Human Amniotic Membrane Graft Plug for Sclerotomy Closure of 23-Gauge Pars Plana Vitrectomy in Eyes with Silicone Oil Tamponade

Key Words:
Human amniotic membrane,Pars plana vitrectomy,Sclerotomy,Silicone oil tamponade.

Summary Statement:
Human amniotic membrane is a promising method of plugging the 23-gauge pars planavitrectomy sclerotomy and can be use by surgeons. Since amniotic membrane tissue is full ofgrowth factors, it helps fast healing and prevents leakage.

Abstract

The aim of this single-center, comparative, interventional case study is to elaborate a method to plug the 23-gauge pars plana vitrectomy sclerotomy using a human amniotic membrane in the eyes having internal tamponade of silicone oil. This study was conducted on 75 eyes of 75patients who underwent 23-gauge pars plana vitrectomy with tamponade of silicone oil. Patientsweredivided into three groups based on sclerotomy closure.Group A consisted of 25 eyes in which the sclerotomy was closed with a human amniotic membrane, Group B consisted of 25 eyes in which the sclerotomy was closed with sutures, and Group C consisted of 25 eyes in which neither sutures nor human amniotic membrane were used. Patients were monitored for a total of six months. Hypotony and subconjunctival silicone oil were not seen in Group A. 12% of those in Group B had subconjunctival silicone oil leaks, but none had hypotonia. On the first postoperative day in Group C, 28% displayed subconjunctival silicone oil, and 16% displayed hypotonia. Further manipulation was required for these four hypotonus eyes; two required the use of sutures, and the other two required the use of a human amniotic membrane. We came to the conclusion that silicone oil tamponade with a human amniotic membrane plug appears to be a promising method for closing the vitrectomy sclerotomy in the eyes.

1. Introduction

Since the introduction of pars plana vitrectomy, different types of sclerotomies have been proposed, whose aim is to decrease operative time, decrease intraocular pressure variation during instrument removal, and reduce conjunctival irritation caused by sclerotomy sutures [1]. The 23-gauge transconjunctival suture-less vitrectomy was first introduced by Eckardt [2] and consists ofcreating an oblique scleral tunnel using a stiletto blade with however insertion of microcannula done as a second step [1]. The 23-gauge allowed, through its concept, andcompared to 20-gauge, a self-sealing and suture-less vitrectomy.

However, the self-closure of sclerotomy remains controversial. Suture-less sclerotomy induces atransient postoperative hypotony as a common complication, due to the fluid leakage of the sclerotomy [3]. Choroidal effusion, although rare (0-1.8%) can also happen but is transient andresolves without any treatment [4]. Contamination of the entire length of the incision can alsooccur by the ocular surface fluid [5]. Surgeons have therefore been apprehensive about thehypothetical weakness of self-sealing sclerotomy, although the mechanisms lying beneath self-sealing sclerotomy appear to be resolved.

Postoperative silicone oil leakage through the sclerotomy can affect the surgical outcome when silicone oil tamponade is used [6]. Additionally, since silicone oil postoperative supplementation requires reoperation (as opposed to gas postoperative supplementation, which is simple), special attention should be paid to sclerotomy closure in cases of silicone oil tamponade [6].

The foetus is encased in a semitransparent membrane called the amniotic membrane in humans.It iscomposed of five consecutive layers: an epithelium, a basement membrane, a compact layer, afibroblast layer, and a spongy layer [7]. It has been used in numerous ophthalmology fields,including covering corneal ulcers, and reconstruction of the conjunctiva. The reason behind its uselies in its anti-microbial and anti-angiogenic properties, and its poor immunogenicity [8,9] Therefore, it looks intriguing to close the sclerotomy with a human amniotic membrane.

The goal of this work is to describe a method for tamponading a 23-gauge pars plana vitrectomy sclerotomy in the eyes with a human amniotic membrane.

2. Materials and Methods

2.1.Study design

We conducted this study in a singlecenter at the Department of Ophthalmology, Lahore GeneralHospital in Pakistan. This study is a comparative, interventional case series between September2019 and March 2020. It was done according to the Declaration of Helsinki ethical standards, hasreceived ethical approval from the local Institutional Review Board, and all patients have signed awritten informed consent form.

2.2.Population

A total of 75 patients (75 eyes) were prospectively enrolled for a 23-gauge pars plana vitrectomy with silicone oil tamponade. Patients with rhegmatogenous retinal detachment met the inclusion requirements, patients who underwent 23-gauge pars plana vitrectomy with1000 cs silicone oil

tamponade,and patients having retinal pathology other than rhegmatogenousretinal detachment in which 5000cs silicone oil or no tamponade was used after pars planavitrectomy were excluded from the study. Three main groups were created from these patients. The patients were divided into groups according to their numbers: patient number 1 was assigned group A, patient number 2 was given group B, patient number 3 was given group C, and so on.

