Correspondence

Diabetic maculopathy

To the Editor of the *British Journal of Ophthalmology*

Sir,—Rubinstein and Myska's article on the treatment of Diabetic Maculopathy (*Brit. J. Ophthalmol.* (1974) 58, 76) is important because of the implications of their results.

There are however grave shortcomings in the factual information given in the paper. These weaken and may even invalidate the conclusions. The most important ones are enumerated below:

- (1) While we are told that the 'worse' eye was treated in each pair of eyes, at no time were we told what criteria were used for the assessment.
- (2) In maculopathy one would have expected the visual acuity to be regarded as the most important criterion, and yet only seven treated eyes had visual acuity less than 6/60 (Table I) while there were at least sixteen such eyes in the untreated group (p. 81, Results). Alternatively, the ophthalmoscopic and fluorescein appearances may have been used, but assessment of these is highly subjective unless a strict grading system is employed; no such system is described here.
- (3) It was difficult to match the conclusions with the evidence presented, *e.g.* the Summary states: '... 38.8 per cent of treated eyes remain unchanged including nine eyes with pre-operative visual acuity below 6/60'. Yet in Table I only seven treated eyes had such poor vision.
- (4) The question of the 'control' group is of fundamental importance in all clinical trials. If the physician's decision is taken to treat the eye with the better or worse vision and leave the other one as untreated control he assumes that the group of poor and good vision eyes are equivalent. Ederer and Hiller (1974) have found that, in patients with diabetic retinopathy, vision deteriorates more rapidly in untreated eyes with good vision than with poor vision. If this is true, and Rubinstein and Myska selected their patients on the basis of visual acuity they have biased their trial in favour of treatment.

Because the design of a clinical trial requires that the treated and untreated eyes be equivalent on the average, allocation of eyes to each group by the ophthalmologist in charge cannot be employed.

The National Trial on Photocoagulation, sponsored by the British Diabetic Association, is a truly randomized trial, and therefore the only type of trial which can give a valid evaluation of treatment for diabetic retinopathy. It is sad that Rubinstein and Myska who have contributed so much to the treatment of diabetic retinopathy did not submit their patients to the National Trial or at least select the eye for treatment by a randomization procedure.

Yours faithfully,

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Reference

EDERER, F., and HILLER, S. (1974) *Amer. J. Ophthalmol.* (in press)

To the Editor of the *British Journal of Ophthalmology*

Sir,—In reply to Miss Kohner's letter, our comments are as follows:

- (1) The principal factor in classifying an eye "better" or "worse" than its fellow eye was a better

or worse visual acuity. In only 9 patients of our series was the visual acuity the same in both eyes; an eye was assessed as "worse" on the grounds of a combination of the greater severity of macular changes (*e.g.* degree of oedema), and the potential threat to the macula from encroaching vessels, hypoxic areas, or hard exudates. A comparison of preoperative visual acuity of treated *v.* untreated eyes may help:

Visual acuity	6/5	6/6	6/9	6/12	6/18	6/24	6/36	6/60 or less
Untreated	13	14	16	15	12	10	5	18
Treated	1	4	15	19	18	6	17	23

(2) and (3) There were regrettably four errors in the original typescript and one printer's error; these should be amended as follows:

- p. 81 Results, 1.9 For 'sixteen of these had vision 1/60 or worse', read '6/60 or worse'
 p. 82 Table IV Title. For '5 years' read '4 years'
 Footnote. For '1/60' read '6/60'
 p. 84 Table V Footnote. For ' $\chi^2 = 156.08$ ' read '56.68'
 Summary, 1. 13. For 'nine' read 'seven'.

Our attention was only recently drawn to these and we hope that Miss Kohner and the readers of the Journal will accept our apology.

(4) Regarding these questions, we do not apologize. The choice of the worse eye for treatment was deliberately made to load the trial against the favourable results, and it seems to have done so: apart from the 9 patients with identical visual acuity in each eye, there were a further 29 patients with visual acuity within 1 Snellen line difference between the two eyes. In this combined group of 38 patients, however "biased" the choice, the paired eyes were nearly equal anyway. The effect of treatment (as assessed by visual acuity change) was as follows:

Result	Better	Same	Worse	Total
Treated	22 (58%)	10 (26%)	6 (16%)	38
Untreated	2 (5%)	8 (21%)	28 (74%)	38

This frequency distribution submitted to chi-squared analysis (Yates' correction applied) gives $\chi^2 = 28.1$; $n = 2$; $P \ll 0.0005$. Would Miss Kohner please compare these figures with Table V of our paper.

We are not impressed by suggestions that the worse maculopathy carries a better visual prognosis than a lesser one (? any statistics). That is contrary to our clinical experience, and spontaneous improvement of diabetic maculae is so rare as to warrant publication of single cases. We tried but were unable to trace the source of this rumour; now Miss Kohner gives us a reference—but, alas, still in press. No doubt the contents of the article referred to are known to her, although oddly enough she qualifies her statement by saying that "if this is true" we biased our trial of treatment in the wrong direction. If it is true—yes—but is it?

Miss Kohner's postscript refers to the Multi-centre Trial sponsored by the B.D.A. We are sorry that we saddened her by contributing to this trial in a small degree only. There were, however, good reasons for that. We planned and commenced our trial of maculopathy treatment before the Multi-centre Trial came off the ground. Our considerable previous experience with photocoagulation seemed favourable and on ethical grounds randomization of patients was not acceptable; neither was randomization of eyes apart from cases of identical bilateral involvement. These—we knew—would

be few and indeed only 9 were seen during *all* the 4 years. We also considered the Pro-forma 4 of the Multi-centre Trial relating to surgical techniques an embarrassingly casual document which ignored the variation of techniques of individual surgeons and their choice of areas for coagulation. At least in Birmingham all the operations were performed by a team of only two surgeons; the way light coagulation was applied was standardized and the choice of targets was based on clear-cut principles—as stated in our paper. The trial, after all, was set up to assess the results of a surgical procedure—does it not worry Miss Kohner just a little that the returns on Pro-forma 4 can give absolutely no idea how the maculopathies were actually treated, what the targets for photocoagulation were, and why?

In our paper we reported on the work we have done. Because of limited resources and time we concentrated on affections of diabetic maculae. The recruitment to the B.D.A. trial—which embraces all types of diabetic retinopathy—is about completed and we believe the code will be broken soon. For establishing the value of photocoagulation for diabetic retinopathy perhaps it is as well that the truth is being searched for in more ways than one.

Yours faithfully,

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Corrigenda

In the article Rubinstein and Myska (*Brit. J. Ophthalm.*, 1974, **58**, 72), please correct pp. 81–84 as shown on p. 1017 (above).

In the article by Arden, Barnard, and Mushin (*Brit. J. Ophthalm.*, 1974, **58**, 183), in the Table on p. 187 the headings of col. 5 and col. 6 have been transposed.