Intraocular pressure during the early postoperative period after 100 consecutive implantations of posterior chamber phakic intraocular lenses with a central hole

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PURPOSE: To study changes in intraocular pressure (IOP) during the early postoperative period in eyes having implantation of a posterior chamber phakic intraocular lens (pIOL) (Visian Implantable Collamer Lens V4c).

SETTING: Clínica Baviera, Instituto Oftalmológico Europeo, Madrid, Spain.

DESIGN: Case series.

METHODS: This retrospective review included the first consecutive eyes having implantation of a spherical or toric myopic pIOL with a central hole at Clínica Baviera from December 2011 to June 2012 by the same experienced surgeon. The IOP was evaluated preoperatively and 1 day, 1 week, and 1 month postoperatively.

RESULTS: The study comprised 100 eyes. The mean IOP changed from 14.6 mm Hg ± 3.4 (SD) (range 8 to 26 mm Hg) preoperatively to 14.5 ± 4.6 mm Hg (range 6 to 30 mm Hg) 1 day postoperatively, 14.2 ± 4.2 mm Hg (range 6 to 29 mm Hg) at 1 week, and 12.3 ± 3.4 mm Hg (range 9 to 24 mm Hg) at 1 month. No statistically significant changes were detected over time postoperatively ($P>.2$). No perioperative complications associated with the implantation of the pIOL were recorded. No pIOLs were explanted, no toric pIOL rotation was detected, and no pupillary block or acute angle closure was observed.

CONCLUSION: The short-term clinical data for the new pIOL model with the central hole (KS-Aquaport) suggest that it is a safe and effective means for controlling postoperative IOP.

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Since the first-generation Visian Implantable Collamer Lens (Staar Surgical Co.) was introduced in 1993, successive models of this posterior chamber phakic intraocular lens (pIOL) have been developed. These IOLs have proven to be effective for the correction of moderate to high ametropia.[1–10] Several studies show that its implantation has no significant influence on postoperative intraocular pressure (IOP)[11] or trabecular pigmentation.[12,13] A statistically significant increase in IOP has been observed in highly myopic eyes 1 month after surgery,[14] although the IOP normalized in all patients when steroid treatment was completed. To prevent pupillary block, peripheral laser iridotomies before implantation or surgical peripheral iridectomies were mandatory. In some cases, these maneuvers cause discomfort for the patient or intraoperative surgical difficulties. Despite the performance of peripheral iridectomies, some studies[15–18] describe cases of pupillary block.

Kimiya Shimizu, in cooperation with Staar Surgical Co., recently developed a new pIOL with an artificial central hole (Visian V4c Implantable Collamer Lens) to overcome these difficulties.[19–21] No significant increase in IOP (>21 mm Hg) occurred in any case during the observation period.[22] The need for iridectomy was obviated by the central hole (KS-Aquaport)

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of the pIOL, which allows free flow of the aqueous humor between both sides of the pIOL. The 0.36 mm central hole defines the new design of this pIOL. This posterior chamber pIOL is a newer version of the Centralflow design developed in 1994.[A] The Visian V4c pIOL was given the Conformité Européene Mark in April 2011. No cases of pupillary block have been reported since then.

In this study, we evaluated early safety results and alterations in IOP after implantation of the Visian V4c Implantable Collamer Lens pIOL for the correction of myopia and myopic astigmatism in consecutive eyes.

PATIENTS AND METHODS

This retrospective review included the first consecutive eyes having implantation of spherical and toric myopic pIOLs (Visian V4c) at Clínica Baviera from December 2011 to June 2012. All procedures were performed by the same experienced surgeon (F.G.-L.). Assessment of IOP was based on a comparison of preoperative and postoperative values at 1 day, 1 week, and 1 month. All study procedures adhered to the recommendations of the Declaration of Helsinki. Written consent was obtained from all participants.

The inclusion criterion was documented stable refraction during the previous 12 months. The exclusion criteria were an anterior chamber depth (ACD) less than 3.0 mm (measured using ultrasonography from the corneal endothelium to the anterior lens capsule) and an endothelial cell count less than 2000/mm^2. Additional exclusion criteria included a history and/or clinical signs of iritis or uveitis, macular or retinal involvement, glaucoma or pigmentary dispersion, monocular vision, lens opacity, and pseudoexfoliation. Both eyes in a patient with keratoconus had intrastromal corneal ring segment implantation 24 months previously and had stable corneal disease; both eyes were included in the study.