The groups are as follows: - Group A: 25 eyes in which the sclerotomy was sealed with a human amniotic membrane (see Video, Supplemental Digital Content 1).
- Group B: 25 eyes in which the sclerotomy was closed with Vicryl 6/0 sutures (see Video, Supplemental Digital Content 2).
- Group C: 25 eyes in which no human amniotic membrane or sutures were used during sclerotomies.
The duration of follow-up was 6 months.

2.3.Surgical Technique: Human Amniotic Membrane Preparation for Intraocular Use

Steps:

1. Get a fresh placenta from the Department of Obstetrics and Gynecology from an elective C-section of apatient who is hepatitis B, C, and HIV negative.
2. Wash the placenta under free-flowing tap water and separate the amniotic membranefrom the placenta.
3. Once the amniotic membrane becomes transparent, wash the membrane with 1000mlof normal saline in which 2 ampoules of injection gentamycin are added.
4. Now transfer the membrane into a bowl containing 02 ampoules of injectiongentamycin.
5. Take 3 sterile bowls each containing 2 ampoules of gentamycin. Transfer themembrane into each bowl one by one after 3-5 minutes.
6. The membrane is now ready for intraocular use.
7. Remove the trocar, grasp the amniotic membrane with the end grasping forceps andplug the sclerotomy with the membrane (see Video, Supplemental Digital Content 1which demonstrates how the amniotic membrane was used).The size of the amniotic membrane is 3 to 6 mm.

2.4.Outcomes

The primary outcome was the rate of complications including postoperative hypotony, andsubconjunctival silicone oil leakage. Secondary outcomes were the rate of displacement of humanamniotic membrane plugs in group A.

2.5.Statistical Analysis

To describe the data, we used the mean, the standard deviation, the frequency, and the percentage. To assess thebaseline characteristics of each group of patients, a one-way ANOVA was used. To compare therate of complications in Group A with that of Group B and C, Fisher's exact test was used. Allstatistical analyses were performed using RStudio (Desktop 1.3.1093). P-values less than 0.05were considered statistically significant.

3. Results

Baseline characteristics of the three groups of patients A, B and C were shown in Table 1. Therewas not a statistically significant difference between groups at baseline (p=0.885). The 23-gaugepars plana vitrectomy with tamponade of 1000cs silicone oil was done for rhegmatogenousretinaldetachment in 75 eyes of 75 patients. Mean age of these patients was 55 +/- 6.51 years and 45patients were males while 30 patients were females.

Table 2 shows the rate of complications in all groups.Human amniotic membrane plugs in Group A's ports remained in 24/25 eyes (96%) of the patients, while one patient's plug was dislodged from one port (4%), but no subconjunctival silicone oil was seen (0%) and none of the patients were hypotensive. 3/25 eyes (12%) in Group B showed subconjunctival silicone oil, however no patient had hypotony.

On the first postoperative day, 4/25 eyes (16%) in Group C had hypotony and 7/25 eyes (28%) had subconjunctival silicone oil. Additional surgery was required for these four hypotonous eyes; two were fixed with sutures and the other two were fixed with human amniotic membrane plugs.

Hypotony and the kind of Sclerotomy closure are statistically significantly correlated (p=0.03). Additionally, there is an association between the type of sclerotomy and subconjunctival oil leaking that is statistically significant (p=0.01).

4. Discussion

Our study shows that the human amniotic membrane plug appears to be a promising technique toclose the vitrectomy sclerotomy in the eyes with silicone oil tamponade. Suture-less sclerotomyinduces a high rate of subconjunctival silicone oil (28%), minimized to 12% by suturing the sclerotomy incision, and to 0% while using the human amniotic membrane plug. Similarly, postoperativehypotony was reduced from 16% with the suture-less technique to 0% with sutures and 0% with ahuman amniotic membrane plug.

The 23-gauge, but also the 25-gauge and lately the 27-gauge pars plana vitrectomy incisions werecreated to limit hypotony caused by the 20-gauge, and to be able therefore to allowself-sealing of the incision, given many disadvantages of sutures. Suture-less self-sealing has beenstudied in numerous studies in the literature and has been demonstrated as safe and effective.

However, when silicone oil tamponade is used, silicone oil leakage seems to be the main problem, andthis is facilitated theoretically, but also practically, by a suture-less incision.Schweitzer et al. have tested the suture-less self-sealing sclerotomy in 23-gauge pars planavitrectomy in 57 patients (57eyes) [1]. A transient postoperative hypotony was recorded in 21%of patients; however, itresolved without any treatment. Nochoroidal effusion and no endophthalmitis were seen. However, in this study, there was no silicone oil injection, and therefore, silicone oil leakage cannot be evaluated. A case of upper lid silicone oil migration causing small lumps has also been reported by Dehghani et al. after suture-less 23-gauge vitrectomy, with eyelid swelling and ptosis [10]. Another case of subconjunctival and orbital silicone oil granuloma (siliconoma) was described by Lee et al. [11]. A case of massive silicone oil migration into the subconjunctival space was also reported after suture-less 23-gauge sclerotomy [12].

