The Effect of Phacoemulsification Cataract Surgery on the Onset and Progression of Diabetic Retinopathy in Patients with Type 2 Diabetes: A Systematic Review and Meta-Analysis

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ABSTRACT

Purpose: To systematically review the literature on the onset or progression of diabetic retinopathy in patients with type 2 diabetes, following phacoemulsification.

Methods: A systematic search of PubMed, CINAHL and EMBASE was conducted. The database search was from 1995 to 2020. Prospective and retrospective observational studies of human participants with a minimum follow-up period of 12 months were included. Citation chaining of all included studies was also performed. No restriction was placed on the duration, control of diabetes or stage of diabetic retinopathy. All included articles were assessed for risk of bias using the Critical Appraisal Skills Programme (CASP) checklist. Pooled odds ratios (ORs) and 95% CIs were calculated using a fixed-effect, Mantel-Haenszel analysis.

Results: A total of six articles met the inclusion criteria. Four were prospective observational studies and two were retrospective. All studies utilised the fellow eye as a control with a follow-up period ranging from 12 to 36 months. The overall pooled odds ratio was 1.34, 95% CI [0.93, 1.94], p=0.12 and showed no statistically significant difference between the phacoemulsification and control group.

Conclusions: This systematic review and meta-analysis suggest that phacoemulsification surgery does not increase the risk of diabetic retinopathy progression or its onset in patients with type 2 diabetes. Significant developments in surgical technique advancing from extracapsular cataract extraction to phacoemulsification, which has assisted in reducing the resulting postoperative inflammation, likely explains these findings. Further studies with longer follow-up duration, larger sample size, more ethnically diverse population groups and that control for known confounding factors will help strengthen this evidence.

Keywords: diabetic retinopathy, phacoemulsification complications, type 2 diabetes mellitus, systematic review, meta-analysis

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INTRODUCTION

Diabetic retinopathy (DR), a microvascular complication associated with diabetes mellitus (DM), is a leading cause of preventable visual impairment.[1] DM is regarded as the epidemic of the 21st century, with estimates in South Asia suggesting a 150% rise in the prevalence of Type 2 diabetes mellitus (T2DM) between 2000 and 2035,[2] with one in three of these individuals predicted to develop diabetic eye disease within their lifetime.[3] T2DM comprises the majority of worldwide cases of diabetes, representing approximately 90% of the cohort.[4] This type of DM is often diagnosed several years after its onset or after complications of the disease occur,[5] and generally develops and presents in adults over the age of 45 years, however it is becoming increasingly prevalent in younger individuals.[6]

In both developed and developing countries, the incidence of cataract progression is also increasing in patients diagnosed with DM.[7] Studies indicate that individuals with diabetes are up to five times more likely to develop a cataract, particularly earlier in life,[8] accentuating the overlapping nature of these conditions.

A cataract, in most instances, occurs due to the natural ageing of the crystalline lens of the eye whereby the increased rigidity of the nucleus leads to the clouding of the lens.[9] Cataract surgery is one of the most common ocular surgical procedures,[10] and typically involves ultrasound phacoemulsification of the natural lens and implantation of an intraocular lens; a procedure that replaced the extracapsular cataract extraction (ECCE) as the method of choice. The phacoemulsification technique involves a small incision into the temporal limbus, generally less than 3.0 mm, where a phacoemulsification probe is inserted to break up and remove the lens from the eye.[10] An artificial intraocular lens is then inserted and no sutures are required to close the wound.[10] In contrast, the ECCE technique involves a 9-13 mm 'shelved' incision running parallel to the limbus.[11] The lens is removed in whole through the incision with a subsequent cortical clean-up of any remaining lens material and insertion of an artificial lens.[11] The incision requires multiple stitches to close the wound, increasing healing time and potentially yielding variable amounts of astigmatism affecting postoperative refractive outcomes.[11]

Patients with DM have a higher risk of developing a complication following cataract surgery,[12] with this risk increasing where an individual has a history of DR.[13] DR is a common, progressive microvascular complication of DM and involves changes to the retinal blood vessels, which can result in bleeding or leaking and subsequent vision-threating damage.[14] DR is largely classified into two different types; non-proliferative diabetic retinopathy (NPDR) where neovascularisation or new blood vessels are absent, and proliferative diabetic retinopathy (PDR) where neovascularisation and haemorrhaging occur either in isolation or together. An individual can also develop diabetic macular oedema, a major complication of DR and the most common cause of visual impairment.[15,16] Whilst various factors, such as improving glycaemic control and lowering blood pressure, are well-known indicators to help reduce progression or development of DR,[17,18] the evolution of DR and its progression is primarily influenced by the duration of diabetes, a factor outside of an individual's control.[19] The risk of developing DR increases linearly in patients with diabetes after 10 years of having the disease.[19] The literature reports that more than 60% of patients with T2DM will eventually experience DR,[19] emphasising the widespread nature of the condition.

