75.3           | 76.9           |
| THA-S-006  | 1 R           | M            | R      | R            | 57      | 58        | 58        | 1.822         | 1.822           | 1.83           | 87.4           | 88.6           | 87.7           |
Appendix H: Trendelenburg Data and TUG Data
### Timed Up-and-Go and Trendelenburg times data for control and MI DA-THA groups at PRE, POST3, and POST6

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Appendix I: Isometric Strength Data
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REFERENCES


22. Stratford PW, Kennedy DM. Performance measures were necessary to obtain a complete picture of osteoarthritic patients. *Journal of Clinical Epidemiology*. 2006;59:160-167.


47. Stratford PW, Kennedy DM. Does parallel item content on WOMAC's Pain and Function Subscales limite its ability to detect change in functional status? BMC Musculoskeletal Disorders. 2004;5.


