Total Hip Arthroplasty is Less Painful at 12 Months Compared with Hemiarthroplasty in Treatment of Displaced Femoral Neck Fracture

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Abstract *Objectives:* The Displaced Femoral (neck fracture) Arthroplasty Consortium for Treatment and Outcomes (DFACTO) study compared total hip arthroplasty (THA) to hemiarthroplasty in the treatment of displaced femoral neck fractures. *Design:* This study was designed as a prospective,

randomized clinical trial. *Setting:* The study was conducted in five US academic and private medical centers. *Patients:* Patients were composed of independent, mentally competent individuals, >50 years old who suffered a displaced femoral neck fracture without existing arthritis at the hip. Forty-one patients were enrolled. *Main outcome measures:* Functional outcomes and quality of life were assessed at 6 and 12 months post-fracture using the SF-36, Western Ontario and McMaster University Osteoarthritis Index (WOMAC), the Harris Hip Score, and the Timed “Up & Go” Test (TUG test). *Results:* Groups were equivalent at baseline in terms of age, comorbid conditions, and functional status. At 6 months, there were no significant differences between the groups using the outcome measures or overall rates of complications. There was one dislocation in the THA group (5.8% of patients). At 12 months, the THA group reported significantly less pain (53.2 ± 10.2) than the hemiarthroplasty group (42.4 ± 11.5) using the SF-36 ($p=0.02$). Using the TUG Test, we observed a greater proportion of THA patients remain functionally independent 1 year after surgery compared the hemiarthroplasty group ($p=0.08$, controlling for age and sex). *Conclusions:* These differences in pain and functional outcomes suggest THA is a viable treatment option for the active elderly displaced femoral neck fracture population.

Level of Evidence: Level I: Randomized controlled trial.

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Introduction

The loss of functional independence and quality of life for previously active individuals after displaced femoral neck fractures represents an important opportunity to improve treatment. The significance of this problem in the USA is

demonstrated by a prevalence of 350,000 hip fractures per year and an aging population.[1] The Displaced Femoral (neck fracture) Arthroplasty Consortium for Treatment and Outcomes (DFACTO) was created to help determine the optimal treatment for displaced femoral neck fractures. DFACTO is a prospective, randomized multicenter clinical trial comparing total hip arthroplasty (THA) to hemiarthroplasty in the treatment of displaced femoral neck fractures.

The significant decline in function and independence after hip fracture is well documented. In elderly patient populations that had been ambulatory before the fracture, 50% of these individuals will be unable to walk independently or return to independent living within 1 year of the injury.[2, 3] In physiologically older patients, attempts to salvage the femoral head with open reduction and internal fixation (ORIF) after a displaced femoral neck fracture are increasingly being avoided due to unacceptable rates of osteonecrosis, malunion, and nonunion.[4]

Although hemiarthroplasty is currently the most common treatment for displaced femoral neck fractures, it is not clear if this is truly the best treatment choice.[5] Many patients undergoing hemiarthroplasty for the treatment of a displaced femoral neck fracture experience compromised function.[6] Furthermore, over the course of a few years, hemiarthroplasty may be associated with destruction of the articulating acetabular cartilage (prosthetic arthritis).[7] This is especially true in patients leading active, independent lifestyles, which can result in the development of debilitating activity related hip pain and the need for conversion surgery.

In a limited group of femoral neck fracture patients who have concurrent ipsilateral degenerative or inflammatory arthritis, total hip arthroplasty has historically been the treatment of choice. Such patients have performed well after surgery, with low rates of complications and revision surgeries, while demonstrating improved functional hip scores and activity levels.[8, 9] Recent studies have indicated patients treated with THA for displaced femoral neck fractures have lower long-term morbidity associated with the implant compared all other treatment options, resulting in lower costs at 2 years.[5, 10]

In light of possibly enhanced function and reduced costs after THA, is there a role for a total hip arthroplasty, rather than hemiarthroplasty, in well-defined subsets of ambulatory patients who suffer a displaced femoral neck fracture in the absence of preexisting activity-related hip pain? The purpose of this study was to compare the outcomes of treatment with THA and hemiarthroplasty after displaced femoral neck fractures in active and independent elderly patients.

Materials and methods

Investigative sites

Five US medical centers screened subjects for potential enrollment in the DFACTO Trial. This trial was approved by the Western Institutional Review Board at the principal investigatory site, as well as each institution's individual

IRB. All patients provided informed consent after a detailed explanation of the risks and alternatives to participation in this study.

