

Cataract

## Self assessed benefit of cataract extraction

N Congdon

Renewed vision for years to come

Cataract is the leading cause of blindness in the world,<sup>1</sup> and the leading cause of low vision in European derived populations.<sup>2</sup> The burden of cataract is likely to increase as the world's population ages.<sup>2</sup> At present, no effective means of preventing cataract exists, with the possible exception of smoking cessation.<sup>3</sup> For the foreseeable future, the sole method of preventing cataract blindness will remain the surgical removal of the opacified lens. Fortunately, successful results are the rule rather than the exception with cataract surgery in the developed world<sup>4-6</sup> and many parts of the developing world.<sup>7-8</sup> Fully 90% of people undergoing cataract surgery can expect to attain vision of 6/12 or better postoperatively,<sup>4-5</sup> and a similar proportion report being satisfied with their surgery.<sup>6</sup>

The fact that cataract remains an important cause of blindness in the developing world, and even in parts of the developed world,<sup>9</sup> suggests that a commitment to improved access to cataract surgical services is required. However, the widespread provision of such services can be expensive: the annual cost of cataract surgery in the United States, for example, exceeds \$US3 billion,<sup>10</sup> and some two thirds of

the US Medicare budget is expended on the examination and treatment of cataract.<sup>11</sup> The strongest argument in favour of increasing expenditures to combat cataract blindness has been the contention that cataract extraction is a highly cost effective surgery.<sup>12-13</sup> However, as the authors of the paper in this issue of the *BJO* (p 1017), note, "three variables must be known in order to support (the) statement (that cataract surgery is cost effective)." While data on the cost of cataract surgery and its impact on vision have generally been widely available, the paper by Lundstrom and Wendel is one of the first to provide evidence on the duration of improved visual function after surgery.

While Lundstrom and Wendel indicate that the proportion of subjects reporting improved vision after surgery declines, not surprisingly, with longer follow up, their conclusion that 80% still have improved function 7 years after surgery is, none the less, extremely encouraging. Healthcare policy makers and governmental and non-governmental organisations engaged in the provision of eye care should be motivated by the fact that currently available surgical treatment for the world's leading cause of blindness is capable not only of

bringing renewed sight now, but for many years to come.

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Triamcinolone acetonide

## Intravitreal triamcinolone therapy for diabetic macular oedema

S A Vernon

Which dosage should we use?

It is less than 4 years ago since publication of the first report on the use of crystalline cortisone in the form

of triamcinolone acetonide to treat recalcitrant macular oedema in patients with diabetes.<sup>1</sup> This report of a single

eye was rapidly followed by a case series from the same author (Jonas),<sup>2</sup> who has remained faithful to a dosage regimen of 20 mg in a number of publications documenting the efficacy and side effects of this novel form of therapy.<sup>3-8</sup> In parallel with Jonas, Martidis and co-workers in the United States<sup>9</sup> reported on the use of a 4 mg dosage in a similar clinical scenario. Since then there have been many reports, including early results from a randomised controlled trial (RCT), utilising this somewhat lower dosage.<sup>10-15</sup> All studies have thus far indicated a significant improvement in macular function and/or structure following injection, at least in the short term.

Why have different dosage regimens been employed? Triamcinolone acetate is conveniently and affordably available in concentrations of 40 mg/ml in a sterile preparation (Kenolog, or Volon A or Kenacort depending on country, Bristol-Myers-Squibb) used commonly in other specialties such as orthopaedics. As 0.1 ml is the maximum volume most eyes can tolerate when injected into the vitreous cavity without causing inevitable central retinal artery occlusion, the maximum dosage of unadulterated triamcinolone one can give at any one time without resorting to paracentesis is clearly 4 mg. Jonas concentrates the triamcinolone crystals using a filter and then injects (after a routine paracentesis) 0.2 ml of a suspension of triamcinolone and Ringer's solution (0.4 ml in the comparative dosage study in this issue of the *BJO* (p 999)).

In the aforementioned study, a small RCT comparing the efficacy of three dosages of triamcinolone (assayed to be 2 mg, 5 mg, and 13 mg of injected triamcinolone), Spandau and colleagues from Jonas's team make a case for the use of the higher dosage in diabetic macular oedema (13 mg was found to be the equivalent of a 20 mg stated dose in Jonas's previous studies). This was based upon a significantly improved outcome in terms of maximum distance visual acuity in the 13 mg group compared with the 2 mg group (but notably not the 5 mg group—a dosage closest to that probably injected in all other series), and a finding of a significant dose/duration effect correlation when all three doses were considered. There are a number of unanswered questions posed by the study such as the duration of oedema before treatment and the numbers in each group who had received laser treatment. It would also be tempting to discount this small study after viewing the data points on the figures where it can be seen that one or two eyes in the 13 mg group appear to be having a disproportionate influence on the results. The results, however, appeal somewhat intuitively, and merit further consideration.

