The Need for Standardization of Visual Safety Assessments in Clinical Trials of Soft Tissue Fillers

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Clinical Signs of Injection Related Visual Compromise (IRVC), by vessel

- Sudden visual loss, typically unilateral and DRAMATIC (NLP, LP, HM)
- Branch retinal artery involvement can result in horizontal hemifield cut- This is rare but also happens immediately and is perceptible to patient
- More typically Central Retinal Artery or Ophthalmic Artery are affected with visual loss to NLP, LP, HM

Clinical Signs of Injection Related Visual Compromise, cont.

- Pain- frequent but not always present
- Ptosis- approximately 50%
- Ophthalmoplegia- to varying extent, estimated approx. 50%
- Skin changes- immediate blanching, common but not always present

Visual Safety Assessment and Soft Tissue Filler Clinical Trials

- Visual safety assessments are (and should be) mandated in clinical trials of soft tissue fillers!
- I have performed and/or participated in protocol development in at least 25 soft tissue filler clinical trials over the past several years
- Safety assessment requirements vary widely

Visual Safety Requirements for Recent IDE Studies

- **Optimal Protocol = OP**: Assess visual acuity (VA), extraocular motility (EOM) and confrontation visual fields (CVF)
- OP plus wait 30 min between injection of each side of the face
- OP + wait 30 min between injection of each side of the face + funduscopic examination performed by PI
- OP + wait 30 min between injection of each side of face + fundus photos taken with special camera with images sent for real-time evaluation

Recommendations for Ocular Safety Assessment

- As IRVC produces sudden and dramatic changes, **Protocol OP (Optimal Protocol) should be adopted for all facial soft tissue filler trials**
  - This protocol is simple and fast to perform and will detect IRVC if it occurs, allowing PI to initiate immediate treatment and transfer arrangements (tx required within 30 min of event)
  - Funduscopic examination and or photography is unnecessary to make initial determination that IRVC has occurred
  - Waiting 30 min to inject the contralateral side lengthens the subject visit but does not increase safety

Additional Recommendations

- Continue to mandate visual safety assessments for all facial soft tissue filler trials (HA, non-HA, fat)

- Do not require visual safety assessments for soft tissue filler trials on anatomic areas below the jawline (e.g. décolletage) as there is no literature or known anatomic basis to support this practice

- Engage network of experts for input on standardized safety assessments