Do modern total knee replacements offer better value for money? A health economic analysis

David F. Hamilton · Nicholas D. Clement ·
Richard Burnett · James T. Patton · Mathew Moran ·
Colin R. Howie · A. H. R. W. Simpson · Paul Gaston

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Abstract

Purpose Cost effectiveness is an increasingly important factor in today's healthcare environment, and selection of arthroplasty implant is not exempt from such concerns. Quality adjusted life years (QALYs) are the typical tool for this type of evaluation. Using this methodology, joint arthroplasty has been shown to be cost effective; however, studies directly comparing differing prostheses are lacking.

Methods Data was gathered in a single-centre prospective double-blind randomised controlled trial comparing the outcome of modern and traditional knee implants, using the Short Form 6 dimensional (SF-6D) score and quality adjusted life year (QALY) methodology.

Results There was significant improvement in the SF-6D score for both groups at one year ($p < 0.0001$). The calculated overall life expectancy for the study cohort was 15.1 years, resulting in an overall QALY gain of 2.144 (95 % CI 1.752–2.507). The modern implant group demonstrated a small improvement in SF-6D score compared to the traditional design at one year (0.141 versus 0.143, $p = 0.94$). This difference resulted in the modern implant costing £298 less per QALY at one year.

Conclusion This study demonstrates that modern implant technology does not influence the cost-effectiveness of TKA using the SF-6D and QALY methodology. This type of analysis however assesses health status, and is not sensitive to joint specific function. Evolutionary design changes in implant technology are thus unlikely to influence QALY analysis

following joint replacement, which has important implications for implant procurement.

Introduction

The volume of total knee arthroplasty (TKA) performed in the United Kingdom over the last ten years has risen dramatically [1], mirroring international practice. Cost effectiveness is an increasingly important factor in today's healthcare environment, and decisions surrounding the choice of arthroplasty prostheses to implant are not exempt from such health economic concerns. Recently, Jenkins et al. [2] demonstrated that TKA was a cost-effective intervention, with a cost per quality adjusted life years (QALY) of £2,101. They intimated that innovations in implant design could influence the economics, with improved outcomes potentially leading to lower costs per QALY gained. However, if improvements in outcome are at a greater implant cost, relative to the status quo, then the converse may occur.

We are unaware of any published study that specifically compares the QALYs gained for two differing TKR designs. Retrospective analysis of 20,000 TKAs from the National Joint Registry of England and Wales demonstrated a significant difference in outcome between various implants, using the Oxford Knee Score and EuroQol-5D [3]. Baker et al. [3] highlight that inter implant differences found were small in magnitude and suggested these may not be clinically relevant. It could be argued however that the differences reported in EuroQol-5D, though not clinically significant, may be significant from a health economic perspective. Assuming the implants were purchased at the same list price, the 0.023 point difference found between the NexGen (Zimmer) and the Genesis 2 (Smith & Nephew) would result in a £2,000 difference in cost per QALY at one year and £145 difference in the lifetime

D. F. Hamilton (✉) · N. D. Clement · R. Burnett · J. T. Patton ·
M. Moran · C. R. Howie · A. H. R. W. Simpson · P. Gaston
Department of Trauma and Orthopaedics, University of Edinburgh,
Chancellor's Building, 49 Little France Crescent,
EH16 4SB Edinburgh, UK
e-mail: d.f.hamilton@ed.ac.uk

cost per QALY, using the methodology established by Jenkins et al. [2]. If such a difference potentially exists between modern implants, there may well be differences comparing new implant technology to older designs.

The aim of this study was to compare the cost-effectiveness of a modern TKA that incorporates new technology, thought to improve patient outcomes, with its design predecessor using QALY methodology. Our hypothesis was that patients receiving the modern TKA would demonstrate improved incremental health-related quality of life gain at one year and enhanced cost effectiveness.

