Original Article

Audit of 1000 consecutive cases of sutureless cataract surgery in children above two years of age

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Purpose: To study the safety of sutureless cataract surgery and risk factors for wound leak of clear corneal incision in children affected with congenital or developmental cataract. **Methods:** It is a retrospective, noncomparative interventional case study involving children in the age group of 2 to 16 years, who underwent cataract surgery with intraocular lens implantation with the minimum follow up of 1 month. **Results:** Out of 1000 eyes studied, lens matter aspiration with intraocular lens implantation with or without primary posterior capsulorhexis and anterior vitrectomy was done in 609 and 391 eyes, respectively. Incisions of 943 eyes did not require sutures while sutures were applied for wound leak in 57 eyes on the table and in 5 eyes on postoperative day 1. Risk of wound leak for suture application was found to be greater in patients; having age less than 5 years ($P < 0.0001$), surgeries performed by junior surgeons ($P < 0.0003$), wound problems ($P < 0.0001$), intraocular lens (IOL) related factors ($P < 0.0001$), use of iris hooks ($P < 0.0001$), and anterior capsulorhexis extension ($P < 0.0001$). On the first postoperative day, anterior chamber reaction ($P < 0.0001$) and fibrinous membrane ($P = 0.0007$) were significantly more in the sutured group. Incidence of postoperative complications was 0.98 per sutured eyes (59 complications in 60 eyes). One patient developed endophthalmitis after suture removal. **Conclusion:** Sutureless clear corneal incision in pediatric patients undergoing cataract surgery can achieve stable wound. However, after hydro closure, every wound should be checked for water tightness and the leaky wound should be sutured.

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Sutureless cataract surgery is now considered as a standard of care in adults. However, the low scleral rigidity and tissue elasticity in children leads to fish-mouthing of internal incision making it leaky and hence it is recommended to suture all incision in pediatric cataract surgery.[1-6] There are several disadvantages of suturing corneal wounds in children, including increased surgical time, foreign body sensation, induced astigmatism, need of repeat anesthesia for suture removal, and dangers associated with suture removal.[7,8] Even absorbable 10–0 polyglactin sutures may require unscheduled removal due to foreign body sensation, vascularization, and broken or loose suture,[9] and if not removed there may be chances of inflammation, infiltrations, and unsightly scarring.

Sukhija *et al*. described viscoplugging of the wound to avoid suture related complications.[10] Minimally invasive surgery using 23 or 25-gauge vitrector cutter has been described in the literature for pediatric cataract surgery in the recent past with the advantage of potentially sutureless surgery.[11,12]

Our center is a high volume pediatric ophthalmic department in central India. We perform approximately 1500 pediatric cataract surgeries every year. We have been routinely practising sutureless clear corneal pediatric cataract surgery in children over 2 years of age for several years. We hereby report our experience of sutureless pediatric cataract surgery in 1000 consecutive eyes of children with congenital or developmental cataract.

Methods

We retrospectively reviewed case records of 1000 consecutive eyes of 645 children (aged 2 to 16 years) who underwent cataract surgery with intraocular lens (IOL) implantation at a tertiary eye care center in central India from January 2010 to December 2016. The study conformed to the tenets of the Declaration of Helsinki. This being a retrospective study, institutional review board approval was taken to ensure anonymity and confidentiality of data. Written informed consent was taken from the patient's legal guardian for surgery. Benefits and potential risks of sutureless and suture techniques were also explained.

Cases with a minimum of one month follow up after surgery were included. Children presenting with traumatic, subluxated or complicated cataract, cataract with microcornea,

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microphthalmos, or any other developmental anomalies, and those with glaucoma were excluded from the study.

Data collection

The demographic data of all the patients were extracted from the case sheets. Preoperative evaluation including a complete history, general physical examination, ocular examination including corrected distant visual acuity (CDVA), slit-lamp evaluation, automated keratometry, applanation A-scan biometry, fundus examination, ultrasonography (in eyes in which a dense cataract precluded the view of the fundus), and the IOL power was recorded. The IOL power calculation was done using SRK/T formula and age-appropriate under-correction was done using Dahan and Drusedau recommendation.[13]

Information on intraoperative complications such as a nondilating pupil, premature entry, larger keratome wound (more than 2.8 mm), damaged wound during surgery, iris prolapse, hyphema, an extension of anterior and posterior capsulorhexis, preexisting posterior capsule defect, and IOL related complications such as broken haptic requiring wound enlargement and IOL exchange were noted. Early postoperative detail and complications such as infection, anterior chamber reaction, hypotony and shallow anterior chamber (grade 1 van herick),[14] iris prolapse, hyphema were noted on the first postoperative day. Late complications such as pigments on IOL, iridocapsular/lenticular adhesions, decentered IOL, visual axis opacification (VAO), ocular hypertension, late endophthalmitis were noted on the thirtieth day and on subsequent follow-up visits. The additional surgical procedure, postoperative CDVA, dilated retinoscopy, and refraction were also noted from the case sheet.

