TITLE PAGE

Full title: Systematic review of the ophthalmic complications of robotic-assisted laparoscopic prostatectomy.

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NV created the concept. JR and NK performed searches, screened results, conducted data extraction and wrote the initial manuscript. MOC performed the statistical analyses. All authors refined the final manuscript and agreed to be accountable for all aspects of the work.

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Manuscript	2,888 words	*Tables*	1
References	52	*Appendices*	5

ABSTRACT

Objectives

This study aims to review ophthalmic injuries sustained during of robotic-assisted laparoscopic prostatectomy (RALP).

Subjects and methods

A search of Medline, Embase, Cochrane and grey literature was performed using methods registered *a priori*. Eligible studies were published 01/01/2010–01/05/2023 in English and reported ophthalmic complications in cohorts of >100 men undergoing RALP. The primary outcome was injury incidence. Secondary outcomes were type and permanency of ophthalmic complications, treatments, risk factors and preventative measures.

Results

Nine eligible studies were identified, representing 100,872 men. Six studies reported rates of corneal abrasion and were adequately homogenous for meta-analysis, with a weighted pooled rate of five injuries per 1,000 procedures (95% confidence interval 3-7). Three studies each reported different outcomes of xerophthalmia, retinal vascular occlusion, and ophthalmic complications unspecified in eight, five and two men per 1,000 procedures respectively. Amongst identified studies, there were no reports of permanent ophthalmic complications. Injury management was poorly reported. No significant risk factors were reported, while one study found African-American ethnicity protective against corneal abrasion (0.4 vs. 3.9 per 1,000). Variables proposed (but not proven) to increase risk for corneal abrasion included steep Trendelenburg position, high pneumoperitoneum pressure, prolonged operative time and surgical inexperience. Compared with standard of care, occlusive eyelid dressings (23 vs. 0 per 1,000) and foam goggles (20 vs. 1.3 per 1,000) were found to reduce rates of corneal abrasion.

Conclusions

RALP carries low rates of ophthalmic injury. Urologists should counsel the patient regarding this potential complication and pro-actively implement preventative strategies.

Keywords

Ocular; ophthalmic; corneal abrasion; robot; prostatectomy.

MANUSCRIPT

1. Introduction

Prostate cancer is the second most common malignancy in males, after non-melanoma skin cancer [1]. Globally, 1.4 million new cases are diagnosed annually, and this continues to rise [1, 2]. In the United Kingdom (UK), the annual incidence of prostate cancer is expected to exceed 60,000 patients by 2030 [3]. Approximately 45% of patients are diagnosed with localised intermediate risk disease [4] and 25-55% of this group undergo surgery [4-7]. Robotic-assisted laparoscopic prostatectomy (RALP) has become the preferred technique in most developed countries, chosen for 84% of men in the United States of America (USA) [8] and 92% in the UK [9].

Compared with open radical prostatectomy, RALP is equivalent in the three critical outcomes of biochemical recurrence, postoperative continence, and erectile function. RALP offers reduced blood loss and length of stay [10]. However, case series and voluntary registries have suggested that RALP exposes patients to unique ophthalmic risks, including corneal abrasion, subconjunctival emphysema, retinal vascular occlusion and ischaemic optic neuropathy [11-14]. Visual loss may be permanent. To date, robust data on the true risk of these complications is lacking, which confounds quality improvement efforts. There is significant variation amongst single centre studies in the estimation of the frequency of ophthalmic injury during RALP, and there have been no systematic reviews. Therefore, the objective of this review is to determine the incidence of ophthalmic injury during RALP. We will also assess risk factors, prevention and treatment. We hypothesise that incidence will be rare at less than 1 in 200 procedures, and that risk factors will include pre-existing ophthalmic comorbidities, steeper Trendelenburg position, longer procedure time and failure to pad closed the eyelids intra-operatively.

