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More than 10 Years of Experience with Immediate Sequential Bilateral Cataract Extraction (ISBCE)—A Retrospective Study

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Abstract

Background: To evaluate the safety of immediate sequential bilateral cataract extraction (ISBCE) with respect to indications, visual outcomes, complications, benefits and disadvantages. Methods: This is a retrospective review of all ISBCEs performed at Kantonsspital Winterthur, Switzerland, between April 2000 and September 2013. The case notes of 500 eyes of 250 patients were reviewed. Of these 500 eyes, 472 (94.4%) had a straight forward phacoemulsification with posterior chamber intraocular lens implantation; 21 (4.2%) had a planned extracapsular cataract extraction; 4 (0.8%) had an intracapsular cataract extraction and 3 (0.6%) had a combined phacoemulsification with trabeculectomy. Results: Over 66% of eyes achieved improved visual acuity (at least 3 Snellen lines) following ISBCE. Median preoperative best corrected visual acuity (BCVA) was 0.5 LogMAR; the interquartile range was [0.4, 1] LogMAR. At one week control the median BCVA was 0.3 LogMAR, IQR [0.1, 0.5] LogMAR. At one month the median BCVA was 0.15 LogMAR, IQR [0.05, 0.3] ($p < 0.01$). There were no sight-threatening intraoperative or postoperative complications observed. Conclusions: ISBCE is an effective and safe option with high degree of patient satisfaction. The relative benefits of ISBCE should be balanced against the theoretically enhanced risks.

Keywords

Cataract, Cataract Surgery, Immediate Sequential Bilateral Cataract Extraction

1. Introduction

The widespread implementation of immediate sequential bilateral cataract extraction (ISBCE) has remained a subject of controversy. As our center has more than ten years of experience with this procedure, a review of the

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available data was performed. While same-day refractive bilateral surgery is nowadays standard practice, ISBCE remains non-routine in the developed world [1]. A survey of the members of the American Society of Cataract and Refractive Surgeons in 2012 revealed that less than 1% surgeons perform bilateral or same-day cataract surgery regularly [2]. The hesitancy to carry out this procedure rests on the fear of bilateral complications (e.g. bilateral endophthalmitis) leading to blindness in both eyes [3]. The safety and efficacy of modern cataract surgery indicate that these reservations are unjustified and should be readdressed. In 2008 the International Society for Bilateral Cataract Surgery was founded to establish the guidelines for ISBCE. The topicality of this issue was recently highlighted in an editorial in the American Journal of Ophthalmology [4].

ISBCE approximately halves the number of required post-operative appointments. This is not only more convenient for the patient, but also more cost-effective and eases the demand on support infrastructure for mobility-restricted patients [5] [6]. With an aging population these considerations will be of increased importance, particularly in an era where health care is obliged to focus on cost efficiency. Some surgeons clearly favor ISBCE because of its rapid visual rehabilitation and obvious practicalities for elderly patients and will perform it on request in the absence of contraindications [7]; however many are hesitant to adopt this methodology, due to the potential risk of bilateral retinal detachment, bilateral corneal decompensation, severe cystoids macular oedema, significant IOL power errors in the first eye that could be refined and thereby prevented in the second eye, and bilateral toxic anterior segment syndrome (TASS) [8].

It is clear that the surgeons' hesitancy is related to the lack of recent data on this subject. Therefore this study reports the visual outcome and complications of a large number of patients undergoing same-day bilateral cataract extraction over a period of more than 10 years.

2. Methods

This was a retrospective study of 250 consecutive patients (500 eyes) who underwent ISBCE under general anesthesia at the Kantonsspital of Winterthur, Switzerland. The study followed the tenets of the Declaration of Helsinki and was approved by the local medical ethics committee. In general, indication for ISBCE was defined as the need for bilateral cataract surgery (reduced visual acuity with evidence of lens opacity as observed at the slit lamp) and where the operation under local anesthesia was not feasible due to general health restrictions. All ISBCE surgeries performed between April 2000 and September 2013 were reviewed.

