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N.B.: When citing this work, cite the original article.

Original publication:

Thor-Henrik Brodtkorb, Martin Henriksson, Kasper Johannesen-Munk, Fredrik Thidell, Cost-effectiveness of C-Leg compared to non microprocessor controlled knees: a modelling approach, 2008, Archives of Physical Medicine and Rehabilitation, (89), 1, 24-30.

<http://dx.doi.org/10.1016/j.apmr.2007.07.049>.

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Postprint available free at:

Linköping University E-Press: <http://urn.kb.se/resolve?urn=urn:nbn:se:liu:diva-11142>

Running head: Cost-effectiveness of C-leg

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Financial support: Kasper Johannesen-Munk and Fredrik Thidell did most of the data collection as part of their final bachelor exam and did receive financial support from Otto Bock for travel expenses associated with the collection of data. Thor-Henrik Brodtkorb has worked as a consultant for Otto Bock and other competing companies for short periods. However, no payment was received from Otto Bock for this project. The authors retained full control over the article's content and decision to submit the manuscript.

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Cost-effectiveness of C-Leg compared to non microprocessor controlled knees: a modelling approach.

Objective: To estimate the costs and health outcomes of C-Leg and non-microprocessor-controlled (NMC) knees using a decision-analytic model.

Design: Data on costs, rates and duration of problems, knee survival, and health-related quality of life were obtained from interviews with patients and prosthetists with experience of both C-Leg and NMC knees. Interview data were assessed in a decision-analytic Markov model to estimate cost-effectiveness from a health care perspective.

Setting: Outpatient.

Participants: A population sample of 20 patients currently using the C-Leg and prior experience of nonmicroprocessor knees, and 5 prosthetists.

Interventions: Not applicable.

Main Outcome Measure: Incremental cost per quality-adjusted life year (QALY).

Results: The mean incremental cost (in 2006 Euros) and QALYs for the C-Leg was €7657 and 2.38, respectively, yielding a cost per QALY gained of €3218.

Conclusions: It is important to provide decision-makers with relevant information on costs and health outcomes of different treatment strategies on actual decision problems despite limited evidence. The results of the study, taking into account both costs and a broadly defined health outcome in terms of QALY, show that given existing albeit limited evidence the C-Leg appears to yield positive health outcomes at an acceptable cost.

Key Words: Artificial limbs; Costs and cost analysis; Decision support techniques; Quality of life; Rehabilitation

Having to experience a transfemoral amputation significantly reduces the patient's potential of living an active life. Therefore, the introduction of the microprocessor-controlled knee, the C-Leg from Otto Bock,^a almost 10 years ago was coupled with great expectations of a possibility of regaining some of this potential. This knee unit offered a microprocessor-controlled swing and stance phase and was, therefore, assumed to increase the functional level of the prosthetic users. Divergent from the earlier non-microprocessor-controlled (NMC) prosthetic knees, passively controlling the flexion and extension during gait with a mechanical unit, the C-Leg offered dynamic control of the flexion and extension during swing and stance phase. This dynamic control in the C-Leg is achieved by sensors in the shin of the prosthesis continually assessing the position of the leg in space as the amputee is walking. The data were fed into a microprocessor inside the knee and the resistance from a hydraulic damper is adjusted to optimize knee stiffness throughout the entire gait cycle.¹ Since the beginning, some studies have shown beneficial results for the C-Leg in comparison to the conventional NMC knee units. Advantages observed have been easier negotiation of stairs and hilly terrain; decreased frequency of stumbles and falls; decreased difficulty in multitasking and higher satisfaction²; lower rate of oxygen consumption³; and biomechanical advantages such as decrease in hip work production, lower peak hip flexion moment at terminal stance, and enhanced smoothness of gait.⁴ However, because the C-Leg is substantially more costly compared with the NMC alternatives, the potential benefits need to be compared with the increased costs since cost-effectiveness has become a key criteria for decision-makers when deciding which health care interventions should be made available in collectively funded health care systems.⁵ At present, the county councils in Sweden have taken different approaches; some are providing the C-Leg, whereas others are not. The advantages observed in current studies⁶ of the C-Leg compared with NMC alternatives are in the form of intermediate outcomes such as speed of gait and energy consumption. However,

