ADVERSE EVENTS OF THE ARGUS II RETINAL PROSTHESIS

Incidence, Causes, and Best Practices for Managing and Preventing Conjunctival Erosion

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Abstract In Brief Author Information Authors Article Metrics Metrics

Purpose: To analyze and provide an overview of the incidence, management, and prevention of conjunctival erosion in Argus II clinical trial subjects and postapproval patients.

Methods: This retrospective analysis followed the results of 274 patients treated with the Argus II Retinal Prosthesis System between June 2007 and November 2017, including 30 subjects from the US and European clinical trials, and 244 patients in the postapproval phase. Results were gathered for incidence of a serious adverse event, incidence of conjunctival erosion, occurrence sites, rates of erosion, and erosion timing.

Results: Overall, 60% of subjects in the clinical trial subjects versus 83% of patients in the postapproval phase did not experience device- or surgery-related serious adverse events. In the postapproval phase, conjunctival erosion had an incidence rate of 6.2% over 5 years and 11 months. In 55% of conjunctival erosion cases, erosion occurred in the inferotemporal quadrant, 25% in the superotemporal quadrant, and 20% in both. Sixty percent of the erosion events occurred in the first 15 months after implantation, and 85% within the first 2.5 years.

Conclusion: Reducing occurrence of conjunctival erosion in patients with the Argus II Retinal Prosthesis requires identification and minimization of risk factors before and during implantation. Implementing inverted sutures at the implant tabs, use of graft material at these locations as well as Mersilene rather than nylon sutures, and accurate Tenon's and conjunctiva closure are recommended for consideration in all patients.

Conjunctival erosion is a serious adverse event associated with the Argus II Retinal Prosthesis. This retrospective study offers recommendations for the prevention and management of this complication, including: placement of inverted sutures at the implant tabs; use of 5-0 Mersilene rather than nylon sutures; graft tissue; and accurate Tenon's and conjunctiva closure.

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