Cost-effectiveness of the AMOArray multifocal intraocular lens in cataract surgery

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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
Two approaches for bilateral cataract surgery were examined, foldable AMOArray multifocal intraocular lens (IOL) versus foldable monofocal IOL.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing bilateral cataract surgery. Patients with eye diseases, other than cataract, that might limit postoperative vision were excluded.

Setting
The setting of the study was outpatient care. The economic study was carried out in Germany.

Dates to which data relate
The effectiveness evidence was gathered in 1995. The data on resource use were collected, in part, in 1995. The price year was 1998.

Source of effectiveness data
The effectiveness evidence was derived a single study, the details of which were published elsewhere (see Other Publications of Related Interest).

Link between effectiveness and cost data
The costing was, in part, carried out retrospectively on the same sample of patients included in the effectiveness study.

Study sample
Power calculations to determine the sample size were performed (apparently in the preliminary phase of the study). These suggested that a sample of 99 patients in each group was required to detect a 0.4 difference in mean scores between the two groups with 80% power and at a 5% level of significance. All of the patients who underwent bilateral implantation of the multifocal IOL were eligible for the study. Of the 126 patients identified, 110 (87%) agreed to participate and were enrolled in the study. A comparison group of 142 patients, who were implanted bilaterally with a monofocal IOL at the same sites as the multifocal patients, met the study criteria and were invited to participate as a control group. Of these, 112 agreed to participate. Reasons for refusal were not stated.
Study design
The authors stated that a retrospective case-control study was conducted, although it could be more appropriately described as a retrospective cohort study. It was carried out in nine centres across the USA. Trained interviewers, who were masked to whether the patient had multifocal or monofocal IOLs implanted, contacted the patients. No follow-up was conducted. However, 10 patients in the multifocal group could not be contacted despite multiple attempts, and 9 patients in the monofocal group were not available because of either subsequent refusal (n=3) or they could not be contacted (n=6).

Analysis of effectiveness
Only patients who were successfully contacted were included in the analysis. Several outcome measures were estimated in the primary study, but only those relevant to the present economic analysis will be reported here, namely:

the percentage of spectacle-free patients;

self-rated quality of vision;

self-rated degree of satisfaction with vision without spectacles (day and night vision); and

self-rated limitation in vision-related function (overall limitation in vision without spectacles, night driving with or without spectacles, and glare, halos, rings with or without spectacles).

Satisfaction and limitation with vision were estimated on a scale of 0 ("not all satisfied" or "no limitation") to 4 ("extremely satisfied" or "extremely limited"). Quality of vision ranged from 0 to 10. The Cataract Type Specification was used to estimate visual-related functional status. The outcomes were converted to percentages by expressing the mean score as a percentage of the maximum score. The study groups were comparable at baseline in terms of the major demographic characteristics. However, a significantly higher percentage of patients in the multifocal group achieved 20/30 or better uncorrected visual acuity in at least one eye (96.9% versus 78.5%), (p<0.001).

Effectiveness results
The percentage of spectacle-free patients was 41% in the multifocal IOL group and 11.7% in the monofocal IOL group.

For vision without spectacles, 90% of multifocal IOL patients had a maximum score for self-rated quality of vision versus 79% of monofocal IOL patients. The corresponding values for vision with best correction were 93% (multifocal) and 87% (monofocal), respectively.

For day vision, 90% of the multifocal IOL patients had a maximum score for self-rated degree of satisfaction with vision without spectacles versus 72.5% of monofocal IOL patients. The corresponding values for night vision were 82.5% (multifocal) and 70% (monofocal), respectively.

The percentage of patients with a maximum score for self-rated limitation in vision-related function was: 7.5% (multifocal) versus 20% (monofocal) for overall limitation in vision without spectacles;

20% (multifocal) versus 13.3% (monofocal) for night driving without spectacles;

8.8% (multifocal) versus 2% (monofocal) for night driving with spectacles;

37.5% (multifocal) versus 7.5% (monofocal) for glare, halos, rings without spectacles; and

35% (multifocal) versus 2.5% (monofocal) for glare, halos, rings with spectacles.

Clinical conclusions
The effectiveness results showed that spectacle-free patients and self-rated quality of vision were better with multifocal IOL than with monofocal IOL. However, some limitations in visual-related function were observed in the multifocal IOL group.

**Measure of benefits used in the economic analysis**
The benefit measures were the percentages of spectacle-free patients, patients without overall limitation in vision-related function without spectacles, patients without limited night vision (without spectacles), and patients without glare, halos or light rings (without spectacles). These were derived from the effectiveness study.

**Direct costs**
Discounting was not relevant since the immediate surgery-related costs were incurred over a short timeframe. The quantities of resource use were analysed separately from the unit costs. All of the calculations in the economic analysis were detailed in an appendix to the article. The health services included in the economic evaluation were drug therapy, consultations, diagnostic and therapeutic procedures, and surgery. The quantity/cost boundary adopted in the study was that of the German health care payer. The source of the cost data was not reported for each item, but the authors stated that German tariffs were used. The total costs of the two interventions were estimated using a "bottom upward" approach. It was assumed that surgery was carried out on an outpatient basis. The resource use data were partially derived from the primary study used in the effectiveness analysis and from the authors' assumptions. The number of spectacles required after surgery represented the most uncertain variable, as it depended on the visual function achieved after surgery. Thus, three scenarios (worst case, base-case, and best case for multifocal lens) were considered. The price year was 1998.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not considered because the authors assumed that all the patients were past the age of retirement.

