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Case Report In situ grommet and fitness for flying

AVK Raju¹, S Saxena², SS Mohapatra³

¹Specialist in Aerospace Medicine, Department of High Altitude Physiology and Hyperbaric Medicine, Institute of Aerospace Medicine IAF, Bengaluru, India, ²Specialist in ENT, Air Force Central Medical Establishment, New Delhi, India, ³Senior Advisor (Aerospace Medicine), HoD, Department of High Altitude Physiology and Hyperbaric Medicine, Institute of Aerospace Medicine IAF, Bengaluru, India.



*Corresponding author: Dr AVK Raju, MBBS, MD (Aerospace Medicine), Department of High Altitude Physiology & Hyperbaric Medicine, Institute of Aerospace Medicine IAF, Vimanapura, Bengaluru - 560 017, Karnataka, India.

avkraju123@gmail.com

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ABSTRACT

Introduction: Current policies followed in the country do not permit aircrew to fly with *in situ* grommet. This paper discusses the aeromedical implications of *in situ* grommet, assessment of its flying fitness, and the factors which may be considered for possible reflighting of such cases.

Case Details: A 19 year old civil pilot developed otitic barotrauma middle ear (right) which was managed with the placement of grommet in the tympanic membrane (TM). He was awarded fitness to fly on removal of grommet and after complete closure of the residual TM perforation. Another case, a 50 year old military pilot, a case of chronic suppurative otitis media (inactive) left ear, after uneventful recovery, was awarded flying medical category initially for *in situ* grommet and subsequently for single dry perforation TM in the left ear with an waiver from the competent medical authority.

Discussion: Insertion of grommet, in cases with middle ear effusion and/or infection following Eustachian tube dysfunction, is a common practice to promote early recovery. However, as per the current policies in India, such aircrew are considered unfit for flying duty. Policies in other countries, military and civil, are mostly silent. This paper recommends the award of flying fitness for aircrew with *in situ* grommet provided that the clinical condition is stable, there are no complications and hearing is normal. This paper also discusses the award of flying fitness for aircrew with single and uncomplicated TM perforation with normal hearing for a specific type of aircraft.

Keywords: Eustachian tube insufficiency, Middle ear infections, Middle ear effusion, Aeromedical concerns, In situ grommet

INTRODUCTION

The three basic functions of eustachian tube (ET) are regulation of middle ear pressure with respect to atmospheric pressure, clearance of middle ear secretions, and protection of the middle ear from nasopharyngeal secretions. Dysfunction of the ET can lead to middle ear effusion and even infection. In cases of non-resolving middle ear effusion, it is a common practice for the ENT surgeons to consider myringotomy and insertion of grommet in the tympanic membrane (TM) of the affected ear to serve as outlet drain from the middle ear cavity and to promote early resolution of the condition.^[1]

The microbial environment within the nasopharynx and middle ear responds to the changes induced by external respiratory viruses by inducing mucosal cell damage which, in turn, promotes bacterial overgrowth. Once the acute infection ends, certain bacteria persist in the middle ear to form a biofilm resulting in chronic infection. These biofilms are highly susceptible to aerobic environments.^[2,3] Hence, placement of a grommet controls the middle ear bacterial infection by increasing the middle ear aeration.^[2]

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Grommet or the tympanostomy tubes were first invented by Politzer in the 19th century. The tubes have evolved with time, and current grommets use design characteristics and material which prevent infection, occlusion of the tube, and promote faster healing. The use of ionized fluoroplastic grommets impregnated with silver oxide has been found to be highly effective in preventing grommet-associated complications.^[4,5]

Aircrew requiring in situ grommet insertion poses unique challenges for flying fitness. As per the existing policies in India,^[6] such aircrew are not considered fit for flying duty. Once the grommet extrudes or is removed, it can leave behind a small perforation, which again is unfit for flying as per the existing guidelines. Civil Aviation Safety Authority (CASA), Australia, permits flying with in situ grommet provided, there are no pain or associated complications.^[7] However, policies in other countries are mostly silent on in situ grommet. Most international medical guidelines, including ICAO Manual (Para 6.3.2.25.1), permit flying with single central dry perforation with normal hearing.^[8] However, the same is considered unfit for flying as per Directorate General of Civil Aviation (DGCA), India guidelines.^[6] This paper brings out two case studies in aircrew related to grommet and flying fitness. This paper also discusses the aeromedical implications of in situ grommet and residual TM perforation following removal of grommet, policies followed in other countries, and recommendations on the aeromedical disposal of such cases.