2. Subjects and methods

2.1 Search strategy

Systematic searches were performed of Medline, Embase and the Cochrane Central Register of Controlled Trials (CENTRAL) by Title or Abstract, utilising keywords and Boolean operators as follows: (ocular, oculo* ophthalm*, optic*, cornea*, eye OR retina*) AND (robot*) AND (prostatectomy) AND (injur*, complication OR adverse). Grey literature was eligible and was also searched, by review of the above search results and bibliographies of retrieved articles, and searching of the proceedings of the Urological Society of Australia and New Zealand annual scientific meeting 2010-2023. Our method for identifying and evaluating data complied with the Preferred Reporting Items for Systematic Reviews and Meta-analyses criteria [15] (***Appendix 1*** and ***Figure 1***). This included registration of our intended analysis on PROSPERO (CRD42023425829). Identified studies were screened by title, followed by abstract, and then full-text review. Studies then progressed to data extraction, including review of references. Two independent authors performed study screening and data extraction using a pre-defined form, with disagreements resolved by a third author (***Appendix 2***). Data extraction was performed twice for accuracy. The final list of included articles was determined by compliance with the inclusion criteria and with the consensus of all authors.

2.3 Study eligibility

Study eligibility was determined utilising the patient population, intervention, comparator, outcome and study (PICOS) method [16]. Eligible studies reported cohorts of >100 men (P) undergoing RALP (I), were not required to have a comparator cohort (C) and stated raw incidence of iatrogenic ophthalmic injury (O). Eligible publications were original full-length articles, published in English between 01/01/2010 – 01/05/2023 (S). All databases and sources were last searched on 01/05/2023. Studies were collated and analysed separately based on ophthalmic complication type.

2.4 Intended analyses

The primary outcomes were the incidence of ophthalmic injury during RALP. Secondary outcomes were permanency of complication, injury risk factors, management and suggested preventative measures. Qualitative summary was intended for all data, tabulating eligible studies' principal aspects. Where sufficient similar studies are available, quantitative synthesis (meta-analyses) of the outcomes was performed. For the primary outcomes, the proportion of events occurring was the basis of a random effects meta-analysis. Secondary outcomes were assessed as odds ratios (e.g. ophthalmological comorbidity presence, eyelid padding or other dichotomized measures) or correlation coefficients (e.g. steeper Trendelenburg position, longer procedure time) following methods described by Cooper *et al*. [17]. Statistical heterogeneity was examined by the I-squared test. There was an insufficient number of studies (<10) to assess publication bias. All analyses were two-tailed and significance was assessed at the 5% alpha level. Injury rates were reported as events per 1,000 procedures. Analyses were conducted in R [18].

2.5. Bias

The authors did not anticipate identifying any randomised controlled trials. Consequently, risk of bias was assessed with the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool, in accordance with the Cochrane Handbook [19, 20]. Each study was independently reviewed by two reviewers (JR, NK) against pre-defined criteria (***Appendix 3***). Instances of disagreement were resolved by consensus. Risk of bias was not used to exclude studies.

3. Results

Database searches returned 150 studies. After 37 duplicate results and 100 irrelevant publications were removed during title and abstract review, thirteen articles were retrieved for full text review (***Appendix 4***). An additional two works were identified from grey literature. After full text review to exclude ineligible studies, nine articles were included, totalling 100,872 men (***Figure 1*** and ***Table 1***) [21-29].

Fig. 1. Preferred reporting items for systematic reviews and meta-analyses flow diagram.