**Currency**
German marks (DM).

**Sensitivity analysis**
Sensitivity analyses were not explicitly carried out. However, the issue of variations in the data was addressed by considering three alternative scenarios.

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

**Cost results**
The total average costs per procedure were:

- DM 1,773.89 for multifocal IOL and DM 1,716.33 for monofocal IOL under the base-case;
- DM 1,815.49 for multifocal IOL and DM 1,832.66 for monofocal IOL under the best case; and
- DM 1,732.30 for multifocal IOL and DM 1,600.01 for monofocal IOL under the worst case.


**Synthesis of costs and benefits**

Average and incremental cost-effectiveness ratios were calculated to synthesise the costs and benefits of the two interventions.

The average cost per spectacle-free patient was DM 4,327 with multifocal IOL and DM 14,669 with monofocal IOL.

The cost per patient without overall limitation in vision-related function (without spectacles) was DM 1,918 with multifocal IOL and DM 2,145 with monofocal IOL.

The cost per patient without limited night vision (without spectacles) was DM 2,217 with multifocal IOL and DM 1,978 with monofocal IOL.

The cost per patient without glare, halos or rings around lights (without spectacles) was DM 2,838 with multifocal IOL and DM 1,855 with monofocal IOL.

The authors stated that similar results were found in the worst- and best-case scenarios.

In the incremental analysis, when comparing multifocal to monofocal IOL, the incremental cost-effectiveness ratio reported was the cost of the multifocal per additional outcome. The multifocal IOL cost an additional DM 196 for each additional spectacle-free patient.

For a 1-point increase in self-rated score for quality of vision, the additional cost would be DM 52 for day vision without spectacles and DM 96 for night vision without spectacles.

For a 1-point increase in self-rated score for satisfaction with vision, the additional cost would be DM 82 for day vision without spectacles and DM 115 for night vision without spectacles.

For self-rated scores for limitations in vision from glare, halos and light rings (without spectacles), the multifocal IOL was dominated by the monofocal lens (the monofocal procedure cost less and fewer patients experienced limitations in these areas).

Results favourable to multifocal IOL were observed in the best-case scenario, while incremental costs per additional benefit measure were found in the worst-case scenario.

**Authors’ conclusions**

The use of the multifocal intraocular lens (IOL) implied a small additional cost relative to monofocal IOL, but patient satisfaction was far higher. However, it was noted that some sub-groups of patients (professional night drivers and astigmatic individuals) might not benefit from the implantation of multifocal IOL.

**CRD COMMENTARY - Selection of comparators**

The choice of the comparator was not explicitly justified. However, in the primary study used to estimate the effectiveness evidence, it was stated that the interventions were two currently used options for patients undergoing cataract surgery. You should decide whether they represent valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**

The analysis of effectiveness used a retrospective study. Wide inclusion criteria were used to select the group of patients, thus the study sample appears to have been representative of the study population. The patients were generally comparable at baseline and the data came from multiple centres. Statistical tests were performed to enrol an appropriate number of patients for the detection of statistically significant differences in the main outcome measures. Only patients who completed the study were taken into account in the analysis. Reasons for initial refusal were not reported. The retrospective design of the analysis could represent a drawback of the study. Selection bias and confounding factors may also have played a role due to the lack of randomisation in allocating the patients to the study.
groups. These issues may limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**
The benefit measures were estimated directly from the effectiveness analysis and were disease-specific measures. Thus, there could be some problems when comparing the benefits of the interventions evaluated in the present study with those associated with other health technologies.

**Validity of estimate of costs**
The perspective adopted in the study was explicitly stated. It appears that all the relevant categories of costs have been included in the analysis. Details of how the total costs were calculated were provided. Accordingly, the unit costs and the quantities of resource use were reported separately, and the price year was given. This simplifies the replication of the study in other settings. The costs were treated deterministically and the source of the unit costs was not reported. The cost estimates were specific to the study setting, but three scenarios based on different quantities of the main cost driver (number of spectacles) were considered. This represented an alternative method of performing a sensitivity analysis. The authors made some assumptions to estimate resource use.

**Other issues**
The authors stated that the effectiveness results obtained in the primary study used to provide data were similar to other published studies. However, the economic results were not compared. The issue of the generalisability of the study results to other settings was implicitly addressed when three scenarios for resource use were considered. Further, details of the cost analysis were provided. However, standard sensitivity analyses would have been more useful to ensure the external validity of the study. The authors noted some limitation of their analysis and discussed the potential advantages and disadvantages of the two interventions under evaluation.

**Implications of the study**
The study results suggest "good patient education and appropriate patient screening prior to surgery will ensure that patients have realistic expectations and the most suitable technology will be used".

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**Other publications of related interest**

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