Outcome Parameters

The primary outcome parameters were alterations in IOP and intraoperative or early postoperative complications. The IOP was recorded during the 3-month period before surgery and 3 to 6 hours, 1 week, and 1 month after surgery. The IOP was evaluated using a noncontact computerized air tonometer (model CT-60, Topcon Corp.). The mean of 3 consecutive measurements was obtained.

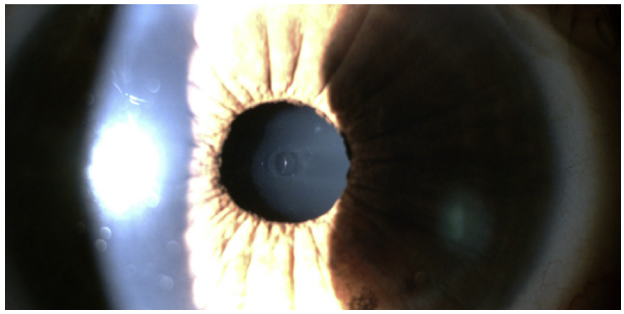

Figure 1. The new pIOL model.

Intraocular Lens

The Visian V4c posterior chamber pIOL was designed to correct myopia and myopic astigmatism (Figure 1). The pIOL is implanted in the posterior chamber behind the iris and in front of the anterior surface of the crystalline lens, with support on the ciliary sulcus. The pIOL is of Collamer, which is a copolymer composed of porcine collagen and hydroxyethyl methacrylate, a collagen-based biocompatible hydrophilic material. The pIOL has a plate-haptic design with a central convex–concave optical zone and a cylinder located on an axis placed in the toric pIOL to address astigmatism on an individual basis. The pIOL has a 360 µm hole or port in the center of the optic that is designed to restore more natural aqueous flow and obviate the need for iridotomy. Two 360 µm perioptic holes facilitate removal of the ophthalmic viscosurgical device (OVD) and provide redundancy for the central optic hole.

The postoperative target in all cases was emmetropia, although in some cases the degree of ametropia could not be corrected with the available power pIOL range and a second refractive laser procedure (bioptics) was necessary. The pIOL sizing, following the manufacturer recommendations, was performed using ultrasound ACD measurements and the horizontal white-to-white (WTW) distance, which was the mean of the 2 WTW measurements obtained with a scanning-slit topographer (Orbscan, Bausch & Lomb) and an excimer workstation caliper (Technolas). The power calculation for the pIOL was performed using software provided by the manufacturer according to the patient's degree of refraction.

Surgical Technique

All patients had a standardized surgical technique under topical anesthesia and oral sedation. Intravenous sedation was required in a few cases. All implantations were performed through a 3.2 mm clear corneal tunnel incision on the steep meridian of the corneal astigmatism (previously marked at the slitlamp). Phenylephrine hydrochloride 10.0% eyedrops were instilled 3 times 90 minutes before surgery, and the eye, eyelids, and skin were irrigated with a mixture of povidone–iodine 5.0% (Betadine) and lidocaine 5.0%. Two paracenteses were created to provide access for the pIOL

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Robert Montés-Micó, PhD, Valencia University, Valencia, Spain, collaborated in the statistical analysis.

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positioning spatulas. Lidocaine 1.0% was then injected into the anterior chamber, which was filled with hydroxypropyl methylcellulose 2% (Ocuvis). The pIOL was implanted in the posterior chamber using an injector cartridge (Staar Surgical Co.) and placed anteriorly to the crystalline lens along the horizontal meridian. The toric pIOLs were oriented according to the marks. Aspiration of the OVD was always performed using a bimanual irrigation/aspiration system through the 2 corneal paracenteses that were created to manipulate the pIOL. The hydroxypropyl methylcellulose was thoroughly removed from the anterior chamber by gently displacing the pIOL and aspirating it through the central port. Intraocular acetylcholine chloride 1.0% was used in cases of iris protrusion only.