Surgical Procedure

A total of 500 eyes were included. Thereof, 472 (94.4%) had a straight forward phacoemulsification with posterior chamber intraocular lens implantation (thereof four sulcus implantations (0.8%)): 463 eyes were operated through a sclero-corneal tunnel and 9 through a clear cornea incisions (only in cases of glaucoma or prior glaucoma surgery and in absence of severe blepharitis). Twenty one (4.2%) eyes had a planned extracapsular cataract extraction. Four (0.8%) eyes had an intracapsular cataract extraction (ICCE) combined with an anterior vitrectomy and praepupillary implantation of an Artisan iris-claw lens (Ophtec B.V., Groningen, Netherlands). Three had a combined phacoemulsification with trabeculectomy (one patient having a bilateral phaco-Trab). All surgical interventions were performed in general anesthesia, these are 142 (56.8%) laryngeal masks, 102 (40.8%) endotracheal anesthesias, 6 (2.4%) fiber-optical intubations. Mean duration of surgery was 56 minutes, SD ± 18 (range 32 - 120). Due to the inability to cooperate in 17 patients the biometry had to be done preoperatively under general anesthesia. In 8 eyes a Malyugin ring was used due to inadequate pupillary dilatation. In 117 (46.8%) of the 250 surgeries each eye was operated by a different surgeon (the first eye (the eye with the better visual potential) was always operated by the most experienced surgeon). The surgeries were performed under complete aseptic separation of the first and second eye according to the general principles of ISBCS [9] [10]: two different instrument sets were used for surgery and the irrigating fluid was changed. In general, different LOT-Numbers were not used for the left and right eye. Intracameral cefuroxime 0.5 ml for prophylaxis of endophthalmitis was instilled at the end of the surgery. Before surgery of the second eye, the surgeon and nurse have undergone sterile routines after independent preparation of the second eye's operative field. Patients with known α-blocker medication (such as Tamsulosin®, Pradif® etc.) were treated with atropin 1% sid for 5 days prior surgery. Blepharitis was treated preoperatively with Tobradex® eyedrops (tobramycinum/dexamethasonum) qid for 5 days.

Postoperative regimen: The postoperative regime included Tobradex® (dexamethasonum 1 mg, tobramycinum 3 mg) eye drops qid. The eye drops were tapered over four weeks. Postoperative controls were on day one, week one and 1 month postoperatively.

3. Results

3.1. Patients' Characteristics

Overall, 250 patients (156 women, 94 men) with a mean age of 80.4 years, SD ± 9.9 (range 26 to 106) were included. Except in 3 patients, all surgeries were performed under inpatient conditions. The mean distance from patient's home to the hospital was 17.5 kilometers, SD ± 14.7 (range 2 - 103).

Ocular co-morbidities: 73 patients (29.2%) had no ocular co-morbidities. 104 eyes (52 patients), 20% of the patient population had a pseudoexfoliation syndrome, an additional 7.6% had PEX-glaucoma (23 eyes, 19 patients), while 6.6% (23 eyes of 17 patients) had another type of glaucoma. Twenty-four percent (120 eyes of 60 patients) presented with blepharitis. There were 15 patients (two cases unilateral) with enophtahlmos. Cornea guttata was present in 4% (20 eyes) of study eyes. There were 122 eyes (24.4%) showing signs of age-related macular degeneration. Amblyopia was observed in 25 cases (10%).

General co-morbidities: Sixty-five (26%) patients were under oral anticoagulation (e.g. Marcumar). Sixty-one (24.4%) patients had diabetes mellitus. Seventy (28%) patients had a reduced mobility (e.g. paraplegia), of these 21 (8.4%) were restricted to a wheel chair. Approximately 20% (49) patients were obese (BMI > 30). Eleven patients had a history of cancer. A co-morbidities-index (score from 0 - 6) was formed by the number of general co-morbidities: mean score was 2.9 in the study population, SD ± 1.1 (range 0 to 6).

3.2. Visual Acuity

Visual acuity was not measurable in 7 patients due to their general conditions (oligophrenia, severe dementia (2), trisomy 21, encephalopathia (2), cerebral paresis). Eighty-four percent of eyes (n = 421) had best corrected visual acuity (BCVA) available preoperatively and one month postoperatively. Visual acuities were reported according to the guidelines of the Society of Cataract and Refractive Surgery. Median preoperative BCVA was 0.5 LogMAR, the interquartile range was [0.4, 1] LogMAR. At one week control the median BCVA was 0.3 LogMAR, IQR [0.1, 0.5] LogMAR. At one month the median BCVA was 0.15 LogMAR, IQR [0.05, 0.3] ($p < 0.01$). There were 13 eyes (2.6%) had worse BCVA at one month control to preoperative, 34 eyes (6.8%) had the same BCVA postoperatively. The gain and loss at one month Snellen lines is shown in **Figure 1**. Two hundred and seventy eight (66%) eyes had a gain of three or more Snellen lines. Six eyes had a loss of three or more Snellen lines, three of which were patients who had a change from count fingers to hand movements. In the remaining three patients: one had reactivation of a herpes keratitis; one had postoperative elevated IOP and consecutive corneal decompensation and one patient had unreliable visual acuity assessment due to psychosis.

