

Cataract surgery

# Simultaneous bilateral cataract surgery

D F Chang

An idea whose time has come?

During the past decade, advances in techniques and technology have led to major changes in cataract surgical practice patterns. The complete transition from large incision extracapsular cataract extraction (ECCE) to phacoemulsification was driven by the ability to accelerate the visual and physical rehabilitation of cataract patients. The subsequent innovations of foldable intraocular lenses (IOLs) and small, clear corneal incisions followed. As a result, previously unimaginable practices—topical anaesthesia, sutureless surgery, and the elimination of patching and physical restrictions—have now become commonplace. In this progression towards ever faster rehabilitation, simultaneous bilateral cataract surgery (SBCS) may be the next and ultimate step.

As evidenced in a consultation forum involving international experts in 1997, simultaneous bilateral cataract surgery remains controversial, and is rarely performed in the United States.<sup>1</sup> In fact, the recently updated American Academy of Ophthalmology Preferred Practice Pattern (Rev 2001) states that “Surgery should not be routinely performed in both eyes at the same time because of the potential for bilateral visual impairment and loss of the ability to adjust surgical plans for the second eye that are based on results from first eye surgery.”<sup>2</sup> There are obvious reasons for the historical reluctance to perform bilateral surgery.

When standard ECCE was the most popular procedure, patients often waited for up to several months between their first and second cataract surgeries. Large incisions were associated with a low, but significant, incidence of early wound problems, and suture induced astigmatism often resulted in poor uncorrected vision for 1–2 months. Visual recovery was more often delayed by prolonged corneal oedema or clinically significant cystoid macular oedema. Refractions often took months to stabilise.

Simultaneous bilateral ocular surgery of any kind cannot be considered if there is either a high complication rate, or if it causes a prolonged period of visual disability. However, as we have seen with LASIK, simultaneous surgery is a viable option if the complication rate is low and

if vision recovery is rapid. What has changed over time, of course, is that cataract surgery can now approach LASIK with regard to safety and rapidity of recovery.

The potential advantages of SBCS are not insignificant. There are special circumstances, such as transportation problems or the need for general anaesthesia, where subsequent second eye surgery might not otherwise be possible. With SBCS, patients with high hyperopia or myopia would be spared the frustration of considerable interim anisometropia. By focusing on clinical outcomes, physicians often underestimate the emotional stress or physical hardship that outpatient surgery and the postoperative period entail for certain patients. For these individuals, eliminating the second separate encounter may be particularly desirable. Finally, all patients experience a faster return to full visual function and their final refraction following uncomplicated SBCS, when compared to two sequential procedures.

In any healthcare system where limited resources may impose rationing or lengthy delays in elective surgery, this might be the best way to safely extend the benefits of cataract surgery to as many eyes as possible

From a logistical standpoint, SBCS significantly reduces the time spent by patients and medical staff in the overall process. There are fewer postoperative visits, reduced administrative paperwork, less temporary disability and missed work, and reduced reliance on the support of family or friends. In this regard, the true economic savings of SBCS extend beyond the cost of the second surgical facility fee.

With all of these potential advantages, the critical question to ask is to what degree are the visual and refractive outcomes compromised by this practice? In this issue of the *BJO* (p 285), Johansson and Lundh add their experience with SBCS to that previously reported in the literature. It is only through outcome studies such as these that this question can be critically understood and analysed.

The authors describe their protocol for SBCS in detail. Most of their guidelines are common sense. The patients must have bilateral symptomatic cataracts, must be well informed, and must desire bilateral surgery on the same day. Patients felt to be at high risk of intraoperative complications are not given this option, and the planned second surgery is not performed in the event of intraoperative complications with the first eye. To the list of poor candidates for SBCS, I would add those at risk of early postoperative complications (for example, uveitis and poorly controlled glaucoma), those at risk of delayed visual recovery (for example, patients with Fuchs' corneal dystrophy), and those at greater risk for refractive surprise (for example, post-LASIK patients).