The clear corneal incisions were closed without suturing by stromal hydration, and 0.1 mL of intracameral cefuroxime 1.0% was injected into the anterior chamber at the end of the procedure. No iridotomies were performed in any case. At the end of the surgery, a drop of brimonidine tartrate 0.2% (Alphagan) was instilled and 250 mg of oral acetazolamide was given to all patients, followed by a further 250 mg 6 hours later. Eyes were examined at the slitlamp 30 minutes later, before the patient left the surgery area, to rule out excessive pIOL vaulting. Moxifloxacin hydrochloride drops (Vigamox) were given during first 2 weeks postoperatively. Rimexolone 1.0% (Vexol 1% ophthalmic suspension) was prescribed in tapering doses over 4 weeks.

Statistical Analysis

Data were analyzed using SPSS software (version 18.0, SPSS, Inc.). Normality of data was verified using the Kolmogorov-Smirnov test. Statistical differences between preoperative IOP and postoperative IOP were analyzed using the Wilcoxon signed-rank test. Differences with a *P* value less than .05 were considered statistically significant.

RESULTS

The study sample comprised 100 eyes (52 right, 48 left) of 56 patients (37 women, 19 men). Spherical pIOLs were implanted in 91 eyes and toric pIOLs in 9 eyes. Table 1 shows preoperative demographic characteristics and pIOL parameters.

Eyes had a baseline preoperative spherical equivalent (SE) of −9.48 diopters (D) ± 3.56 (SD) (range −3.37 to −23.12 D). One month after surgery, the SE was −0.25 ± 0.62 D (range +0.37 to −4.50 D). At this time, 70 (70%) eyes had an uncorrected distance visual acuity (UDVA) that was equal to or better than the preoperative corrected distance visual acuity (CDVA). One month after surgery, 97 (97%) eyes had a CDVA that was equal to or better than the preoperative CDVA. No eye lost 2 or more lines of CDVA. Three eyes lost 0.5 lines of CDVA. Six eyes had a postoperative SE greater than 1.00 D (range −1.25 to −4.50 D); 5 of these received the highest power myopic pIOL available (−18.00 D). Six bioptic procedures were performed in 4 patients as follows: 3 arcuate keratotomies, 2 photorefractive keratectomies, and 1 laser in situ keratomileusis. The mean efficacy, based on the quotient of postoperative UDVA and preoperative CDVA, was 1.03 ± 0.27 (range 2.00 to 0.25), and the mean safety, based on the quotient of postoperative CDVA and preoperative CDVA, was 1.16 ± 0.24 (range 2.50 to 0.94).

The mean IOP was 14.6 ± 3.4 mm Hg (range 8 to 26 mm Hg) before surgery. Postoperatively, the mean IOP was 14.5 ± 4.6 mm Hg (range 6 to 30 mm Hg) at 1 day, 14.2 ± 4.2 mm Hg (range 6 to 29 mm Hg) at 1 week, and 12.3 ± 3.4 mm Hg (range 9 to 24 mm Hg) at 1 month. No statistically significant alterations were detected over time after implantation ($P > .2$). Figure 2 shows the IOP variations compared with the preoperative measurement (baseline value) in each eye at each follow-up visit. It reflects the percentage of eyes over the whole sample that had increased IOP (1 to 2 mm Hg, 3 to 4 mm Hg, 5 mm Hg, >5 mm Hg, or ≥10 mm Hg), decreased IOP (1 to 2 mm Hg, 3 to 4 mm Hg, or ≥5 mm Hg), or no change in IOP (0 mm Hg) from baseline. No eye had an IOP greater than 30 mm Hg in any postoperative measurement. In 6 eyes, the IOP increased significantly (≥10 mm Hg) during the early

Table 1. Demographic data of patients and characteristics of the pIOL.