to capture the larger panorama of health and well-being thought to be important and meaningful to patients, quality-adjusted life years (QALYs) is the recommended outcome in economic evaluations of health care interventions.⁷ With this measure, the time spent in a health state is weighted by a quality-adjustment weight, or utility, between 0 (dead) and 1 (full health).⁷ Because QALYs is a generic health outcome, treatments prolonging life or enhancing health-related quality of life (HRQOL) can be compared. Furthermore, comparison between different disease areas is possible, making QALYs a useful outcome in economic evaluations performed to inform policy decisions regarding the allocation of scarce health care resources.⁷ Therefore, intermediate outcomes are difficult to relate in a meaningful manner to the additional costs incurred by the provision of a C-Leg. For instance, relating the additional cost of a C-Leg to lowered energy consumption is difficult to interpret. In the case of the C-Leg, or indeed other prosthetic knees, we are unaware of any studies measuring the effect of providing a patient with a knee prosthesis in terms of quality of life (QOL) or measures eligible for conversion to QOL.

Given this lack of evidence concerning HRQOL and cost-effectiveness of prosthetic knees, different courses of action are possible for decision-makers facing the decision whether a treatment strategy, in this case a C-Leg, should be provided by the health care system. One approach would be to wait for high-quality evidence to become available before making a decision, whereas another is to use current available information, albeit limited, and explicitly take the large amount of uncertainty into account when making the decision. The first option is a de facto decision, namely, that the new treatment strategy is not cost-effective or indeed clinically effective if one were only concerned about some health outcome, as such a decision implicitly assumes that the existing treatment is superior, meaning the new treatment should not be adopted.⁵ There are several arguments against this approach advocating the second alternative of using the available evidence in a clear analytical framework.⁸ With this

framework, available information can be synthesized in a decision-analytic model to establish costs and health outcomes of the treatment strategies of interest. By properly describing the quality and quantity of the evidence, the uncertainty in model inputs such as relative treatment effect, costs, and QOL can be incorporated in the analysis and, ultimately, give an estimation of the uncertainty of key interest, namely, that in the cost-effectiveness estimate.

Although there is no published evidence on QOL and costs regarding the C-Leg, decision-makers still have to make recommendations regarding the provision of the C-Leg. Therefore, the purpose of this study was to estimate the costs and health outcomes of the C-Leg and NMC knees while using a decision-analytic model based on newly collected data on HRQOL of patients with the C-Leg.

Methods

Cost-Effectiveness Model

The costs and health outcomes of treating patients with a C-Leg compared with treating patients with an NMC knee was determined by using a Markov model.⁹ Although, to our knowledge, Markov models were not applied to the field of prosthetics earlier, Markov models are well-recognized methods for analyzing clinical and economic consequences of medical decisions, particularly in long-term diseases characterized by repeating risks of events over time.⁹ In a Markov model, hypothetical patients reside in one of a set of mutually exclusive health states at each and every point in time. During intervals of equal length referred to as Markov cycles, patients can make transitions from 1 state to another, with the probability of moving between health states being determined by transition probabilities.⁹ Each health state in the model is associated with costs and health outcomes. Costs and health outcomes for each Markov cycle are accumulated and summarized for the cohort of hypothetical patients at the end of the analysis.

The analysis was undertaken from a Swedish health care perspective including costs directly associated with the health care provider. Costs were expressed in Euros (€) at the 2006 price level. Health outcomes were expressed as QALYs. When calculating QALYs, the time spent in a health state is weighted by a quality-adjustment weight, or utility, between 0 (dead) and 1 (full health), representing the QOL associated with the health state.⁷ Costs and QALYs were discounted by 3% per annum according to recent guidelines.¹⁰

The time horizon for the analysis was 8 years from the delivery of the first prosthesis because this is the functional time of a C-Leg guaranteed by the manufacturer. Sensitivity analysis of

the time horizon of 1 and 4 years was performed to examine the consequences of not benefiting from the total survival time of the C-Leg.

