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ORIGINAL RESEARCH

Use of Cryopreserved Amniotic Membrane During Pterygium Excision: Health Economic Analysis

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Purpose: To determine the health economic opportunity cost or gain associated with performing pterygium excision surgery using the TissueTuck technique with cryopreserved amniotic membrane (AM) instead of conjunctival autograft (CAU).

Methods: We performed a literature review to determine the average surgical duration of pterygium surgery using CAU with fibrin glue or sutures to calculate the average time saved with the TissueTuck technique. Such time savings was then used to determine the opportunity revenue gain per national average Medicare reimbursement if adjusted to the average surgical duration of cataract surgery.

Results: The time savings achieved using the TissueTuck technique over CAU with fibrin glue is 8.9 min per procedure, which can be applied to additional MSICS or phacoemulsification procedures to generate an opportunity revenue gain of $1167 or $762 per 2022 National Average Medicare reimbursement, respectively. After subtracting the current list cost of AmnioGraft (ie, $645), the opportunity gain is $522 or $117 if the time saving is applied to the above procedures, respectively. Alternatively, the time savings achieved by using the TissueTuck technique over CAU with sutures is 23.4 min per procedure, which can be applied to additional MSICS or phacoemulsification procedures to generate an opportunity revenue gain of $3068 and $2004 per TissueTuck procedure or $2423 or $1359 when accounting for the list cost of AmnioGraft, respectively.

Conclusion: The TissueTuck surgical technique using cryopreserved AM for pterygium takes less time, has lower recurrence rates, and provides an opportunity gain compared to pterygium excision with CAU.

Keywords: amniotic membrane, conjunctival autograft, health economics, pterygium

Introduction

Pterygium is a relatively common ocular disorder in which abnormal fibrovascular tissue of the conjunctiva encroaches onto the cornea, which can impair vision and quality of life.[1] Currently, surgical excision is the only effective treatment option for pterygia that involves meticulous excision of the pterygium followed generally by graft placement with either conjunctival autograft (CAU) or cryopreserved amniotic membrane (AM).[2] Compared to the bare sclera technique, use of a CAU or AM graft has been shown to improve post-surgical outcomes and reduce recurrence rates to less than 10%.[3–6]

Ambulatory and outpatient facilities have been increasingly utilized to perform the majority of ophthalmic procedures worldwide. Between 1996 and 2006, the volume of outpatient surgeries at freestanding ambulatory surgery centers (ASCs) increased by 300%.[7,8] As the demand for outpatient and ambulatory surgery increases, there is also increasing importance to minimize the supply costs or minimize the time to perform ophthalmic surgeries in order to allocate more time for additional revenue generating surgeries. This is particularly relevant for pterygium excision as there are multiple surgical approaches, and the reimbursement to ASCs is the same when using either AM or CAU graft for pterygium excision (CPT code 65426). However, the supply cost of AM grafts is not separately identified or billed to Medicare, which may impel ASCs and their physicians to use CAU to mitigate additional costs. Nevertheless, cryopreserved AM is readily available and avoids the need to harvest a graft, thus, potentially shortening operative time. A recent retrospective study of 582 eyes demonstrated that the TissueTuck procedure takes 14.7 minutes on average.[9] A shorter surgical duration of using AM with the TissueTuck technique may enable other revenue generating procedures such as cataract

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surgery to be performed to offset the supply costs of AM. Thus, the purpose of this health economics study is to determine whether the TissueTuck procedure with AM is a more economically efficient procedure for pterygium excision compared to CAU in the ASC environment.

Materials and Methods

We performed a literature review to determine the average surgical duration for pterygium surgery using CAU with fibrin glue or sutures as well as the average surgical duration for phacoemulsification and manual small incision cataract surgery (MSICS). The difference in surgical times between the TissueTuck and CAU techniques (fibrin glue or sutures) was then calculated to determine the time savings with the TissueTuck technique. The time saved with the TissueTuck technique was then extrapolated to calculate the potential revenue gain if used to perform additional cataract surgeries (MSICS or phacoemulsification). Because pterygium recurrence is a clinically meaningful outcome that is widely reported following surgical excision, a literature review was also conducted to compare the average recurrence rate of the TissueTuck technique to that of CAU with sutures or fibrin glue.

