

Systematic Review

A Comprehensive Analysis of the Literature on Implant-Related Complications in Anterior Bleb Forming Glaucoma Surgery

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ABSTRACT

Purpose

To make an account of published implant-related complications (IRC) by a systematic review of the literature.

Methods

A systematic search of Pubmed and Scopus databases and Google Scholar engine was performed with selection criteria to detect papers on IRC. We excluded unrelated papers and reviewed selected ones. We considered papers that did not explicitly state about occurrence or not occurrence of IRC as non-IRC reporting. Main outcome measures were the number of papers reporting on complications, IRC, and types of IRC.

Results

After the search, selection, and addition, we studied 109 papers. Incidence of IRC was 4.5%, half required explantation. While 26 implant studies found IRCs (23%), 13 case reports on surgical complications, 8 (61.5%) of them reported IRC. Frequent complications were conjunctival erosion, blockage of the tube, migration to anterior chamber or damage to surrounding tissues.

Conclusion

Most papers did not report on IRC. Length or nature of studies may skew finding IRC. The incidence of IRC was 4.5%. Hard and sharp implants carry a greater risk of IRC and explantation.

Keywords

Implant-related complications (IRC); Glaucoma surgery; Anterior bleb forming.

INTRODUCTION

Glaucoma is a chronic progressive optic neuropathy that may cause severe visual loss and affect the quality of life. The front line of treatment consists of reducing intraocular pressure. Most patients achieve good medical control: some require one or more surgical procedures. Although conventional filtering surgery is effective has only moderate success and are subject to risks. Some devices have been designed and introduced to improve success and risks. Some of these implants are associated with classical conventional fistulizing surgery or to newer filtering procedures

that intend the construction of a paralimbal bleb (subconjunctival, Subtenon's or intra-scleral). Regulatory bodies have studied the security and effectiveness of these implants and authorized for human application. Some systematic reviews or meta-analysis show that support for the use of these devices may be limited.¹⁻⁴ This study aimed to make an account of published implant-related complications (IRC), this is complications directly caused by the implant, by a systematic review of the literature up to April 2015. Only implants that contribute to creating a paralimbal bleb were considered since those are the ones that are used as an alternative to trabeculectomy or non-penetrating deep sclerectomy and are

potentially avoidable. We excluded equator bleb creating implants, angular devices or anterior chamber to supraciliary space shunts from the scope of this study. We were also interested to know how many of the papers referred to complications related to the implants.

METHODS

Search Strategy

Three different search engines were used: Pubmed, Google Scholar and Scopus in April 2015. The search was performed over all fields of bibliographic references. We applied three levels of search restriction and combined controlled Mesh and natural languages. Language filters were applied. Inclusion criteria: any series of patients, whether prospective or retrospective and case reports in English, Spanish or French (filtered) found introducing the selected keywords. The word “complication” was extended to the abstract search also. Exclusion criteria: reports on other glaucoma

drainage devices like Ahmed or Krupin Valve, Baerveldt or Molteno drainage devices. Any anterior chamber to supraciliary or suprachoroidal shunts like Gold Micro Shunt or ESNOPER V-2000. Papers in any other languages. Keywords: “prostheses and implants/ complications”, “glaucoma drainage implants”, implant, ex-press, esnoper, SK gel, aqua flow, collagen implant, Hem Acrylic, reticulated hyaluronic acid, T flux, thiobarbituric acid-reactive (T BAR), filtering surgery, filtering surgeries, deep sclerectomy, non-penetrating deep sclerectomy, viscocanalostomy, trabeculectomy, sclerostomy. Mendeley reference manager (www.mendeley.com,⁵ Elsevier) detected duplications. Refer to Table 1 for search strategy.

Initial Revision Strategy: The Selection of Papers for Revision

All papers’ titles were reviewed by a team of trained or in training ophthalmologist in search of papers that reported on paralimbal bleb forming surgical procedures with the implantation of a device. When in doubt, we reviewed the abstract. We excluded papers reporting on surgical procedures without an implant, different pro-