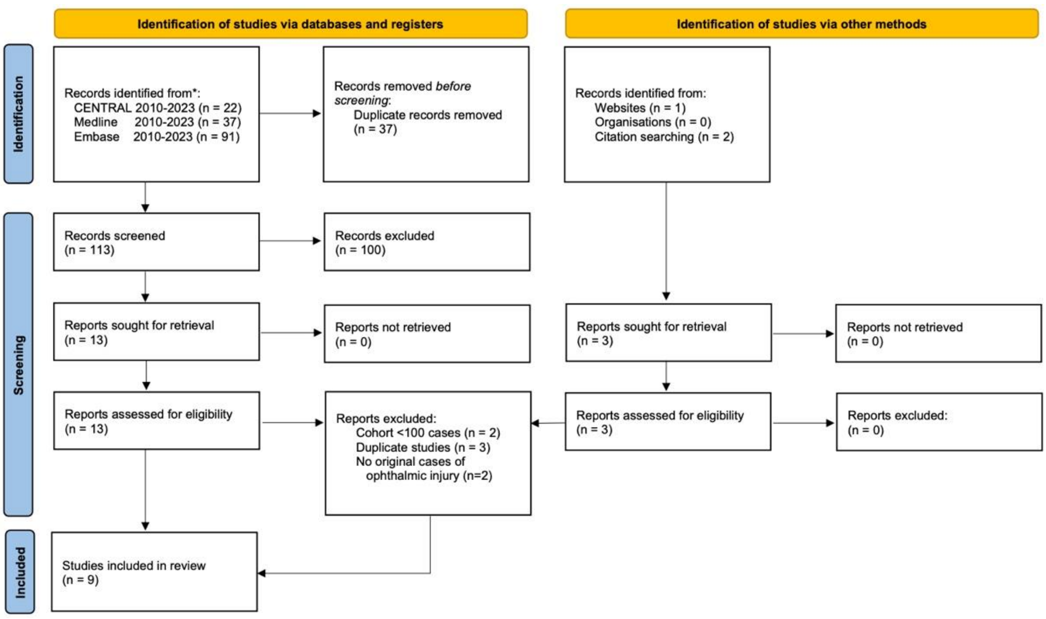


Table 1. Eligible studies.

Year	First author	Nation	Study type	Mean age (years)	Mean OT time (hours)	Complication	Events	Total no. patients	Follow up (months)
2010	Lavery	USA	Conf.	Unclear	1.93	Corneal abrasion	5	1028	Unclear
2011	Agrawal	USA	Article	60 †	2.67 †	Xerophthalmia ‡	27	3317	24.2
2013	Ghazi	USA	Article	60 †	2.97 †	Corneal abrasion	7	1503	28.9
2013	Hashimoto	Japan	Article	64.5	3.17	Retinal artery occlusion	1	200	35
2013	Large	USA	Conf.	59.6 §	3.53 §	Corneal abrasion	18	3001	0.23
2013	Liss	USA	Article	61.2	Unclear	Corneal abrasion	4	1000	38.7
2014	Wen	USA	Article	61.3	Unclear	Eye, any	102	61656	Unclear
2015	Sampat	USA	Article	61.5 §	Unclear	Corneal abrasion	99	28521	Unclear
2018	Brooks	USA	Article	60.3	Unclear	Corneal abrasion	8	646	Unclear

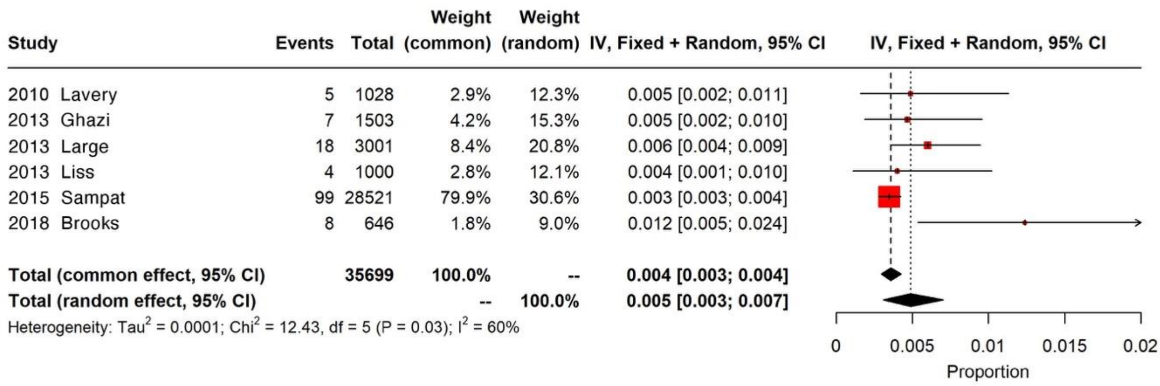
Conf.: conference abstract. **No.**: number. **OT**: operating theatre. **USA**: United States of America.

†: median. **‡**: Eye irritation/dryness and photophobia resulting in ophthalmologic consultation.

§: means of sub-groups with and without ophthalmic injury compared, and not significantly different.

