

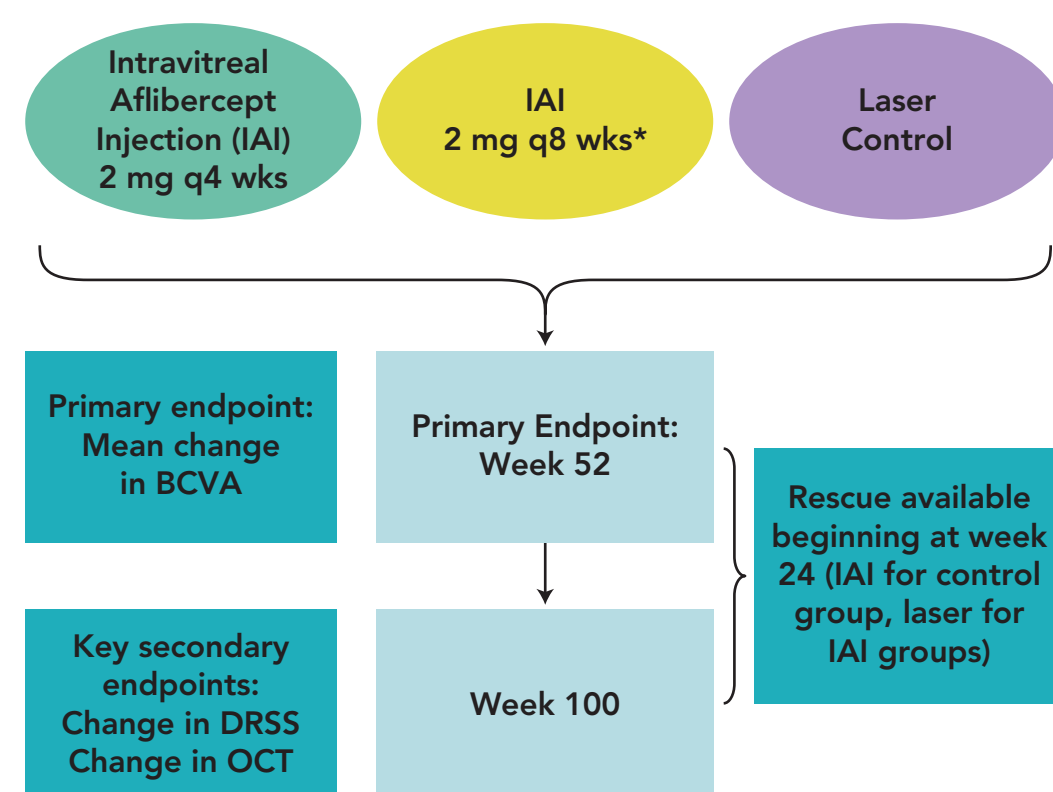
Impact of Cataract Surgery on Visual and Anatomic Outcomes in Patients treated for Diabetic Macular Edema (DME) in the VISTA and VIVID Trials

Andrew A. Moshfeghi, MD, For the VIVID and VISTA Study Investigators

Roski Eye Institute, University of Southern California, Los Angeles, CA

BACKGROUND

Randomized, multicenter, double-masked trials in patients with clinically significant DME with central involvement and ETDRS BCVA 20/40 to 20/320
Randomized and Treated N=404 (VIVID) N=461 (VISTA)



*Following 5 initial monthly doses

- IAI given q4 weeks or q8 weeks (following 5 monthly doses) significantly improved visual and anatomic outcomes over laser at week 52. These improvements were sustained through week 100 with both IAI regimens.
- In an integrated safety analysis, the most frequent serious ocular adverse event at week 100 was cataract (2.4%, 1.0%, and 0.3% for 2q4, 2q8, and control).