Surgical procedure

All the surgeries were performed by pediatric ophthalmologists including fellows (under supervision) and consultants. Based on their years of surgical experience of pediatric cataract surgeries, surgeons were considered either senior (>5 years) or junior (<5 years).

Under general anesthesia, one superior triplanar main clear corneal 2.8 mm incision with keratome and two uniplanar side ports of 1 mm each on either side of the main incision were made with lance tip. The anterior capsule was stained with trypan blue dye. Anterior continuous curvilinear capsulorhexis (CCC) was initiated with cystitome and completed by utrata forceps. After hydrodissection, lens matter aspiration (LMA) was done either using phaco-aspiration and bimanual irrigation and aspiration cannula followed by implantation of single-piece foldable acrylic (hydrophobic or hydrophilic) IOL. A primary posterior capsulotomy (PPC) with 23-gauge vitrector was done in patients less than 8 years old, mentally retarded children, and those having nystagmus. Later, preservative-free moxifloxacin (0.05 cc) was injected intracamerally.

All the wounds were closed by stromal hydration after reforming the anterior chamber with air. Seidel's test with sterile fluorescein strip along with our own described "air bubble test" was done to find leakage from any wounds in first 50 cases. In air bubble test after hydration of wounds at the end of the procedure, full chamber air bubble was injected in the anterior chamber. If there was a leakage of air with or without applying gentle pressure on the globe or if there was an extension of the bubble at the internal wound [Fig. 1a], it was labelled as leaky wound and the incision was then closed with 10–0 nylon suture [Fig. 1b] followed by removal of the air bubble. In the absence of leakage of air and negative Seidel's test, the air was removed, and the chamber was filled with balanced salt solution and wounds were hydrated again. In the rest 950 cases, we confirmed sealability of wound only with air bubble test. We assessed both air tightness and subsequently water tightness by applying gentle external pressure on corneal apex. If hypotony or shallowing of the anterior chamber was noticed, then sutures were taken irrespective of retention of air bubble. Wounds were left sutureless in the absence of any signs of leakage [Fig. 2].

Postoperative evaluation and management

Postoperative treatment included moxifloxacin (0.5%) eyedrop four times a day, prednisolone acetate (1%) eight times daily for a week then tapered over next 5 weeks and homatropine 2% eyedrop three times for 2 weeks.

Patients with the flat anterior chamber, hypotony, or leaky wounds were taken up for suturing on postoperative day 1. Glasses were prescribed at the end of the first month and amblyopia therapy in the form of patching was started in amblyopic patients.

Suture related complications (vascularization of the cornea, loose suture, suture infiltration, and foreign body sensation) were also noted at follow-up visits and suture removal was done in these cases, if required and followed thereafter.

Statistical analysis

Statistical analysis was performed using a data analysis tool pack of Microsoft excel and Epi info 7 (7.2.2.6, Centers for Disease Control and Prevention). Mean, median, and standard deviation ranges were evaluated for continuous variables while for categorical variables, frequency and percentages were recorded. Independent *t*-test was used to compare mean values. Bivariate regression analysis was evaluated using Chi-square test and Fischer exact test to compare frequency more than 5 and less than 5, respectively. The factors associated with the need for sutures during surgery or in the early postoperative period were determined by calculating the odds ratio of various modifiable and nonmodifiable baseline and intraoperative variables (univariate). Multivariate regression analysis was also performed for factors which were found significant in univariate analysis. *P* value of less than 0.05 within 95% CI was considered statistically significant.

