KEY SURGICAL PEARLS OF THE IMPLANT INSERTION PROCEDURE FOR THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB (PDS)

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Purpose: The PDS is an investigational drug delivery system designed for continuous intravitreal ranibizumab release. Key surgical pearls from optimization of the PDS implant insertion procedure are reported herein.

Methods: The Ladder phase 2 (NCT02510794) and ongoing phase 3 Archway (NCT03677934) trials compare PDS with monthly intravitreal ranibizumab 0.5 mg for treatment of neovascular age-related macular degeneration. Experiences during implant insertion procedures in these trials informed evolution of PDS surgical methodologies, with the goal of optimizing surgical outcomes.

Results: The implant insertion procedure has 7 major steps to ensure good surgical outcomes: conjunctival peritomy, implant preparation, scleral dissection, laser ablation of pars plana, pars plana incision, implant insertion, and conjunctival and Tenon’s capsule closure. Controlled scleral dissection and avoiding grasping wound edges preserves scleral integrity. Edge-to-edge laser ablation of the pars plana while maintaining a final incision size of 3.5 mm ensures a secure implant fit and postoperative hemostasis. Delicate/precise handling and dissection of the conjunctiva and Tenon’s capsule with non-toothed forceps during peritomy and closure is critical to preserve tissue integrity over the implant flange. Engaging both the conjunctiva and Tenon’s capsule is key when anchoring to the anterior limbus with scleral bites. To minimize chance of wound dehiscence, multiple 3:1:1 sutures should be placed away from the implant.

Conclusion: Attention to sclerotomy construction, laser application, and handling of the conjunctiva and Tenon’s capsule may prevent early and late complications. Appropriate adherence to the optimized procedures maximizes optimal surgical outcomes. These procedures evolve as needed to support successful outcomes.