Eligibility criteria

Inclusion criteria included (1) age >50 years, (2) ability for independent ambulation before fracture, (3) displaced femoral neck fracture (Garden III or IV which the surgeon considered not amenable to treatment with ORIF)[11] and (4) ability to comprehend and read either English or Spanish.

Exclusionary criteria included (1) chronic severe dementia (defined as <23 out of 30 on Folstein MMSE),[12] (2) pathologic fracture, (3) other concomitant long bone fractures or fractures requiring surgical repair, and (4) preexisting arthritis of the hip.

Randomization and treatment options

After IRB approval, all patients admitted to each of the five institutions with displaced femoral neck fractures were screened for study inclusion. After medical clearance for surgery, patients meeting all eligibility criteria were approached regarding potential enrollment. Patients providing informed consent were randomized to one of two treatment groups employing an opaque sealed-envelope technique. Envelopes were opened only after the patient and surgeon agreed to accept either treatment group assignment. All envelopes (with surgeon coinvestigator signature placed during unsealing) were collected. Envelope opacity (non-transilluminability) was ensured with the inclusion of a sheet of black construction paper to reduce the potential for investigator randomization assignment manipulation. Each site had an individual blocked randomization scheme, which was verified at the coordinating site for compliance. The patient was randomized before being brought to the operating room to allow for appropriate OR set-up and staffing.

The surgeons were given the option to use a posterior (posterolateral) approach with enhanced soft tissue repair or direct lateral (Modified Hardinge) approach for surgery. In the THA group, the only stipulation enforced by the protocol was employment of a prosthetic head was ≥ 28 mm. In the hemiarthroplasty group, surgeons were allowed to choose a unipolar or bipolar prosthesis. Fixation methods (press-fit stem vs cement) were also left to the surgeons' discretion in both groups. The implant components were all recorded, including head size and type of cement used.

Data collection

Patients' baseline functional status and general health were assessed at the time of randomization with the Western Ontario and McMaster University Osteoarthritis Index and the SF-36.

Western Ontario and McMaster Universities (WOMAC) Osteoarthritic Index is a self-administered 24-item questionnaire, consisting of three sections to assess the dimensions of pain, joint stiffness, and physical disability (5, 2, and 17 questions, respectively).[13]

It has been applied to many lower extremity disorders, and it is currently the most commonly used outcome measure by hip and knee surgeons.[14]

The Short Form-36 (SF-36) has 36 questions with responses either as yes/no question or on a five-point scale. There are eight subscores derived from these questions, encompassing physical function, role limitations due to physical health, role limitations due to emotional problems, vitality, mental health, social function, bodily pain, and general health.[15] It has been shown to have excellent reliability and validity, and is one of the most widely used measures in a multitude of patient populations, including the elderly.[16]

Patients reported their current health problems, whether they were receiving treatment for that problem, and whether it limited their activities. Investigators documented the trade names, sizes and type of components used, surgical time (skin to skin), post-operative complications, and length of stay.

Outcomes were measured at regular follow-up visits at 6 and 12 months after fracture and treatment using the quality of life and functional status measures of the SF-36 and WOMAC as well as the Harris Hip Score and the functional performance measure called the TUG.

The functional tasks assessed by the TUG include rising to a stand from a chair, walking at a normal pace with any walking aids normally used, negotiating a 180° turn, returning to the chair, and then sitting again.[17] This test was chosen as other studies have shown it to be useful for quantifying functional mobility, and it may also be helpful in after clinical change over time.[18, 19]

The Harris Hip Score is a hip-specific measure to assess a patient's subjective evaluation of pain, ability to walk certain distances, put on shoes and socks, use public transportation, and climb stairs as well as use of walking aids, limp, and comfort level while sitting. The physician adds leg length discrepancy and range of motion which is then calculated in to a score from 1–100 in which higher scores indicate better function.[20]

Complications, additional hospitalizations, care utilization, reoperations, and ambulatory status were also assessed and noted by the physician during follow-up.

pooled standard deviation for the SF-36 subscales (an average of 11.78 vs 35, as used in previous power estimate). Using this true pooled standard deviation, we determined our study size had the ability to detect an effect size of 11 with an alpha of 0.05 with 80% power.