Parameter	Mean ± SD	Range
Age (y)	32.9 ± 6.8	21, 49
Refractive sphere (D)	−8.68 ± 3.43	−2.25, −22.50
Refractive cylinder (D)	−1.61 ± 1.21	−0.25, −5.00
CDVA (Snellen lines)	0.85 ± 0.18	0.3, 1.0
pIOL spherical power (D)	−10.20 ± 3.09	−4.00, −18.00

CDVA = corrected distance visual acuity; pIOL = phakic intraocular lens

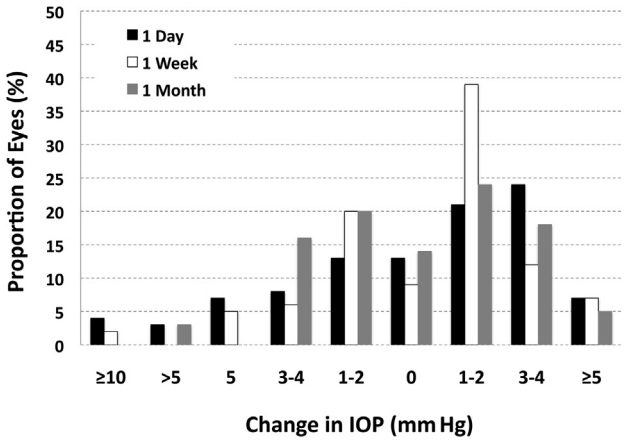

Figure 2. Percentage of eyes over the whole sample with changes from preoperative IOP 1 day, 1 week, and 1 month postoperatively (IOP = intraocular pressure).

postoperative period with respect to baseline values (4 eyes at 1 day and 2 eyes at 1 week). The IOP was higher than 25 mm Hg in 6 eyes (5 patients) during the study. At discharge, no eye had an IOP that was 10 mm Hg or more above the preoperative IOP measurement.

No perioperative complications related to pIOL implantation were detected. No eye had a postoperative pIOL vaulting grade of 0 (pIOL in contact with the lens) or 4 (excessive angular narrowing due to anterior displacement of the iris), both of which would have required pIOL explantation. In addition, no toric pIOL rotation, pupillary block, or acute angle closure was recorded.

DISCUSSION

Fujisawa et al.[19] report that inserting an Implantable Collamer Lens pIOL alters the dynamics of the aqueous humor. In contrast, other authors showed that its insertion had no significant effect on postoperative IOP[11] and that it narrowed angle width without increasing trabecular pigmentation (compared with values after laser iridotomy), thus indicating that this approach is safe regardless of pigmentary changes in the trabecular meshwork.[12,13] In their analysis of highly myopic eyes, Jiménez-Alfaro et al.[14] reported a statistically significant increase in IOP 1 month after surgery. This increase normalized by 3 months in all patients after steroid treatment was completed.

During the past decade, several authors[15–18] have reported cases of pupillary block, a complication that carries a potential risk for loss of vision. To prevent pupillary block, the conventional technique requires 2 preoperative laser iridotomies or 1 intraoperative peripheral iridectomy, leading to discomfort for the patient and difficulties for the surgeon. Peripheral iridectomies can cause complications, such as iritis, intraocular hemorrhage, increased IOP, posterior iris synechia, lens zonule damage, and corneal decompensation. Intraoperative iridectomy is a laborious maneuver that is not free from complications, such as iris or angle bleeding or iris pigment dispersion. Furthermore, in some cases, these peripheral iridectomies can produce dysphotopsia, which may require complex treatments, such as iris suture or corneal tattooing.

Our standard surgical technique for implantation of the conventional Implantable Collamer Lens was to perform a surgical iridectomy using an anterior segment vitrectomy. The introduction of the V4c model obviated this maneuver, reducing surgical time and eliminating potential associated complications (inflammation, pigment dispersion, and iris hyphema due to bleeding). This approach may also have had a positive impact on the changes in IOP after surgery. Despite these advantages, the port design of the V4c model raises doubt about whether it alone can control postoperative IOP.

In a pilot study, Shimizu et al.[22] did not find a significant increase in IOP during the early postoperative period (3 to 6 hours). In our study, at the first reading, 5 eyes had an IOP over 22 mm Hg (30 mm Hg, 28 mm Hg, 25 mm Hg, 24 mm Hg, and 24 mm Hg). We consider obstruction of the trabecular meshwork or even of the central hole by residual OVD material to be the main cause of this increase. Postoperative trabeculitis may also have affected early changes in IOP; however, the minimal surgical trauma, reduced intraoperative time, and absence of intraoperative iridectomy minimized the degree of impact of the inflammation on IOP.