Whether vitrectomy or intravitreal triamcinolone, perhaps combined with cataract surgery, proves to be optimal for an individual patient/eye will require much more research

Examination of the literature, comparing Jonas's results with those of others, fails to create a clearcut difference in outcome between dosage regimens for many reasons. These include differing entry criteria (with or without previous macular laser, duration of

oedema, levels of acuity at baseline), methods of acuity measurement (EDTRS chart versus Snellen chart), the presence or lack of supporting evidence of efficacy such as optical coherence tomography (OCT), and methods of comparison (randomised trial versus non-randomised case or case-control series). However, a common feature of all series extending to 6 months or longer is a rapid improvement phase, followed by a plateau phase and then regression, at least in some eyes.

Martidis *et al*,<sup>9</sup> using 4 mg, reported that three of the eight eyes at 6 months required re-injection for recurrence of oedema with loss of vision. In the study by Massin *et al*<sup>11</sup> (4 mg), the difference in macular thickness (which correlates well with visual improvement) measured by OCT at 6 months compared with baseline had become non-significant owing to recurrence of oedema in five of the 12 injected eyes. In addition, at no stage was there a significant difference between the acuity in treated and the control (untreated) eyes. However, Sutter *et al* (RCT with 4 mg versus subconjunctival placebo),<sup>10</sup> at 3 months, showed a significant visual improvement in treated eyes with 24% improving by 10 or more EDTRS letters. In the study by Ciardella *et al*,<sup>12</sup> 8/30 (27%) of eyes had received at least one re-injection (again 4 mg) because of recurrence of oedema at a median time of 6 months between the first and second injection. Audren *et al*,<sup>16</sup> used pharmacokinetic-pharmacodynamic modelling of OCT readings, estimated the mean maximum duration of effect of a 4 mg injection to be 140 days. In Jonas's largest series to date, in which triamcinolone was the only treatment for diabetic macular oedema, a dosage of 20 mg (probably 13 mg active triamcinolone) resulted in an improvement of at least two Snellen lines in 68% of the 97 treated eyes with a mean increase of 2.6 lines at best.<sup>4</sup> There was no tendency to regress over the first 4 months following injection but by 6 months the effect of injection on acuity had become insignificant in a group analysis, a finding similar to our own series<sup>13</sup> utilising a 4 mg injection.

The lack of any comparative data on lens morphology and density and macular thickness in Spandau's study is unfortunate as acuity some months after injection may be compromised by cataract formation.<sup>17</sup> Comparative data on all aspects of visual function, including the much neglected reading ability<sup>13,18</sup> and complication rates, in particular cataract and glaucoma, will only be answered by further prospective RCTs, which should begin to utilise

subjective patient generated outcome measures relating visual improvement to time of perceived benefit.

The use of intravitreal triamcinolone has given new hope to many patients with chronic diabetic macular oedema often permitting them to read again, even if only for a few months.<sup>13,18</sup> Whether vitrectomy<sup>19</sup> or intravitreal triamcinolone, perhaps combined with cataract surgery,<sup>20</sup> proves to be optimal for an individual patient/eye will require much more research. The National Eye Institute in the United States has funded studies examining the efficacy of intraocular steroids in diabetic retinopathy and retinal vein occlusion.<sup>21</sup> Those practising elsewhere should take into account the results from Professor Jonas's team when formulating their protocols for similar research.

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## Low vision

# A revolution in Welsh low vision service provision

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Failure of the service in Wales was perhaps best reflected in the inadequate number of low vision assessments

People in Wales with impaired vision have recently benefited from the arrival of a new nationwide community based low vision service. Undoubtedly, this is a dramatic and welcome development for all those with untreatable sight loss, not just those registered blind or partially sighted. But what has motivated the Welsh Assembly to take this radical step?

One reason is that visual impairment in Wales, like the rest of the United Kingdom, is reaching epidemic proportions. Since 1982, the number of people in the United Kingdom registered blind and partially sighted<sup>1</sup> has almost doubled and now stands at 359 000.<sup>2–4</sup> However, the registers are known to underestimate the number with untreatable sight loss by a factor of twofold to threefold and so there may be more than 1 000 000 people in the United Kingdom with untreatable low vision.<sup>5–6</sup> This estimate is supported by a recent Medical Research Council trial that has established that one in five people over the age of 75 have a binocular visual acuity below 6/12.<sup>7</sup> In many parts of Wales, the combined prevalence of registerable visual impairment (that is, both blind and partial sight registrations) now exceeds 2%.<sup>8</sup> The magnitude of the problem will undoubtedly increase because most sight threatening eye disease is age related and the number of people aged 60 and over is projected to increase by 57% over the next 30 years.<sup>9</sup>