All were single centre non-randomised cohort studies, and seven were prospective in nature. Mean or median age was reported by eight cohorts and ranged from 60.0 to 64.5 years. Mean or median operative time was available for five cohorts, and varied from 1.93 to 3.78 hours. Two studies compared age and operative time between RALP patients with and without ophthalmic injuries, with both finding no significant difference [25, 28].

Fig. 2. Meta-analysis of incidence of corneal abrasion during robotic-assisted laparoscopic prostatectomy



3.1. Ophthalmic injury type, incidence and permanence

Six studies reported rates of corneal abrasion and were adequately homogenous for meta-analysis, with a weighted pooled rate of five injuries per 1,000 RALPs (95% confidence interval 3-7, I^2 =60%) (***Figure 2***) [21, 23, 25, 26, 28, 29]. Three studies each reported the distinct ophthalmic complication of ophthalmic complications unspecified [27], retinal vascular occlusion [24] and xerophthalmia (defined as '*eye irritation/dryness and photophobia resulting in ophthalmologic consultation*') [22], with incidence of two, five and eight injuries per 1,000 RALPs, respectively. No study reported any permanent ophthalmic complications.

3.2. Risk factors

Attempting to discern risk factors, two studies compared RALP cohorts with and without corneal injury, using univariable [25] and multivariable [28] regression analysis. Only one, namely *Sampat et al.*, identified a significant factor for ophthalmic injury, with African compared with White ethnicity observed to have a protective effect (0.4 vs. 3.9 per 1,000) [28]. This remained statistically significant on multivariate analysis. Four studies hypothesised potential risk factors for corneal injury during RALP, unsupported by data. Suggested risk factors were steeper Trendelenburg position (four studies) [23, 26, 28, 29], longer operative time (two) [23, 28], higher pneumoperitoneum pressures (one) [28] and anaesthetist learning curve (one) [28]. Only one study reported the approximate angle of Trendelenburg position used in their practice [27].

3.3. Treatment of injury

Only one study discussed specific management of observed ophthalmic injuries. Ghazi *et al*. reported successful treatment of corneal abrasions with eye drops [23].

3.4. Prevention of injury

Two studies introduced preventative measures to reduce corneal abrasions, and then compared injury incidence before and after intervention. The precautions were either an occlusive dressing (Tegaderm®) over closed eyelids [21] or foam safety goggles (SunMed iGuard® #9-0210-00) [26]. Both resulted in a significant reduction in the incidence of corneal abrasion, reducing from 23 to 0 injuries per 1,000 [21] and from 20 to 1.3 injuries per 1,000 [26], respectively.

3.5. Assessment of bias

The ROBINS-I tool suggested that while risk of bias was low for three studies, it was moderate or high for four and two studies respectively (***Appendix 5***). Governance information was often absent, including conflict of interest (missing in six studies), financial disclosure (two) and ethics approval (two). Publication bias was not formally assessed as the number of studies included was small.

4. DISCUSSION

Ophthalmic injury in non-ophthalmic surgery is a known phenomenon. The most significant end of the spectrum is permanent vision loss, whose aetiology may be retinal vascular occlusion (most common), posterior ischaemic optic neuropathy or cortical (occipital lobe) blindness [30, 31]. International registries suggest 70% of cases arise secondary to spinal surgery, followed by cardiac (9%) and orthopaedic surgery (6%) [12]. However, for patients undergoing RALP, details such as incidence, permanence, risk factors and prevention have remained unclear.

This represents the first systematic review of ophthalmic injury during RALP. Overall, risk appears low. Among the three types of ophthalmic injury identified, there were two to eight events per 1,000 procedures. The most robust data exists for corneal abrasion, for which meta-analysis of six studies found weighted pooled incidence of four events per 1,000 procedures (***Figure 2***). Hashimoto *et al*. reported retinal vascular occlusion at a rate of approximately five events per 1,000 RALPs [24]. Two other studies presented unique ophthalmic complications, from which few conclusions can be drawn. Wen *et al*. reported ophthalmic complications unspecified [26], but with a surprisingly near-zero incidence of two events per 1,000 RALPs, lower than this review's weighted pooled incidence of corneal abrasions, itself just one of many possible types of ophthalmic complications [27]. Agrawal *et al*. reported xerophthalmia ('eye irritation/dryness and photophobia resulting in ophthalmologic consultation') rates of approximately eight events per 1,000 RALPs [22]. However, we believe this complication is likely analogous to corneal abrasion, albeit without sufficient certainty to allow pooled meta-analysis with the other six studies. It was reassuring that amongst the >100,000 patients in the identified studies, there were no confirmed cases of permanent vision loss. While possible, for men undergoing RALP, this disastrous outcome appears exceedingly rare, confined to case reports [32] and anonymous-submission international registries [12, 33].

