The St. Leger total knee replacement: a false economy
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The St. Leger total knee replacement (TKR) was compared with the Kinemax Plus TKR for patients with osteoarthritis. The St. Leger TKR is a posterior cruciate retaining total condylar knee replacement.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with osteoarthritis who had undergone TKRs.

Setting
The setting was tertiary care (a teaching hospital). The economic study was carried out in Bristol, UK.

Dates to which data relate
The effectiveness evidence was collected from 1993 to 1996 for the Kinemax Plus TKR group, and from March 1995 to February 1997 for the St. Leger TKR group. The dates for the resources and prices used were not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
The St. Leger group was a single surgeon cohort of patients compared with the Kinemax Plus group, which was performed by two other surgical teams. Age- and gender-matched patients with primary Kinemax Plus TKRs were selected and compared with the St. Leger group. Power calculations were not reported.

The St. Leger group had a total of 53 TKRs in 47 patients. Thirty-four patients with 38 St. Leger TKRs were able to complete the Oxford Knee Score questionnaire. The mean age at operation for this group was 74.0 years (range: 62 - 82). The Kinemax Plus group had a total of 53 TKRs in 49 patients. Thirty-six patients with 38 Kinemax Plus TKRs were able to complete the Oxford Knee Score questionnaire. The mean age at operation for this group patients was 73.7 years (range: 62 - 85).
Study design
This was a single-centre, retrospective, observational study (cohort study). The mean follow-up was 70.32 months for the St. Leger group and 81.57 months for the Kinemax Plus group. No blinding method for the outcome assessment was reported.

In the St. Leger TKRs, 4 patients (4 TKRs) were lost to follow-up and 13 were either dead or too demented to comply. In the Kinemax Plus TKRs, 2 patients (2 TKRs) were lost to follow-up and 11 patients (13 TKRs) were either dead or too demented to comply.

Analysis of effectiveness
The primary health outcomes assessed were the Oxford Knee Scores, the mortality rate and the rate of revision. All of the patients were contacted by post and asked to complete the Oxford Knee Score questionnaire, as the score shows the patient’s perception of what entails a lifestyle altering operation. The Oxford Knee Score is a 12-item simple and validated questionnaire, designed as a measure of outcome for TKR. A knee that was minimally painful and did not disable the patient would receive a score of 12. A knee that the patient believed to be maximally painful and disabling would receive a score of 60. Any patients who failed to respond to the initial postal questionnaire were contacted by telephone, and then completed the questionnaire verbally.

In addition to the questionnaire, the patients were asked to say whether they had any further operations on their knee after their primary knee replacement. Those patients who stated that they had had, or were due to have further operative procedures on their knee had their clinical notes reviewed. The authors stated that the groups were comparable at baseline in terms of age at operation, gender and diagnosis, although details were not reported. Adjustments for confounding factors were not reported.

Effectiveness results
The mortality in the St. Leger and Kinemax groups was comparable (24% versus 28%).

The mean Oxford Knee Score was 32.03 (range 15 - 52; standard deviation, SD=11.61) for the St. Leger group and 28.27 (range 12 - 48; SD=10.29) for the Kinemax Plus group. Although the St. Leger group had worse Oxford Knee Scores, this difference was not statistically significant.

Using revision as an end point and including all patients except those lost to follow-up, the cumulative survival rate was 100% for the Kinemax group and 91.2% for the St. Leger group. Three St. Leger knees were revised. All of these revisions were for persistent knee pain that improved after revision. Amongst surviving knees there was a trend towards superior results in the Kinemax group, however this was not significant. There was a significant difference in the rate of revision between the two groups, (p<0.005).

Clinical conclusions
This study showed that Oxford Knee Scores were not significantly different between the prostheses, and that the St. Leger device had a significantly worse survival rate.

Measure of benefits used in the economic analysis
No summary measure of benefit was used. The cost and effects were left disaggregated and the study was therefore classified as a cost-consequences analysis.

Direct costs
The direct costs included the mean price for a primary Kinemax Plus TKR and St. Leger TKR operations, and the mean price for a revision TKR. Discounting was not carried out, although it was appropriate as revision TKR occurred several years after the initial TKR. The quantities and the costs were not analysed separately. The quantities and costs were
estimated from actual data. Prices were used instead of costs and these were taken from the North Bristol NHS Trust database. The dates for resources used and the price year were not reported.

**Statistical analysis of costs**
No statistical tests were reported. The authors reported the mean values of each group, but no variability estimate (such as the SD or interquartile range).

**Indirect Costs**
The indirect costs were not included.

**Currency**
UK pounds sterling (GB£).

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The mean cost to the North Bristol NHS Trust for a primary Kinemax Plus TKR operation was approximately 7,500. The mean cost of the St. Leger group was not reported.

The mean cost for a revision TKR was approximately 11,000.

The St. Leger group of patients cost approximately 33,000 more than the Kinemax Plus group of patients. The cost-saving of prosthesis was 26,500.

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors' conclusions**
The St. Leger group had non significantly inferior Oxford Knee Scores than the Kinemax group and significantly worse survivorship of the prosthesis. Although the St. Leger prosthesis was cheaper (650) than the Kinemax (1,150), the initial saving was dwarfed by the ultimate cost of revision procedures.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the comparator used. It reflected standard practice in the authors' setting. You should judge whether these procedures are relevant in your setting, or whether other comparators from other techniques and TKRs modalities could also have been relevant.

**Validity of estimate of measure of effectiveness**
The analysis was based on a convenience retrospective sample, which might have led to bias and limitations in the validity of the comparison between groups. For example, there might have been confounding factors affecting the results obtained because of different cointerventions associated with time. Appropriate statistical analyses were not
undertaken to ensure comparability of the patient groups. Since no significant clinical differences were detected in mean Oxford Knee Score and surviving knees (which were the primary outcomes of the study), concerns about sample size and power are important. Moreover, the authors did not provide evidence that the study sample was representative of the study population, which may limit the external validity of the study. The study represented a single surgeon’s experience with St. Leger TKRs, which also limits the extrapolation of the results to other settings.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
The cost analysis was performed from the perspective of a single provider. Although not stated, some relevant costs were omitted from the analysis, such as those associated with complications, or hidden medical, laboratory or radiographic costs. If side effects were similar between the groups, their omission is unlikely to have affected the authors’ conclusions. The costs and the quantities were not reported separately. This will hamper the extrapolation of this analysis to other settings. No statistical or sensitivity analyses of the quantities and prices were carried out, thus limiting the generalisability of the results. The price year was not reported, which will prevent any future reflation exercises. Discounting was not carried out even though revision TKR costs were assessed over more than two years.

**Other issues**
The authors reported "survivorship figures for the Kinemax Plus group of patients are comparable to other published series of the Kinemax", but no further details were reported. The issue of generalisability was not explicitly addressed, but the fact that the authors carefully chose the diagnoses and patients implied that the results of the study should be considered only for these types of patients. The authors appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors stated one limitation of their study in that the lack of preoperative Oxford Knee Scores in either group meant that it was impossible to quantify the degree of improvement that the patients derived from their operations.

**Implications of the study**
This study showed that substituting one total condylar knee replacement for a similar prosthesis did not ensure that the results with the new prosthesis would be similar. The authors did not make any specific recommendations for changes in policy or practice and/or the need for further research. An adequately powered, prospective, randomised controlled trial associated with an economic evaluation is needed to confirm the results of this study.

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None stated.

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**Other publications of related interest**
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