DR can have a distressing influence on the quality of life of an individual, often causing intermittent or permanent vision loss and, in advanced stages, blindness.[20] Additionally, the burden of the disease has a detrimental effect on the economy and the healthcare system.[3] Alarming projections of the prevalence of DR indicate that the costs to the healthcare system will only continue to rise as the population ages through both direct and indirect costs, including loss of productivity and loss of well-being. In Australia, in 2009, the total economic impact of vision loss was estimated to be $16.6 billion, the equivalent of $28,905 per person over the age of 40 years.[21] DR was found to contribute to 2% of all vision loss amongst Australians aged over 40 years in 2009, corresponding to an economic burden of approximately $33.2 million.[21] It is due to this widespread burden that further research aiming to improve patient outcomes and reduce the number of preventable complications related to DR is imperative.

To date various studies have investigated the effect of phacoemulsification on DR onset or progression in patients with DM,[22-25] however many of these are not specific to T2DM or have short follow-up periods, making it difficult to draw conclusions. Some studies have suggested that cataract surgery increases the risk of DR onset or progression,[26-28] whilst others have reported that onset or progression is simply the natural course of the disease as opposed to a surgical complication.[22,24,25] Those that have reported a likely relationship between surgical cataract intervention and DR progression have suggested that the breakdown of the blood-aqueous or blood-retina barriers seen in patients with DM may lead to increased postoperative complications and may instigate the onset or progression of DR.[26,29-30] The aim of this systematic review was to summarise the available literature focusing on the impact of standard ultrasound phacoemulsification cataract surgery on the onset of DR or its progression in T2DM patients. The study was restricted to patients with T2DM, as this cohort accounts for the majority of individuals diagnosed with diabetes,[4] and so as to ensure that the differences in the pathophysiology of DM type did not influence the outcome.

METHODOLOGY

Database search strategy

A search of the electronic databases PubMed, CINAHL and EMBASE was conducted for studies published between 1995 and 2020. Studies before 1995 were excluded as ECCE was the standard surgical method utilised during this period. Search terms included medical subject headings (MeSH) terms in addition to variations of terms for diabetes mellitus, phacoemulsification and diabetic retinopathy. This included Type 2, diabet*, non-insulin dependent diabet*, NIDDM, adult onset diabet*, cataract surgery, cataract removal, cataract extraction, DR, diabetic eye disease, DMO and diabetic macular *edema. Boolean operators such as 'and' and 'or' were also used to combine terms. No language restrictions were applied. Citation chaining was also performed.

Types of studies

Prospective and retrospective observational studies, including case control and cohort studies on human participants, were included. Randomised controlled trials were not sought given that, whilst ideal, it is not feasible or ethical to allow a patient with a cataract and related functional vision impairment to remain untreated.

Only full articles were included; conference abstracts and reviews were excluded. A minimum postoperative follow-up period of 12 months was required to ensure adequate time for the assessment of DR pathology progression or onset.

Participants

Studies reporting on the onset or progression of DR in individuals with T2DM undergoing ultrasound phacoemulsification cataract surgery were included. No restriction was placed on the duration of diabetes, control of diabetes or the presence or stage of DR.

Outcome measure

The primary outcome measure of this study was the onset or progression of DR following phacoemulsification cataract surgery in comparison to the non-operated fellow eye serving as the control.

Study selection

Search results were merged using the reference management software EndNote X9®. Duplicates were removed and titles and abstracts were screened. The full paper of all remaining entries was acquired and evaluated based on the inclusion criteria. The study selection was performed by two independent reviewers (DC and LM). If at any stage there was a disagreement, a third researcher (KK) was available to independently review the entry.

Data extraction

To extract data from the selected studies, a predesigned data extraction form was utilised. This was an amended version of the Cochrane Collaboration Data Collection Form,[31] tailored specifically for this systematic review. The main data items extracted included: patient characteristics such as age and gender, diabetes duration and progression of DR following intervention. Data were extracted by one reviewer (DC), and subsequently verified by the second reviewer (LM).