Methods

Study population and trial design

Data was obtained prospectively from patients participating in an on-going double-blind randomised controlled trial comparing a modern TKA (Triathlon), with an implant of older design chronology (Kinemax, both Stryker Orthopaedics, Mahwah, NJ). The Kinemax was a non-sided implant that used the traditional multi-radius design. The Triathlon, in contrast, adopts a single-radius of curvature, sided, femoral component, with shorter posterior femoral condyles and a thinner anterior femoral condyle. Ethical approval was granted by the local research ethics committee (Ref: 06/S1103/50) and logged with the International Standard Randomised Controlled Trial Number Register (Ref: CCT-NAPN-21982). Inclusion criteria consisted of unilateral symptomatic knee osteoarthritis, planned primary knee arthroplasty with standard implants (without augments) and capacity to give informed consent.

Patients were identified through the clinics of six consultant surgeons at the study centre and were recruited through informed consent. Patients were allocated to either implant using a bespoke computer randomisation program. Both the patient and researcher were blind to allocation, and remained so throughout the trial period. Surgery was conducted using standard hospital protocol and instrumentation for each prosthesis, employing intra-medullary referencing for the femur and extra-medullary referencing for the tibia. A measured resection technique was employed, cutting the femur first, to establish a joint line, and using posterior referencing to size the femoral component. Femoral implant rotational alignment was set with reference to the transepicondylar axis and Whitesides line. The tibial component was implanted with a 3-degree posterior slope and neutral varus/valgus alignment. No patients underwent patellofemoral resurfacing. Cemented, cruciate retaining, fixed bearing implants were used. Post-operative rehabilitation and all other aspects of patient care were identical for both groups as per our unit's routine post-operative care pathway and the trial protocol.

Outcome assessment

Assessments were made pre-operation and at six, 26 and 52 weeks postoperatively. This analysis focuses on the SF-36 [4], a generic health questionnaire that assesses the patient's perceived physical and mental health using eight dimensions. A single preference-based index measure however is required to calculate QALYs. Brazier et al. [5] described the SF-6 dimensional (SF-6D) score, which is such a measure, calculated using ten of the 36 component scores from the SF-36. The SF-6D evaluates six domains: physical functioning, role limitations, social functioning, pain, mental health, and vitality. An individual patient's health state is reported based on the six digit code for each domain, of which there are 18,000 possible health states. This index is measured on a scale of 0.30 to 1.00, where 1.00 represents perfect health and 0.30 represents the worst health state (death). The health state gained from the TKA is derived from the difference between pre-operative and one-year SF-6D, multiplied by the time spent in that state, to derive QALYs gained or lost. The minimal clinically important difference (MCID) is the smallest change of score to be of importance. This has been demonstrated as a change of 0.03 in the SF-6D [6], which we accepted as the MCID needed to demonstrate a difference between implants.

Predicted life expectancy was used to estimate the QALYs gained until the end of the patient's life. This was derived from publicly available life tables based on the patient's age and gender at time of surgery (specific to the population at risk) [7]. This methodology assumes static health after one-year and no need for further intervention, which is considered the undiscounted health gain [8]. The QALYs gain was discounted at a rate of 5 % for each year of life expectancy to reflect a diminishing gain with time [9], as has been previously employed in arthroplasty health economic analysis [2]. The cost per QALY was then calculated (QALY gained/cost of prosthesis) at one year and for the expected lifetime of the cohort (adjusted and unadjusted). The list costs of the implants used in this study were identical, at £3,000.

Statistical analysis

Analysis was performed using Statistical Package for Social Sciences version 17.0 (SPSS Inc., Chicago, IL, USA). Data was normally distributed, thus parametric tests were used to assess continuous variables for differences between pre and postoperative scores and between study groups. The Student's *t*-test, unpaired and paired, was used to compare linear variables between groups. Dichotomous variables were assessed using a chi-square test or a Fisher's exact test if there were five or less for any categorical variable. Statistical significance was accepted at $p < 0.05$.