POST HOC SUBANALYSIS

OBJECTIVE

- To evaluate the effect of cataract surgery on visual and anatomic outcomes through week 100 in patients being treated with IAI or laser for DME

METHODS

- 579 patients with confirmed medical history of no cataract surgery prior to study enrollment were assessed to determine if they underwent cataract surgery
 - Laser (n=197)
 - Combined IAI (n=382)
- Need for cataract surgery was at the investigator's discretion
 - There was no protocol mandated period between cataract surgery and study treatment
- Patients who received rescue treatment prior to surgery were censored at time of rescue treatment

RESULTS

Figure 1. Time to First Cataract Surgery (Study Eye)

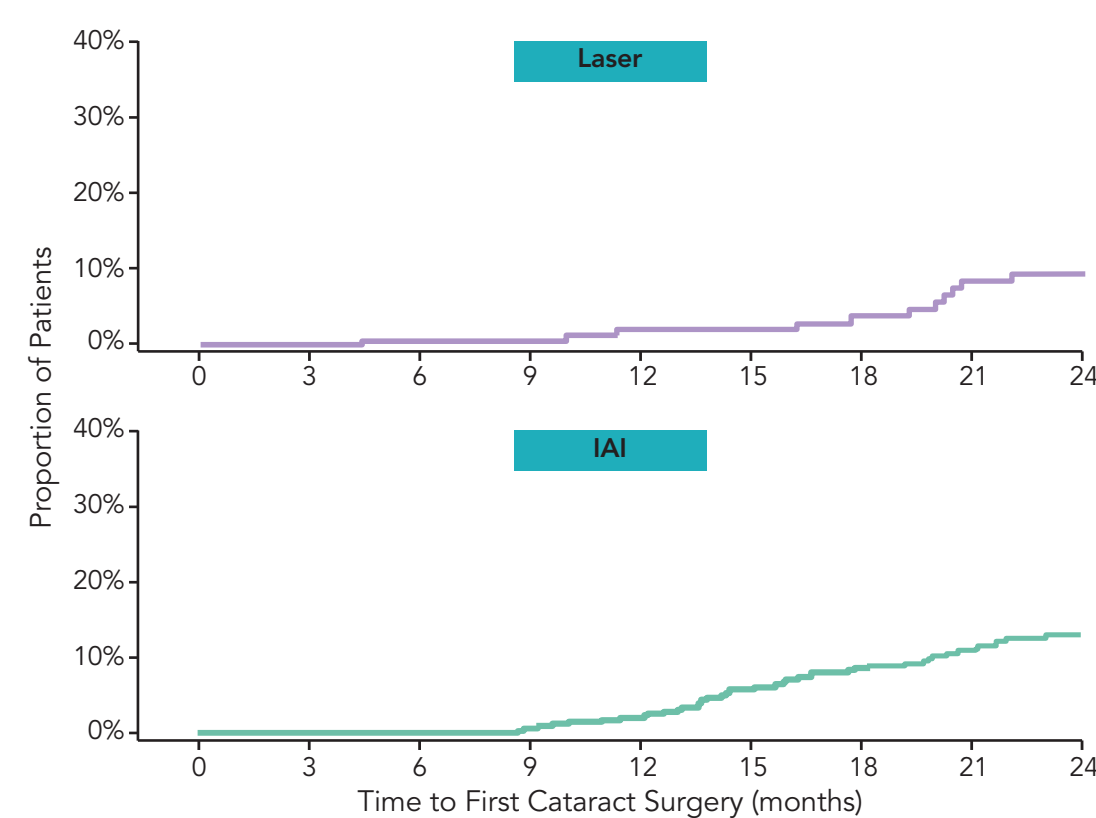


Figure 2. Mean Change in BCVA After Cataract Surgery

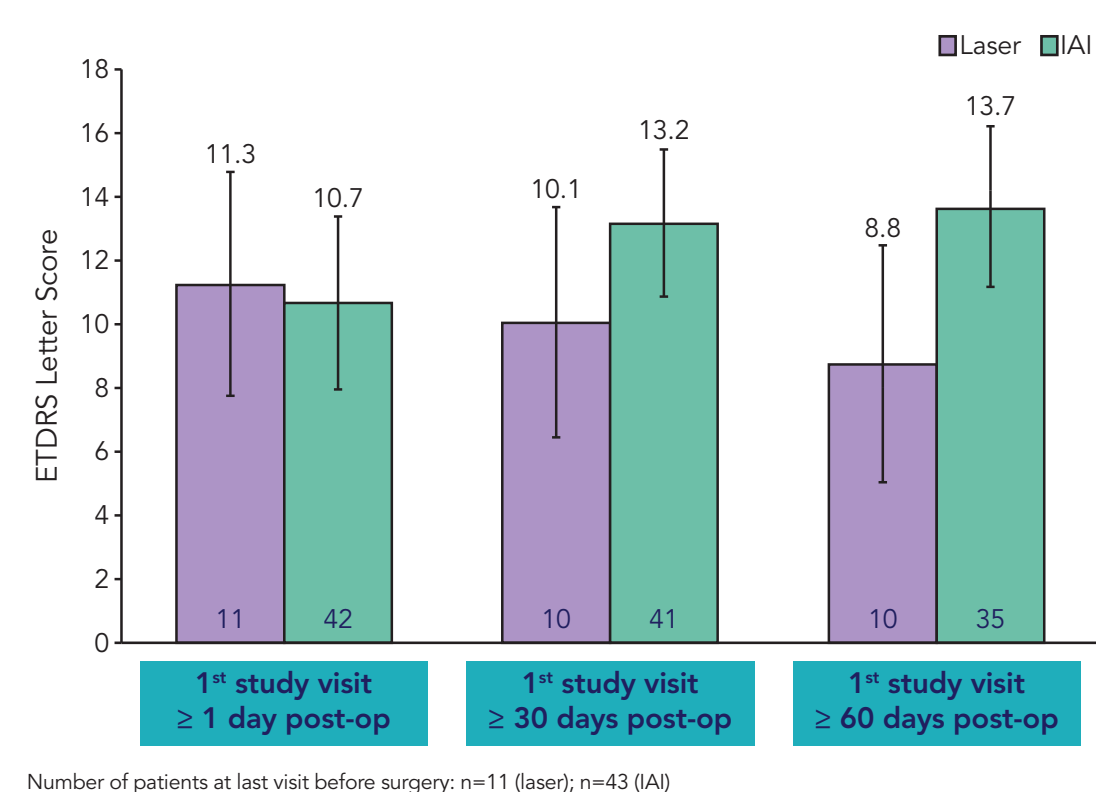


Figure 3. Mean Change in Central Retinal Thickness (CRT) After Cataract Surgery

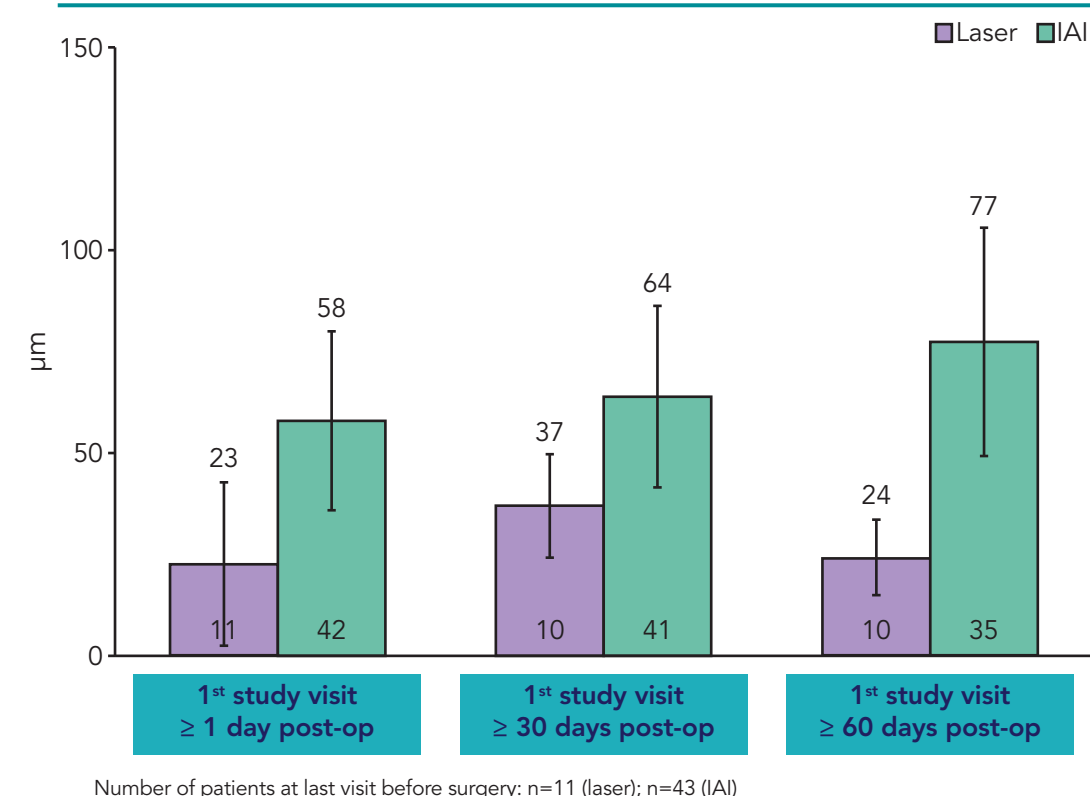


Figure 4. Mean BCVA Over Time

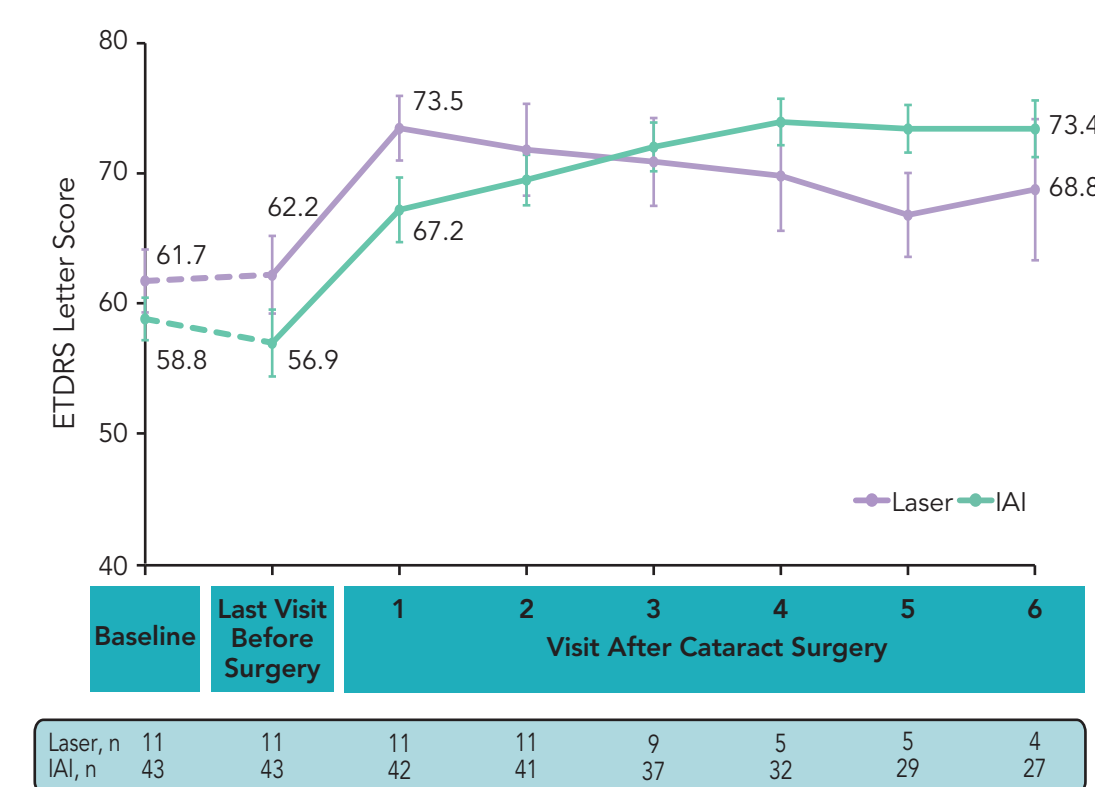