#	Searches on Google Scholar	Results
1	((implant* OR collagen implant OR collagen implants OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”) AND complication) AND (glaucoma)	11600
2	(implant* OR esnoper OR skgel OR aquaflow OR “ex-press” OR “collagen implant” OR “collagen implants” OR “Hemacrylic” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”) AND complication* AND Glaucoma-“Molteno Implants”-Molteno-Ahmed-“Krupin valve”-“krupin valves”-Baerveldt)	2300
3	(“Filtering Surgery” OR “Trabeculectomy” OR “Filtering Surgeries” OR “deep sclerectomy” OR “Sclerostomy” OR “deep sclerectomies” OR viscocanalostomy) AND (implant* OR esnoper OR skgel OR aquaflow OR “ex-press” OR “collagen implant” OR “collagen implants” OR “Hemacrylic” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”) AND complication* AND Glaucoma-“Molteno Implants”-Molteno-Ahmed-“Krupin valve”-“krupin valves”-Baerveldt)	1572
#	Searches on Scopus	
4	(TITLE(implant* OR esnoper OR sk gel OR aqua flow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”) OR ABS(implant* OR esnoper OR sk gel OR aqua flow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”)) AND (TITLE(complication*) ORABS(complication*)) AND (TITLE(glaucoma) OR ABS(glaucoma)) AND (LIMIT-TO(LANGUAGE,“English”) OR LIMIT-TO(LANGUAGE, “French”) OR LIMIT-TO(LANGUAGE,“Spanish”))	1533
5	(TITLE(implant* OR esnoper OR skgel OR aquaflow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”) OR ABS(implant* OR esnoper OR skgel OR aquaflow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”)) AND (TITLE(complication*) OR ABS(complication*)) AND (TITLE(glaucoma) OR ABS(glaucoma)) AND NOT TITLE-ABS-KEY(Molteno* OR Ahmed OR “Krupin valve*” OR baerveldt) AND (LIMIT-TO(LANGUAGE,“English”) OR LIMIT-TO(LANGUAGE,“French”) OR LIMIT-TO(LANGUAGE,“Spanish”))	1106
6	(TITLE(“Trabeculectom*” OR “Filtering Surger*” OR “deep sclerectom*” OR “Sclerostomy” OR viscocanalostom*) OR ABS(“Trabeculectom*” OR “Filtering Surger*” OR “deep sclerectom*” OR “Sclerostomy” OR viscocanalostom*)) AND (TITLE(implant* OR esnoper OR skgel OR aquaflow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”) OR ABS(implant* OR esnoper OR skgel OR aquaflow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”)) AND (TITLE(complication*) OR ABS(complication*)) AND (TITLE(glaucoma) OR ABS(glaucoma)) AND NOT TITLE-ABS-KEY(Molteno* OR Ahmed OR “Krupin valve*” OR baerveldt) AND(LIMIT-TO(LANGUAGE,“English”)ORLIMIT-TO(LANGUAGE,“French”) OR LIMIT-TO(LANGUAGE,“Spanish”))	273
#	Searches on Pubmed/Medline	
7	(“Prostheses and Implants/complications”[Mesh] OR ((implant*[tiab] OR esnoper[tiab] OR skgel[tiab] OR aquaflow[tiab] OR “express implant”[tiab] OR “express implants”[tiab] OR “collagen implant”[tiab] OR “collagen implants”[tiab] OR “HemacrylicMetha Stealth”[tiab] OR “reticulated hyaluronic acid”[tiab] OR “T flux”[tiab] OR “T bar”[tiab]) AND complication*[tiab])) AND (“Glaucoma”[Mesh] OR glaucoma*[tiab])	1249
8	(TITLE(implant* OR esnoper OR skgel OR aquaflow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”) OR ABS(implant* OR esnoper OR skgel OR aquaflow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”)) AND (TITLE(complication*) OR ABS(complication*)) AND (TITLE(glaucoma) OR ABS(glaucoma)) AND NOT TITLE-ABS-KEY(Molteno* OR Ahmed OR “Krupin valve*” OR baerveldt) AND(LIMIT-TO(LANGUAGE,“English”) OR LIMIT-TO(LANGUAGE,“French”) OR LIMIT-TO(LANGUAGE,“Spanish”))	967
9	(TITLE(“Trabeculectom*” OR “Filtering Surger*” OR “deep sclerectom*” OR “Sclerostomy” OR viscocanalostom*) OR ABS(“Trabeculectom*” OR “Filtering Surger*” OR “deep sclerectom*” OR “Sclerostomy” OR viscocanalostom*)) AND (TITLE(implant* OR esnoper OR skgel OR aquaflow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”) OR ABS(implant* OR esnoper OR skgel OR aquaflow OR “express implant*” OR “collagen implant*” OR “Hemacrylic Metha Stealth” OR “reticulated hyaluronic acid” OR “T flux” OR “T bar”)) AND (TITLE(complication*) OR ABS(complication*)) AND (TITLE(glaucoma) OR ABS(glaucoma)) AND NOT TITLE-ABS-KEY(Molteno* OR Ahmed OR “Krupin valve*” OR baerveldt) AND (LIMIT-TO(LANGUAGE,“English”) ORLIMIT-TO(LANGUAGE,“French”)ORLIMIT-TO(LANGUAGE,“Spanish”))	314

