**BEACON1**

**Full Title:** Secondary Full Thickness Macular Hole after Pars Plana Vitrectomy

**Acronym:** SHOES (Secondary macular HOlE Study)

**Proposer name:** Aman Chandra1, Michael Mikhail2

**Proposer position:**

1. Consultant Ophthalmologist, Research Associate
2. Consultant Ophthalmologist

**Proposer location:**

1. Southend University Hospital NHS Foundation Trust, Anglia Ruskin University, Essex
2. St Helens and Knowsley Teaching Hospitals NHS Trust

 **Proposer email:**

1. amanchandra@gmail.com
2. drmok@hotmail.co.uk

**Other members of study design group:** David Steel, Teresa Sandinha, Madi Haifa, Nikos Dervenis, Haseeb Akram

**What you are studying:** Full Thickness Macular Holes after Pars Plana Vitrectomy

**What is your primary research question?**

What are the clinical features and outcomes for full thickness macular holes which have developed in vitrectomised eyes?

**Background and importance:**

A secondary full thickness macular hole (sFTMH) is a well-known postoperative complication of vitrectomy surgery though infrequently reported. Incidence and patient demographics of sFTMH do not appear to follow the usual pattern of idiopathic primary full thickness macular hole.

sFTMH after PPV has been described after surgery for rhegmatogenous retinal detachments (RRD), epiretinal membranes (ERM), vitreomacular traction syndrome (VMTS), and myopic foveoschisis. The majority of papers describe sFTMH developing after retinal detachment surgery particularly in cases of macula off RRD.

 Although the mechanism of sFTMH formation in a vitrectomised eye’s is incompletely understood, it may be related to tractional (e.g., residual vitreous cortex, epiretinal membrane formation) or non-tractional factors (e.g., lamellar hole and CMO, inflammation and myopia).

Macula off detachments have are thought to be a contributing factor and current theories postulate epiretinal membranes and/or cystoid macular oedema contributing to traction in a vitrectomised eye. However, these publications are published on less than 50 patients; making true descriptions of clinical and ocular risk factors, previous surgical characteristics, clinical features and treatment outcomes difficult to determine.

Also, surgical prognosis for postoperative sFTMH is less well characterised compared to idiopathic FTMH. Therefore, this study will help to find out about the surgical outcomes of post-vitrectomy macular holes and prognostic factors for visual outcomes.

This study will add to the literature by characterisation of sFTMH post vitrectomy in terms of its incidence, demographics, contributing factors and surgical outcomes.

By understanding these features more clearly, vitreoretinal surgeons will be able to perhaps identify those at greater risk, and eventually develop techniques to reduce the risk to these patients and ultimately improve treatments.

**Case definition:**

A secondary full thickness macular hole can be defined as a full thickness defect in the fovea area subsequent to PPV. PPV may have been completed for any condition except primary FTMH. sFTMH should be confirmed with OCT diagnosis.

**Inclusion criteria:**

* Full thickness defect in the fovea with an attached retina, subsequent to Pars Plana Vitrectomy
* Any age

**Exclusion criteria:**

* Previous PPV for Full thickness macular hole alone or accompanied by retinal detachment
* Full thickness defect in the fovea with an attached retina, subsequent to Pneumatic Retinopexy or Scleral Buckling surgery

**Likely incidence:**

Studies on this condition suggest an incidence of 0.5% - 1.9% (references below). In a recent local review, we identified 6 cases over 3 years (approximately 0.2% of PPV). In Liverpool; 19 cases were identified over 5 years. This equates to approximately 1.5 cases per surgeon per year.

**Prospective/Retrospective data collection?**

Prospective collection would allow detailed information to be collected. Interested participants are likely to have a high index of suspicion to identify these patients and collect phenotype data.

**If Retrospective:**

**Eligible study period:** Jan 2015 - Dec 2019 (5 years)

**Target completion for end of data collection:** 1-year from start of case collection

**If Prospective:**

**Case collection period:** June 2021 – June 2022

**Follow up duration:** 12 months

**Primary outcome measure:** Clinical features of sFTMH

**Secondary Outcome measures:**  Incidence, previous ocular histories, phenotype data, outcome

**Pre-planned analysis outline:**

**Data collection form(s):** Formatted excel chart available from study leads via email. Remember all data must be anonymised

**Images required:** OCT images. Must be anonymised and coded with local study number only. Horizontal line scan through centre of macular hole at a time point either at diagnosis or time of surgery for hole

**References**

* Ersoz MG, Hocaoglu M, Muslubas IS, Arf S, Karacorlu M. Characteristics and management of macular hole developing after rhegmatogenous retinal detachment repair. Japanese Journal of Ophthalmology. 2021 Mar 18:1-9.
* Schlenker MB, Lam WC, Devenyi RG, Kertes PJ. Understanding macular holes that develop after repair of retinal detachment. Canadian Journal of Ophthalmology. 2012 Oct 1;47(5):435-41.
* Benzerroug M, Genevois O, Siahmed K, Nasser Z, Muraine M, Brasseur G. Results of surgery on macular holes that develop after rhegmatogenous retinal detachment. British Journal of Ophthalmology. 2008 Feb 1;92(2):217-9.
* Moshfeghi AA, Salam GA, Deramo VA, Shakin EP, Ferrone PJ, Shakin JL, Fastenberg DM. Management of macular holes that develop after retinal detachment repair. American journal of ophthalmology. 2003 Nov 1;136(5):895-9.