CASE DETAILS

Case - I

A 19-year-old civil flying aspirant during his first flying experience as a passenger, while on the descent phase, developed pain in his right ear. He tried middle ear pressure equalization techniques but did not get any relief. During his subsequent flying experience, he again developed pain in the same ear during the descent phase which did not resolve with middle ear pressure equalization techniques. On apprehension that recurrent otalgia could prove detrimental to his plans as a career pilot, he consulted an ENT surgeon who placed a single grommet in the anteroinferior quadrant of the pars tensa of the right TM. With in situ grommet, he successfully completed his flying training in South Africa. After completion of training, he was assessed "Fit" in Class I medical examination at South Africa with the in situ grommet right TM. On return to India, during evaluation for Class II Medial examination, ENT examination revealed a healthy grommet in situ. There were no signs of complications such as discharge, bleeding, and presence of a polyp or growth. His pure tone audiometry (PTA) and tympanogram (ET function) values were within normal limits. He was awarded temporary unfit medical category

on account of post-myringotomy with *in situ* grommet with advice for review with cure certificate. Following this, he got the grommet removed and reported for review at the Institute of Aerospace Medicine, Indian Air Force (IAM, IAF). During the review, a diagnosis of the right chronic otitis media inactive mucosal type with small central perforation was made and was awarded a temporary unfit medical category for TM perforation. In due course of time, the individual made complete recovery of the TM. Subsequently, he cleared his Class II and later Class I medical examination.

Case - II

A 50-year-old military aircrew from a fighter stream was detected with single perforation in the pars tensa of his left TM. A diagnosis of chronic suppurative otitis media (inactive) left ear was made. The aircrew was surgically managed with tympanoplasty (left TM). Post-surgery, the TM developed retraction with residual perforation along with mild symptoms. The aircrew was surgically managed by insertion of a grommet in the TM. After a successful recovery, with the *in situ* grommet, he was awarded fitness for flying with a waiver from the competent authority, IAF. In due course of time, the grommet extruded naturally leaving a single dry perforation in his left TM. Subsequently, he was awarded a flying medical category for single dry TM perforation again with a waiver from the competent authority.

DISCUSSION

Our first case was a civil aircrew with in situ grommet in one ear with all other ENT parameters and investigations normal. He already had a Class I flying certificate from a different country. However, he was assessed unfit for flying duty as per the existing guidelines in India. The aircrew could earn medical certification to fly only on removal of in situ grommet and after complete healing of the small dry central perforation. Our second case was a military fighter pilot who was awarded a flying fitness for in situ grommet and subsequently for single healed dry TM perforation following a comprehensive aeromedical evaluation and waiver by the competent authority. Follow-up in the subsequent reviews did not reveal any deterioration of the condition. These cases bring out few important aeromedical issues; (a) the policies followed in different countries for disposition of the cases with in situ grommet and residual TM perforation are different. (b) There is a potential for reflighting such aircrew, thus conserving the trained personnel in their flying profession. However, before considering them for fitness for flying duty, a thorough aeromedical evaluation, possible complications, and likely aeromedical implications must be considered. These issues have been discussed in the subsequent paragraphs and recommendations have been

suggested for possible aeromedical disposal of aircrew with *in situ* grommet and residual TM perforation.

Short-term medical complications associated with in situ grommet include otorrhea, infection, blockage of grommet (granulation tissue), dislodgement, or premature extrusion. While long-term complications include myringosclerosis, TM atrophy, and permanent perforation.^[9] Of these, myringosclerosis was found to be the most common complication developing in 40-50% of grommet insertion cases. However, it is seen that myringosclerosis was not detrimental to hearing.^[10,11] When grommet insertions were needed more than once, focal atrophy of the TM at the tube insertion site was seen in up to 40% of TMs.^[12] However, focal atrophy of the TM does not adversely affect long-term TM function as long as there is no development of middle ear atelectasis.^[13] Aeromedical complications that can possibly arise due to in situ grommet include entry of infection due to sweat, pain, deafness, tinnitus, bleeding, and free ventilation with ambient air which has the potential to induce vestibular vertigo and disorientation.