On the other hand, Olivieira et al. have shown in a study done on 20 patients who underwent 23-gauge transconjunctivalsuture-less vitrectomy with silicone oil tamponade that none of the 20patients (0%) had hypotony or silicone oil leakage [13]. Another retrospective analysis done on 19 consecutive eyes with silicone oil injection divided into self-sealing versus sutured sclerotomies also showed, unlike our study, no subconjunctival silicone oil leakage in the suture-less group [6].
No subconjunctival silicone oil was also reported in the sutured group. No cases of postoperative hypotony were encountered. The authors concluded that the procedure for sclerotomy closure (suture vs. suture-less) did not influence postoperative intraocular pressure and silicone oil leakage. However, we should note that they used 25-gauge and not 23-gauge transconjunctival vitrectomy. Kayani et al. have compared 23- to 25- gauge pars plana vitrectomy for posterior segment disease in 58 eyes, and have concluded that both techniques are minimally invasive and safe; 23-gauge has stiffer instruments and is suitable for a larger number of pathologies, while the 25-gauge needs careful handling since its instruments are delicate [14]. Kapran et al. [15] have shown a decrease in intraocular pressure caused by subclinical amounts of leakage in suture-less sclerotomies at 2 hours postoperatively; this decreased pressure disappeared after the first day.

Our study has shown 28% of silicone oil leakage in the suture-less group and 12% of leakage even
in the sutured group, while no silicone oil leakage was observed for the amniotic membrane plug. Since amniotic membrane tissue is full of growth factors, it helps fast healing and prevents leakage. It has had very wide applications in ophthalmology, especially in repairing retinal tissue through a regeneration process [16].

This study is not devoid of limitations. First, it only included patients having a rhegmatogenous retinal detachment. Second, we did not compare 23-gauge to 25- and 27- gauge pars plana vitrectomy. Third, only 1000cs silicone oil tamponade was used in this study.

5. Conclusion

In comparison to suturing the sclerotomy or even not suturing it, the human amniotic membrane graft plug appears to be a promising option for sclerotomy closure of 23-Gauge pars plana vitrectomy in eyes with silicone oil tamponade. To support our findings, additional randomised multicenter investigations are required.

6. Annexes

6.1.Tables

Table 1: Baseline patients characteristics between group A, group B and group C. Group A:a graft plug comprised of amniotic membrane of a human was used to plug the sclerotomy (AMG). Group B: Vicryl 6/0 wereused to close the sclerotomy. Group C: Suture-less and no AMG.

Sr. No.	Age	Gender	Laterality	Group
1	47	F	R	A

2	53	M	L	A
3	55	M	L	A
4	42	M	R	A
5	53	F	L	A
6	57	M	L	A
7	67	M	R	A
8	55	F	R	A
9	49	M	L	A
10	51	F	L	A
11	42	M	R	A
12	57	M	L	A
13	45	F	L	A
14	50	M	L	A
15	53	M	R	A
16	58	M	L	A
17	47	M	L	A
18	60	F	L	A
19	58	F	R	A
20	49	F	L	A
21	47	M	L	A
22	52	M	L	A
23	54	F	R	A
24	62	F	R	A
25	47	F	R	A
26	65	F	L	B
27	64	M	L	B
28	53	M	L	B
29	51	F	L	B
30	55	F	L	B
31	49	F	L	B
32	53	M	R	B
33	60	F	L	B
34	61	F	R	B
35	54	M	L	B
36	49	F	R	B
37	51	M	L	B
38	55	F	R	B
39	60	F	L	B
40	49	F	L	B
41	56	F	L	B
42	51	M	R	B
43	62	M	L	B
43	53	M	L	B
45	49	M	L	B
46	63	M	R	B

47	58	M	R	B
48	51	M	R	B
49	49	M	L	B
50	55	F	L	B
51	61	M	L	C
52	49	M	R	C
53	53	M	R	C
54	57	M	L	C
55	62	M	L	C
56	48	F	L	C
57	57	M	R	C
58	47	M	R	C
59	50	M	L	C
60	55	M	L	C
61	59	M	L	C
62	49	F	L	C
63	51	M	R	C
64	52	M	L	C
65	57	M	R	C
66	50	F	L	C
67	52	M	L	C
68	60	M	R	C
69	62	M	R	C
70	57	F	L	C
71	52	F	L	C
72	55	F	R	C
73	58	M	L	C
74	52	M	L	C
75	59	F	R	C

Table 2: Complications following sclerotomy. Hypotony and subconjunctival silicone oil (SO)leakage.

Group	**Hypotony**	**Subconjunctival leakage of SO**
A	0	0
B	0	03
C	04	07

6.2.List of Supplemental Digital Content

Supplemental Digital Content 1. wmv
Supplemental Digital Content 2. wmv

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