Treatment Strategies

The 2 treatment strategies under investigation were either fitting an active prosthetic user with an expected lifetime of more than 8 years with a C-Leg (C-Leg strategy) or fitting patients with an NMC knee appropriate for active patients (referred to as NMC knee strategy). When fitting patients with a C-Leg, the patients are provided with a prosthesis and guaranteed a working knee, given that the yearly maintenance of the knee is performed in accordance with the manufacturer's recommendations. This service plan is offered for 8 years, after which the prosthetist is recommended to change the knee for a new unit because the cost of retaining the guarantee for the ninth year is a quarter of that of a new knee. Accordingly, the lifetime of the knee in the C-Leg strategy was set to 8 years. In the NMC knee strategy, there is no equivalent yearly service available. In this strategy, the patients are given a knee that is used until it breaks. If the knee breaks, it is replaced by a new knee.

Model Structure

The model used to estimate cost and health outcomes of the 2 strategies under consideration consisted of a simple 2-state Markov structure (fig 1). The patients start in the "year 1 with prosthesis" state, either with a C-Leg or an NMC knee. If the knee does not break in the first cycle (year), patients are transitioned to the "year 2 with prosthesis" state. This procedure is repeated for all cycles as indicated in the figure. During any cycle, patients in the NMC knee strategy face a yearly probability of the knee breaking as indicated by the box in figure 1. The C-Leg is guaranteed to be functional for 8 years if maintained in accordance with the manufacturer's recommendation; hence, this probability was set to 0 for this strategy. If the

prosthesis breaks in the NMC knee strategy, the prosthesis is replaced, and a cost for the new knee is incurred. As can be seen in figure 1, patients then return to the “year 1 with prosthesis” state. Being in any treated with prosthesis state, the patients acquire costs and health outcomes depending on treatment strategy and the number of problems patients experience during a cycle, which is described in detail later.

Figure 1: Simplified model structure

The cycle length in the model was set to 1 year. This is a compromise between the increased detail the model would offer regarding the disease if using a shorter cycle length and the increased complexity of the model. Thus, given the progression of the current patients and the detail of the material available, 1 year seemed appropriate.

Data

Given the lack of evidence on cost and effects concerning transfemoral prostheses and the C-Leg, it was not possible to rely on previously published data to populate the model. Therefore, we collected data by interviewing patients with the C-Leg and their prosthetist. Hence, patient data and informed judgments were obtained on parameter values in the model. Although resulting in data more prone to bias than data from a clinical trial, it can be argued to represent the best available evidence to inform the decision at present.

Seven prosthetic clinics in southern Sweden and 12 clinics in Denmark providing patients with the C-Leg were contacted and asked to participate in the study. Three clinics in Sweden and 5 in Denmark agreed to participate. These clinics were then asked to identify patients based on the following inclusion criteria: unilaterally amputated, over the age of 18 years, having used the C-Leg for the past 6 months, and having used NMC knees recommended for active patients before the provision of the C-Leg. A total of 20 patients (14% of the C-Leg patients in the target population) were willing and able to participate in the study (table 1). The main reasons for having changed to the C-Leg were that the prior knee did not fully meet the needs of the patients, such as safety, durability, and negotiation of stairs. This also appears to be the regular prescription pattern among prosthetists; because of the higher initial cost of providing a patient with a C-Leg, it is only prescribed to patients when their needs are not fully met by NMC knees. Patients were interviewed, by using interview guides, to inform a number of predefined questions. Interviews were mainly performed in person (n=18), but in 2 cases interviews were performed by telephone. In these 2 cases, the questions and rating scales were sent to the patients by mail before the interview. To acquire further knowledge of the clinical consequences of using the C-Leg versus NMC knee, such as costs, fitting time, and service, 5 certified prosthetists were interviewed by using an interview guide. All

prosthetists had experience of providing patients with both the NMC knee and C-Leg. The mean experience among the prosthetists of providing the C-Leg was 5 years and equal or longer experience of providing NMC knees.

Table 1. Patient Characteristics	
Characteristics	Values
Age (y)	41.0±2.53
Sex (men/women)	20/14
Time since amputation (y)	16.0±2.6
Time with C-Leg (mo)	45.0±5.17
NOTE. Values are mean ± standard error (SE) or n.	