Statistical methods

The comparisons between the hemiarthroplasty and THA groups were made on a pairwise basis which were analyzed using the intention to treat principle. The SF-36, WOMAC, and Harris Hip Scores was first analyzed in its raw form, without adjustments, and then again using SPSS (SPSS Version 13.0, Chicago, IL, USA) to construct a linear regression model aiming to minimize the effect of age and gender on the outcome variables. For the unadjusted analysis, an independent samples *t* test was used to compare continuous variables. Kaplan-Meier survival curves were also constructed. The adjusted analysis used a step-wise forward regression to try to control for covariates. Because of significant variability in our small sample size and the high attrition of subjects (typical in hip fracture studies), the models accounting for age, gender, and number of comorbid conditions were not significantly better than the mean only model for each of the subjective outcome measures. Differences between the groups are reported in unadjusted mean differences in score, with 95% confidence intervals constructed for each comparison. No adjustments have been made for multiple significance testing. A logistic regression model was constructed and used for the analysis of the categorical TUG data to control for the significant predictors of age and sex only.

Results

Clinical study logs at the five sites revealed 114 patients were screened for this study over the 18-month enrollment period. There were 41 patients initially enrolled in the

Study size

This study was designed to demonstrate the feasibility of a larger randomized, multicenter design with multiple surgeons treating subjects with displaced femoral neck fractures. An initial power analysis was done using three SF-36 domains as primary outcomes (physical functioning, physical component summary score and mental component summary score) at 0.0167 level, for an overall alpha level of 0.05. To detect a 20-point difference in each of these categories (anticipating a pooled standard deviation of 35) it was determined each arm needed 74 subjects to achieve 80% power. Accounting for 25% attrition, a recruitment goal of 200 patients was set.

However, recruitment was much slower than expected and enrollment was capped at 40. We saw a much lower

Table 1. Baseline demographics and hospital outcomes

	Total Hip Arthroplasty (N=17)	Hemiarthroplasty (N=23)	P value
Mean age (SD)	82 (7)	77 (9)	0.21
Female	41%	61%	
Ethnicity			
Caucasian	16	19	
Black or African-American	0	1	
Hispanic	1	1	
Avg. number of co-morbid conditions (range)	3.5 (0–7)	4.2 (1–11)	0.29
Duration of operation in min. (SD)	89.1 (35.8)	82.0 (35.1)	0.66
Mean length of stay (SD)	7.7 (5.5)	5.4 (2.8)	0.18
Median length of stay	7	6	

Table 2. Baseline co-morbid conditions

Number of Subjects with Condition (Percent of Group)	Total Hip Arthroplasty (N=17)	Hemiarthroplasty (N=23)	P value
Heart disease	4(24)	9(39)	0.33
Hypertension	10(59)	17(74)	0.50
Lung disease	2(12)	3(13)	1.00
Diabetes	4(24)	2(9)	0.37
Ulcer/other stomach	1(6)	3(13)	0.62
Kidney disease	2(12)	1(4)	0.56
Liver disease	0	2(9)	0.50
Anemia	2(12)	3(13)	1.00
Cancer	2(12)	6(26)	0.43
Depression	7(41)	8(35)	0.75
Osteoarthritis (other than at hip)	11(65)	13(57)	0.75
Chronic back pain	7(41)	13(57)	0.52
Rheumatoid arthritis	0	4(17)	0.12
Other	5(29)	12(52)	0.20

study; 23 were randomized to the hemiarthroplasty group, 18 were randomized to the THA group. One THA patient withdrew immediately after surgery and refused to have her baseline data included, so the size of the group was 17 patients. The overall recruitment rate was 38%, with the most common reason for exclusion (23% of those excluded) being dementia (defined as <23 out of 30 on the Folstein MMSE). In all patients having the treatment to which they were randomized, it is by random chance within the block randomization used at each of the five sites that the unequal number of subjects in each group resulted.

Baseline demographics, health status and initial hospital outcomes

After randomization, there were no significant differences seen in the demographics between the two groups or the self-reported comorbid conditions. Additionally, there were no significant differences between the groups in the immediate post-operative course (Tables 1 and 2 below).

Functional outcomes

At baseline and 6 months, there were no significant differences between the groups in the WOMAC or SF-36 scores (Table 3).

At 12 months, the THA group had significantly less bodily pain than the hemiarthroplasty group (53.2 ± 10.2 vs 42.4 ± 11.5 , $p=0.02$). General trends towards improved scores in other SF-36 subscales, the WOMAC and Harris Hip Score were also observed. One notable exception to this is the stiffness component of the WOMAC, which indicates patients receiving a hemiarthroplasty have less stiffness than those with a THA; however, this does not seem to correlate to reported pain in these groups (Table 3).