Assessment of bias

To assess the quality of the literature obtained, the Critical Appraisal Skills Programme (CASP) for cohort and case control studies was used. The two reviewers (DC and LM) independently assessed the quality of each paper with any disputes resolved by discussion with a third reviewer (KK). The studies were scored out of 10, with each of the first ten CASP questions worth one mark. A score of one was awarded for a 'yes' answer and a score of zero was awarded for 'can't tell' or 'no'. A score of seven or above indicated low bias and was required for inclusion.

Statistical analysis

Dichotomous data were combined for a meta-analysis whereby odds ratios (ORs) were calculated with 95% confidence interval (CIs) in a fixed-effect model using the Mantel-Haenszel (M-H) statistical method. Heterogeneity was evaluated with a chi-square test and I^2 statistics where $p > 0.05$ and/or an $I^2 < 50\%$ was considered homogeneity. Statistical analyses were performed with the ReviewManager statistical software package (Version 5.4.1, Nordic Cochrane Centre, Copenhagen, Denmark).

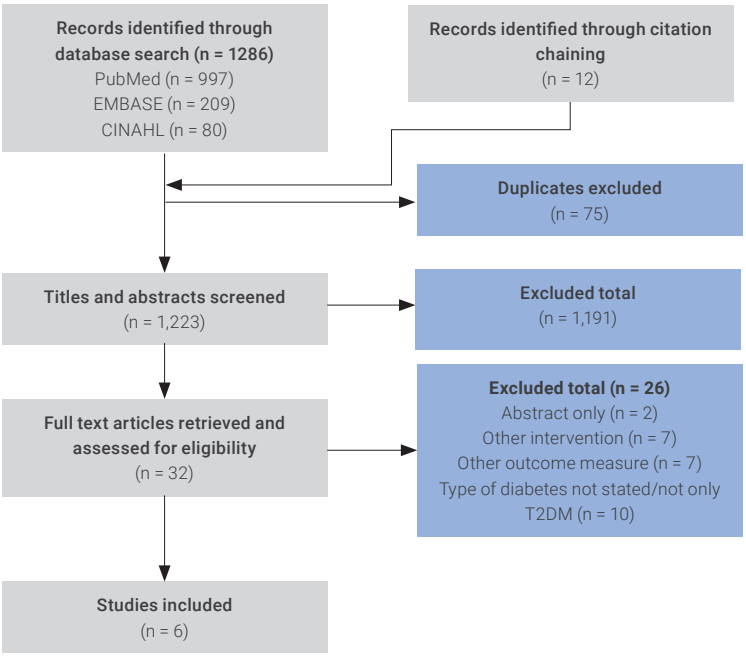

Figure 1. PRISMA flowchart overview of search results.

RESULTS

The results of the search are outlined in Figure 1. A total of 1,286 articles were identified. After removing duplicates and screening titles and abstracts, 32 full-text articles were retrieved for further review. Of these, a total of six articles met the inclusion criteria. Table 1 provides a summary of the key characteristics of the included studies. All six studies were observational and included the contralateral eye as a control; four were prospective and two were retrospective. All six were determined to be of high quality or considered to have a low risk of bias based on the CASP assessment (Table 2).

For the meta-analysis, 751 eyes were included across the six studies, with 392 of these eyes undergoing phacoemulsification.[32-37] No heterogeneity was noted between the studies ($x^2 = 0.20$, $p = 4$, $I2 = 0\%$, $p = 1.00$) and therefore a fixed-effect model was used. The pooled OR did not favour either of the two groups in terms of progression or onset of DR (OR = 1.34, 95% CI [0.90, 1.94], $p = 0.12$). Figure 2 displays the forest plot summarising the results of the meta-analysis.