Risk factors for ophthalmic injury during RALP remain challenging to elucidate. None were found to be significant. For corneal abrasion, the most common of the iatrogenic events, this is despite two studies performing univariable [25] or multivariable [28] regression analyses. Risk factors which were hypothesised (but not proven) included steeper Trendelenburg position, longer operative time, higher pneumoperitoneum pressures and anaesthetist learning curve [23, 26, 28, 29], while Sampat *et al*. found African ethnicity to have a significant protective effect [28]. The proposed linking mechanism is corneal desiccation with prolonged anaesthesia, combined with increased corneal and eyelid thickness due to over-zealous intravenous fluids and positional raised intra-ocular pressure, leading to abrasion of the dry cornea squashed against the eyelid [34-36]. For retinal artery occlusion, only a single case was identified [24]. Hashimoto *et al*. did not suggest any risk factors, and no details were reported for this patient. Other authors have suggested that the chief intra-operative risk factor for retinal artery occlusion is prolonged Trendelenburg position, with the likely pathophysiology of anaesthesia-related reduced mean arterial blood pressure and positional increased intra-ocular pressure combining to reduce central retinal artery perfusion below a critical threshold [37]. No cases of ischaemic optic neuropathy were reported in the identified studies. Despite occurring in only a handful of case reports, much has been made of this potential complication in RALP [12, 31, 34]. Expert opinion suggests that the chief risk factor is prolonged Trendelenburg and abdominal insufflation, with a proposed process of pursuant raised central venous, optic nerve [38] and intra-ocular pressure impairing flow in the posterior ciliary and perforating pial arteries, causing anterior and posterior ischaemic optic neuropathy, respectively [31]. Somewhat blurring the picture are studies such as that by Taketani *et al*., which performed detailed visual field testing on 25 men undergoing RALP [39]. Comparing the seven patients with transient post-operative visual defects with those maintaining normal vision, intra-operative intraocular pressure and procedure duration were not significantly different. However, the small sample size limits confidence, and it is likely that the perfusion threshold for the relevant arteries differs between individuals.

Clearly, the above three different ophthalmic injuries all have raised intraocular pressure in common. It is clear that for essentially all patients, with and without pre-existing ocular pathology, intraocular pressure rises with Trendelenburg position and pneumoperitoneum, and normalises when the patient is returned to the horizontal [40-42]. Glaucoma, the leading cause of irreversible blindness worldwide, has prevalence of 4% of adults aged >40 years [43]. It is due to optic nerve damage from intraocular pressure above the normal range of 10-21 mmHg. Therefore, previous researchers of ophthalmic injury during RALP have also believed glaucoma may increase risk [39]. However, we found no evidence to support this sub-part of our hypothesis. This is in keeping with several other negative studies. In 1,868 RALP patients, Chalmers *et al*.'s observed that that retinal and central nervous system comorbidities did not influence complications [44]. Several studies of RALP [45] or like procedures (with both Trendelenburg position and pneumoperitoneum) [42, 46] have found that compared with patients with treated glaucoma, those with newly diagnosed (untreated) glaucoma [45, 46] or with no ocular pathology [42], have equivalent intra-operative intraocular pressure changes and low incidence post-operative visual loss.