Results

A total of 1000 eyes of 645 consecutive patients (2 to 16 years of age group) that underwent LMA with IOL implantation were retrospectively studied. Numbers of male and female patients were 457 and 188, respectively. Mean age of the patients was 7.96 ± 3.9 years. LMA with IOL implantation and PPC with anterior vitrectomy were performed in 609 (60.9%) eyes. Rest 391 (39.1%) eyes underwent only LMA with IOL implantation. Sutures were applied in 54 (5.4%) eyes having wound leak at the end of surgery. Sutures were applied only to the main port in 47 eyes, only to the side ports in 3 eyes; while all the ports were sutured in 4 eyes. Postoperatively on day 1, wound leak was noted in 3 of 946 nonsutured eyes and in 2 of 54 eyes in which sutures were applied on the table. All 5 eyes were taken

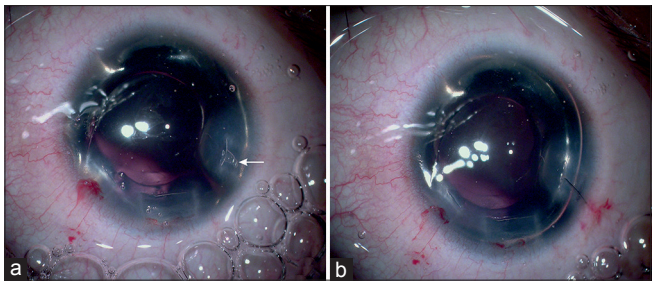

Figure 1: (a) White arrow shows leakage and extension of bubble at the site of internal incision of the wound. (b) Well retained single air bubble in anterior chamber and intraoperative suture application at the site of wound leak

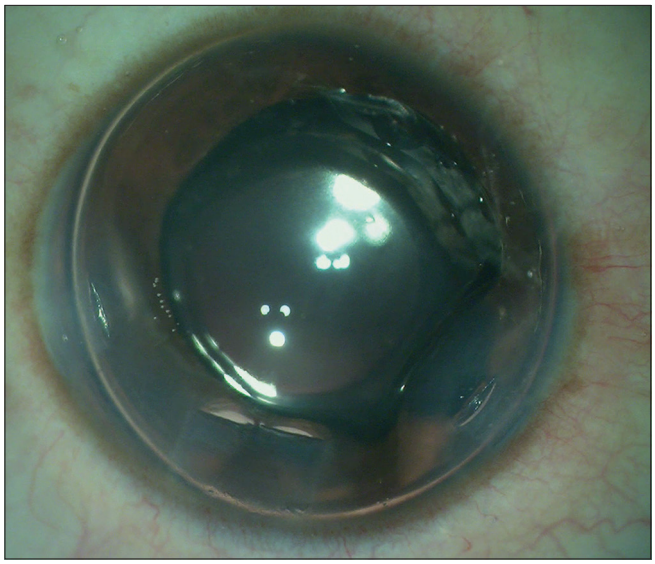

Figure 2: Wound closure by stromal hydration and air bubble

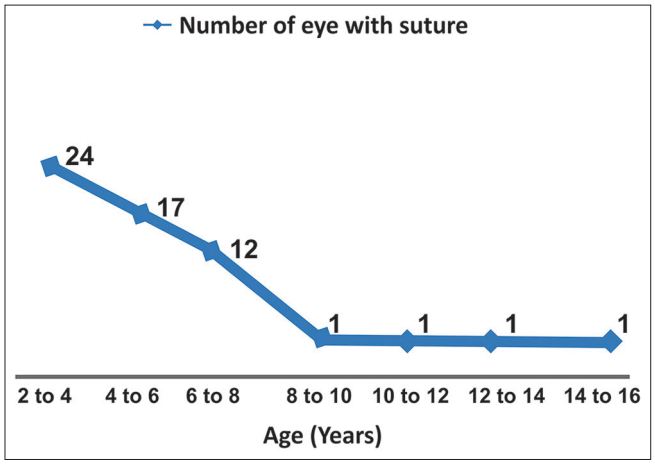

Figure 3: Line chart showing number of eyes with suture in different age groups

up for resuturing the next day. Demographic profile of the patients is enlisted in [Table 1].

The modifiable and nonmodifiable risk factors or events associated with placement of sutures that were studied included age, surgeons experience, pupillary dilatation,

Table 1: Demographic Characteristics

	Number of cases	Percentage
Mean Age (years)	7.96±3.90	
2-5 Years	303	30.3%
5-8 years	291	29.1%
>8 Years	406	40.6%
Gender		
Male	457	70.9%
Female	188	29.1%
Eye		
Right	580	58%
Left	420	42%
Laterality (645 children)		
Unilateral	290	45%
Bilateral	355	55%
Patient Underwent PPC + AV	609	60.9%
Suture applied on table	54	5.4%

PPC=Primary posterior capsulorhexis, AV=Anterior vitrectomy

extremes of axial length (<20 mm or >26 mm), wound-related complications, application of iris hooks, extension of anterior CCC, pre-existing posterior capsular dehiscence, and primary posterior capsulotomy with anterior vitrectomy. For the purpose of analysis, the patients were grouped according to their age and according to the experience of operating surgeons (senior or junior).