cedures all together (posterior forming blebs, angular surgery, anterior chamber to supraciliary or suprachoroidal shunts), different languages or animal studies. We included systematic reviews and meta-analysis of implanting surgical procedures studies to secure relevant studies that our search could have missed out, but carefully made sure we did not duplicate the study papers by doing so.

Full text of all included papers was requested for revision. New references were found during revision and added under the same criteria.

Ethical Committee approval was not requested as no patient information was searched at any time.

Outcome Measures

The following outcomes were measured: total number of papers after exclusions, number of papers that report complications, number of papers that report IRC, type of implant, type of IRC found as extrusion, migration, damage to surrounding tissue, dysfunctional implants, explanted cases, relocated cases, other (Table 2).

Table 2. Definition of Outcomes to be Measured	
Outcomes to be Measured	
•	Number of papers found once the non-related are excluded
•	Number of papers that report complications
•	Number of papers that report implant-related complications
•	Type of implant-related complications found with every implant
○	Extrusion
○	Migration
○	Damage of surrounding tissue
○	Obstructed
○	Explanted cases
○	Relocated cases
○	Other

Papers' revision was directed to find a statement on complications within the method and the results sections of the article. We did not look for complications reports within the dis-

ussion section nor conclusions of the papers. Since the presence or absence of complications report is not interpretable, only one reviewer read through every paper. A paper was considered to report on IRC if the actual complication was reported or it explicitly stated that no IRC was found during the study. Papers that did not state one thing or the other were considered not to report on IRC. In case of doubt, the paper was consulted with the senior ophthalmologist in the study group.

A register of complications was established to include both studies with and without complications' reports.

RESULTS

The result from the search of the three engines was 253 papers from Scopus, 314 from Pubmed and 1572 from Google Scholar that were reduced to 1102 after removing redundant papers. All titles of those papers were reviewed to discard unrelated ones when in doubt the abstract was used. Finally, 120 full-text articles were requested for review. From systematic revisions and meta-analysis, we found 28 new unknown references that were also requested. From a total of 148 papers, 23 were excluded due to belonging to animal or experimental implants studies, reporting on the different procedure, German language, or unfound full text. Of the 125 reviewed papers, 9 were systematic reviews, and 7 were meta-analysis that included studies already reviewed by this research team.¹⁻¹⁶ Therefore, the final number of papers considered for study purposes was 109 (Figure 1).¹⁷⁻¹²⁶

All these papers correspond to studies or case reports that report on glaucoma implant surgery and also on surgical complications (100% of the 109 papers reviewed). Out of the 109 papers reviewed, 75 (68.8%) did not report on IRC, 34 (31.2%) reported on IRC, 6 (17.6% of the IRC reporting papers) explicitly reporting an absence of IRC (4 prospective and 2 retrospective studies). Of the 59 prospective studies (54.1%, of 109), 17 reported on IRC (28.8%, of 59). Of the 37 retrospective studies (33.9%, of 109), 9 (24.3%, of 37) reported IRC. Thirteen of the papers (11.9%, of