Results

Two hundred and thirty-seven consecutive patients were invited to participate in the trial, of which 212 consented. Twenty-nine patients either withdrew from the trial or were lost to follow-up (Fig. 1). For QALY analysis, fully completed pre-operative and postoperative SF-6D assessments were required. An additional 59 patients failed to provide complete data, resulting in a cohort of 124 patients for analysis, of which 54 were male and 70 female. SF-6D score improved significantly from 0.628 (SD 0.210) pre-operatively to 0.769 (SD 0.130) postoperatively (95 % CI 0.118–0.166, $p < 0.0001$ paired t -test). There were no differences between the study cohort ($n = 124$) and those lost to follow-up ($n = 59$) in age ($p = 0.78$), gender ($p = 0.31$), comorbidity ($p > 0.34$), pre-operative ($p = 0.76$) or postoperative ($p = 0.87$) SF-6D score.

The study cohort consisted of 60 (48.4 %) patients randomised to a Kinemax TKA and 64 (51.6 %) patients randomised to a Triathlon TKA. There were no differences in age, gender, or comorbidity between groups (Table 1). Patients in the Triathlon group demonstrated worse pre-

operative SF-6D scores, though this was not significant (95 % CI -0.04 to 0.05 , $p = 0.67$). There were no differences in SF-6D between the groups at any of the time points assessed, although an improved in early outcome in the Triathlon group (at six weeks) bordered on significance (Table 2). There was significant improvement in the SF-6D for both groups at one year compared with pre-operative score (Table 3). A greater improvement was seen in the Triathlon group, though this difference did not reach significance (Table 3).

Overall life expectancy for the study cohort was 15.1-years, resulting in an overall QALY gain of 2.144 (95 % CI 1.752–2.507). The greater improvement in SF-6D for the Triathlon group resulted in a greater QALY gain for that group, for both unadjusted and adjusted gains over the lifetime of the cohort. The difference was not statically significant ($p = 0.94$), but did reach the defined MCID for the SF-6D over the predicted lifetime of the implant. This difference in health gain resulted in the Triathlon costing £298 less per QALY at one year, but diminished to less than £30 per year over the projected lifetime of the cohort (Table 3).

Fig. 1 CONSORT flow chart

Table 1 Comparison of case-mix variables between the study cohorts

Case-mix variables	Kinemax (<i>n</i> =60)	Triathlon (<i>n</i> =64)	Difference/ Odds ratio	<i>p</i> accepted at <0.05 ^a
Age (years, mean, SD)	68.9 (9.8)	69.1 (9.6)	0.2	0.92 ^b
Gender (<i>n</i> , % of group)				
Male	28 (46.7 %)	26 (40.1 %)	1.5	0.50
Female	32 (53.3 %)	38 (59.9 %)		
Comorbidity (<i>n</i> , % of group)				
Heart disease	10 (16.7 %)	5 (7.8 %)	2.36	0.13
Hypertension	35 (58.3 %)	37 (57.8 %)	1.02	0.95
Respiratory disease	8 (13.3 %)	9 (14.1 %)	0.94	0.91
Stroke	3 (6.7 %)	4 (6.3 %)	0.79	0.76
Diabetes mellitus	4 (13.3 %)	7 (10.9 %)	0.58	0.40
Peptic ulcer disease	8 (13.3 %)	6 (9.4 %)	1.49	0.49
Renal disease	2 (3.3 %)	0	2.10	0.14
Liver disease	0	1 (1.6 %)	1.95	0.33
Anaemia	2 (3.3 %)	8 (12.5 %)	0.24	0.06
Depression	4 (6.7 %)	9 (14.1 %)	0.44	0.18
Back pain	24 (40.0 %)	31 (48.4 %)	0.71	0.35
Pain in other joints	39 (65.0 %)	39 (60.9 %)	1.19	0.64