3.3. Complications

Intraoperative: There was one intraoperative conversion of anesthesia type (from laryngeal mask to endotracheal anesthesia). A posterior capsule rupture with subsequent sulcus implantation of intraocular lens occurred in 4 eyes (0.8%). In one eye an accidental sulcus implantation resulted in a rhexis fixated optic. An intraoperative conversion to ICCE because of zonula dialysis was performed in 4 eyes (0.8%). Two eyes (0.4%) had intraocular lens (IOL)-shooter-related problems (broken haptic of the IOL while inserting: Hoya PY-60AD and Hoya 251). In 15 patients (6.3%) an intraoperative floppy-iris syndrome (IFIS) was described. In one eye with IFIS a sector-iridectomy was performed because of an irisprolapse.

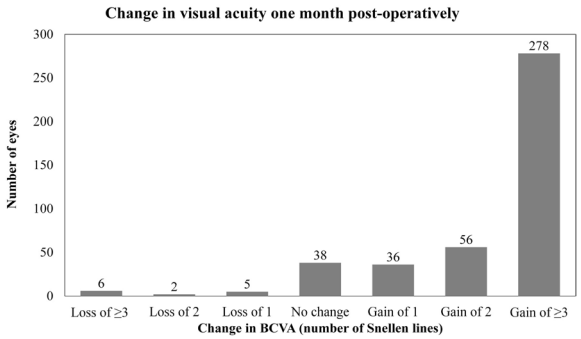

Figure 1. One month change in BCVA after simultaneous bilateral cataract surgery.

Postoperative: Postoperative hypertony (IOP > 30 mmHg) was observed in 4 eyes (0.8%), ICCE has been performed in 3 of these eyes. Two eyes had a postoperative reactivation of a herpes keratitis. One eye after extracapular cataract extraction had a postoperative wound dehiscence with iris incarceration (due to eye rubbing). One eye (0.4%) had a corneal decompensation (preoperatively cornea guttata had been observed). Following uncomplicated phacoemulsification postoperative conversion from a dry AMD to a wet AMD was observed in one eye and two eyes suffered from a prolonged anterior chamber-inflammation (TASS-suspect) and needed intensive anti-inflammatory therapy.

4. Discussion

This retrospective study demonstrates that ISBCE is a safe option with low risks of sight-threatening complications. ISBCE is has a growing popularity worldwide, with some regions adopting general implementation, such as Canary Islands where 80% of all cataract surgeries are performed in this way [11]. Patient satisfaction has been reported as high, with 91% willing to recommend it to their friends and family [12]. Nevertheless, until now ISBCE has remained an exception. Ophthalmic surgeons state that the fear of bilateral sight-threatening complications, especially potentially devastating outcome of bilateral endophthalmitis is the limiting factor [8]. However, there have only been four cases of simultaneous bilateral endophthalmitis ever published [3] and all had breached the aseptic protocol published by the International Society of Bilateral Cataract Surgeons (ISBCS) [9]. In the recently reported summary of 95,606 immediate sequential bilateral cataract surgeries in America (191,212 eyes), there was no cases of bilateral endophthalmitis [13]. These data are consistent with our findings.

It is not simply simultaneous bilateral endophthalmitis which impedes acceptance; it is the potential for functional blindness. Bilateral endophthalmitis and bilateral blindness are often assumed to be synonymous, however with prompt modern management, this is not the case. Recent data reveal that approximately one third of eyes with endophthalmitis achieve final acuity of 0.3 LogMAR units or better [14]. Using this information, the potential risk of simultaneous bilateral endophthalmitis with final vision of worse than 0.3 LogMAR is less than half the risk of simultaneous bilateral endophthalmitis, which is already exceptionally low [15].