Since non-simultaneous bilateral cataract surgeries are often performed several weeks apart, the incidence of late postoperative complications, such as retinal detachment or late corneal decompensation, is less relevant to the SBCS question. Such complications would not have affected the decision or timing for second eye surgery. Likewise, intraoperative complications, such as vitreous loss, dropped nucleus, or choroidal haemorrhage, should automatically disqualify the second eye for same day surgery. Thus, in analysing the downside to SBCS, the most important complications to consider would be those occurring during the early postoperative period. Some, such as endophthalmitis, are vision threatening and others, such as refractive surprise, are not. Some, such as moderate corneal oedema or toxic anterior segment syndrome, are temporary. All of these complications could have altered the timing or outcome of the second operation.

A number of authors have reported their results with simultaneous bilateral cataract surgery.<sup>3–12</sup> Each of these series demonstrated excellent clinical outcomes comparable to single eye cataract surgery. Only Benazra's report in 1978 on 448 SBCS patients undergoing intracapsular cataract extraction (ICCE) included one patient who suffered bilateral vision loss due to bilateral endophthalmitis.<sup>3</sup> This patient had septicaemia and dysentery, and the same surgical instruments were used for both eyes.

In 2001, Smith and Liu reviewed the literature citing seven reports published between 1995–8 with a total of 2859 SBCS patients.<sup>10</sup> Some series utilised ECCE while others used phaco procedures. There was a combined total of four cases of endophthalmitis, none bilateral, equaling a rate of 0.14%. Since then four additional series, including that of Johansson and Lundh, have been published demonstrating excellent results.<sup>11–13</sup> Totan's series included results in 19 paediatric or teen-aged patients.<sup>11</sup>

Kontkanen and Kontkanen recently published results from 2715 patients operated on by two surgeons between 1996 and 2001.<sup>13</sup> There were two cases of unilateral endophthalmitis, none bilateral, in this series. Thus, although the risk of bilateral endophthalmitis is often cited as a prime deterrent to SBCS, there has not been a single occurrence in the 6000 cases reported in the literature since 1995.

What is less clear from these and other studies is to what extent the refractive results are compromised in SBCS. Knowing the refractive result of the first operation affords the opportunity to adjust or bias the IOL selection in the second eye. As in most of the previous series reported, Johansson and Lundh do not provide detailed results on the refractive accuracy in their SBCS population. At present, the ability to adjust the refractive target in the second eye may be the single most valuable advantage of staged, sequential surgery. However, the better the individual surgeon's refractive outcomes are, the less important this becomes. A future technology, such as Calhoun Vision's (Pasadena, CA, USA) light adjustable IOL that may allow for precise, postoperative adjustment of the IOL power, could eliminate these concerns altogether.

Short of adjustable IOL technology, current surgical techniques would seem to have improved the feasibility of SBCS when compared to the past. Biometry accuracy has been improved with the use of immersion ultrasound or optical coherence biometry (IOL Master, Zeiss Humphrey). The growing preference of combining topical non-steroidal anti-inflammatory drugs with steroids postoperatively may further reduce the incidence of cystoid macular oedema (CMO). The reduction in average phaco times achieved through newer phaco technology and methods such as phaco chop are diminishing the incidence of early corneal oedema. Finally, small, temporal, clear corneal incisions are astigmatically neutral and stabilise

quickly. Johansson and Lundh state that a prerequisite for SBCS is the patient's informed preference for this. An additional prerequisite should be the surgeon's own confidence and ability to consistently accomplish these goals of refractive accuracy, a low complication rate, and rapid visual recovery without patching.

While the clinical advantages or disadvantages of SBCS to the patient are the most important consideration for physicians, it is difficult to ignore the economic ramifications. In the United States, payment for the second eye surgery is reduced if performed on the same day. This recognises the reduced time needed for preparation and postoperative care, compared to separate procedures performed on different days. Some think that this creates a financial disincentive to SBCS.