Available military guidelines for disposal of aircrew with grommet in situ are sparse. DGCA, India, does not have any guideline for in situ grommet; however, perforation of TM is not compatible with flying.^[6] International Civil Aviation Organization in the Manual of Civil Aviation Medicine does not make any reference on in situ grommet.^[8] Existing guidelines by Joint Aviation Authorities governing civil aviation in Europe do not comment on certification with in situ grommet.^[14] Guide for medical examiners published by Federal Aviation Administration, USA also does not make any reference on *in situ* grommet but states that all ENT cases with prosthesis need careful evaluation giving due consideration to kind of prosthesis used, the person's ability to cope up with the prosthesis, clinical progress following surgery, and the extent of hearing acuity attained or compromised. Certification for flying duties can be considered on a case to case basis by FAA, provided there is no active infection involved, symptoms have resolved, adequate hearing acuity is present, and there are no associated complications, especially dizziness and disequilibrium.^[15] Guide for Aviation Medical Examiners published by South African Civil Aviation Authority again does not comment on flying with in situ grommet.^[16] However, the case of civil aircrew discussed as Case - I successfully cleared his Class I medical examination with in situ grommet. CASA of Australia in its Designated Aviation Medical Examiner's Clinical Practice Guidelines on ENT makes a reference for disposal of civil aircrew with in situ grommet. The guidelines clearly state that flying with in situ grommet is permitted provided the aircrew presents with no complications or pain and tympanometry and PTA values are within acceptable values.^[7]

Although complications associated with grommet insertion are known to occur, the incidence is very less to cause concern as suggested by an article published in the Menoufia Medical Journal which came to this conclusion after studying 220 cases of otitis media effusion managed with situ grommet.^[17] In another study, where the patients were mostly children, 181 patients with myringotomy and grommet insertion over a period of 2 years were analyzed. The study again indicated that the complication rates with *in situ* grommet were low.^[18] From these studies, it is evident that the complication rate with *in situ* grommet is relatively less. In view of this, an attempt to reflight civil aircrew with *in situ* grommet with no presenting complications definitely merits due consideration.

Most international medical guidelines permit flying with single dry perforation of the TM. Para 6.3.2.25.1 of Chapter III in the 3rd edition of ICAO Manual of Civil Aviation Medicine states that a well-healed single dry perforation can be permitted for flying.^[8] FAA medical guidelines permit an aircrew to fly with a single central dry perforation with normal hearing.^[15] CASA, Australia medical guidelines, permits chronic TM perforation provided that it is small, dry, not associated with pain, hearing loss, or other aviation relevant symptoms.^[7] Varying from the existing guidelines practiced worldwide, DGCA in India, however, currently does not permit aircrew to fly with perforation of TM.^[6] Taking the above into consideration, possible aeromedical complications such as introduction of infection or induction of vestibular vertigo, if acceptable for flying with single dry perforation of TM, should logically also be acceptable with in situ grommet as both TM perforation and grommet, behave in similar fashion in the aviation environment and pose similar challenges.

Cases of ET dysfunction with or without effusion can benefit from in situ grommet placement in the TM of the affected ear. The available literature on the subject shows that complications associated with in situ grommet are not significant to cause any major aeromedical concern. It is observed that a recognized International Civil Aviation agency permits aircrew to fly with in situ grommet in the TM provided that the aircrew exhibits clinical recovery without any complications and comply with the hearing standards. Considering above, aircrew with in situ grommet can be considered fit to fly when there is complete resolution of the middle ear infection without any complications. Unlike in situ grommet, adequate guidelines by International Civil Aviation Authorities are available on single dry perforation in the TM to suggest award of medical certification to fly. Hence, all cases of single dry central perforation TM can also be considered for the award of flying medical category.

RECOMMENDATIONS

Based on the above discussion, the following recommendations are made for aeromedical disposal of aircrew for civil and military flying:

In situ grommet in civil aircrew

Uncomplicated in situ Grommet does not pose significant risk to aerospace safety and hence such aircrew can be considered fit for flying duties. Certification for flying duties can be considered provided there is no active infection, symptoms have resolved, adequate hearing acuity is present and there are no associated complications especially dizziness and disequilibrium. All such cases after Grommet insertion may be initially observed in 'Temporary Unfit Flying' for four weeks allowing him time for healing. This will also allow monitoring of development of any possible infections or complications. Subsequently, they may be re-flighted to 'Pilot in Command (PIC) with a Qualified Experienced Pilot (QEP)', if they continue to remain asymptomatic, have adopted well to the Grommet, there are no post-surgical complications, possess normal clinical and hearing standards. Ability to withstand Ear Clearance Run in Decompression Chamber may be checked on a case to case basis. They may be reviewed monthly by AMA/Company Doctor and quarterly by local ENT Surgeon. After a period of one year of observation, award of 'full flying medical category' can be considered. At any time, if the Grommet gets extruded on its own or is removed, the flying category can be appropriately considered based on the residual defect and clinical and aeromedical evaluation.