Surgical Time: Cataract Surgery

A literature search of the PubMed electronic database and Google Scholar was performed in July 2022 to retrieve all relevant studies that reported the surgical times of phacoemulsification and MSICS. All studies included in this review were retrieved either from the above databases or from references cited therein. The search results were restricted to articles that were published within the last twenty years (ie, 2002 and onward). No language restrictions were applied. The search strategy combined terms related to disease ("cataract") with terms related to the procedure ("phacoemulsification") OR ("manual small incision" OR "MSICS") and surgical time ("minutes" or "min" or "surgical time"). The titles and abstracts of studies were screened to identify those that fulfilled the inclusion criteria: prospective studies; patients undergoing cataract surgery with phacoemulsification or MSICS; studies that reported the average surgical time. The outcome measure assessed was the surgical time, which was generally defined as total time spent to complete surgery. The mean surgical duration was calculated for both phacoemulsification and MSICS by taking the weighted average of all relevant studies.

Surgical Time: Pterygium Excision with Conjunctival Autograft

A literature search in the PubMed electronic database and Google Scholar was similarly conducted in July 2022 for studies assessing the reported surgical times for pterygium excision with CAU secured with sutures or fibrin glue. Only publications within the last five years (ie, 2017 and onward) were assessed. There were no language restrictions. The keywords used in the search were "fibrin glue", "suture", "pterygium", "conjunctival autograft", and "surgical time", or "operative time", or "minutes", or "min". Abstracts were reviewed to determine eligibility, and when the abstract alone could not provide the necessary information, the full text of the article was reviewed. References of relevant articles were also reviewed for eligibility. Only studies that fulfilled the following inclusion criteria were included in the analysis: prospective studies; patients undergoing pterygium surgery with CAU; use of fibrin glue and/or sutures to secure the graft; and studies that reported the average surgical time, which was generally defined as total time spent to complete surgery. The mean surgical duration was calculated for both CAU with fibrin glue and CAU with sutures by taking the weighted average of all relevant studies.

HEOR Analysis

The opportunity gain of performing the TissueTuck procedure with AM (AmnioGraft; BioTissue, Miami, FL) was determined by applying the time savings with the TissueTuck technique to perform additional cataract surgeries. The surgical duration of pterygium excision using CAU with either fibrin glue or sutures was calculated by taking the weighted average of the reported surgical times over the last five years, which were found using the methods listed previously. The average surgical duration of the TissueTuck technique was recently reported to be 14.7 minutes in a large retrospective case series of 582 eyes.[9] The resultant time savings was measured by calculating the difference in the average operative time between the TissueTuck procedure and the CAU techniques (fibrin glue or sutures).

The time saved with the TissueTuck technique was then extrapolated to calculate the potential revenue gain if used to perform additional cataract surgeries (MSICS or phacoemulsification). This was calculated by dividing the times saving with the TissueTuck technique by the average surgical time of the given cataract surgery (phacoemulsification or MSICS). To determine the potential revenue gain, the above value was then multiplied by the national average Medicare reimbursement for cataract surgery to ASCs (CPT: 66984), which is $1062 per Medicare.gov. The current list price of AmnioGraft, $645, was then subtracted to yield the opportunity gain per TissueTuck procedure. All costs were expressed in US dollars.

$$\left(\frac{(CAU - TissueTuck)_{surgicaltime}}{Surgical\ time\ of\ cataract\ surgery} X \$1062\right) - \$645$$