Another reason for the Welsh Assembly's decision is that the cost of failure to provide an effective low vision service is high. Without appropriate rehabilitation, visual loss can have a devastating impact on the individual and is associated with depression, falls, and loss of independence.<sup>10</sup> The cost to society is no less significant. A recent review of the costs associated with blindness has highlighted the scale of the economic impact of visual impairment and suggests that the annual UK bill for residential care, just for those on the blind register, is approximately £715 million.<sup>10</sup>

Thankfully, the impact of visual impairment can be reduced by an effective low vision service. Low vision services have traditionally operated at the interface between healthcare and social care involving ophthalmologists, optometrists, social workers, and rehabilitation workers. The service helps people with visual impairment to remain independent by providing low vision aids such as magnifiers, which optimise residual vision, and by appropriate rehabilitation training.<sup>11</sup> Although many studies have shown low vision service provision to be beneficial in terms of functional ability and patient satisfaction<sup>12–17</sup> the effect on quality of life is less clear—that is, while low vision service provision appears to improve some aspects of vision related quality of life (in particular, those that relate to near vision and reading) it

does not improve all aspects.<sup>15–17</sup> Furthermore, it appears that more complex services, involving supplementary home based low vision rehabilitation, are no better at improving vision related quality of life than conventional (hospital based) low vision rehabilitation.<sup>18</sup>

Access to the new service has been optimised by ensuring that services are geographically spread throughout Wales

In reality, however, there has never been a “low vision service.” Instead, there is a patchwork of services, excellent in some areas and woefully inadequate in others—that is, a true postcode lottery. A survey of low vision service provision in the United Kingdom in 1998 highlighted the fragmented nature of the service with differences in availability and accessibility and a lack of communication between healthcare and social care professionals.<sup>8</sup> A review of services in 2001 showed that one of the main problems in Wales was service access.<sup>19</sup> Like many other parts of the United Kingdom, access to low vision services in Wales was restricted by a convoluted referral route typically involving referral from an optometrist to a general practitioner to an ophthalmologist and, eventually, on to a low vision service provider, and then to social services. A survey of waiting times showed that in some parts of Wales people with low vision had to wait up to 18 months to access a low vision service.<sup>19</sup> Access in Wales has also been restricted by the poor geographical distribution of services. People with a visual impairment, many of whom are elderly and with multiple disabilities, were frequently required to make a round trip of 100 miles or more, often on routes not served by public transport, to reach the nearest service provider. Failure of the service in Wales was perhaps best reflected in the inadequate number of low vision assessments. In 2000, there were only 4500 low vision assessments serving a visually impaired

population of at least 55 000—that is, a single assessment for every 12 people who might benefit.<sup>19</sup>

In recognition of these factors, the National Assembly in Wales has taken the radical step of introducing a nationwide low vision service. The new service, which opened its doors in the summer of 2004, is based on the conventional hospital eye service model but is located in community based optometric practices and exists alongside established services in secondary care. It is staffed by accredited optometrists and a limited number of dispensing opticians, who have successfully passed a theoretical and practical course in low vision administered by Cardiff University, working in close association with ophthalmologists, social services, education, and the voluntary sector. Waiting times are expected to be less than 2 weeks. Low vision aids are provided on a loan basis and home visits are made where necessary. A "vision passport" has been introduced which, like the "personal child health record," promotes individual empowerment, provides information, and facilitates inter-agency communication. Access to the new service has been optimised by ensuring that services are geographically spread throughout Wales. Currently, 95 optometrists, nine dispensing opticians, and one ophthalmic medical practitioner have been accredited (about one quarter of the optometrists in Wales) and a further 120 are undergoing training or have shown an interest (contact details can be obtained from the corresponding author). It is estimated that low vision services are provided at 121 sites across Wales. Referrals into the service are accepted from general practitioners, ophthalmologists, optometrists, social services, and from individual patients themselves. Indeed, anyone whose visual acuity is 6/12 or less, N6 or less, or whose field is significantly restricted, may access the service.

The arrival of the first national low vision service in Wales is a welcome and, some would say, long overdue development. In all, 1166 people were seen by Christmas 2004; 87% were seen within 2 weeks and 95% within a

month. With improved access and universal coverage, the service should enable everyone living in the Principality with impaired sight to continue to make best use of their sight. Of course, the service is being audited and the impact on those that use it will be evaluated. Evaluation of the effectiveness of visual rehabilitation is essential and funding for this evaluation has been built into the service. Even if the service is found to be effective in Wales it may not be the most appropriate model for all parts of the United Kingdom. Indeed, in Northern Ireland, 10 new outreach clinics have been established in secondary care,<sup>20</sup> and in England four pilot services have been funded under the new Eye Care Pathways project,<sup>21</sup> and 66 local low vision service committees have been set up. However, half a decade on from the publication of recommendations for future low vision service delivery,<sup>22</sup> endorsed by the then secretary of state for health, many people with low vision in the United Kingdom are still not receiving low vision care. We hope that it is not too long before everyone with low vision in the United Kingdom can benefit from assured investment in these important services.

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