Single dry central perforation of TM in civil aircrew

In lines with provisions laid down by ICAO and FAA, a single well-healed dry central perforation TM with normal hearing may be considered fit to fly as "PIC with QEP" after a comprehensive evaluation provided that there are no symptoms and hearing is normal. The aircrew can be upgraded to full flying medical category on autoclosure of TM perforation or after successful tympanoplasty.

Military Flying

Pressure changes in the military aircraft are significantly different then civil aircraft. Further, military guidelines are usually more stringent compared to civil aviation. Aircrew with *in situ* Grommet or Single Dry Central Perforation TM may be considered fit Transport/Helicopter flying provided; they remain asymptomatic, have adequate hearing standards as per the stream, free of complications and can withstand Ear Clearance Run. Re-flighting of such aircrew will be gradual subject to a complimentary Executive Report on Flying on Type. Fitness for fighter flying may be considered on a case to case basis after a comprehensive aeromedical evaluation subject to documentary review and waiver by the Competent Authority.

Declaration of patient consent

Patient's consent not required as patients identity is not disclosed or compromised.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

- Dhingra PL, Dhingra S. Eustachian tube and its disorders. In: Diseases of Ear, Nose and Throat and Head and Neck Surgery. 7th ed. New Delhi: RELX India Pvt. Ltd.; 2018. p. 61.
- 2. Perkins JA. Medical and surgical management of otitis media in children. Otolaryngol Clin North Am 2002;35:811-25.
- Akyıldız I, Take G, Uygur K, Kızıl Y, Aydil U. Bacterial biofilm formation in the middle-ear mucosa of chronic otitis media patients. Indian J Otolaryngol Head Neck Surg 2013;65:557-61.
- 4. Chole RA, Hubbell RN. Antimicrobial activity of silastic tympanostomy tubes impregnated with silver oxide: A double blind randomized multicenter trial. Arch Otolaryngol Head Neck Surg 1995;121:562-5.
- 5. Biedlingmaier JF, Samaranayake R, Whelan P. Resistance to biofilm formation on otologic implant materials. Otolaryngol Head Neck Surg 1998;118:444-51.
- 6. Handbook for DGCA Empanelled Medical Examiners/ Examination Centres. New Delhi: Directorate General of Civil Aviation Medical Cell (Govt of India); 2018. p. 33-4.
- Authority CAS. ENT (Ear, Nose, and Throat) General. Civil Aviation Safety Authority. Civil Aviation Safety Authority; 2016. Available from: https://www.casa.gov.au/licences-andcertification/aviation-medicine/ent-ear-nose-and-throatgeneral. [Last accessed on 2020 Apr 20].
- Manual of Civil Aviation Medicine. Doc 8984 AN/895. International Civil Aviation Organization. 3rd ed. Canada: Manual of Civil Aviation Medicine; 2012. p. 389-410.
- Rosenfeld RM, Schwartz SR, Pynnonen MA, Tunkel DE, Hussey HM, Fichera JS, *et al.* Clinical practice guideline: Tympanostomy tubes in children. Otolaryngol Head Neck Surg 2013;149:S1-35.
- Goldstein NA, Roland JT, Sculerati N. Complications of tympanostomy tubes in an inner city clinic population. Int J Pediatr Otorhinolaryngol 1996;34:87-99.
- 11. Maw AR. Development of tympanosclerosis in children with otitis media with effusion and ventilation tubes. J Laryngol Otol 1991;105:614-7.
- 12. Maw AR, Bawden R. Tympanic membrane atrophy, scarring, atelectasis and attic retraction in persistent, untreated otitis media with effusion and following ventilation tube insertion. Int J Pediatr Otorhinolaryngol 1994;30:189-204.
- 13. Li Y, Hunter LL, Margolis RH, Levine SC, Lindgren B, Daly K, *et al.* Prospective study of tympanic membrane retraction, hearing loss, and multifrequency tympanometry. Otolaryngol

Head Neck Surg 1999;121:514-22.

- JAA Manual of Civil Aviation Medicine. Englewood, Colorado, Europe: Joint Aviation Authorities; 2009. p. 1-329.
- 15. Guide for Aviation Medical Examiners. Federal Aviation Administration: United States of America; 2019. p. 44-51.
- 16. Guideline for Aviation Medical Examiners. South Africa: South African Civil Aviation Authorities; 2017. p. 1-226.
- 17. Ragab A, Mohammed A, Abdel-Fattah AA, Afifi AM.

Prevalence of complications associated with tympanostomy tube insertion. Menoufia Med J 2015;28:918-22.

 Haque S, Hashmi S, Prinsley P. Impact of ENT follow up after myringotomy and grommet insertion. West London Med J 2009;1:51-60.

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