^a Chi-square or Fishers exact test (if *n*≤5) unless stated otherwise

^b Unpaired *t*-test

Discussion

This study has demonstrated that clinical and functional improvements in patient outcome achieved with modern implant designs [10, 11] are not reflected in health economic analysis using the SF-6D and QALY methodology. We found significant health gains in both implant groups beyond the MCID of the assessment tool; however, despite a trend towards earlier recovery in the Triathlon group and a greater QALY gain at one year, this was not statistically significant. Over the patient's expected remaining lifetime, the difference in the QALY resulted in a cost saving of approximately £30 per year using the Triathlon implant.

The failure to show a meaningful difference in QALY in this cohort is particularly interesting as substantial clinical and functional differences have been demonstrated between these groups at one year [10, 11]. The SF-6D questionnaire (as with all QALY tools) asks a very limited set of questions and reflects only large changes in health status, such as following coronary artery bypass grafting or arthroplasty. These tools are

generic health assessment instruments and are not sensitive to more subtle, but important, clinical and functional differences in patient outcome which can be influenced by implantable technology. It is widely acknowledged that generic tools are not specific enough to evaluate patient function, thus arthroplasty outcome is typically evaluated with disease or joint specific tools such as the WOMAC or Oxford scores or through direct measures of physical performance [12]. It is important to recognise that cost-effectiveness is calculated on the basis of achieving substantial improvements in health and quality of life. It is highly unlikely that the ability to perform ever more demanding functional tasks and partake in recreational sports, which currently drives implant development, will impact upon health-related quality of life assessment.

A limitation of this study is that a number of patients did not fully complete the SF-6D, with a resultant loss of 59 patients (32 %) from the study cohort. There were, however, no differences in patient demographics, pre-operative or postoperative SF-6D scores between those who completed and failed to complete the SF-6D questionnaire fully. This

Table 2 Comparison of pre-operative and postoperative SF-6D scores for both study cohorts

SF-6D (mean, SD)	Kinemax (<i>n</i> =60)	Triathlon (<i>n</i> =64)	Difference (mean, 95 % CI)	<i>p</i> accepted at <0.05 ^a
Pre-operative	0.631 (0.114)	0.623 (0.127)	0.009 (−0.052 to 0.034)	0.67
Postoperative				
Six weeks	0.670 (0.143)	0.719 (0.116)	0.049 (−0.002 to 0.100)	0.06
Six months	0.771 (0.128)	0.778 (0.136)	0.006 (−0.046 to 0.058)	0.81
One year	0.773 (0.123)	0.766 (0.138)	0.007 (−0.039 to 0.054)	0.75

p <0.05

Table 3 Health economic analysis using the improvement in the SF-6D health evaluation score at one-year postoperative for both groups

Health economic analysis	Kinemax (<i>n</i> =60)	Triathlon (<i>n</i> =64)	Difference (mean, 95 % CI)	<i>p</i> accepted at <0.05 ^a
Health valuation (scale 0.3–1.0)				
Pre-operative (mean, SD)	0.631 (0.114)	0.623 (0.127)	0.009 (−0.052 to 0.034)	0.67
Post-operative (mean, SD)	0.773 (0.123)	0.766 (0.138)	0.007 (−0.054 to 0.039)	0.75
Difference (mean, 95 % CI)	0.141 (0.106 to 0.176)	0.1430 (0.108 to 0.178)	0.002 −0.047 to 0.051)	0.94
<i>p</i> value ^b	<0.0001	<0.0001		
Life expectancy (mean years, SD)	15.1 (7.8)			
QALYs gained (years, mean, 95 % CI)	2.13 (1.60 to 2.66)	2.16 (1.63 to 2.69)	0.03	0.95
Implant cost	£3,000	£3,000	–	
One year cost per QALY	£21,277	£20,979	£298	
Lifetime cost per QALY	£1408	£1389	£19	
Lifetime cost per QALY (5 % disutility)	£1982	£1954	£28	

^a Unpaired *t*-test^b Paired *t*-test

lost to follow-up rate is comparable to other cost-utility studies. The double blind randomised trial design and equal patient numbers lends to the validity of our results.