Recurrence of Pterygium Excision

A literature search of the PubMed electronic database and Google Scholar was performed in July 2022 to retrieve all prospective, comparative studies that assessed and compared the recurrence rates of primary pterygium excision with CAU using fibrin glue versus sutures. All studies included in this review were either searched directly from the above databases or from relevant references cited therein. The keywords used in the search were "pterygium", "conjunctival autograft", "fibrin glue", "suture", and "recurrence". The titles and abstracts of studies were screened to identify those that fulfilled the inclusion criteria: prospective comparative studies or randomized controlled trials; patients with primary pterygium; pterygium surgery with CAU; comparison on the efficacy of fibrin glue versus sutures; recurrence rate at six months. Only studies published within the last twenty years were included, and no language restrictions were applied. The outcome measure assessed was the rate of pterygium recurrence at six months, which was generally defined as the presence of postoperative fibrovascular tissue extending beyond the limbus onto the cornea. The number of cases with recurrence was calculated for each study, and the total recurrence rate was calculated by dividing the total number of recurrences by the total number of subjects of the included studies to yield a cumulative average. The recurrence rate of each procedure was then compared to that of the TissueTuck technique.[9] To ensure comparability, the recurrence rate using the TissueTuck technique was calculated only for those subjects with primary pterygium and those who completed at least six months of follow-up.

Results

Operative Time: Pterygium Excision with CAU versus TissueTuck Technique

A total of 18 studies assessing the surgical duration of CAU with fibrin glue or sutures met the eligibility criteria and were included for analysis. All studies were randomized controlled trials aside from four prospective comparative studies.[10–13] Eight studies compared the use of fibrin glue versus sutures,[12,14–20] six studies compared CAU with fibrin glue to other treatment arms,[11,21–25] and four studies compared CAU with sutures to other treatment arms.[10,13,26,27] In brief, the majority of studies harvested the CAU from the superotemporal quadrant of the bulbar conjunctiva, seven of which reported the use of conjunctival limbal autograft to include part of the superficial limbus.[10,12,13,17,18,24,27] Aside from one study that reported the use of autologous fibrin glue,[20] the fibrin glues used in the studies were commercially available products such as Tisseel® (Baxter Healthcare Corporation, Glendale, CA) and FIBINGLURAAS® (Shanghai RAAS Blood Products Co., Ltd, China). In the majority of the studies assessing CAU with sutures, the graft was anchored to the episclera and attached to the adjacent conjunctiva with interrupted 8–0 Vicryl sutures or 10–0 nylon sutures. Cakmak et al[10] and Wang et al[19] reported the use of 7–0 Vicryl and 10–0 Vicryl, respectively. Use of mitomycin c (MMC) was reported in only one study.[20] Studies varied with respect to the populations evaluated and surgical technique used; however, these variations were not taken into consideration in this analysis.

Of these 18 studies, the surgical duration was reported for CAU with fibrin glue in 14 prospective studies and CAU with sutures in 12 prospective studies. Of 796 eyes/cases that underwent pterygium excision and CAU with fibrin glue, the weighted average duration of surgery was 23.6 minutes (Table 1).[11,12,14–25] Twelve studies reported the surgical duration for CAU with sutures, with an average operative time of 38.1 minutes among 640 eyes (Table 2). [10,12–20,26,27] As

Table 1 Average Operative Time for Pterygium Excision with CAU Secured with Fibrin Glue

Study (Author, Year)	Eyes (N)	Time (Min)
Jha and Simba, 2022[22]	118	12
Sune and Sune, 2021[24]	31	23.2
Sutyawan et al, 2021[17]	15	21.8
Huang et al, 2020[25]	30	20.1
Patil and Dasar, 2020[14]	30	24.2
Singh et al, 2019[15]	312	33.3
Sati et al, 2019[21]	42	15.1
Alamdari et al, 2018[20]	60	10.4
Kumar and Singh, 2018[12]	20	36.2
Gong et al, 2018[11]	40	18.8
Wang et al, 2017[19]	28	20.2
Suryaa et al, 2017[16]	25	19.5
Wadgaonkar et al, 2017[18]	25	15.8
Shrivastava et al, 2017[23]	20	23
TOTAL	**N=796**	**23.6 min**

Abbreviations: CAU, conjunctival autograft; Min, Minutes; N, Number.

