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## Glaucoma PHYSICIAN

ARTICLE

# New Supraciliary Interventions for Glaucoma

Increased attention is being given to this anatomic space for glaucoma procedures.

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Glaucoma is a progressive neuropathy, and lowering intraocular pressure (IOP) is the main modifiable risk factor for stopping its progression.<sup>1,2</sup> Surgery is generally needed when medical therapy and laser do not provide adequate IOP reduction.



The decision on the surgical management of glaucoma is a delicate balance between achieving an adequate IOP reduction and minimizing surgical complications. Traditional glaucoma surgeries, such as trabeculectomy and glaucoma drainage devices, are very efficient in lowering IOP; however, they are still associated with high complication rates.<sup>3</sup> Microinvasive glaucoma surgery (MIGS) has emerged as a group of surgical procedures that lower IOP with a higher safety profile and in a more physiologic manner, causing minimal trauma to surrounding tissues.<sup>4</sup> MIGS can be classified based on their outflow mechanism: Schlemm's canal or suprachoroidal/supraciliary space. Supraciliary MIGS increases aqueous humor drainage by enhancing the uveoscleral outflow pathway. These bleb-free procedures avoid bleb-related complications and cause minimal impact on possible future glaucoma filtering surgeries.

## History of Supraciliary and Suprachoroidal Devices

Although suprachoroidal MIGS devices are still not as widely implemented as Schlemm's canal MIGS, this compelling approach for outflow enhancement is not a new concept, and there are reports of using this approach back in the 1900s.<sup>5,6</sup> A cyclodialysis cleft was created to increase the aqueous humor drainage from the anterior chamber to the suprachoroidal space. However, this used to lead to unpredictable outcomes and variable healing response, with significant IOP reduction following cleft formation, followed by an IOP spike associated with the closure of the cleft. A stented cyclodialysis can help to keep the cyclodialysis cleft open and consequently achieve more durable and predictable IOP outcomes.

The Cypass microstent (Alcon) was the first suprachoroidal MIGS device approved by the FDA and showed promising IOP-lowering results.<sup>7</sup> Due to endothelial safety concerns seen at 5 years of follow-up with suboptimally implanted anteriorized stents, this device was voluntarily withdrawn from the market.<sup>8</sup> The endothelial cell loss (ECL) was associated with device placement, with a greater likelihood of ECL when more retention rings were visible.<sup>8</sup> Eyes with 2 or more retention rings visible on gonioscopic examination were 2.8 times more likely to have greater than 30% ECL at 5 years than eyes in the microstent group with less than 1 visible ring.<sup>8</sup>

## New Interventional Approaches to the Supraciliary Space

Recently, 2 new interventional technologies are emerging: The AlloFlo (Iantrek) and the Miniject (iStar Medical). The first consists of creating a cyclodialysis cleft followed by homologous endoscleral cleft reinforcement and bioscaffolding with a proprietary allograft biotissue. The AlloFlo (Figure 1) is a flexible and conforming 5 mm length allogenic implant made of minimally manipulated scleral allograft from a homologous acellular matrix using high-precision microtrephination.<sup>9</sup> The AlloFlo procedure entails using a novel cyclodialysis interventional system to create a bioscaffolded supraciliary reservoir using durable structural reinforcement without any exogenous hardware, serving as a substrate for aqueous conductivity and outflow.<sup>10</sup> The biotissue is highly biocompatible and minimizes the possible mechanical damage a synthetic device could cause to the eye. A first-in-human study showed a robust IOP reduction of 40% when combined with cataract surgery, and 80% of patients achieved more than 20% IOP reduction. Preliminary results showed a favorable safety profile, with only 11% ECL at 1 year after phaco-combined surgery.<sup>9</sup>

