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Preference-Based Quality of Life of End-Stage Ankle Arthritis Treated with Arthroplasty or Arthrodesis

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ABSTRACT

Background: Health state values, or “utilities,” are an important preference-based measure of quality of life used by health economists. This study describes the utilities reported by a multicenter cohort of subjects with end-stage ankle arthritis treated with ankle arthrodesis or total ankle arthroplasty. **Materials and Methods:** Subjects with end-stage ankle arthritis were enrolled in a multicenter prospective cohort study. All subjects received either ankle arthrodesis or total ankle arthroplasty. Participants completed baseline SF-36 outcome evaluations preoperatively and at 1-year followup. Preference-based quality of life was assessed using health state values (HSVs) derived from the SF-36 (SF-6D transformation). **Results:** 107 subjects were included. The mean baseline SF-6D health state value for the TAA group was 0.67 (95% CI 0.64 to 0.69) and 0.66 (95% CI 0.63 to 0.68) for the arthrodesis group. At 1-year followup, the mean reported health state value was 0.73 (95% CI 0.71 to 0.76) for the total ankle arthroplasty group and 0.73 (95% CI 0.70 to 0.76) for the ankle arthrodesis group. The 1-year followup results approach age- and gender-matched US population norms. Health state values poorly correlated with age, however, significant differences between genders were detected. **Conclusion:** These data demonstrate an improvement in preference-based quality of life following ankle arthroplasty or arthrodesis. The results also provide necessary data that can be used in future cost-effectiveness analyses.

Level of Evidence: II, Prospective Comparative Study

Key Words: Health State Values; Utilities; Quality of Life; Ankle Arthritis; Total Ankle Arthroplasty; Ankle Arthrodesis

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INTRODUCTION

End-stage ankle arthritis is a debilitating disease with a significant impact on physical function and quality of life. Glazebrook et al. reported that patients with end-stage ankle arthritis scored approximately two standard deviations below normal population scores for all symptoms and functional SF-36 subscales scores.⁶ Further, the mental and physical disability caused by end-stage ankle arthrosis was shown to be at least as severe as that observed in patients with end-stage hip arthrosis.

Health state values, or “utilities,” are a measure of preference-based Health Related Quality of Life (HRQoL) often used by health economists. However, unlike most generic quality of life measures, health state values are unique because they quantify society’s preferences or value for defined health states.⁷ The health state reported by a subject is converted into a single numeric value where 0 represents death and 1 describes full health. These values are clinically useful because they provide an additional metric to measure patient-reported HRQoL and allow comparisons of HRQoL between patients of differing illnesses.

Health state values are also extremely important for economic evaluations. Cost-effectiveness analysis is a standardized method of quantifying the cost per health benefit achieved. Recommendations from the Panel on Cost-Effectiveness in Health and Medicine have suggested that the quality-adjusted life year (QALY) should be used as the unit of health benefit in these economic evaluations.¹⁰ In order to determine the QALYs gained by an intervention, researchers multiply the health state value and the duration spent in each respective health state. Without health state value data collected from relevant orthopaedic patient populations, orthopaedic surgeons are limited in their ability to demonstrate the cost-effectiveness of their treatments. As health care systems are forced to make difficult funding decisions, it is imperative that orthopaedic surgeons be able to

participate in discussions about technology assessment and resource allocation.

The health state values for patients treated surgically for end-stage ankle arthritis using total ankle arthroplasty or ankle arthrodesis are unknown. We sought to describe the health state values obtained from a multi-center cohort of subjects with end-stage ankle arthritis treated with ankle fusion or total ankle arthroplasty. Our secondary objective was to provide data that can facilitate future economic evaluations involving patients with ankle arthritis. We hypothesized that subjects would report health state values below age- and gender-matched population normative data, and that surgical treatment would significantly improve their preference-based quality of life.

PATIENTS AND METHODS

Study subjects were enrolled prospectively in the Canadian Orthopaedic Foot and Ankle Society (COFAS) Multi-centered Ankle Arthritis Outcome Study. Participants were enrolled in four study centers: (1) University of British Columbia/ BC Foot and Ankle Clinic, St. Paul's Hospital, (2) Dalhousie University/Queen Elizabeth II Health Sciences Centre, (3) University of Toronto/St. Michael's Hospital and University Health Network-Western Division, and (4) Memorial University/St. John's Health Science Centre. Institutional review board approval was obtained at each respective study site and consecutive enrollment of eligible participants occurred between 2002–2008. Patients were included if they were skeletally mature and had end-stage ankle arthrosis that was treated with total ankle arthroplasty or ankle arthrodesis. Exclusions included prior ankle arthrodesis or arthroplasty, osteonecrosis of the talus, ipsilateral midfoot deformities, or weight greater than 113 kg (250 lb).