The incremental cost per QALY for each implant was (as expected) dependent upon the cost of the prosthesis used. The two implants were identical in list price at the time of implantation, thus any increase in the QALY gained by one implant would result in a decreased cost per QALY for that prosthesis. This was the case for the Triathlon, although the monetary saving over the projected lifetime of the implant was low. Implant costs vary between manufacturers; a recent review of implant costs suggested massive variation in TKA price from £1,188 to £7,998 dependant on hospital size and surgeon preference [13]. This disparity in price may reflect the research and manufacturing costs associated with different prostheses, but questions should be asked as to whether any large increases in implant costs are worth the functional benefit achieved. It is important that any such differences are determined in well-designed clinical studies for every new implant to allow procurement teams to assess whether they should support the introduction of a particular design.

It may also be appropriate to consider setting a ceiling cost for a standard TKA, above which it becomes cost ineffective. Currently in the UK, the cost of a knee replacement is fixed at a predefined tariff. Using these tariffs a recent report found an average cost per QALY gained to be £5,623 for the first five years after surgery [14]. Another study analysed the cost per QALY for the life expectancy of their patient cohort and demonstrated a cost per QALY of £4,704, accounting for deterioration in outcome with time and potential revision of the costs [2]. There is consensus then that the cost per QALY for knee arthroplasty is far below the value of £20,000 suggested by the UK national institute for clinical excellence

as the threshold by which interventions are deemed cost effective [15].

Variation is reported for QALY after TKA in studies using the EQ-5D, with a gain range from 0.267 to 0.320 at one year [2, 3, 14]. This may be due to the implants used and case-mixes of the cohorts analysed [3]. The QALY gains demonstrated by these studies are approximately double the gains that we observed at one year using the SF-6D. This discrepancy has been previously highlighted [16, 17], and the ratio of the QALYs gained varies from 1.5 to 3.6 times greater with the EQ-5D relative to the SF-6D for non-operative measures for knee pain [17]. This supports our finding of a health gain of 0.141 using the SF-6D, which is around half of that observed with the EQ-5D questionnaire for TKA at one year [2, 3, 14]. The EQ-5D perhaps offers a greater sensitivity resulting in a lesser cost per QALY than the SF-6D questionnaire; however, this may overestimate the true cost-effectiveness of the TKA. It is important that this difference is recognised in the reporting of QALY.

An uncomplicated TKA incorporates the costs of the procedure, implant, and period of hospitalisation. There are no on-going maintenance costs such as would be encountered in a drug trial. However, the benefit of a TKA may diminish over time (accounted for in our analysis) and is at risk of revision [2]. We did not adjust our cost analysis for revision but made the assumption of equivalent implant survivorship at 15 years, as there is no long-term data available for the Triathlon prosthesis. The National joint registry of England and Wales reports the five-year revision rate for the Triathlon prosthesis as 1.7 %, compared to 2.7 % for the Kinemax [18]. We elected not to use these figures in our projection analysis for the lifetime cost per QALY as we cannot be sure they will remain constant in the longer term. If the early survival difference

persists into the long term however, this would result in a further reduced cost per QALY for the Triathlon prostheses, suggesting that manufactures should perhaps focus on implant longevity to drive the health economic benefits of their designs.

The decision as to which implant should be used for surgery varies with local factors. This decision however should be influenced by patient outcomes and implant longevity. The cost effectiveness of TKA using the QALY methodology seems to be influenced little by the design of the prostheses, which perhaps suggests that QALY analysis fails to capture the actual functional change in the patient. Any increase in implant list cost for new designs would need to be justified by substantial improvements in patient outcome to achieve the cost effectiveness of contemporary implants.

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