Highly myopic patients are more prone to steroid-related increases in IOP. We use topical rimexolone 1.0%, which is known for its minimum effect on IOP.[23,24] Nevertheless, during the first month after surgery, 10 eyes required temporary topical hypotensive treatment. Consistent with other authors,[1,14] we attribute the increase in IOP during the first month after surgery to the effect of postoperative inflammation and topical steroids. One month after surgery, 3 eyes had an IOP of more than 21 mm Hg (24 mm Hg, 22 mm Hg, and 22 mm Hg). Considering the preoperative measurement was 21 mm Hg, 21 mm Hg, and 16 mm Hg, respectively, and the central corneal pachymetry was 560 µm, 596 µm, and 552 µm, respectively, these values were not considered clinically relevant. Likewise, at the end of our study, 3 eyes had more than a 5 mm Hg increase in IOP over the preoperative value; however, the increases were not considered clinically relevant. After topical steroid treatment, no eye required further hypotensive treatment to maintain IOP.

One main concern about the Visian V4c pIOL is the possibility of pupillary block caused by obstruction of the central port. No cases of pupillary block were reported in our series or in any of the few previously published studies (theoretical and in vivo).[20–22] Only by increasing the number of implantations will we know whether the central port ensures the free flow of aqueous humor in all possible clinical situations. We agree with other authors that these findings show that this new surgical approach, which does not require additional iridectomies, is a safe alternative to conventional myopic pIOL refractive procedures.[22] In addition, a further study to evaluate the potential association between IOP and pIOL vaulting should be performed.

In summary, short-term clinical data for the new Visian V4c pIOL with the KS-Aquaport suggest safe control of IOP after surgery. Future studies are necessary to substantiate these early results.

WHAT WAS KNOWN

- Insertion of a Visian Implantable Collamer Lens pIOL is a safe and effective treatment option for correction of refractive error.
- Insertion of a pIOL requires preoperative neodymium:YAG iridotomies or intraoperative peripheral iridectomy to prevent the increased IOP associated with pupillary block.

WHAT THIS PAPER ADDS

- Implantation of the new pIOL model with a central hole to correct moderate to high myopia provided good IOP outcomes during the early postoperative period.