The TUG results (Table 3) show a nonnormal distribution with large standard deviations with minimal differences in mean times. To account for the nonnormal distribution, we categorized the TUG results using parameters set forth by the original authors to gage the functional status of ambulatory individuals (Fig. 1).[17] The proportion of patients in the THA group who were classified as totally independent in their daily activities was greater than in the hemiarthroplasty group, nearly reaching statistical significance (50 vs 23%, $p=0.08$, Fig. 1). Additionally, the

Table 3. Comparison of patient-assessed and functional outcomes between hemiarthroplasty and THA

	Hemiarthroplasty (Max N=23)	Total Hip Arthroplasty (Max N=17)	Difference	95% CI for Difference	P value
At 6 months					
SF-36 Subscales(1–100)					
Physical function	32.6(12.4)	30.4(13.1)	2.2	−7.9, 12.3	0.66
Bodily pain	45.7(8.6)	46.0(15.4)	−0.3	−10.4, 9.9	0.96
Mental component summary score	47.6(13.2)	47.6(15.3)	0.0	−11.5, 11.5	0.99
Physical component summary score	39.1(8.6)	38.1(12.2)	0.9	−7.6, 9.4	0.82
WOMAC (1–100)					
Pain (injured side)	85.0(13.6)	91.9(13.5)	−6.9	−16.5, 2.6	0.50
Stiffness	75.0(19.8)	71.2(29.5)	3.4	−16.5, 24.1	0.70
Function	73.9(18.5)	58.1(38.4)	15.8	−9.6, 24.3	0.19
Harris hip score (1–100; injured side)	77.1(12.0)	76.1(26.5)	1.0	−11.8, 14.2	0.84
Timed “Up & Go” (sec)	14.2(6.2)	13.9(6.1)	.3	−10.85, 9.5	0.92
At 12 months					
SF-36 subscales (1–100)					
Physical function	32.8(10.0)	33.5(12.0)	−0.7	−10.1, 8.6	0.87
Bodily pain	42.4(11.5)	53.2(10.2)	−10.8	−20.1, −1.5	0.02
Mental component summary score	49.0(12.0)	55.7(15.8)	−6.7	−18.5, 5.1	0.25
Physical component summary score	36.4(9.2)	40.2(9.9)	−3.8	−11.8, 4.4	0.35
WOMAC (1–100)					
Pain (injured side)	88.5(13.6)	92.5(14.6)	−4.0	−16.3, 8.2	0.50
Stiffness	86.5(16.5)	71.3(31.2)	15.2	−13.0, 18.7	0.14
Function	78.7(16.8)	75.9(19.8)	2.8	−15.3, 8.4	0.71
Harris hip score (1–100; injured side)	80.6(14.3)	84.2(12.0)	−3.6	−15.3, 8.3	0.55
Timed “Up & Go” (seconds)	16.5(10.1)	17.2(13.5)	.7	−10.8, 9.5	0.89

Fig. 1 Predicted functional independence based on TUG time: THA vs hemiarthroplasty (controlling for age and sex) ≤10 s: freely independent subjects; >10 s: possible difficulty with transfers, stairs, or walking outdoors; increased risk of fall

self-reported ambulatory status at 12 months parallels our findings for the objective TUG test. A greater proportion of the subjects in the THA group ambulate independently (82 vs 62%) at 1 year (Fig. 2), although this statistic was not significant in itself ($p=0.25$). We found the time to complete the TUG is significantly correlated to the physical functioning subscale of the SF-36 (Fig. 3).

Adverse events

The complication rates after surgery were not significantly different between the two groups (Table 4). There was one dislocation in the THA group (5.8% of THA group) occurring 5 months after surgery, requiring operative revision. Since the start of data collection, we have seen 11 deaths in 40 patients (27.5% overall mortality at a mean follow-up of 19 months for all patients, range 13 to 33 months, Fig. 4). Seven of these deaths have been in the hemiarthroplasty group, while four deaths have occurred in the THA group (30.4 vs 23.5%, $p=0.20$).

Discussion

This trial demonstrates the feasibility of conducting a well-designed research protocol in a higher functioning hip fracture population using a multicenter design in which all participating surgeons are willing to perform a THA, if allocated. We present the results of this novel trial to lay the groundwork for future investigations to conclusively determine the best surgical option for active, elderly adults who suffer a displaced femoral neck fracture.