Table 2 Average Operative Time for Pterygium Excision with CAU Secured with Sutures

Study (Author, Year)	Eyes (N)	Time (Min)
Yang et al, 2021[13]	56	36.5
Sutyawan et al, 2021[17]	15	41.7
Patil and Dasar, 2020[14]	30	36.1
Singh et al, 2019[15]	312	43.3
Yan et al, 2019[27]	34	24.3
Alamdari et al, 2018[20]	60	13.3
Kumar and Singh, 2018[12]	20	53.3
Celik, 2018[26]	15	48
Cakmak et al, 2017[10]	20	33.8
Suryaa et al, 2017[16]	25	50.4
Wadgaonkar et al, 2017[18]	25	33.6
Wang et al, 2017[19]	28	32.4
TOTAL	**N=640**	**38.1 min**

Abbreviations: CAU, conjunctival autograft; Min, Minutes; N, Number.

previously reported, the average operative time for pterygium excision using the TissueTuck technique is 14.7 minutes.[9] Thus, the time saved in performing the TissueTuck technique in lieu of CAU with fibrin glue or sutures is 8.9 and 23.4 minutes, respectively.

Operative Time of Cataract Surgery

We performed a similar literature review to determine the average operative time of phacoemulsification and MSICS in order to calculate the opportunity gain if the time saved with the TissueTuck technique was then used to perform cataract surgery. A total of 23 prospective studies reported surgical times for MSICS and phacoemulsification. The average operative time for MSICS and phacoemulsification was reported in 11 and 17 prospective studies, respectively. Among 1721 eyes that underwent MSICS,[28–38] the average operative time was 8.1 minutes (Table 3). Among 2748 eyes that underwent phacoemulsification, the average operative time was 12.4 minutes in 17 prospective studies (Table 4).[28,30,35,37–50]

Table 3 Average Operative Time for MSICS

Study (Author, Year)	Eyes (N)	Time (Min)
Parajuli et al, 2020[34]	68	8
Kongsap, 2019[33]	21	13.2
Bhargava et al, 2016[28]	76	11.2
Singh et al, 2012[36]	110	7.7
Venkatesh et al, 2010[38]	117	8.8
Singh et al, 2009[37]	89	5.3
Ruit et al, 2007[35]	54	9
Gogate et al, 2007[30]	200	8.5
Degenring, 2004[29]	128	11.6
Gogate et al, 2003[31]	358	12
Hennig et al, 2002[32]	500	4
TOTAL	**N=1721**	**8.1 min**

Table 4 Average Procedure Times for Phacoemulsification

Study (Author, Year)	Eyes (N)	Time (Min)
Day et al, 2020[40]	393	17.8
Roberts et al, 2019[47]	200	14.7
Perone et al, 2018[44]	85	8
Titiyal et al, 2018[48]	77	8.3
Bhargava et al, 2016[28]	70	14.2
Joshi, 2016[42]	32	18
Ugurbas et al, 2012[50]	128	12
Baillif et al, 2012[39]	101	19.2
Venkatesh et al, 2010[38]	113	12.2
Raskin et al, 2010[45]	50	9.9
Liyanage et al, 2009[43]	105	15
Singh et al, 2009[37]	93	7
Ruit et al, 2007[35]	54	15.5
Gogate et al, 2007[30]	200	15.5
Rengaraj et al, 2004[46]	306	6.8
Tsuneoka et al, 2002[49]	637	8.7
Funatsu et al, 2002[41]	104	19.2
TOTAL	**N = 2748**	**12.4 min**

HEOR Analysis

The National Average Medicare reimbursement to ASCs for any cataract surgery is $1062 (CPT code: 66984). Thus, the opportunity gain of performing TissueTuck over CAU with fibrin glue is 109.9% (8.9 min/8.1 min) of the time/revenue of one MSICS ($1167). When accounting for the current list price of AmnioGraft ($645), the opportunity gain is $522 per TissueTuck procedure. If performing phacoemulsification, the opportunity gain is 71.8% (8.9 min/12.4 min) of the time/revenue of one cataract procedure ($762), yielding an additional $117 per TissueTuck procedure. Alternatively, if TissueTuck is performed instead of CAU with sutures, the opportunity gain is 288.9% (23.4 min/8.1 min) of one MSICS ($3068) or an additional $2423 per TissueTuck procedure. If performing phacoemulsification, the opportunity gain is 188.7% (23.4 min/12.4 min) of one cataract procedure ($2004), resulting in an additional $1359 per TissueTuck procedure (Table 5). Based on this analysis, the TissueTuck procedure is no longer economically feasible if the price of AmnioGraft exceeds $762.