REFERENCES

1. Zaldivar R, Davidorf JM, Oscherow S. Posterior chamber phakic intraocular lens for myopia of −8 to −19 diopters. J Refract Surg 1998; 14:294–305
2. Sanders DR, Brown DC, Martin RG, Shepherd J, Deitz MR, DeLuca M. Implantable contact lens for moderate to high myopia: phase 1 FDA clinical study with 6 month follow-up. J Cataract Refract Surg 1998; 24:607–611
3. Jiménez-Alfaro I, Gómez-Tellería G, Bueno JL, Puy P. Contrast sensitivity after posterior chamber phakic intraocular lens implantation for high myopia. J Refract Surg 2001; 17:641–645
4. Uusitalo RJ, Aine E, Sen NH, Laatikainen L. Implantable contact lens for high myopia. J Cataract Refract Surg 2002; 28:29–36
5. Bloomenstein MR, Dulaney DD, Barnet RW, Perkins SA. Posterior chamber phakic intraocular lens for moderate myopia and hyperopia. Optometry 2002; 73:435–446
6. Implantable Contact Lens in Treatment of Myopia (ITM) Study Group. U.S. Food and Drug Administration clinical trial of the Implantable Contact Lens for moderate to high myopia. Ophthalmology 2003; 110:255–266. Available at: http://old.iloveeye.com/pds/FDA.pdf. Accessed July 15, 2013
7. Lackner B, Pieh S, Schmidinger G, Hanselmayer G, Dejaco-Ruhswurm I, Funovics MA, Skorpik C. Outcome after treatment of ametropia with implantable contact lenses. Ophthalmology 2003; 110:2153–2161
8. ICL in Treatment of Myopia (ITM) Study Group. United States Food and Drug Administration clinical trial of the Implantable Collamer Lens (ICL) for moderate to high myopia; three-year follow-up. Ophthalmology 2004; 111:1683–1692
9. Pineda-Fernández A, Jaramillo J, Vargas J, Jaramillo M, Jaramillo J, Galíndez A. Phakic posterior chamber intraocular lens for high myopia. J Cataract Refract Surg 2004; 30:2277–2283
10. Kamiya K, Shimizu K, Igarashi A, Hikita F, Komatsu M. Four-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. Arch Ophthalmol 2009; 127:845–850. Available at: http://archopht.jamanetwork.com/data/Journals/OPHTH/10098/ecs80073_845_850.pdf. Accessed July 15, 2013
11. Kohlhaas M, Druschel S. Intraocular pressure after phakic posterior chamber intraocular lens implantation: 5-year follow-up. J Cataract Refract Surg 2005; 31:2230
12. Chun YS, Park IK, Lee HI, Lee JH, Kim JC. Iris and trabecular meshwork pigment changes after posterior chamber phakic intraocular lens implantation. J Cataract Refract Surg 2006; 32:1452–1458
13. Abela-Formanek C, Kruger AJ, Dejaco-Ruhswurm I, Pieh S, Skorpik C. Gonioscopic changes after implantation of a posterior chamber lens in phakic myopic eyes. J Cataract Refract Surg 2001; 27:1919–1925
14. Jiménez-Alfaro I, Benítez del Castillo JM, García-Feijoó J, Gil de Bernabé JG, Serrano de la Iglesia JM. Safety of posterior chamber phakic intraocular lenses for the correction of high myopia; anterior segment changes after posterior chamber phakic intraocular lens implantation. Ophthalmology 2001; 108:90–99; discussion by SM MacRae, 99
15. Bylsma SS, Zalta AH, Foley E, Osher RH. Phakic posterior chamber intraocular lens pupillary block. J Cataract Refract Surg 2002; 28:2222–2228
16. Smallman DS, Probst L, Rafuse PE. Pupillary block glaucoma secondary to posterior chamber phakic intraocular lens implantation for high myopia. J Cataract Refract Surg 2004; 30:905–907
17. Vetter JM, Tehrani M, Dick HB. Surgical management of acute angle-closure glaucoma after toric implantable contact lens implantation. J Cataract Refract Surg 2006; 32:1065–1067
18. Chan KC, Birchall W, Gray TB, Wells AP. Acute angle closure after implantable contact lens insertion unresponsive to surgical peripheral iridectomy. J Cataract Refract Surg 2008; 34:696–699
19. Fujisawa K, Shimizu K, Uga S, Suzuki M, Nagano K, Murakami Y, Goseki H. Changes in the crystalline lens resulting from insertion of a phakic IOL (ICL) into the porcine eye. Graefes Arch Clin Exp Ophthalmol 2007; 245:114–122
20. Shiratani T, Shimizu K, Fujisawa K, Uga S, Nagano K, Murakami Y. Crystalline lens changes in porcine eyes with implanted phakic IOL (ICL) with a central hole. Graefes Arch Clin Exp Ophthalmol 2008; 246:719–728
21. Uozato H, Shimizu K, Kawamorita T, Ohmoto F. Modulation transfer function of intraocular collamer lens with a central artificial hole. Graefes Arch Clin Exp Ophthalmol 2011; 249:1081–1085
22. Shimizu K, Kamiya K, Igarashi A, Shiratani T. Early clinical outcomes of implantation of posterior chamber phakic intraocular lens with a central hole (Hole ICL) for moderate to high myopia. Br J Ophthalmol 2012; 96:409–412. Available at: http://bjo.bmj.com/content/96/3/409.full.pdf. Accessed July 15, 2013
23. Leibowitz HM, Bartlett JD, Rich R, McQuirter H, Stewart R, Assil K. Intraocular pressure-raising potential of 1.0% rimexolone in patients responding to corticosteroids. Arch Ophthalmol 1996; 114:933–937
24. Assil KK, Massry G, Lehmann R, Fox K, Stewart R. Control of ocular inflammation after cataract extraction with rimexolone 1% ophthalmic suspension. J Cataract Refract Surg 1997; 23:750–757

OTHER CITED MATERIAL

A. Zaldivar R, "Standard Procedure, Exceptional Results. Reviewing 18 Years of Experience Implanting Phakic IOLs," Cataract & Refract Surgery Today Europe. Insert: Highlights from the 2011 ICL/Toric ICL Experts Symposium January 2012; pages 2–3. Available at: http://bmctoday.net/crstodayeurope/pdfs/0112_insert.pdf. Accessed July 15, 2013

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