Despite limited statistical power, significantly improved outcomes in the THA group were seen regarding pain and ambulatory status 1 year after surgery. The 10-point difference between the groups in the pain subscale of the SF-36 at 12 months represents a both statistically and clinically significant outcome. While we did not see this difference in pain influence the reported functional status of the other outcome measures, we did see it reflected in the TUG performance measure. A greater proportion of the THA patients remained independent 1 year after surgery as compared to those patients in the hemiarthroplasty group, nearly reaching statistical significance. This data supports the use of performance measures in a hip fracture population, as they may reveal diverging functional differences before patient-reported measures.

While the average operative time would have been expected to be 10–15 min longer for the total hip arthroplasty, our data suggest that this might not be a large difference in skin-to-skin time, on average. This most likely reflects the large proportion of participating surgeons that are primarily arthroplasty surgeons and are very familiar and experienced with the THA operation but supports that differences between the groups are not a function of additional time under anesthesia. Many of the subjects in the THA group received press-fit stems, additionally reducing mean surgical time.

Conducting well-designed, randomized clinical trials in the hip fracture population has proven to be challenging. Surgeons often have strong preferences regarding the appropriate treatment for an individual patient, in part due to the paucity of quality studies comparing outcomes. Comparing results across studies also proves challenging as many different outcome measures can be applied, yet few are proven valid for this specific population. With a natural morbidity at 1 year of ~25% (independent of fracture type or surgical procedure), it is difficult to predict which patients will stand to benefit most from alternative options intended to give the best chance of functional recovery.[21]

Historically, surgeons have avoided the use of total hip arthroplasty for the treatment of femoral neck fractures due to the higher risk of prosthetic hip dislocation when compared to hemiarthroplasty. In this study, we did witness one hip dislocation in the THA group (1 in 17; 5.8%). It was successfully treated after a second dislocation with a revision that has resulted in no further episodes of instability. Although not statistically significant, we cannot discount this complication. A far larger longitudinal study of patients with displaced femoral neck fractures will be

Fig. 2 Ambulatory status at 12 months

Fig. 3 Correlation of Timed “Up and Go” and SF-36 Physical Functioning

necessary to prove or disprove the hypothesis that THA (when compared to hemiarthroplasty) will result in a smaller number of reoperations and therefore be cost-effective. With pain at 1 year higher for the hemiarthroplasty group, it is anticipated that some patients in the hemiarthroplasty group may eventually require conversion to THA secondary to pain due to “prosthetic arthritis”.

We feel results of this study can be generalized to the greater population of competent, independent hip fracture patients as surgeons were given the opportunity to use either a bipolar or unipolar prosthesis for subjects in the hemiarthroplasty group. Of the 23 patients, only five received a bipolar prosthesis. We are aware that there are significant geographical and institutional preferences regarding the use of bipolar vs unipolar prostheses.[22, 23] However, the results from this study, in conjunction with other recent studies utilizing only bipolar models, suggest that regardless of the type of prosthesis used in a hemiarthroplasty operation, patients receiving a total hip have significantly less pain at 1 year.[5, 24]

Table 4. Complications within 6 months of fracture repair

Adverse Events within 6 months of surgery	THA (N=17)	Hemi (N=23)
Anemia	4	3
Cardiac Arrhythmia	2	1
Dislocation	1	0
GI Bleeding	0	1
Illeus	2	0
Myocardial Infarction	3	0
Pneumonia	0	3
Pulmonary Embolus	1	0
UTI	0	3
Wound infection	0	1
Death	1	5
Other	2	4
Total	15	16

$p=0.10$

The small number of patients in this study does limit the statistical power to detect true differences in functional outcomes and quality of life, especially with mortality rates reducing the long-term follow-up of the subjects. We did not require the patient or the person administering the TUG to be blinded to the procedure, but given the objective nature of the performance test, the bias was minimized. A cost-analysis was not performed during this pilot study. Particularly in multicenter studies across hospital systems, this task proves difficult to do accurately, but will no doubt be important as further evaluation of these treatment options is conducted. Another important limitation to the generalizability of these data is that DFACTO was created by the communication and collaboration of hip arthroplasty specialists who serve as principal investigators at each site. Most surgeon-investigators felt comfortable placing the acetabular component of total hip arthroplasty, but a few primarily trauma surgeons did not. In these instances, care of the patient was transferred to an available hip arthroplasty specialist before randomization.

Decreased pain at 1 year and improved functional independence, (without a significantly greater incidence of complications) suggest THA is a viable treatment option for the active, mentally competent elderly hip fracture popula-

Fig. 4 Survivorship of THA vs hemiarthroplasty: time to death or revision

tion. Further study will best define the criteria for treatment decisions and evaluate potential diverging long-term functional outcomes and differing rates of reoperation over time.

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