On the other hand, SBCS should result in significantly reduced cost to the payer—either the patient or the healthcare system. In the United States, predicted future increases in the number of patients requiring cataract surgery may eventually challenge society's ability to pay. Throughout the developed world, cataract surgery already leads all other procedures in terms of frequency and aggregate cost to the healthcare system. Growing waiting lists for cataract surgery are common in many countries. The option of eliminating coverage for second eye surgery would be objectionable, since the functional improvement from bilateral cataract surgery has been well documented.<sup>14</sup> However, cost pressures might eventually force a choice between performing SBCS versus providing surgery for only one eye.

Given the state of modern cataract surgery, simultaneous bilateral cataract surgery would seem to be a logical option for experienced surgeons to offer to selected patients. The patient's primary motivation may be functional, emotional, logistical, or economic. The collective literature from the past 7 years seems to support the safety of this

approach when strict, conservative protocols are followed. In any healthcare system where limited resources may impose rationing or lengthy delays in elective surgery, SBCS might be the best way to safely extend the benefits of cataract surgery to as many eyes as possible.

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Amblyopia

# Amblyopia therapy

B W Fleck

## More evidence that we need evidence

The evidence base for amblyopia treatments is not well developed.<sup>1,2</sup> A study by Tan *et al* in this issue of the *BJO* (p 291) documents differences in amblyopia treatments between the UK and Germany, Switzerland, and Austria ("German speaking countries"). A recent study from the United States also showed significant differences in treatments between centres.<sup>3</sup>

What gaps in our evidence base for amblyopia treatment does the study by Tan *et al* expose?

The upper age limit for treatment of newly diagnosed cases was significantly higher in German speaking countries than in the United Kingdom. Our knowledge of the responsiveness to treatment of each type of amblyopia in each age group is limited.<sup>4-7</sup>

The dose of part time occlusion therapy prescribed was significantly greater in German speaking countries than in the UK. There were also differences in the circumstances in which full time occlusion was prescribed. When treatment failed, occlusion treatment was discontinued at a younger age in the UK than in German speaking countries. Only limited studies of occlusion dose-response have been published.<sup>8,9</sup>

Spectacles alone, in place of spectacles plus occlusion, were used more widely in the UK than in German speaking countries for the initial treatment of severe anisometropic amblyopia. Only limited studies of spectacles only treatment of amblyopia are available in the literature at present.<sup>10</sup> In addition, the therapeutic effects of spectacle wear may have confounded studies of occlusion treatment in the past.

Atropine penalisation was more likely to be used as a first line treatment for amblyopia in German speaking countries than in the UK. However, occlusion was used much more widely than atropine penalisation in all countries. Only limited studies of atropine penalisation have been performed,<sup>10-13</sup> until very recently.<sup>14</sup>

Orthoptists in all countries believed a negative psychological effect of occlusion therapy was infrequent. While the negative psychological impact of amblyopia has been studied,<sup>15</sup> very little work on the possible negative psychological effects of occlusion treatment has been undertaken.

Despite differences in treatments, orthoptists from all countries gave very similar estimates of the success rates of treatment. Actual treatment outcomes, however, remain entirely unknown in most departments. Once again these results show that current practice is based on value beliefs held by ophthalmologists and orthoptists rather than on measured evidence.

A number of very important amblyopia treatment trials are currently under way, and many of the questions raised in the study by Tan *et al* will be answered during the next 3 years. Recent advances in methodology have made these trials possible.<sup>16</sup> Definitions of the types of amblyopia have been standardised.<sup>14</sup> The use of logMAR visual acuity charts has become widespread, and validated test strategies have been developed.<sup>17</sup> The need for robust baseline visual acuity measurements<sup>16,17</sup> and spectacle adaptation have been recognised.<sup>16</sup> Compliance with occlusion therapy may now be measured in a reliable way.<sup>16,18</sup>

In the future, atropine penalisation may be the first line treatment for the majority of children with amblyopia

Occlusion treatment for strabismus was first described in 1722.<sup>19</sup> A randomised trial of treatment versus no treatment (ever) is probably not justified, as there is sufficient evidence that treatment leads to improved visual acuity in the majority of patients,<sup>5</sup> that this improvement is maintained,<sup>20</sup> and that the natural history is not one of spontaneous improvement.<sup>21</sup> Clarke and collaborators in north east England have recently completed a multicentre trial that includes a no treatment arm for a limited period. Patients with anisometropic amblyopia were randomised to no treatment, spectacles alone, or spectacles plus occlusion.<sup>22</sup> The no treatment group was crossed over to treatment after 1 year.