As noted in Figure 2, all six studies reported no significant difference between phacoemulsification surgery and DR progression or onset.[32-37] Five of the included papers reported no intraoperative complications.[32,33,34,36,37] The only paper to report complications reported two cases where a conversion to ECCE was required due to the extension of the anterior capsulorhexis.[35] All included prospective cohort studies had

Table 1. Study characteristics of included studies

Study country of study	Study design	Type of diabetes and retinopathy	Sample size (number of eyes)	Follow-up period	Age Mean ± SD (range)	Gender (M/F)	Duration of diabetes, years, Mean ± SD (range)
Squirrell et al (2002)[32] Sheffield, UK	Prospective observational study with the contralateral eye as a control	T2DM	n = 100 (50 operated eyes, 50 control eyes)	12 months	(59 – 88)	27/23	(2 – 38)
Krepler et al (2002)[33] Vienna, Austria	Prospective observational study with the contralateral eye as a control	T2DM Mild-to-moderate NPDR	n = 79 (42 operated eyes, 37 non-operated eyes)	18 months	72.1 ± 9.7	13/28	16.0 ± 11.0
Liao and Ku (2003)[34] Keelung, Taiwan	Retrospective observational study with the contralateral eye as a control	T2DM No DR Mild-to-moderate NPDR	n = 74 37 patients (Binocular surgery = 14 Monocular surgery = 23 51 operated eyes, 23 non-operated eyes)	3 years	66.8 ± 6.23	14/23	7.75 ± 6.89
Chatterjee, Savant and Stavrou (2004)[35] Birmingham and Midland Eye Centre, UK	Retrospective observational study with the contralateral eye as a control	T2DM	n = 60 30 patients (Binocular surgery = 9, only one eye included in study) Monocular surgery = 21 30 operated eyes, 30 non-operated eyes)	12 months	68.9 ± 10	15/15	9.4 ± 7.6
Romero-Aroca et al (2006)[36] Barcelona, Spain	Prospective cohort study with the contralateral eye as a control	T2DM No DR or NPDR	n = 264 (132 operated eyes, 132 non-operated eyes)	12 months	(62 – 91)	60/72	(5 – 35)
Suto et al (2006)[37] Tokyo, Japan	Prospective cohort study with the contralateral eye as a control	T2DM No PDR	n = 174 (87 operated eyes, 87 non-operated eyes) Divided based on perioperative glycaemic control Gp1: Rapid correction (n = 27) Gp2: Poor control (n = 30) Gp3: Good control (n = 30)	12-months	Gp1: 63.0 ± 10.6 Gp2: 63.1 ± 9.2 Gp3: 63.1 ± 6.6	Gp1: 15/12 Gp2: 13/17 Gp3: 11/19	Gp1: 7.8 ± 5.9 Gp2: 8.4 ± 4.9 Gp3: 9.1 ± 5.6

T2DM = type 2 diabetes mellitus; DR = diabetic retinopathy; NPDR = non-proliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy

minimal dropouts, however across all included prospective cohort studies, seven patients died during the studies and five were lost to follow-up.[32,33] The included retrospective studies also had 26 cases excluded due to inadequate data,[34,35] and a series of individuals having bilateral cataract operations with an interval of fewer than six months between the two surgeries.[35] Each study only had one surgeon performing the phacoemulsification on all patients, removing the variable of surgeon experience as a possible factor in progression which has been observed in previous studies.[38]

All articles shared similar exclusion criteria including marked asymmetry in preoperative DR between eyes,[32,36] eyes with a history of ocular diseases such as glaucoma, uveitis, maculopathies or trauma,[33,34,36,37] and previous various ophthalmic procedures including laser treatment.[33,34,36,37] Two papers excluded patients if their cataract was very dense, precluding classification of DR.[33,34] One paper excluded patients if their fellow eye had a lens opacity likely to preclude adequate fundal examination, or if the fellow eye had had cataract surgery within 12 months.[32] Four papers limited the type of DR included in their studies, two excluded patients who had PDR,[36,37] one only included patients with no DR or only mild-to-moderate DR,[34] and one only included patients who had DR classified as mild-to-moderate NPDR in both eyes.[33]

DISCUSSION

Cataract has been found to be one of the major causes of functional visual impairment in the diabetic population.[8,34] However, there is varying evidence regarding the impact of phacoemulsification cataract surgery on the onset or progression of DR within the T2DM population. The literature suggests that the advancement in the method of surgery from ECCE or intracapsular cataract extraction (ICCE) to ultrasound phacoemulsification itself has yielded significantly better results.[8] The standard phacoemulsification technique enables the surgeon to remove the cataract through a smaller incision, reducing surgical inflammation, which may result in decreased breakdown of the blood-retinal barrier.[36,39] A breakdown in the blood-retinal barrier resulting in vasogenic oedema is likely a key factor that leads to progression of DR.[40] Given that phacoemulsification is associated with reduced inflammation, quicker recovery times, for both vision and healing, and rarely requires stitches,[41] this could potentially explain why no significant link has been found between phacoemulsification and DR progression in this study.