Figure 5. Mean CRT Over Time

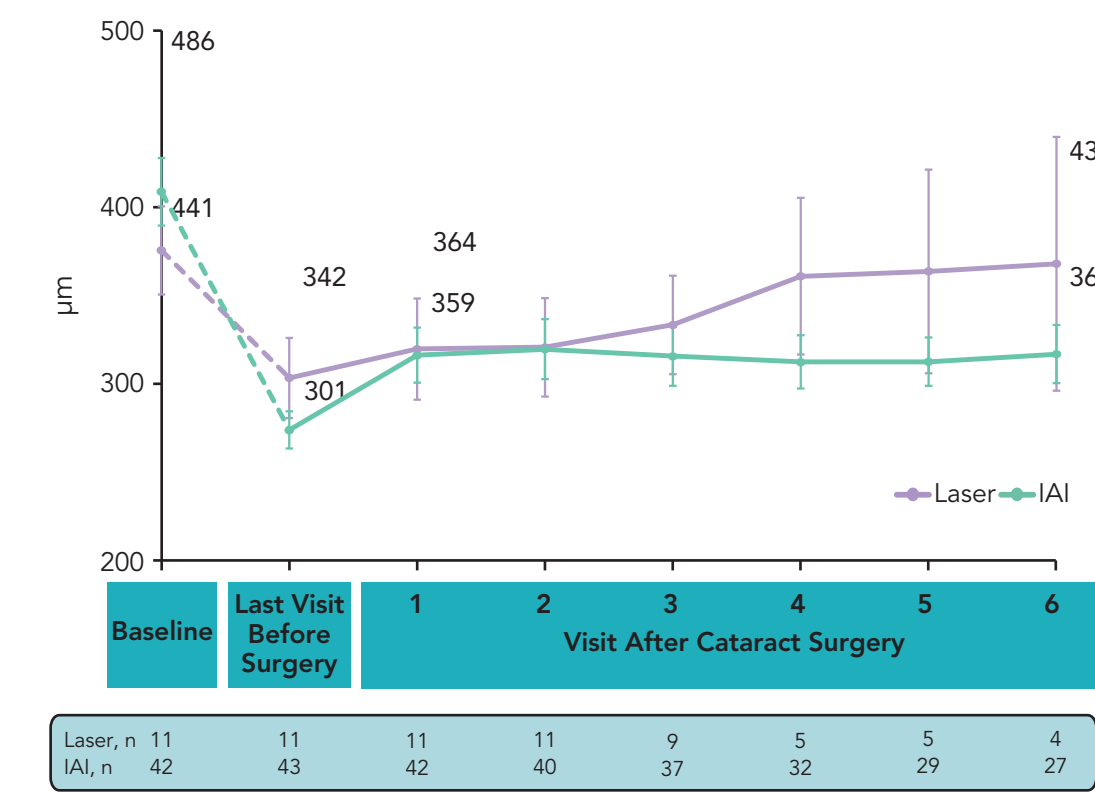


Figure 6. Proportion of Patients Dry on OCT Before and After Cataract Surgery

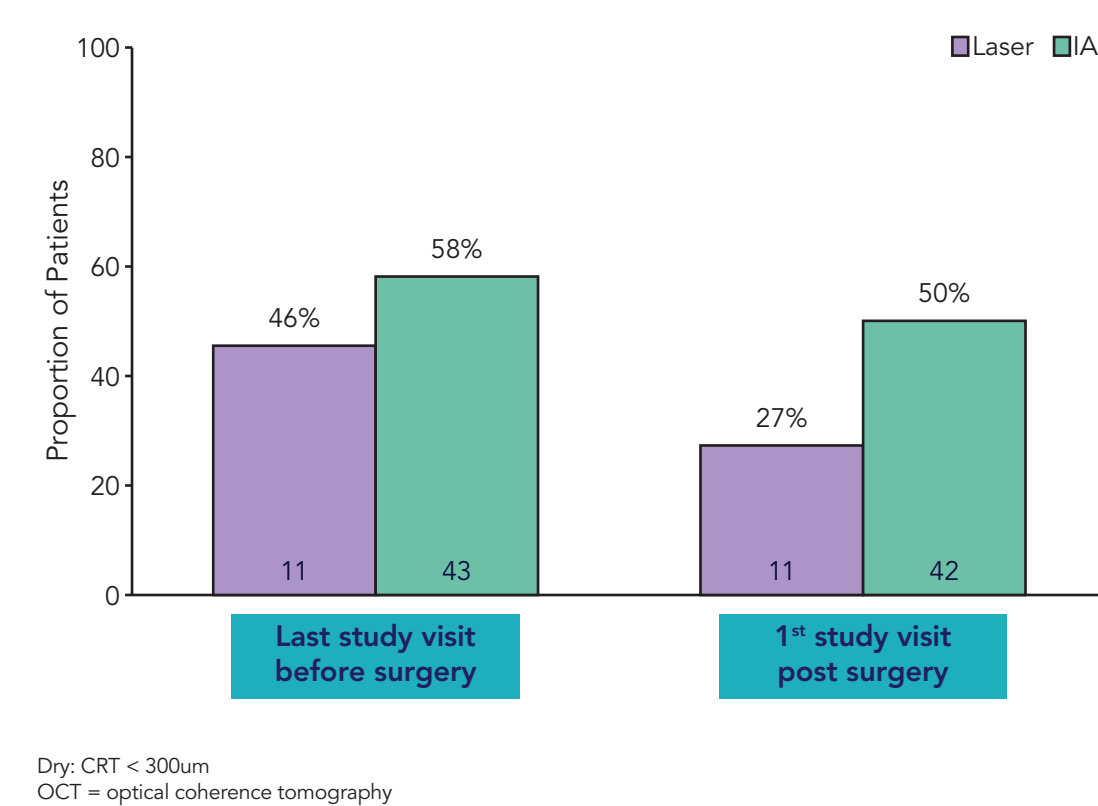


Figure 7. Time to Sustained Incidence of Dryness After Surgery

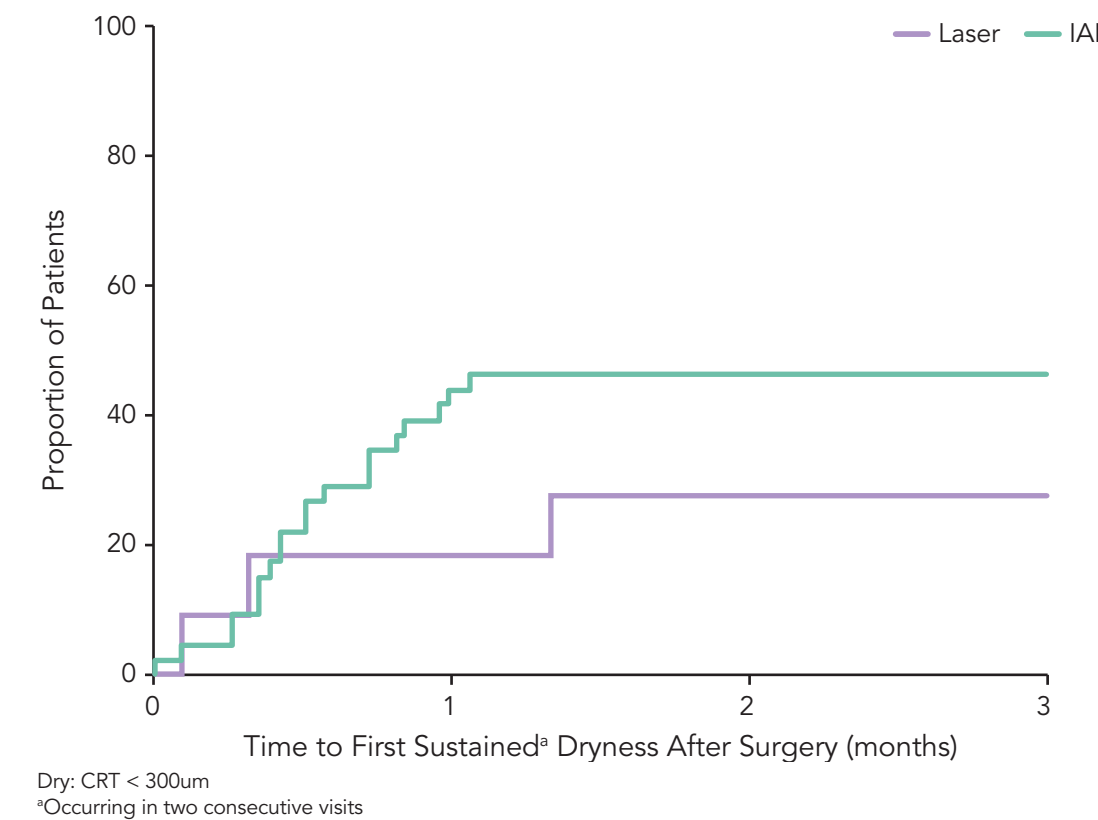