Moseley, Fielder, and colleagues at Imperial College London have painstakingly developed robust treatment outcome methodology over a number of years.<sup>10,16,18,23</sup> Careful assessment of baseline logMAR visual acuity,<sup>16</sup> a prolonged period of spectacle adaptation,<sup>10,16,23</sup> and electronic monitoring of treatment

compliance<sup>16,18,23</sup> are the key elements of the Monitored Occlusion Treatment of Amblyopia Study (MOTAS). Pilot results have been published,<sup>23</sup> and preliminary outcome data were presented at ARVO in May 2002.<sup>24</sup> The dose-response relation for occlusion therapy was measured in an observational study of 4-6 year old children with strabismic, anisometropic, or combined strabismic and anisometropic amblyopia. Compliance with occlusion treatment was poor—in the order of 50%. This finding must raise doubts about the reliability of other occlusion treatment outcome trials that do not use continuous electronic compliance monitoring.

The dose-response relation for occlusion therapy was similar for all three types of amblyopia studied. Children under 6 years of age showed a more rapid rate of improvement than older children—85% of improvement occurred during the first 6 weeks of treatment. The dose-response relation was linear during the first 160 hours of treatment. Improvement plateaued after 6 months.

These results are extremely valuable and peer reviewed publications from these studies are eagerly awaited.

A series of large multicentre amblyopia treatment study (ATS) trials are now under way in North America, under the chairmanship of Jonathan Holmes.<sup>25</sup> The studies are funded by the National Institute of Health, and undertaken by the Pediatric Eye Disease Investigator Group.<sup>26</sup> Initial methodology studies have been completed.<sup>17,27,28</sup> The 6 month outcome of ATS 1 was published recently.<sup>14</sup> This was a trial of atropine penalisation versus occlusion treatment for moderate amblyopia (20/40-20/100) in 3-6 year old children. The treatments had a very similar outcome at 6 months. However, parents (slightly) preferred atropine penalisation to occlusion treatment.

ATS 2 is ongoing, and consists of three randomised controlled trials (RCTs) of occlusion dosage. In moderate amblyopia (20/40-20/80), 2 hours per day is compared with 6 hours per day of occlusion. In severe amblyopia (20/100-20/400) 6 hours per day is compared with full time occlusion. The incidence of amblyopia recurrence will be observed for 12 months after treatment cessation. This will lead to a RCT of maintenance occlusion treatment versus no treatment for the prevention of amblyopia recurrence. The methodology of ATS 2 is particularly open to the criticism that compliance monitoring is relatively weak.

The RCT phase of ATS 3 has recently commenced (Jonathan Holmes, personal communication). This is a study of older children found to have amblyopia of 20/40-20/400. One trial compares spectacles alone and spectacles plus occlusion

plus atropine penalisation in 7–12 year olds. A second trial compares spectacles alone and spectacles plus occlusion in 13–17 year olds.

ATS 4 also commenced recently (Jonathan Holmes, personal communication). This is a RCT of weekend atropine penalisation versus daily atropine penalisation in moderate amblyopia.

The results of these studies, along with additional studies derived from their methods, will soon allow evidence based treatment of amblyopia for the first time—300 years after occlusion treatment was introduced. What will Tan *et al* find in 5 years' time, if they repeat their study? Firstly, atropine penalisation may be the first line treatment for the majority of children with amblyopia. Secondly, and more importantly, amblyopia treatment advice given by ophthalmologists and orthoptists around the world will be consistent, and evidence based.

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