This systematic review supports the hypothesis that phacoemulsification cataract surgery does not significantly impact on the progression of DR or onset.[31-37] The consensus postulates that any progression seen following phacoemulsification surgery is likely related to the natural course of the disease. Interestingly, two out of the six studies reported cases of DR progression only in the non-operated eye,[32,36] and of the 392 operated eyes across these six studies, progression of solely the operated eye was reported in only eight cases.[32,35,36]

The natural course of DR is thought to vary across individuals and that progression is likely related to multiple factors.[42] It is well known that there are various factors, including duration of diabetes, HbA1c levels, hypertension and insulin treatment,[43] that can influence the progression of DR regardless of surgical intervention and indeed five of the included studies investigated this.[32,34-36] Whilst Romero-Aroca et al[37] reported mean HbA1c, mean duration of diabetes, insulin treatment, the severity of DR and low-density lipoproteins all influenced progression, Liao and Ku[34] noted the presence of DR preoperatively, duration of diabetes, and HbA1c levels all impacted progression, Chatterjee, Savant and Stavrou[35] described only patient race to be significant, Suto et al[37] noted pre-existing maculopathy to be statistically significant, and Squirrell et al[32] reported both preoperative mean HbA1c and insulin treatment influenced progression.

Romero-Aroca et al[36] specifically reported that arterial hypertension (p=0.402, p=0.07) and triglycerides did not influence DR progression (p=0.0509, p=0.0521) for both the operated and non-operated eyes respectively, however the

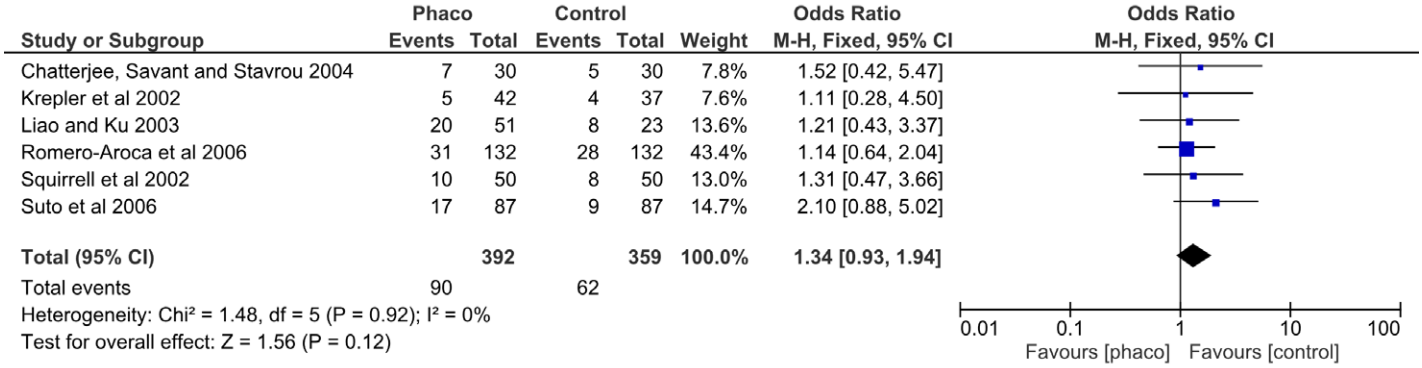

Figure 2. Forest plot of the influence of phacoemulsification surgery on diabetic retinopathy onset or progression.

Table 2. CASP assessment of quality summary

CASP Item	Squirrell et al (2002)[32]	Krepler et al (2002)[33]	Liao & Ku (2003)[34]	Chatterjee, Savant & Stavrou (2004)[35]	Romero-Aroca et al (2006)[36]	Suto et al (2006)[37]
Research question	1	1	1	1	1	1
Recruitment	1	1	1	1	0	0
Data collection	1	1	1	0	1	1
Outcome and bias	0	0	0	1	1	1
Confounding factors	1	0	0	1	1	1
Follow-up period	1	1	1	1	1	1
Reporting of results	1	1	1	1	1	1
Precision of results	1	1	1	1	1	1
Reliability of results	1	1	1	1	1	1
Application of results	1	0	1	0	0	0
Total score	**9**	**7**	**8**	**8**	**8**	**8**

severity of DR (p=0.002, p=0.001), mean HbA1c (p<0.001, p<0.001), mean duration of DM (p=0.019, p=0.028), insulin treatment (p=0.037, p=0.006) and LDL cholesterol (p=0.004, p=0.004) were associated with a higher incidence of DR progression. Squirrell et al,[32] supported some of these findings, reporting that preoperative mean HbA1c (p=0.003, p=0.001) and insulin treatment (p=0.008, p=0.04) were factors that significantly affected retinopathy progression in both the operated and non-operated eyes. Additionally, it similarly found that pre-existing hypertension was not a statistically significant risk factor (p=0.85, p=0.87). However, in contrast to Romero-Aroca et al,[36] their findings did not support that the duration of DM was an influencing factor of progression (p=0.42, p=0.74).