Transition Probabilities

Patients with an NMC knee face a yearly risk of the knee breaking and, thus, have to change to a new knee. To allow for the fact that this risk increases with time, this probability was incorporated in the model as a function of time elapsed since fitting the prosthesis. The probabilities were estimated by using a parametric time-to-event survival model with a Weibull distribution to the data of the estimated survival times of the NMC knee prosthesis.¹¹ The input for the Weibull regression was based on the interviews with the patients where they estimated the lifetime of an NMC knee based on their prior experiences with these knees. The mean survival time for the knee ± standard error was found to be 2.0±.18, which is in accordance with earlier findings.¹² The results of the Weibull regression indicated an increasing hazard of a prosthesis failure with respect to time elapsed because fitting the prosthesis as the ancillary gamma parameter was well above 1 (2.77±1.19). The constant in

the regression was $.11 \pm .69$. Applying appropriate formulas, the fitted hazard function was transformed to yearly probabilities of a prosthesis failure (fig 2).

Figure 2: Probability of prosthetic knee failure for the NMC knee.

Costs

The resources used that were associated with the different health states and transitions were obtained from the interviews with the prosthetists and from manufacturers of the prosthetic components. All costs were allocated to the cycle in which they occurred, and the mean costs used in the analysis are found in table 2. In both treatment strategies, the patients could encounter problems during a year at a rate dependent on whether the patients had a C-Leg or NMC knee. A problem was defined as the occurrence of a situation of malfunction of the knee resulting in the need for the patient to seek help from the prosthetist. The rates and the duration of the problem were elicited from the interviews with the patients (table 3). The

problems are associated with a cost and a decrement in QOL in the model. The additional costs acquired when having a problem were elicited from the interviews with the prosthetists (see table 2).

Table 2. Cost Parameters in the Model		
Cost Items	Mean $\pm$ SE	Distribution
Cost of C-Leg (€)	14,128 $\pm$ NA	Fix
Cost of foot for C-Leg (€)	690 $\pm$ 151	Normal
Production hours for C-Leg prosthesis	35.0 $\pm$ 2.5	Normal
Total cost of providing a patient with an initial C-Leg (€)	17,003 $\pm$ NA	NA
Cost of NMC knee (€)	2730 $\pm$ NA	Fix
Cost of foot for NMC knee (€)	1810 $\pm$ 85	Normal
Production hours for NMC knee prosthesis	34.0 $\pm$ 2.2	Normal
Total cost of providing a patient with an initial NMC knee (€)	6635 $\pm$ NA	NA
Prosthetist time when encountering a problem with C-Leg	3.5 $\pm$ 0.3	Normal
Prosthetist time when encountering a problem with NMC knee	4.5 $\pm$ 0.4	Normal
Cost per hour for a prosthetist (€)	62 $\pm$ NA	Fix
Abbreviation: NA, not applicable.		

Table 3. Utility and Problem Parameters in the Model		
Parameters	Mean Value	Distribution
Utility for patients with a functional C-Leg	0.83	β (11, 2)
Utility for patients with a functional NMC knee	0.53	β (13, 11)
Decrement in utility when having a problem	18%	γ (82.35, .01)
Number of problems per year with C-Leg	0.24	γ (9.98, .02)

Table 3. Utility and Problem Parameters in the Model		
Parameters	Mean Value	Distribution
Duration of problem for patients with C-Leg (y)	0.16	β (1.0, 5.6)
Number of problems per year with NMC knee	2.25	γ (8.27, 0.27)
Duration of problems for patients with NMC knee (y)	0.15	β (2.0, 12.4)

An additional cost in the C-Leg strategy is included because of the yearly service of the knee. The cost was estimated by using the yearly cost incurred by the manufacturer to service the knee and the time demanded by the prosthetist, as elicited in the interviews (table 4). The patients in the NMC knee strategy are using the knee until it breaks and are then fitted with a new knee. When changing the knee, only the cost of the new knee was added to the patients because this is assumed to coincide with a problem and would, therefore, not incur additional prosthetist time.