Figure 8. Change in BCVA and Time Between Last Injection and Surgery

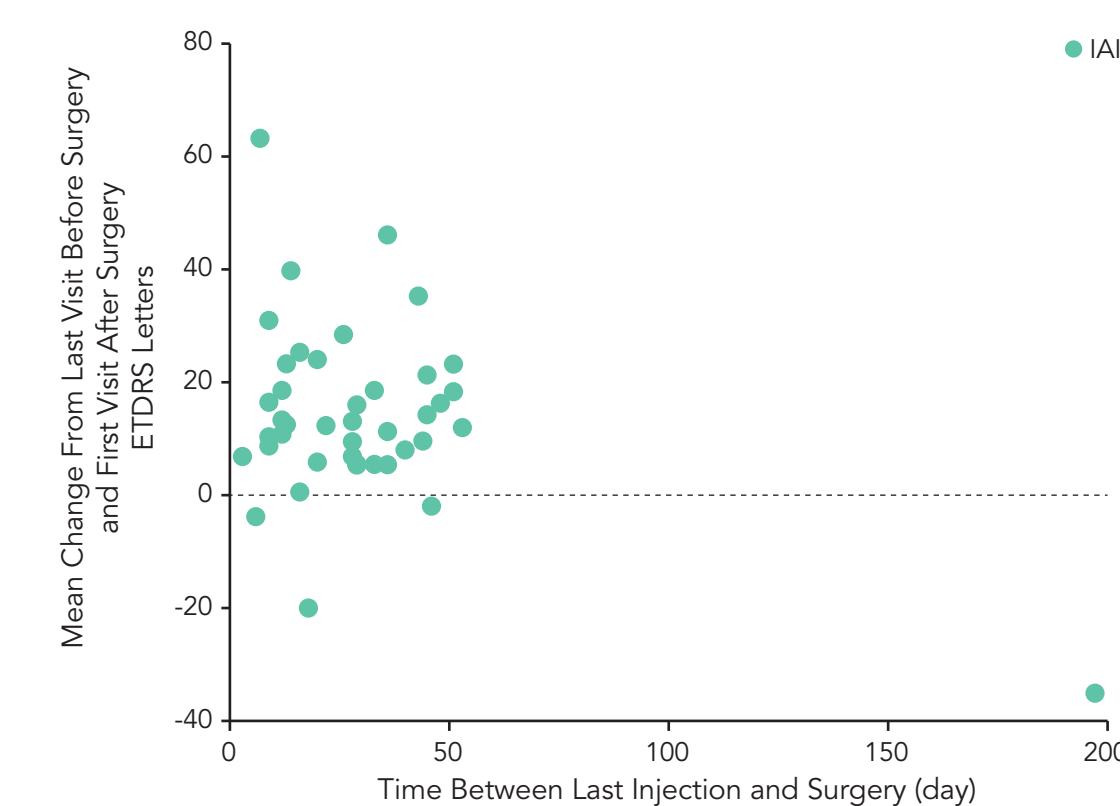
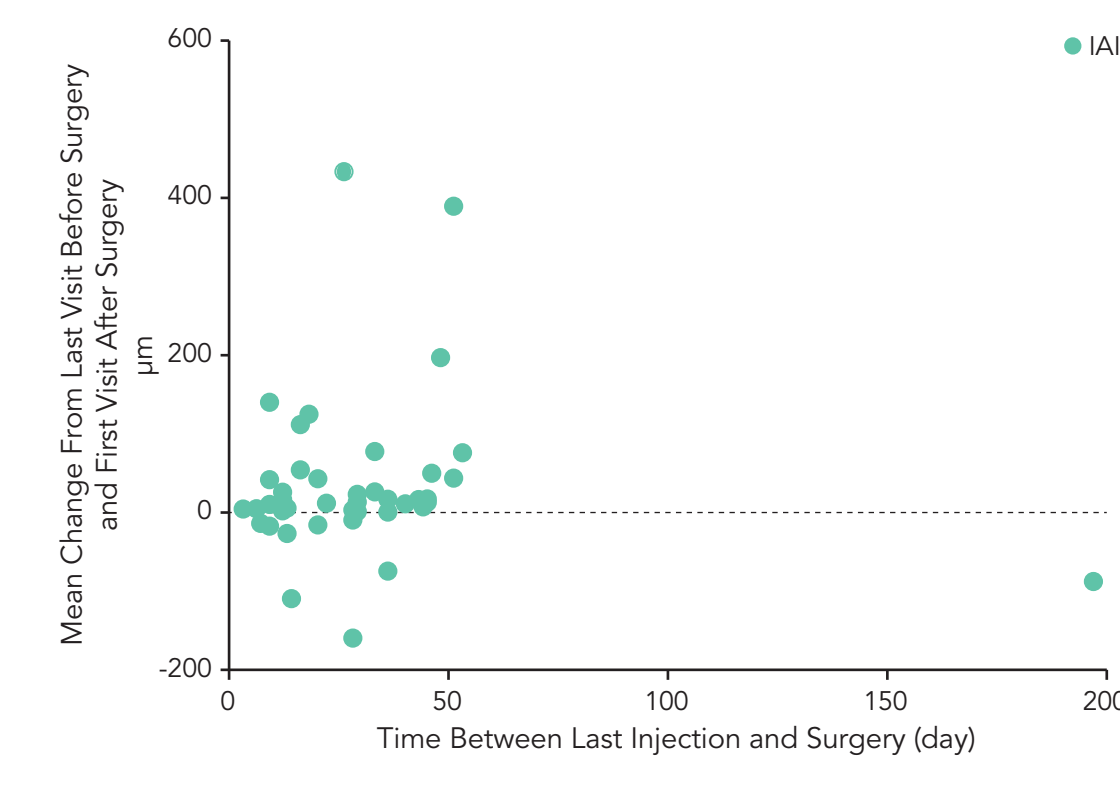


Figure 9. Change in CRT and Time Between Last Injection and Surgery



STRENGTHS AND LIMITATIONS

- Strengths
 - Sub-analysis of large controlled phase 3 studies
 - Fixed dosing in IAI treatment groups
- Limitations
 - Post hoc analysis
 - Small number of patients had cataract surgery during the follow-up

CONCLUSIONS

- Time to cataract surgery was not dependent on treatment group assignment
- No change in BCVA was observed from baseline to last visit before surgery despite decrease in CRT
- As expected, there was no negative impact on visual acuity as a result of cataract surgery.
 - BCVA improved in both treatment groups after surgery
- Despite an increase in CRT after cataract surgery, mean CRT in the IAI group remained lower than in the laser group
 - Visual acuity gains trended higher for patients being treated with IAI as compared to laser in this short-term post hoc analysis