Figure 1. Final Number of Papers Considered for Study Purposes

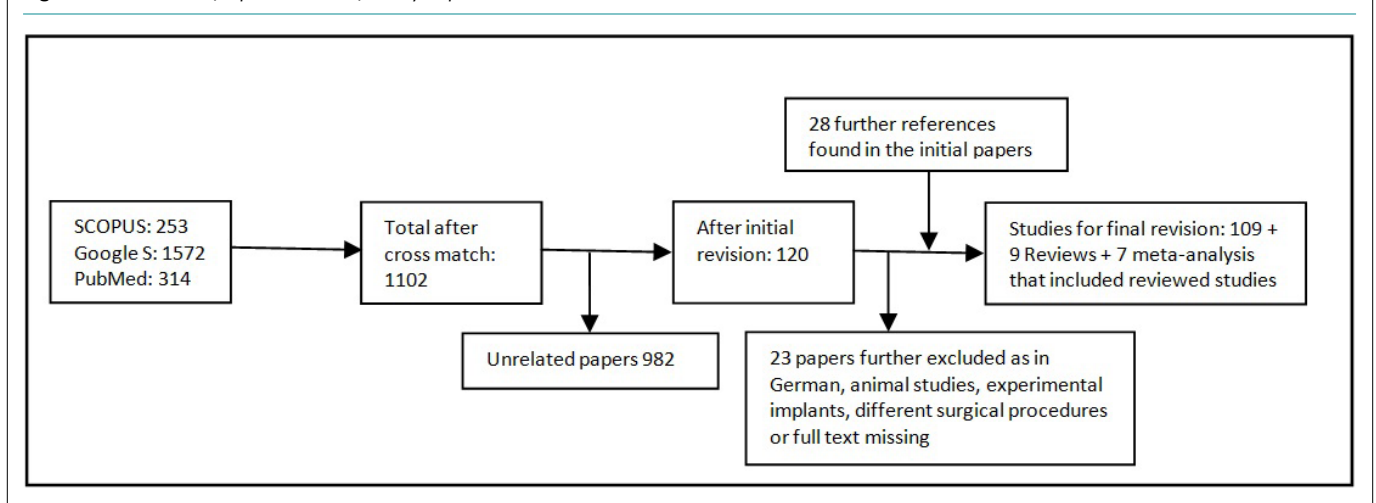


Table 3. Understudy Implants, IRC Reporting Papers, Number of Study Eyes (Eyes with Implants in IRC Reporting Papers) and Number of Complicated Cases

Implant	N° of Papers*	N° IRC Papers**	N° of Study Eyes	N° Complicated Cases
Express (Steel)	38	22 (57,9%)	940	54 (5,7%)
Collagen Implant	25	5 (16,6%)	208	9 (4,3%)
SK-gel (Hyaluronic acid)	25	3 (12%)	185	2 (1,07%)
T-flux (Acrylic)	15	1 (7,14%)	25	1 (4%)
Ethicon 1/0 Chromic Catgut	1	1 (100%)	23	1 (4,3%)
PMMA	1	1	30	0
ePTFE	1	1	35	0
Ologen (Collagen)	9	1	33	0
HEALA Flow	1	0	0	0
Aquaflow (Collagen)	5	0	0	0
Total	109	35	1479	67 (4,5%)

*Twelve papers tested two or three implant devices; **One paper tested two devices PMMA and Collagen implant

Table 4. Reported Complications

Implant Complication	SK-gel	Collagen Implant	T-flux	Express	Ethicon 1/0 chromic catgut
Migration or malposition	1 migration to subconjunctival space		1 migration into anterior chamber	1 misplacement 1 migration to subconjunctival space 5 into anterior chamber	1 into anterior chamber after blunt trauma
Extrusion	1 conjunctival erosion and extrusion that did not require explants or repositioning			20 conjunctiva erosions (15 without scleral flap, 4 with sclera flap, 1 unknown)	
Damage to surrounding tissues		1 Corneal abrasion 5 Descemet mb. detachment		5 iris touch 2 endothelial touch 1 Corneal abrasion 1 crystalline lens touch 1 scleral flap erosion only	
Obstructed				14	
Explanted		3 During hypotony repair surgery		2 unreported reasons 1 due to infection	
Explanted as treatment of complication				26	
Repositioned				3 relocated due to other complication Other causes	

109) were case reports, 8 (61.5%, of 13) reported IRC.

The total population of eyes considered in this study was 5831 (population range per study: 1-345), 4576 of which had been implanted (78.4%), the others belonging to control groups. The population of eyes with an implant included in studies that reported on IRC was 1479. Of those, the number of eyes that suffered an IRC was 67 (4.5%). Table 3 shows the implants understudied, the number of IRC reporting papers, the number of study eyes and the number of complicated cases.