Table 4. Yearly Cost of C-Leg Maintenance				
Year	Service Fee (€)	Prosthetist Time (h)	SE	Total (€)
1	0	2	0.5	125
2	0	2	0.5	125
3	0	2	0.5	125
4	1292	2	0.5	1417
5	1292	2	0.5	1417
6	1938	2	0.5	2062
7	2153	2	0.5	2278
8	1292	2	0.5	1417

Utilities

The utility weights needed to calculate the QALYs in the analysis were obtained from the interview with the patients. The patients were asked to assess their current QOL and estimate their QOL given they had not had the C-Leg (see table 2). The rating scale in the EuroQol visual analog scale (VAS)¹³ was used for these assessments. Being provided with the EuroQol-VAS, respondents were asked to rate their current health state with the C-Leg. To obtain the utility rating of having an NMC knee instead of a C-Leg, the patients were asked to picture themselves in their current situation of life but using a prosthesis fitted with their prior NMC knee instead of a C-Leg. The rating for this hypothetical situation was assessed in the same manner as the rating of the current state by using EuroQol-VAS. Because of the potential bias of valuing previously experienced health states, we also let the prosthetists perform a proxy rating of the health state with and without the C-Leg as a validation exercise, but we did not use the values directly in the analysis. This resulted in a mean rating from the 5 prosthetists of .83 and .60 for the C-Leg state and the NMC knee state, respectively. To explore the influence of the uncertainty regarding the rating of QOL and the impact of this parameter on the result, the utility of both the C-Leg and the NMC knee patients was set equal at .83.

Similar to the assessment of the utility values when having a functional knee, the utility values for the periods when the patients had experienced a problem was assessed by asking the patients to rate their QOL when having a problem using the EuroQol-VAS. This was done for a C-Leg and an NMC knee. The mean utility value when experiencing a problem was $.68 \pm .06$ for the C-Leg strategy and $.42 \pm .06$ for the NMC knee strategy. The decrement of QOL if the patients experienced a problem in the model was set equal for both strategies (see table 3). During the yearly planned service of the C-Leg, the patients receive a replacement

knee and are, therefore, able to maintain their level of function and QOL; therefore, no utility decrement was assumed for this procedure. This assumption is not needed for the NMC knee strategy because the yearly service is not applicable.

Data Analysis

The results were calculated as the extra cost per QALY gained of a C-Leg strategy compared with an NMC knee strategy, known as the incremental cost-effectiveness ratio (ICER). The ICER is the ratio of the difference in costs between the 2 alternatives to the difference in health outcome (in this instance QALYs) between the 2 alternatives given by the following formula:

$$ICER = \frac{CostCleg - CostNMK}{EffectCleg - EffectNMK}$$

Thus, the ICER shows the mean incremental cost of gaining an extra QALY by using a strategy with a C-Leg rather than a strategy with an NMC knee.

According to recent guidelines, the model was analyzed by using second-order Monte-Carlo simulation to reflect uncertainty in the model inputs.¹⁴ With this approach, values are drawn randomly from defined probability distributions in the model (see Table 2 and Table 3), and costs and QALYs are established for both strategies. This process is repeated 5000 times, providing 5000 estimates of the ICER, which reflects the uncertainty in the outcome. The uncertainty surrounding the estimated ICER also reflects the uncertainty in the decision of using a C-Leg strategy rather than an NMC knee strategy. The proportion of the 5000 simulations that result in an ICER below the threshold value that decision-makers are willing

to pay for a QALY is the probability of the C-Leg being cost-effective.¹⁵ Because there is no single true willingness to pay for a QALY, this probability can be presented for a range of willingness-to-pay values in so-called cost-effectiveness acceptability curves. These curves make it possible for the decision maker to establish the willingness to pay in a specific application and then assess the probability that the treatment strategy is cost-effective.

Because of our method for collecting parameter values being more prone to bias than prospectively collected data, we performed 1-way sensitivity analyses for all parameters and three 2-way sensitivity analyses with parameters fixed at their 99th percentile value most unfavorable to the C-Leg in addition to the probabilistic sensitivity analysis. By performing these analyses, the impact of individual parameter values on the result can be shown because this may be less evident in the probabilistic analysis. However, it should be remembered that the probability of the values applied in these analyses, given the characterized uncertainty in the probability distributions, is very low (1%). Therefore, these analyses should be seen mainly as illustrative because the uncertainty in the decision to adopt the C-Leg given current evidence is appropriately described by the results from the probabilistic analysis.