Looking more broadly then, evidence from aforementioned international registries, the Anesthesia Patient Safety Foundation and Shen *et al*.'s review of 5.6 million patients undergoing spinal, orthopedic, cardiac, or general surgery procedures have found that in addition to procedure type, risk factors include male gender, age <18 years, obesity, increased Charlson Comorbidity Index, pre-operative anaemia, head down posture (prone or Trendelenburg position), procedure duration surgery >6.5 hours, increased intra-operative blood loss, blood transfusion and minimal use of intravenous colloid resuscitation [30, 31, 47]. Several of these variables increase hydrostatic and osmotic forces that through the Starling equation can be expected to increase net movement of fluid into the optic nerve, retro-orbital space and eyelids [31]. Although not proven to date, with the exception of paediatric age, we believe that these variables will also be risk factors for ophthalmic injury during RALP.

Urologists should have a working knowledge of management of potential ophthalmological injuries during RALP. All patients should receive simple bedside examination for visual acuity and to exclude large foreign bodies, followed by referral for ophthalmology consultation. For patients with corneal abrasion, the most common injury, treatment consists of topical non-steroidal anti-inflammatory drugs and/ or topical antibiotics [48]. Eye patching is no longer recommended. Retinal vascular occlusion, ischaemic optic neuropathy and cortical blindness are ophthalmological emergencies. In brief, treatment of retinal vein occlusion involves intra-vitreal injection of anti-vascular endothelial growth factor agents [49]. Management of retinal artery occlusion varies widely, typically involving agents to reduce intra-ocular pressure, increase arterial blood oxygen content and dissolve clot [50]. Care for patients with peri-operative posterior ischaemic optic neuropathy, treatment includes supportive measures of correcting hypotension and anaemia, and potentially high dose steroids [51]. Patients with suspected cortical blindness should be urgently assessed and managed as for potential stroke.

Most will agree prevention is better than cure. Two eligible studies were able to demonstrate significant reductions in ophthalmic injury after introducing either occlusive eyelid dressings or foam safety goggles [23, 26]. In a study of 1500 men undergoing RALP which pre-dated our enrolment period, converting from eye tape to eye patches reduced the incidence of corneal abrasion from 3% to 1% [52]. We note that Danic *et al*.'s aforementioned 3% corneal abrasion rate occurred while using a Trendelenburg of 45°. In spinal patients, where both the risk of injury and evidence base is strongest, recommended preventative steps include minimising all of the following: degree and duration of Trendelenburg, high pneumoperitoneum pressures, hypotension and large volumes of intravenous crystalloid [31]. Therefore, for urologists performing RALP, we recommended choosing one of the above ocular precautions. While this review did not find evidence to support or reject the following measures in RALP patients, it may also be prudent to consider limit Trendelenburg position (we use <25 degrees), limit pneumoperitoneum (we use 12mmHg), limit operative duration and in partnership with your anaesthetist, avoid hypotension and over-use of crystalloid. Wen et al.'s examination of >160,000 patients undergoing radical prostatectomy via open, laparoscopic or robotic route found that ophthalmic injury rates were slightly higher (0.22% vs 0.17%; p=0.011) in the non-robotic cohorts, suggesting that many of these recommendations may be applicable to urologists performing radical prostatectomy regardless of approach [27].

For urologists performing RALP, these findings may influence their practice in two ways. Firstly, this meta-analysis may aid in counselling patients more accurately on the low risk (approximately 0.5%) of ophthalmic injury, which is almost always transient and without permanent loss of vision. Secondly, the advocated preventative strategies can be incorporated into routine practice, to further reduce risk.

4.1. Limitations

The inclusion of no randomised controlled trials, only one study outside of the United States of America and no patients more recent than 2014 limit generalisability of these findings. In a time of multiple minor and major variations to performing RALP, most studies did not report their technique. Only one study reported the angle of Trendelenburg position used in their cohort [27]. None of the included studies prospectively specifically screened for ophthalmic complications. Hence, the observed rates may be an under-estimate. However, there are strengths, including the inclusion of predominantly prospective studies and the pooled sample of >100,00 patients.

4.2. Conclusion

For patients undergoing RALP, ophthalmic injury is rare and almost always self-limiting. No risk factors have been identified. Preventative occlusive eye dressings or foam goggles have proven efficacy, while limiting Trendelenburg, pneumoperitoneum, procedure duration, hypotension and excessive intravenous crystalloid appear reasonable precautions, while currently lacking evidence in RALP.

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