Among nonmodifiable variables, younger age was found to be a significant risk factor ($P < 0.0001$) for suture application. The risk was 3.4 times higher if the patient's age was less than 5 years. This was also reflected in the line chart [Fig. 3] which showed an initially steady decline in the incidence of suture application until 8 years, followed by a steep decline in older age groups. Other nonmodifiable risk factors like sex, shorter (< 20 mm) or longer (>26 mm) axial length as was not found to be having significant risk for application of sutures ($P > 0.05$).

In univariate analysis, modifiable risk factors that were significantly associated ($P < 0.05$) with application of sutures were [Table 2]: junior surgeon (OR-2.7), PPC (OR-3.63), wound-related complications (OR-48.33), intraoperative use of iris hooks (OR-26.2), capsulorhexis run away (OR-9.5), pupil dilatation <6 mm (OR-8.5). However, on multivariate analysis following factors were found to be significantly associated with suture application [Table 3]: anterior capsulorhexis extension (OR-18.11), iris hooks (OR-45.18), pupil size <6 mm (OR-4.43), and wound-related complications (OR-48.12).

On the first postoperative day, severe anterior chamber inflammation (reaction greater than two and fibrinous membrane) was significantly more in sutured eyes. The shallow anterior chamber was seen in eight (0.8%) eyes in sutureless group, out of which three required suturing of the ports due to presence of leakage. Two patients in the suture group also required resuturing. The incidences of late complications such as lens decentration, pigments on IOL, and VAO were statistically insignificant in both groups [Table 4]. We did not find early or late endophthalmitis in any case despite leaving ports sutureless.

Table 2: Risk factor for wound leak

	Suture less, *n*=943 (%)	Suture, *n*=57 (%)	Total	OR (95% CI)	*P*
Age					
2-5 Years	270 (28.6%)	33 (57.9%	303	3.4 (1.9-5.9)	<0.0001
5-8 years	271 (28.7%)	20 (35.1%)	291		
>8 Years	402 (42.6%)	4 (7%)	406		
Sex					
Male	643 (68.2%)	33 (58%)	676	0.64 (0.4-1.1)	
Female	300 (31.8%)	24 (42%)	324		
Surgeon					
Senior	718 (76.1%)	31 (54%)	749	2.7 (1.5-4.6)	0.0003
Junior	225 (23.9%)	26 (46%)	251		
Axial Length					
>26 mm	116 (12.3%)	5 (9%)	121	0.6 (0.3-1.7)	0.43
<26 mm	196 (20.8%)	8 (14%)	204	0.6 (0.3-1.3)	0.21
Wound problem*	15 (1.5%)	25 (30%)	40	48.33 (23.2-100.3)	<0.001
Pupil size <6 mm	23 (2.4%)	10 (18%)	33	8.5 (3.8-18.9)	<0.001
Use of iris hooks	5 (0.5%)	7 (12%)	12	26.2 (8.0-85.6)	<0.001
Anterior CCC extended	31 (3.3%)	14 (25%)	45	9.5 (4.7-19.3)	<0.001
Iatrogenic PCR/pre-existing PC dehiscence	24 (2.5%)	3 (5%)	27	2.1 (0.6-7.2)	0.210
Procedure					
LMA + IOL	382	9	391	3.63 (1.7-7.4)	0.001
LMA + IOL + PPC + AV	561	48	609		

*Premature entry, excessively large wound (more than 3.2 mm), damaged wound during surgery, broken haptic requiring wound enlargement and IOL exchange. CCC=Continuous curvilinear capsulorhexis, PCR=Posterior capsular rent, LMA=Lens matter aspiration, IOL=Intraocular lens, PPC=Primary posterior capsulotomy, AV=Anterior vitrectomy