Results

The analysis resulted in a mean incremental cost for the C-Leg of €7657 and 2.38 incremental QALYs gained, yielding a cost per QALY gained of €3218 (table 5). The uncertainty surrounding the cost-effectiveness of a C-Leg strategy is shown in the cost-effectiveness acceptability curve (fig 3). For instance, if the decision-maker has a willingness to pay €10,000 per QALY, the probability of C-Leg being cost-effective is 93%.

Table 5: Results

	Total cost per patient (€)	Effectiveness, QALY	Incremental cost per patient (€)	Incremental effectiveness QALY	Incremental cost/QALY (€)
C-leg	25,146	5.98	7657	2.38	3218
NMK	17,488	3.60

Figure 3 Cost-effectiveness acceptability curve for the C-leg strategy

Sensitivity scenarios

The sensitivity scenarios performed did not result in cost-effectiveness ratios that substantially would change the estimated cost-effectiveness of the C-Leg strategy. However, the QOL associated with each prosthesis during the year appeared to have some impact on the cost-effectiveness. When analyzing the scenario with equal QOL of .83 for both treatment strategies, the resulting cost per QALY was €23,524. The uncertainty coupled with the scenario is presented in figure 3. Despite this rather unfavorable assumption, the C-Leg is still below general acceptable thresholds of cost-effectiveness. The scenarios with a time horizon of 1 year and 4 years resulted in a cost per QALY of €30,311 and €5814, respectively. The results from the 1-way sensitivity analyses (table 6) revealed that the only single parameters influencing the results of the analysis to some degree were the utility value associated with

using 1 of the 2 knee alternatives. However, they did not alter the result of the C-Leg being cost-effective using conventional values for willingness to pay for a QALY. The 2-way sensitivity analyses did not alter the ICER to such an extent that the decision would be altered, except for the analysis using the low 99th percentile QALY value for the C-Leg and the low 99th percentile value for number of problems with NMC knee yielding a high ICER (see table 6).

Table 6. Parameter Impact				
Parameter	Parameter Values	Incremental Cost	Incremental QALY	ICER
Utility NMC knee	.75	7656	.87	8837
Utility C-Leg	.54	7698	.28	27,761
Utility NMC knee and problem NMC knee	Utility .75	10,550	.64	16,400
	Problem .83			
Utility C-Leg and problem C-Leg	Utility .54	7999	.25	32,453
	Problem .45			
Utility C-Leg and problem NMC knee	Utility .54	10,550	.14	77,121
	Problem .83			

Discussion

The results of this study show that using the C-Leg rather than an NMC knee is associated with a cost per QALY of €3218. To gain QALYs at such a low cost would in most instances be seen as a good use of resources in the health care sector. Needless to say, the analysis comprises several caveats that should be considered when interpreting the results. Our results are to a large degree based on informed judgments that can be seen as suboptimal in relation to performing a clinical trial investigating the effectiveness of using the C-Leg instead of the NMC knee. This information is not available at present and is unlikely to become available in the near future. However, the decision of whether to support the use of the C-Leg is still highly present, and, as argued previously, we believe that it is better to try and use the current available information to inform the decision than to assume that nothing at all is known about this decision problem. One advantage with this approach is that the analysis can easily be updated should more evidence become available. Because all parameters in the model are defined with probability distributions, the uncertainties surrounding these are also reflected in the results. As shown in the cost-effectiveness acceptability curve, there was a high probability of the C-Leg being cost-effective even for willingness to pay values well below conventional thresholds. However, such an analysis only considers statistical uncertainty surrounding the model input but does not relate to structural uncertainty, such as the omission of important events or cost items in the model. Given the relatively sparse amount of data available, such an uncertainty is likely to be higher than if more information had been available from clinical trials. One issue of structural uncertainty that was investigated was the analytic choice of a time horizon of 8 years instead of a lifetime perspective as generally advocated in cost-effectiveness analysis. This assumption runs the risk of favoring the C-Leg strategy. The uncertainty introduced is because of the fact that all patients given a C-Leg will