Table 5 Opportunity Gain of the TissueTuck Technique

	Opportunity Gain with MSICS	Opportunity Gain with Phaco
CAU with fibrin glue	$522 /TT procedure	$117 /TT procedure
CAU with sutures	$2423 /TT procedure	$1359 /TT procedure

Abbreviations: CAU, conjunctival autograft; MSICS, manual small incision cataract surgery; phaco, phacoemulsification; TT, TissueTuck.

Table 6 Recurrence Rates at 6 Months Following Pterygium Excision and Conjunctival Autografting with Sutures or Fibrin Glue

Study (Author, Year)	Recurrence Rate, % (N)	
	Fibrin Glue	Sutures
Cioba et al, 2022[51]	12.1% (4/33)	0% (0/28)
Sarkar et al, 2020[60]	7.7% (2/26)	23.1% (6/26)
Singh et al, 2019[15]	1.3% (4/312)	2.2% (7/312)
Kumar and Singh, 2018[12]	0% (0/20)	5% (1/20)
Parekh et al, 2017[55]	0% (0/30)	0% (0/30)
Patkar and Muley, 2017[56]	0% (0/30)	6.6% (2/30)
Wang et al, 2017[19]	3.6% (1/28)	7.1% (2/28)
Qi-Feng and Wei, 2015[58]	3.3% (1/30)	10% (3/30)
Priya and Hedge, 2015[57]	5% (2/40)	5% (2/40)
Nishant et al, 2014[53]	3.3% (1/30)	20% (6/30)
Vichare et al, 2013[61]	3.3% (1/30)	10% (3/30)
Rubin et al, 2011[59]	4.8% (1/21)	7.7% (2/26)
Yüksel et al, 2010[62]	6.9% (2/29)	13.8% (4/29)
Ozdamar et al, 2008[54]	0% (0/12)	0% (0/12)
Koranyi et al, 2004[52]	10% (2/20)	17.4% (4/23)
TOTAL	**3.0% (21/691)**	**6.1% (42/694)**

Rate of Recurrence: Pterygium Excision with CAU versus TissueTuck Technique

A total of 15 prospective comparative studies[12,15,19,51–62] assessed the recurrence rate at six months for eyes receiving CAU with sutures or fibrin glue following excision of primary pterygium. Twelve studies were randomized controlled trials, and three studies were prospective comparative studies, in which randomization was not reported.[12,55,61] Eight studies reported the use of conjunctival limbal autograft, in which the autograft was dissected towards the cornea to include part of the superficial limbus.[12,52,54–56,60–62] Aside from one study that reported the use of autologous fibrin glue,[51] the fibrin glue used in the studies were commercially available products such as Tisseel® (Baxter Healthcare Corporation, Glendale, CA). No studies reported use of intra-operative MMC.

From the 15 studies, the overall recurrence rate at six months following excision of primary pterygium with CAU is 3.0% (21/691 eyes) when securing the graft with fibrin glue and 6.1% (42/694 eyes) when using sutures (Table 6). [12,15,19,51–62] In contrast, the recurrence rate using the TissueTuck technique is 0.4% (2/486 eyes) at six months in eyes presenting with primary pterygium.[9]

Discussion

Compared to hospital and inpatient settings, ASC facilities have allowed for greater productivity and lower healthcare costs without sacrificing the quality of care, which has impacted all relevant healthcare stakeholders including patients, payers, and physicians.[63,64] ASCs have been particularly beneficial for ophthalmological care, as more than 95% of

ocular surgeries are performed in outpatient settings.[65] Nonetheless, ASC facilities are confronted with increasing costs of supplies, administration, and labor and decreasing payer care contracts. Hence, importance has been placed on procedural efficiency to identify surgical techniques that can lower input costs while maximizing outputs, such as revenue and of quality of care.[66]