It is clear that re-education of ophthalmologist is needed in order to resolve the prejudices against this procedure. The ISBCS promotes the transfer of knowledge and guidelines has been created which can be found on the website of ISBCS (http://isbcs.org/) [9]. In our high-risk patient population, many with ocular and systemic comorbidities, there were no cases of bilateral sight-threatening complications, which is in part due to the high safety measures and hygiene standards implemented. However, the ISBCS guidelines were not strictly adhered to, for instance different LOT-Numbers were not used. On the other hand, a strict patient selection protocol was implemented, patients considered for ISBCE, were carefully examined preoperatively in order to assess any risk factor of potential infection. For instance, patients with blepharitis were identified and treated preoperatively. Intraoperatively, the surgeries of the two eyes were considered as two absolutely separate interventions. Immunocompromised patients and patients with poorly controlled diabetes were not selected for ISBCE. Although the risk of bilateral endophthalmitis can never be truly independent of events, these operational protocols help to segregate the procedures and reduce the risk of infection. Consequently, the risk of toxic anterior segment syndrome (TASS) is also mitigated. Unlike endophthalmitis, TASS is a sterile inflammatory reaction and can be caused by contaminated instruments, phacoemulsification machines, irrigating fluids, and incorrect preparation of intracameral antibiotics. The use of pre-prepared intracameral antibiotics should help to reduce this risk by minimizing errors in mixing and diluting antibiotics in the perioperative period. We had two patients with a suspect of unilateral TASS. However, there is one case of bilateral TASS reported after bilateral cataract surgery [16]. The two surgeries were performed 1 day apart, with no causative factor for TASS found. This suggests that temporal segregation is insufficient to prevent bilateral TASS, and thus should not be a reason to dissuade surgeons from offering patients the choice of immediate sequential surgeries.

Financial penalties to the surgeon also doubtlessly influence decisions. Reimbursement for same-day second eye surgery varies greatly, from 50% by Medicare and Medicaid in the United States, to no reimbursement in Japan and Israel [6]. Pressure from health insurers to reduce cost is increasing, in Switzerland ISBCE has been reimbursed by health insurers since 2009. Therefore, it is not surprising that the number of performed ISBCE nationally is increasing (**Figure 2**).

Recently, the cost difference between delayed sequential cataract surgery (DSCS) and ISBCE was evaluated in the United States for patients covered by Medicare. Nationally, it was estimated that costs to Medicare could

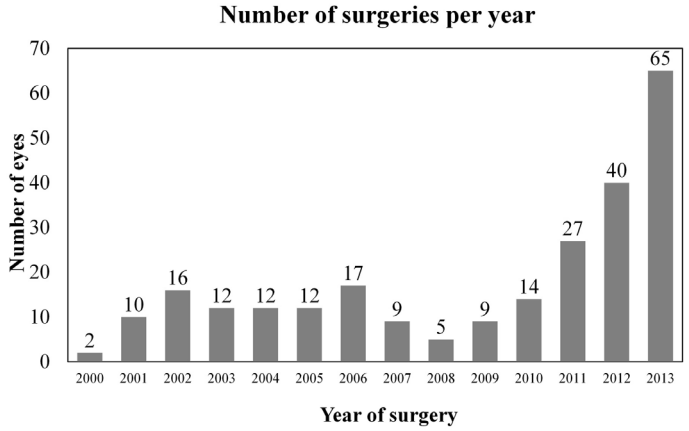

Figure 2. Number of surgeries per year.

have been reduced by approximately $522 million with the switch from DSCS to ISBCE in 2012. With a change to ISBCE, the cost to a West Tennessee Medicare patient was estimated to be reduced by $174 for direct medical costs, $40 for travel costs, and $138 for lost wages (total cost reduction range, $329 - $649). The total Medicare-based societal cost reduction was estimated to be potentially $783 million [17]. If we assume that on average about seven appointments in total are needed in the case of DSCS, that is, a preoperative exam visit followed by two interventional days and a total of four postoperative visits. With ISBCE the effort required is reduced by almost half. This aspect has direct impact for the patient [18] and will be of increased importance in the near future, with an aging population and thus the mobility of patients is expected to decrease further. In addition, special transports and trained personnel for the disabled patients (28% of our patient population had reduced mobility) are necessary, the costs of which are considerable. Given the escalating burden of the cost of healthcare and the ever-growing competing demands on limited resources, we believe the risk of functional blindness is low enough to justify the widespread introduction of ISBCE.

5. Conclusion

This study shows that ISBCE may be effective and safe option with growing popularity. However, a proper patient selection and high standards in cataract surgery are mandatory. Moreover, concurrent relevant ocular and periocular disease should be managed before surgery, and bilateral surgeries should be avoided in patients at higher risk of infection. In such a scenario, the relative benefits of ISBCE counter balance the theoretically enhanced risk of ISBCE.

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