have the possibility to use the C-Leg all 8 years and, thus, get the most benefit out of the initial cost. We believe that an analysis over a lifetime perspective would not be correct because these type of knees are most likely not applicable for the patients' remaining lifetime. When choosing to provide a patient with this knee type, the prosthetist still has to take the patient's possibility to use the knee for the survival time into account. The structural uncertainty induced by the time horizon of 8 years was investigated in 2 scenarios (1y, 4y) instead of the 8 years used in the base-case analysis. With these time horizons, none of the C-Leg patients would benefit optimally from the functional time of the C-Leg. However, this did not lead to results that would change the conclusions. The cost per QALY was only marginally higher in the 4-year case, whereas the 1-year scenario must be seen as a definitely worst case for the C-Leg (still the ICER was not unacceptably high).

Furthermore, it could be argued that our method of collecting the utility weights for calculating the QALYs might be biased toward the C-Leg because the patients are currently using the C-Leg and, therefore, might favor this in their rating. C-Leg users might only remember the negative aspects of their prior knee units; the C-Leg might have been introduced because patients were unsatisfied with their prior knee unit and so forth.¹⁶ The variances of the utility weights have, as suggested earlier,⁵ been increased in the model compared with the measured variance in an attempt to reflect this additional uncertainty in the analysis. However, the similarity between patient and proxy ratings done by the prosthetists strengthens the belief in the values used in the analysis. It should be noted that the results from the scenario in which equal utility for both the C-Leg and NMC knee was used showed that the C-Leg would still be considered cost-effective for conventional values of willingness to pay, although coupled with higher uncertainty (see fig 3). A reason for this finding is the fact that not only is the C-Leg offering the patient a better life per se, but it is also coupled with a considerably lower rate of problems compared with the use of an NMC

knee. This aspect has received little attention in previous research and might be an area of further investigation. A further implication that this finding highlights is the importance of manufacturers of prosthetic components taking the reliability of the components and the ease of use for the patient into account. The positive results that we found in QOL when using the C-Leg is also in accordance with the previously published articles finding the C-Leg to have a positive effect on parameters such as gait speed, energy consumption, and cognitive performance, which most likely also contribute to a higher QOL for the patient.

Similar to the risk of bias described regarding elicitation of the utilities, this risk of bias can of course be argued to be true even for the rates and duration of problems and the survival of the NMC knee. However, when assessing these parameters, the patients had more objective memories to refer to because they are more likely to remember the number of times changing knees and how often they had to seek help at the prosthetic clinic to resolve these problems with their prosthesis. The lower numbers of problems stated by the patients when fitted with a C-Leg compared with the NMC knee strategy are also strengthened by utterance from the prosthetist confirming this decreased rate of problems. As for the mean lifetime of an NMC knee elicited in the interviews, this was pointed out in accordance with previous findings from laboratory testing.¹² It was evident from the 1-way sensitivity analyses that these values alone are not likely to change the cost-effectiveness of the C-Leg. However, should the true values for the number of problems when having an NMC knee and the utility for the C-Leg simultaneously turn out to be in the low 99th percentile region, the C-Leg would not be deemed cost-effective. One should bear in mind though that, from the current observed material, this is highly unlikely to occur.

Conclusions

In this article, we have argued for the importance of providing decision makers with relevant information on costs and health outcomes of different treatment strategies on actual decision problems even when there is only limited information available. We have provided an example in which costs and a broadly defined health outcome in terms of QALYs have been estimated, showing that the C-Leg appears to yield positive health outcomes at an acceptable cost. As pointed out in the discussion, the proposed framework and empirical analysis are not without criticism. However, we believe that the advantages of this approach, especially in the area of devices in which the regulatory framework of, for instance, pharmaceuticals, is mostly lacking, are greater than the disadvantages. It is important to remember that the alternative to using an approach in which the currently available evidence is synthesized in a clear and transparent manner is implicit decision making with little or no information about the rationale for decisions. The present analysis shows that such an approach might have led to many patients not receiving a C-Leg, despite the fact that it appears to be cost-effective.

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