Table 3: Multivariate analysis

Term	Odds ratio	95% C.I. (range)		Coefficient	S.E	*Z*-Statistic	*P*
Junior surgeon	1.11	0.47	2.60	0.10	0.43	0.24	0.80
Age	8.80	2.95	26.26	2.71	0.55	3.90	0.0001
AL <20	0.84	0.26	2.67	-0.16	0.58	-0.28	0.77
AL >26	1.29	0.35	4.72	0.25	0.66	0.39	0.69
Anterior CCC extended	18.11	6.51	50.38	2.89	0.52	5.55	0.00
Iris hooks	45.18	9.86	206.85	3.81	0.77	4.90	0.00
Iatrogenic PCR/pre-existing PC dehiscence	1.32	0.16	10.62	0.27	1.06	0.26	0.79
Pupil <6 mm	4.43	1.35	14.57	1.48	0.60	2.45	0.01
Wound problems	48.12	17.55	131.94	3.87	0.51	7.52	0.00

AL=Axial length, CCC=Continuous curvilinear capsulorhexis, PCR=Posterior capsular rent

Table 4: Early and late post-operative complication in patients

	Suture less, *n* (%)	Suture, *n* (%)	Odds ratio	*P*
AC reaction >2*	91 (9.6%)	32 (56.1%)	11.9	<0.0001
Fibrinous pupillary membrane*	21 (2.2%)	6 (10.5%)	5.1	0.0007
Shallow AC (VH 1,2)*	8 (0.8%)	2 (3.5%)	4.2	0.07
Lens decentration**	18 (1.9%)	3 (5.2%)	2.8	0.1
Pigments on IOL**	21 (2.2%)	3 (5.2%)	2.4	0.15
Visual axis opacification**	34 (3.6%)	4 (7.0%)	2.0	0.19

*Complications on first postoperative day, **Complications observed till last follow up. AC=anterior chamber, VH=Van herick grading of anterior chamber depth, IOL=Intraocular lens

Suture related complications included corneal vascularization in 16 (28%), loose suture with discomfort in 14 (24%), infiltrate in 4 (7%), repeat anesthesia for suture removal in 20 (35%), resuturing in 4 (7%) eyes. Notably, one patient developed endophthalmitis post suture removal. Overall incidence was 0.98 per sutured eyes.

Discussion

Even though the wound size in pediatric cataract surgery has reduced from 6 mm to nearly 2.2–2.8 mm with the advent of the foldable intraocular lens, still almost all eyes land up getting sutures.

Incisions in the children are less stable and leaky wounds may increase the risk of the shallow anterior chamber, synechiae, IOL displacement, iris prolapse, hypotony, and endophthalmitis.[9,15-17] Hence, sutures are considered gold standards for the closure of incisions. Sutures in children, however, induce significant astigmatism which can be amblyogenic.[8] It is also a source of discomfort which may endanger hygiene. Repeated general anesthesia or sedation is also required for suture removal. Though polyglactin suture is claimed not having disadvantages of nylon material, one study[9] reported otherwise and removal of 10–0 polyglactin suture was required due to various complications. Sukhija *et al.* described viscoplugging of the wound to avoid suture related complications.[10] However, there is a possibility of a rise in intraocular pressure with the use of high molecular weight viscoelastic and high-early postoperative astigmatism that has a potential amblyogenic effect. Minimally invasive sutureless pediatric cataract surgery with 23 or 25-gauge vitrectomy cutter (without IOL implantation) has been described in recent literature with the advantage of potentially sutureless approach.[11,12]

The sutureless approach has not been studied in detail in the past and hence, we feel that sutures can be avoided in most of these cases, provided proper surgical technique is made available. In this retrospective study, we looked at wound stability of 2.8 mm clear corneal incision and 1 mm side port in consecutive 1000 cases of congenital and developmental cataract in children from 2 to 16 years. Cases of traumatic cataract and associated ocular anomalies were excluded because of altered anatomy of ocular structures which may contribute to increased risk of wound leak. We suture all incisions in children younger than 2 years of age.

Our sutureless approach in pediatric cataracts was based on many previously reported studies in the literature. Ernest *et al.* in their experimental study had proposed "square incisional geometry as most stable and ideal".[18] Similarly, Masket and Belani reported that square-shaped clear corneal wounds that are meticulously checked for sealing were stable postoperatively as demonstrated by the absence of hypotony and wound leakage.[19] Martin Grueterich reported using sub 2 mm incisions in 32 eyes of 22 children with congenital cataract between 2 to13 years of age.[20] None of the eyes required suturing during the postoperative period.

In contrast to the above studies, Basti *et al.*[21] in their study of 25 eyes recommended against leaving wound sutureless in children. However, in their study, the incision size was 6 mm scleral tunnel as they used rigid IOLs. Moreover, in their study, they said that the wounds can be left unsutured in children more than 11 years of age.