All participants prospectively completed the SF-36 generic health-related quality of life (HRQoL) instrument. Followup assessment with the SF-36 was performed at 1-year post-surgery. All patients were followed in a prospective cohort manner. Five experienced surgeons (more than 50 TAA cases) performed the vast majority of procedures; this was felt to eliminate the potential influence of a learning curve on the results. The decision to perform total ankle arthroplasty or ankle arthrodesis was made by the attending physician after considering relevant patient factors and preferences.

Health state values were calculated using raw data obtained from the SF-36. The data was transformed using an algorithm described by Brazier et al.³ This transformation uses raw scores from 11 SF-36 items to create six dimensions (SF-6D). The SF-6D dimensions include physical functioning, role limitation, social functioning, bodily pain, mental health, and vitality. Each dimension has four to six levels and thus, 18,000 possible health states are defined. Summing the weighted values for each dimension derives a single health state value. The boundaries of the SF-6D

utility scores are from 0.30 to 1.00 with a score of 1.00 representing full health. The psychometric properties of the SF-6D instrument have been established, and it has been extensively compared to other utility instruments, such as the Euroqol-5D and Health Utilities Index.^{8,9}

The primary outcome of this study was the mean SF-6D health state value at 1-year post-ankle arthroplasty or arthrodesis. Summary statistics were performed for basic demographic information. Differences between the study cohort and excluded individuals without full 1-year followup were tested with Fisher's exact test for dichotomous variables and student's t-test for continuous variables. The change in the baseline and 1-year health state values were tested using a paired t-test. Differences between the 1-year results of the total ankle arthroplasty and ankle arthrodesis treatment groups were tested with a student's t-test. Significance for all inferential statistics was set at $p \leq 0.05$. Univariate analysis of age and gender as predictors of SF-6D scores was performed using correlation coefficients and a student's t-test. Age and gender were also used as predictors in a final multiple linear regression model with the mean SF-6D value as the dependent variable.

RESULTS

Two hundred fourteen potentially eligible subjects were identified from the original COFAS cohort. Two hundred participants had complete baseline SF-36 data to allow transformation to SF-6D health state values, and 107 of these patients had followup data at 1-year post-surgery. These 107 subjects comprised our study cohort and are summarized in Table 1. There were no differences in age ($p = 0.36$), gender ($p = 0.32$), treatment received ($p = 0.78$), or baseline health state values ($p = 0.96$) between the study cohort and the 93 subjects excluded because of incomplete 1-year followup data. The study cohort consisted of 57 males (53%) with a mean age at surgery of 57.5 (95% CI, 55.0 to 60.1) years. Subjects within each treatment group were similar in gender ($p = 0.08$). There was a significant difference in mean age

Table 1: Participant Demographics

| | TAA | AA |
|---|-------------|-------------|
| Sample Size, $n =$ | 61 | 46 |
| Gender [†] | | |
| Male | 28 | 29 |
| Female | 32 | 16 |
| Mean Age at Surgery (Years \pm SD) [‡] | 62 \pm 10 | 54 \pm 11 |

[†], Gender for two participants was not available. [‡], Difference in age between treatment groups is significant ($p = 0.0003$). SD, standard deviation.

between the groups, with the total ankle arthroplasty group being approximately 8 years older ($p = 0.0003$). Sixty-one (57%) participants were treated with total ankle arthroplasty.

There was no difference in the mean baseline SF-6D values between the treatment groups ($p = 0.64$). The mean baseline health state value for the TAA group was 0.67 (95% CI 0.64 to 0.69) and 0.66 (95% CI 0.63 to 0.68) for the arthrodesis group. At 1-year post surgery, the mean reported health state value was 0.73 (95% CI 0.71 to 0.76) for the total ankle arthroplasty group and 0.73 (95% CI 0.70 to 0.76) for the ankle arthrodesis group (Table 2). The increases from baseline to 1-year health state values were significant in both treatment groups ($p < 0.0001$); however, no statistically significant difference was detected between the 1-year results of the ankle arthroplasty and arthrodesis groups ($p = 0.75$). These 1-year followup results approach age- and gender-matched US population norms (ages, 55 to 64 years; males, 0.78; females, 0.77).⁵

Similar to the trend seen in US population normative data, univariate analysis suggests women report lower health state values. The cohort's mean baseline HSV for males was 0.69 (95% CI 0.66 to 0.71) and 0.64 (95% CI 0.62 to 0.66) for females ($p = 0.0046$). A similar difference in mean scores was seen at 1-year as well. Age appeared to poorly correlate with the health state values at baseline ($r = 0.14$) and at 1-year followup ($r = 0.23$). Linear regression was also performed using age and gender as predictors of the SF-6D values. The regression model was able to account for only 10% of the SF-6D score variance at baseline (adjusted $R^2 = 0.096$) and 3% of the variance at 1-year postoperatively (adjusted $R^2 = 0.028$).

DISCUSSION

The results of this study confirm that patients with end-stage ankle arthrosis report lower health state values than age- and gender-matched US population norms. These results also suggest that surgical treatment for end-stage ankle arthritis improves the health state values experienced by patients.