Suto et al,[37] investigated a slightly different set of individual preoperative factors compared to the other studies. Their findings agreed with both Romero-Aroca et al[36] and Squirrell et al,[32] that pre-existing hypertension was not a statistically significant risk factor for retinopathy progression (p=0.10). Interestingly, Suto et al[37] did not support that preoperative glycaemic control was statistically significant (p=0.08), suggesting that postoperative progression of retinopathy occurs at the same rate regardless of whether preoperative glycaemic control is improved. They also found that preoperative retinopathy of stage 43 or worse as per the Early Treatment Diabetic Retinopathy Study (ETDRS), and pre-existing nephropathy both were not statistically significant (p=0.49, p=0.21, respectively). The only factor in this study found to statistically influence retinopathy progression was pre-existing maculopathy (p=0.04).

Unlike other studies, Chatterjee, Savant and Stavrou[35] also focused on a specific population; patients of South-Asian and Afro-Caribbean ethnicity. They found that in this cohort insulin treatment was not a statistically significant influencing factor (p=0.09), but that the race of patients (p=0.02) may be an important consideration. They reported that the progression of retinopathy or maculopathy occurred more often in Afro-Caribbeans compared to South Asians.

Finally, Liao and Ku,[34] had the longest follow-up period of three years, providing more insight into the long-term effects of phacoemulsification surgery. They reported no statistically significant difference in the rate of DR progression between operated and non-operated eyes at one year (p=0.39) and three years (p=0.35) postoperatively. However, they found that the presence of DR preoperatively influenced progression. They observed that patients who preoperatively had no DR had less progression at both the one-year postoperative (12.5%) and three-year postoperative (25%) interval, compared to those with mild to moderate DR preoperatively (57.9% and 63.2%, respectively). As expected, they discovered that the duration of DM was significantly longer in those who had DR progression at both the one-year and three-year postoperative interval and that HbA1c levels were significantly higher in the eyes with the progression of retinopathy one year postoperatively. HbA1c levels at three years were not reported and a statistical analysis was not provided for these factors.

Limitations

Due to the relatively short follow-up period of most studies, between 12 and 18 months,[33,34,36-38] caution must be taken when interpreting the findings, as the progression of retinopathy beyond this period has not been considered. The modest pooled sample size, and the lack of control for known

confounding factors in the included studies, make the findings' generalisability difficult. Additionally, not restricting the stage of patients' DR could have potentially influenced results. If late-stage DR such as PDR was excluded completely from the datasets, results could have potentially been impacted.

It must also be noted that one paper included cases where a conversion from phacoemulsification to ECCE was performed,[35] and that some papers did not report any intraocular complications during surgery, or dropout rates.[37] This could also influence the outcome or skew the interpretation of the results.

Future research should focus on larger and more ethnically diverse cohort studies and analyses should stratify for known confounding factors to best isolate the influence of standard phacoemulsification surgery alone on the progression of DR in the T2DM population. Ideally, utilising the patients' fellow, non-operated eye to serve as the control in these studies would also be of benefit, as seen in these studies. However, it is noteworthy that this can be clinically difficult as patients with bilateral cataracts generally only wait approximately 9-12 months for their second surgery.[44]

CONCLUSION

This systematic review suggests that standard ultrasound phacoemulsification cataract surgery does not significantly impact the progression of diabetic retinopathy or its onset in the type 2 diabetes mellitus population. Significant advancements in surgical technique from extracapsular cataract extraction to phacoemulsification have likely assisted in decreasing the possibility of diabetic retinopathy progression or onset by reducing the resulting inflammation following cataract surgery. Future studies should include a longer follow-up period, larger sample size, an ethnically diverse population and should control for known confounding factors to facilitate a better understanding of the effect of phacoemulsification on diabetic retinopathy progression.

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