We had fashioned the clear corneal wound in a way that width of incision was 2.8 mm and length 2 mm making the wound almost square and triplanar. We used stromal hydration to seal clear corneal wound rather than using suture. At the end of the procedure, we checked for a wound leak by doing Seidel's test and/or air bubble test. In air bubble test, we looked for air bubble leak or extension of the bubble at the internal lip of incision after filling the anterior chamber completely with a single air bubble. The ports were sutured if found leaky.

Out of 1000 cases in our study, 943 eyes were left unsutured on the table during surgery. Only 3 (0.3%) of those cases needed suturing in the first postoperative day due to wound leak and shallow anterior chamber.

When we analyzed the events associated with wound leak and need of sutures, we found age as one of the major risk factors. Children >5 years were 3.4 times less likely to have wound leak or need of suture as compared to those <5 years. The risk increased progressively with decreasing age. The mean age of children in which sutures were applied was 5.5 ± 3.8 years compared to 8.1 ± 4.0 years in those wherein no sutures were applied. This may be related to increasing scleral rigidity, decreased elasticity, and lesser vitreous up thrust with increasing age. However, we could avoid suturing in 89.1% (270 of 303) of children less than 5 years of age. Other factors that were found to be associated with an increased likelihood of suture placement were surgeon's experience, an additional procedure such as PPC and AV, wound-related complications, use of iris hooks, and extension of anterior CCC.

The odds of wound leak were 3.63 times more in patients with PPC and AV, as compared to patients without PPC and AV. This was indirectly related to age as PPC and AV were performed in all children younger than 8 years of age. The odds of applying suture were 2.7 for junior surgeons. Longer duration of surgery, greater manipulation of the surgical wound and imperfect wound construction may have accounted for this. Multivariate analysis did not find these two as an independent risk factor.

Factors such as broken haptic requiring wound enlargement and IOL exchange, premature entry, wound damage during surgery for reasons obvious increased the risk of wound leak by 48 times. We noted that the risk of wound leak was greater (OR-26.2) in eyes needing mechanical dilation using iris hooks. The multiple stab incisions required to place iris hooks alter the anatomical integrity and ultimately wound stability.

The risk of wound leak was 9.5 times higher in eyes with extensions of anterior capsulorhexis. It was common in younger children (total n = 45 with a mean age of 4.5 ± 1.7 years) due to its elastic nature. Sutures were probably used in these cases to avoid IOL instability in the presence of irregular capsular support. Sutures avoided anterior chamber fluctuation while closing the ports and maintained proper in the bag IOL position.

The sutures were removed under all aseptic precautions in operation theatre. Majority of suture related complications were insignificant except a case of endophthalmitis. Suture removal has been reported having a small risk of endophthalmitis in the literature.[22-24] The patient was managed with prompt pars plana vitrectomy and intravitreal antibiotics with favorable outcomes.

The average preoperative visual acuity in our study was 1.07 logMAR and the average postoperative visual acuity was 0.30 logMAR, which was comparable with other studies.[25-27]

We were not able to evaluate visual acuity in 279 eyes both preoperatively and postoperatively due to lack of cooperation and were excluded in this analysis.

To our knowledge, this is the largest study on outcomes of sutureless cataract surgery in children between 2 to 16 years of age. In our consecutive series of 1000 developmental and congenital cataract, we were able to leave the wounds unsutured in most cases. In our experience, suturing clear corneal wounds in pediatric cataract surgery can be avoided. However, one may need to be careful and suture the wound in the presence of risk factors such as a very young child, use of iris hooks, extended capsulorhexis, wound-related complications, or surgical inexperience.

The strength of our study is its large sample size. We took all the consecutive cases of congenital and developmental cataract in children so as to reduce the selection bias. The surgeries were done by multiple surgeons with varying surgical experience which makes the study more widely applicable.

However, our study was limited by the fact that it was a retrospective study with some inherent biases. The follow up was short, so long-term complications of leaving the wound unsutured could not be ascertained.

Conclusion

The sutureless clear corneal incision can achieve stable wound closure in children more than 2 years of age. It reduces surgery and anesthesia duration making it faster and safer for patients. It avoids suture related complications and needs for repeated anesthesia for suture removal and risk of endophthalmitis. However, every wound should be thoroughly checked for leakage at the end of surgery and if found leaky should be sutured.

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Conflicts of interest

There are no conflicts of interest.

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