The results of this study are consistent with previous reports documenting the significant impact of ankle arthritis on quality of life.⁶ Our data is also consistent with studies demonstrating an improvement in functional outcome following total ankle arthroplasty or ankle arthrodesis.^{1,12}

Significant health state value improvements were experienced by subjects in the total ankle arthroplasty and ankle arthrodesis groups. Although no differences between the treatment groups could be detected at 1-year, both groups reported increases from baseline that exceed the suggested minimally important difference for the SF-6D. Using the SF-6D instrument, changes of greater than 0.03 (95% CI 0.029 to 0.037) provide strong evidence for patient perceived improvements in their health states.¹³

The present data extends the work of previous authors by providing health state values from a large, multi-center cohort of prospectively followed subjects with end-stage ankle arthrosis. We believe this is the first report of utility data from an ankle arthritis population treated with arthrodesis or total ankle arthroplasty. Our results provide a preference-based measure of HRQoL demonstrating individuals with end-stage ankle arthritis report lower measures of quality of life than age- and gender-matched population norms. More importantly, the health state values reported from our cohort can be used to facilitate necessary economic evaluations.

A limited number of economic studies, particularly cost-effectiveness analyses, have been published in the orthopaedic literature.² This reflects an unfortunate deficiency in orthopaedic research because it results in a lack of evidence to support the cost-effectiveness of many current orthopaedic interventions. In the foot and ankle literature, SooHoo and Kominski performed a cost-effectiveness analysis comparing total ankle arthroplasty to ankle fusion.¹¹ Since there were no published reports of health state values from patients with end-stage ankle arthrosis at the time of their analysis, the authors were forced to estimate the utilities associated with hindfoot arthritis, ankle fusion, and ankle replacement. Estimating the effectiveness of interventions is a common practice in economic analyses; however, without data collected from relevant study populations, the conclusions of these economic analyses can often be limited. Our cohort has reported health state values that are lower than the estimates used in SooHoo and Kominski's cost-effectiveness analysis. These findings further stress the need for future cost-effectiveness analyses using data collected directly from representative cohorts.

The strengths of our study include the prospectively collected data, the multi-center recruitment, and the relatively large cohort size. There are, however, some limitations to our results. This study's cohort consists of only half the subjects enrolled in the larger COFAS Multicenter Ankle Arthritis Outcome Study. The reasons for the missing data included: lost to followup, incomplete data collection, and the inability to transform SF-6D scores with missing SF-36 responses. Substantial losses to followup threaten the validity of any research study, including our own data. This may lead to over- or under-estimations of the true treatment efficacy. Differential losses between treatment groups may also add respondent biases favoring one of the

Table 2: Mean Health State Values, SF-6D (95% CI)

| | TAA | AA |
|----------|------------------|------------------|
| Baseline | 0.67 (0.64–0.69) | 0.66 (0.63–0.68) |
| 1 year | 0.73 (0.71–0.76) | 0.73 (0.70–0.76) |

TAA, Total ankle arthroplasty; AA, Ankle arthrodesis.

treatments. Although we cannot ensure the patient followup rate has not affected our estimates of the true health state values, the similar losses to followup per group do not support a respondent bias favoring one of the treatment groups.

Finally, we were unable to account for medical comorbidities that may affect the mean health state values reported by the cohort. If the prevalence of significant medical comorbidities is high, then our cohort's utilities will likely be lower than a healthy cohort with isolated ankle arthrosis. Despite this limitation, it should be recognized that the comorbidities existing pre-operatively do not disappear post-operatively, and thus the improvement in health state values likely reflect improvement due to total ankle arthroplasty or ankle arthrodesis.

Collecting health state values from study participants can be performed using several methods. Traditional methods include time-consuming interviews using standard-gamble or time-tradeoff techniques.⁷ More commonly, researchers are using short generic patient-reported questionnaires to obtain these data. The Euroqol-5D (EQ-5D), Health Utilities Index Mark 3 (HUI3), and the SF-6D are emerging as commonly used utility instruments across most medical disciplines. The EQ-5D and HUI3 are both self-administered instruments that require less than 4 minutes to complete.⁵ The SF-6D can also be administered as a stand-alone instrument; however, it is most commonly transformed from completed SF-12 or SF-36 questionnaires.^{3,4} Given the importance of health state values for facilitating economic analyses and comparing the quality of life across differing patient populations, and given the relative ease and minimal respondent burden of these utility instruments, orthopaedic surgeons should be encouraged to report health state values with their clinical results.

This study has used the SF-6D transformation algorithm to obtain health state values from patients with end-stage ankle arthrosis treated with total ankle arthroplasty or ankle arthrodesis. These data describe the impact of ankle arthrosis using a societal preference-weighted measure of quality of life, and the results provide necessary data for future cost-effectiveness analyses. Further collection of health state

values from subjects with varying foot and ankle pathologies must be encouraged to ensure orthopaedic interventions improve quality of life and demonstrate their cost-effectiveness.

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