Reviewer’s report

Title: Randomised controlled single-blind study of conventional versus depot mydriatic drug delivery prior to cataract surgery [ISRCTN 78047760]

Version: 1 Date: 7 June 2006

Reviewer: Giovanni Milazzo

Reviewer’s report:

General
The author describes a new depot mydriatic and non-steroidal anti-inflammatory drug delivery system to obtain pupil dilatation and they compare it with the more conventional approach of multiple mydriatic and non-steroidal anti-inflammatory drop applications. The authors conclude that this new depot drug delivery system appears to be an effective method for pupillary dilatation prior to routine cataract surgery which is well tolerated by patients. The trial is well designed in terms of bias controls. Some questions should be answered in order to conclude that the system is effective and well tolerated.

Major Compulsory Revisions
1. It should be described the material used for the wick and the method of preparation of soaked wick (ratio of diclofenac 0.1%-tropicamide 1% and phenylephrine 2.5% solutions; time of soaking);
2. It should be provided information regarding the ocular residence time of the soaked wick;
3. It should be specified the time lag between the application of the wick and the measurement of the pupil diameter.
4. Why the author used proparacaine before the insertion of the mydriatic-soaked wick? The use of proparacaine may affect the penetration of mydriatic drugs into the eye. Because of this, it is difficult to conclude if a satisfactory degree of mydriasis can be reached by the mydriatic-soaked wick itself or if it is necessary the use of proparacaine before the insertion of the wick.
5. The conclusion that the new drug delivery system is well tolerated cannot be drawn because of the use of proparacaine. Tolerability should be evaluated in absence of topical anaesthesia.
6. Was the pupil diameter maintained in the per-operative in the two groups, suggesting that surgical miosis was not influenced by reducing the number of mydriatic applications? Such data should be provided.

Minor Essential Revisions
1. A table with the mean value of pupil diameter, standard deviation, median and p-values between the two groups should be provided. Upper and lower quartile are not necessary if Figure 2 is showed.

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:
'I declare that I have no competing interests'