| TABLE 55 Total mean costs and total mean QALYs for the medical management and surgery groups according to ITT |  |
|---|--|
| and PP at 1 year for the complete case  |  |

|                    |                              | PP at 1 year          |          |          |
|--------------------|------------------------------|-----------------------|----------|----------|
|                    | Treatment<br>allocated (ITT) | Medical<br>management | Surgery  | Total    |
| Total costs        | Medical                      | £1201.61              | £3718.18 | £1316.00 |
| Total QALYs        | management                   | 3.5665                | 2.6076   | 3.5229   |
| Number of patients |                              | 84                    | 4        | 88       |
| Total costs        | Surgery                      | £989.06               | £3525.38 | £2981.89 |
| Total QALYs        |                              | 3.7016                | 3.7447   | 3.7354   |
| Number of patients |                              | 18                    | 66       | 84       |
| Total costs        | Total                        | £1164.10              | £3536.40 | £2129.57 |
| Total QALYs        |                              | 3.5904                | 3.6797   | 3.6268   |
| Number of patients |                              | 102                   | 70       | 172      |

Note: cells highlighted by shading refer to PP at 1 year groups considered for the incremental analysis.

## TABLE 56 Health-related quality of life (EQ-5D) according to PP analysis

| Completed questionnaires returned at each time point |   |           | Mean (SD) EQ-5D |                       |   |
|--|---|-----------|-----------------|-----------------------|---|
| Surgery<br>(n = 178ª)                                | Medical<br>management<br>( <i>n</i> = 179ª) | Follow-up | Surgery         | Medical<br>management | Difference in mean<br>EQ-5D (surgery–medical<br>management) (95% Cl) <sup>b,c</sup> |
| 108  | 162   | Baseline  | 0.7184 (0.2394) | 0.7266 (0.2553)       | –0.0082 (–0.0691 to 0.0528)   |
| 108  | 143   | 3 months  | 0.8059 (0.2393) | 0.6910 (0.3068)       | 0.1148 (0.0446 to 0.1851)   |
| 102  | 153   | Year 1    | 0.7773 (0.2323) | 0.7064 (0.2703)       | 0.0709 (0.0065 to 0.1353)   |
| 83   | 129   | Year 2    | 0.7903 (0.2442) | 0.7170 (0.3133)       | 0.0733 (-0.0068 to 0.1532)  |
| 89   | 127   | Year 3    | 0.7897 (0.2521) | 0.7563 (0.2492)       | 0.0336 (-0.0356 to 0.1018)  |
| 88   | 122   | Year 4    | 0.7785 (0.2636) | 0.7550 (0.2678)       | 0.0236 (-0.0498 to 0.0969)  |
| 87   | 110   | Year 5    | 0.7771 (0.2812) | 0.7654 (0.2782)       | 0.0117 (-0.0674 to 0.0908)  |

a *n* refers to number of patients originally randomised to each trial arm.

b Cls estimated using OLS regression.

c Unadjusted for baseline EQ-5D.

## TABLE 57 Costs associated with resource use for PP analysis

| Returned questionnaires in each<br>year  |                       | Mean (SD) resource-use cost (£)<br>according to PP at 1 year |                   | Incremental mean             |  |  |
|--|-----------------------|--|-------------------|------------------------------|--|--|
| Surgery                                  | Medical<br>management | Year   | Surgery           | Medical<br>management        | cost (surgery–medical<br>management) (95% Clª) (£) |  |
| 104                                      | 154                   | 1 <sup>b</sup>   | 3241.78 (1263.80) | 361.28 (668.12)              | 2880.50 (2634.08 to 3126.91)                       |  |
| 86                                       | 133                   | 2  | 82.57 (373.46)    | 159.80 (366.76)              | -77.23 (-177.98 to 23.51)                          |  |
| 92                                       | 128                   | 3  | 79.80 (349.15)    | 289.27 (913.00)              | -209.47 (-406.78 to -12.15)                        |  |
| 88                                       | 124                   | 4  | 96.49 (368.53)    | 314.70 (1362.96)             | -218.21 (-512.14 to 75.72)                         |  |
| 90                                       | 112                   | 5  | 43.17 (133.98)    | 233.60 (645.33)              | -190.43 (-326.93 to -53.93)                        |  |
| Cost category                            |                       |  |                   |                              |  |  |
| Surgery in year 1                        |                       | 2780.73 (1756.83)  | 0 <sup>c</sup>    | 2780.73 (2704.69 to 2856.76) |  |  |
| Reflux-related hospital night admissions |                       | 403.07 (1305.30)   | 315.49 (833.69)   | 87.58 (-242.21 to 417.37)    |  |  |
| Reflux-related hospital day admissions   |                       | 159.78 (423.32)  | 231.64 (608.67)   | -71.86 (-236.56 to 92.84)    |  |  |
| Reflux-related GP visits                 |                       | 130.93 (940.68)  | 193.31 (465.70)   | -62.37 (-176.00 to 51.26)    |  |  |
| Medication                               |                       | 87.69 (217.69)   | 383.01 (525.63)   | -295.32 (-424.17 to -166.47) |  |  |

a Cls estimated using OLS regression.

b Refers to the patients who returned the final year 1 questionnaire.

c By definition, none of the medical management patients in PP underwent surgery.