In this health economic analysis, we focused on the procedural efficiency of pterygium surgery which is a commonly performed procedure in ophthalmic ASCs.[67] Meta-analysis suggests that the overall prevalence of pterygium is 10.2%, though not all cases proceed with surgical excision.[68] The most common techniques of performing pterygium surgery involve the use of a CAU or AM graft that is applied to the ocular surface with fibrin glue or sutures. Of these techniques, our analysis demonstrated that the average surgical time of using AM with fibrin glue via the TissueTuck procedure was substantially lower than the time needed to perform pterygium excision with CAU with either fibrin glue or sutures, saving approximately 9 to 23 minutes, respectively. Furthermore, using AM with fibrin glue was the most cost-effective intervention, even though the initial supply cost of AM was greater than CAU. This cost effectiveness is primarily a result of the opportunity to perform additional cataract surgeries with the time savings, which is one of the most commonly performed surgical procedures.[69,70] The overall opportunity gain of using AM with fibrin glue over CAU techniques ranged from $117 to $2423 per pterygium surgery. In order for CAU with fibrin glue or suture to be the lower cost alternative procedure, the overall supply cost of AM would need to exceed $762 or $2004, respectively, which is far greater than the current list price of $645. As a result, the procedural efficiency of AM greatly reduces the operating time and overall total operation cost despite an obvious supply cost difference between AM and CUA.

Clinically, our analysis also demonstrated that the pterygium recurrence rate is lower with AM and fibrin glue when compared to CAU with fibrin glue or suture (0.4% vs 3.0–6.1%). Although the clinical superiority of AM over CAU is still an ongoing debate, and the recurrence rates after pterygium surgery are variable in the literature, we have reported that the TissueTuck technique using AM and fibrin glue is a highly reproducible and formulaic technique that produces similar outcomes regardless of pterygium size.[9] Aside from a low rate of recurrence, we have also previously shown that the TissueTuck technique yields a great aesthetic outcome with low rates of other complications attributed to pterygium excision such as granuloma formation and diplopia in extreme lateral gaze. Furthermore, cryopreserved AM is readily available and avoids the need to harvest a graft in case of future glaucoma surgery. Hence, procedural efficiency of performing surgery with AM and fibrin glue is substantiated by increasing productivity without adversely affecting the quality of care.

There are several limitations with the present study. First, the cost-effectiveness of using AM may vary depending on the negotiated supply cost at different ASCs across different regions of the country. Furthermore, the current analysis did not consider the supply cost of suture versus fibrin glue, hospital versus freestanding ASC surgical times, potential realized and opportunity cost of revision surgeries and postoperative care due to pterygium recurrence or other complications, overtime for staff to complete the day's list of cases, and surgical duration from other surgeons using the TissueTuck technique. However, our analysis is quite thorough as we compared the outcomes of 582 cases using the TissueTuck technique to 640 to 796 cases of CAU technique using only prospective studies. Furthermore, there may be additional value from the patients' perspective, as there could be shorter waiting times and better quality of life as prolonged operative duration has been associated with complications.[71] Those patients may also be more likely to return for other surgeries and refer their colleagues to the surgeon that performed the pterygium excision. This is especially relevant to many physicians performing the surgeries, as 90% of ASCs are owned in-part by physicians and 65% are solely owned by physicians.[72] Additionally, this will benefit the overall healthcare burden as it accommodates the increased demand for outpatient services, as there is an increasing incidence of surgical procedures performed and improved patient access to better insurance coverage. Another limitation of this analysis is that the rate of recurrence was assessed at six months, which has been reported by several prospective comparative studies as demonstrated by our literature review. Nevertheless, we previously reported that the recurrence rate using the TissueTuck technique was 1.7% (7/420) at one year for both primary and recurrent pterygium,[9] which is still lower than the cumulative average rate of recurrence at six months for CAU with sutures and fibrin glue (6.1% and 3.0%, respectively). Overall, this study should aid those ASC facilities interested in optimizing procedural efficiencies and builds off prior findings that showed CAU with fibrin glue is more cost-effective than CAU with sutures.[73]

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