A summary of the complications is in Table 4. The most common IRC was conjunctival erosion; 20 cases after Express implantation (15 through a full-thickness scleral incision, four under

a partial-thickness scleral flap and one unreported technique) that required implant removal, and one case of SK-gel that healed under observation. Obstruction of Express tube occurred in 14 cases. Four Express tubes migrated postoperatively into the anterior chamber (AC) and another one was introduced in the AC during the procedure. Another Express tube migrated to the subconjunctival space, as it occurred to an SK gel implant, and a further Express tube was found misplaced. A T flux implant migrated to the patient's anterior chamber. A fragment of Ethicon 1/0 chromic catgut, placed under a deep sclerectomy flap, migrated into de AC also. Sixteen cases of damage to surrounding tissues were found, 5 Descemet membrane detachments and one corneal abrasion after collagen implant, five iris touch, two endothelial touches, one corneal abrasion, one crystalline lens touch that induced a white cata-

ract and one scleral flap extrusion, without conjunctival erosion, after Express implantation. Three primary explanation of Express tubes, one due to a bleb infection and two for unreported reasons, as well as three collagen implant removal during the hypotony repair. A total of 29 Express tubes (3% of all tubes implanted) and three collagen implants (1.4% of all implanted) were explanted.

DISCUSSION

The market offers implants in an attempt to improve post-operative survival, efficacy or safety for patients requiring glaucoma surgery. Some studies, however, suggest that traditional trabeculectomy or newer deep sclerectomy without implants might be just as effective in reducing intraocular pressure. Devices, therefore, attempt to improve prognosis, but its mere physical presence may also increase risks. This study aimed to make an account of published IRC by a systematic review of the literature up to April 2015. We only studied implants that contribute to creating a paralimbal bleb. Equator bleb creating implants, angular devices or anterior chamber to supraciliary space shunts are not within the scope of this study.

Our search produced a total of 1102 papers. The use of natural language and mesh terms explain such a large number of papers found. The initial selection resulted in 120 papers of which 23 were further excluded, and another 28 were added during revision. Seven systematic reviews, nine meta-analysis, 13 case reports, 37 retrospective and 59 prospective studies were reviewed. Only an explicit account of IRC was considered as a report. All papers reviewed (109/109) reported surgical complications. Only 31.2% reported on IRC: 6 (17.6%) of those (4 prospective and two retrospective), reported an absence of IRC. Only 28.8% of all prospective and 24.4% of all retrospective studies reported on IRC. It was therefore interesting to find that of 13 case reports dealing with complications, 8 (61.5%) were about IRC. We suspect that the discrepancy in IRC incidence reported in retrospective and prospective studies compared to case reports might be related to the length of the studies and although inconclusive, could be relevant. Issues related to reporting could justify further research.

Sixty-seven cases of IRC of 1479 (4.5%) patients were found, of which 31 required implant removal. Our estimation of IRC incidence might be biased by the search or the selection method. The incidence of Express removal was 3% before the tube was guarded under a scleral flap: that reduced the risk but did not eliminate it. The initial design of the technique may show that the risk of extrusion was underestimated. Risk of misplacement or injury to surrounding tissues like Descemet membrane, corneal endothelium or the crystalline lens is also relevant as well as migration into the anterior chamber of mainly the express tubes.

The physical properties of the implant are relevant: harder and sharper implants that remain longer, increase the risk of complications, mainly extrusion. In our study, the steel implant Express accounts for most cases of explanted, extruded or migrated cases. Also, non-absorbable acrylic T flux tends to migrate if left unfixed. Soft and absorbable implants tend to be more respectful. We speculated that tensile vectors generated by scaring tissue

might tend to move rigid pieces and to fold soft material: this could explain the migration of implants or simple orientation changes. The intermittent robbing effect of the eyelid over the conjunctiva exerts an external pressure (tissue towards implant) that injures the tissue in the opposite direction (implant towards sclera, conjunctiva or both). Both mechanisms are active in all operated eyes, so the risk to induce complications exists.

Study limitations include missing relevant papers by the search (no excerpta medica dataBASE (EMBASE) search) or the selection method: the initial search failed to detect 28 relevant papers added later. It is possible that relevant data from studies was filtered out by title or abstract selection. A further limitation is late publication of this study that was finalized in 2016 and sent for publication in 2019. Finally, this review relies on what authors report on their papers, under or overreporting issues would modify these results. However, the study remains useful to stress the fact that an implant might induce complications by itself. Also, the type and shape of the material are relevant and worth bearing in mind at the time of assessing the purpose and usefulness of the implant. Further, the importance of considering IRC at the time of designing studies to make them sensible to complication detection and reporting.

CONCLUSION

An IRC incidence of 4.5% resulted from this study, of which about a half required removal. Harder and sharper implants carry a higher risk. It is worth considering the implant's function and the risk it may carry its implantation before making the clinical decision of using them. Studies should consider this risk and be methodologically designed to detect them.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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