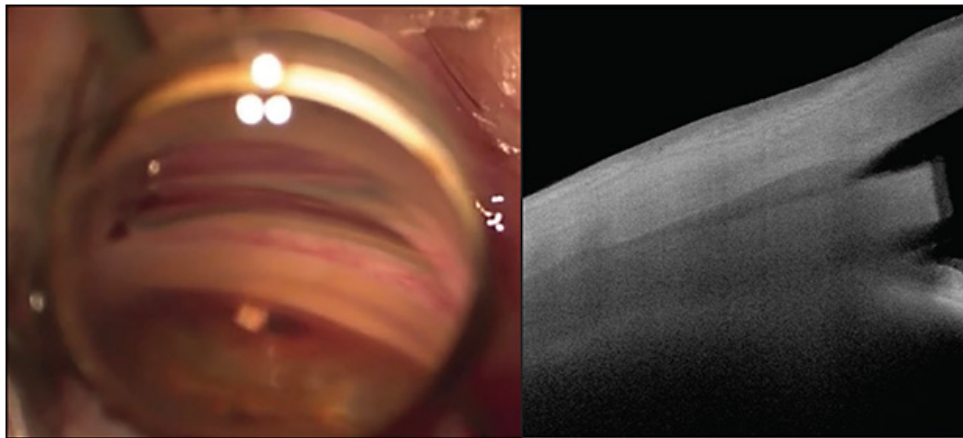


Figure 1. Gonioscopic view showing the AlloFlo implant (Iantrek) in proper position within the cyclodialysis cleft (A). Image courtesy of Iantrek. Optical coherence tomography imaging of the AlloFlo showing the homologous allograft implant and its isoechoic coherence and bioconformity to the native supraciliary tissues (B).

The Miniject (Figure 2) is a 5 mm length device made of the company's Star material, which is a soft, biocompatible, medical-grade silicone that conforms to the eye anatomy.<sup>11</sup> It is designed to significantly reduce IOP by enhancing natural outflow from the anterior chamber to the supraciliary space. The device has had CE mark approval since 2021 and is under FDA investigational study. Previous studies showed encouraging results regarding IOP outcomes, with an IOP reduction of 36% compared to baseline.<sup>12,13</sup> A favorable endothelial safety profile was reported with minimal endothelial cell density loss (4.5% to 7% in 2-3 years) and no patients with more than 30% ECL in standalone procedures.<sup>2,13</sup> It is possible that there is minimal ECL because of the soft, flexible, and conforming nature of the material and because only 0.5 mm of the implant resides in the anterior chamber.<sup>11</sup>



Figure 2. Correct placement of iStar Medical's Miniject biointegrating supraciliary MIGS. Courtesy of Chrys Dimitriou at Colchester Eye Centre, UK.

## Conclusion

With the recent suprachoroidal and supraciliary MIGS implants promising outcomes and favorable safety profiles, this route has regained attention as a target for MIGS approach. This route has a particular advantage over Schlemm's canal MIGS in that there is no hypotensive limitation effect caused by episcleral venous pressure. Therefore, this route could possibly offer a more robust IOP reduction compared to Schlemm's canal MIGS while maintaining the high safety profile of the MIGS procedures.<sup>4</sup> Another possibility is dual-outflow intervention, combining suprachoroidal procedures with Schlemm's canal MIGS as a complementary approach in patients who could benefit from having the 2 natural outflow pathways enhanced. While these results are encouraging, more clinical evidence is still needed to confirm the clinical utility of supraciliary intervention. **GP**



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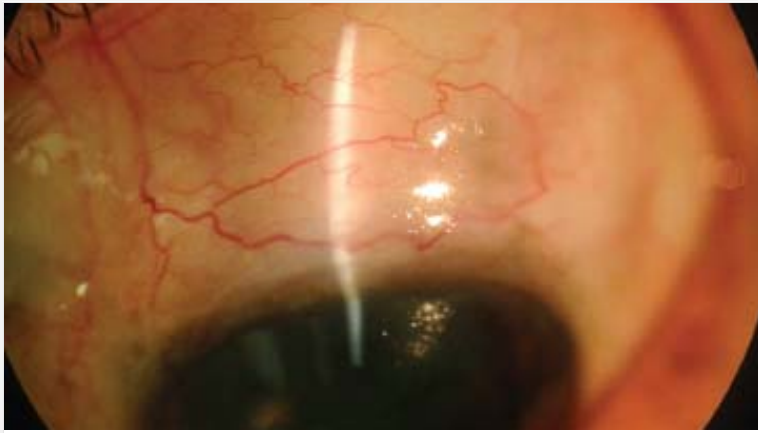


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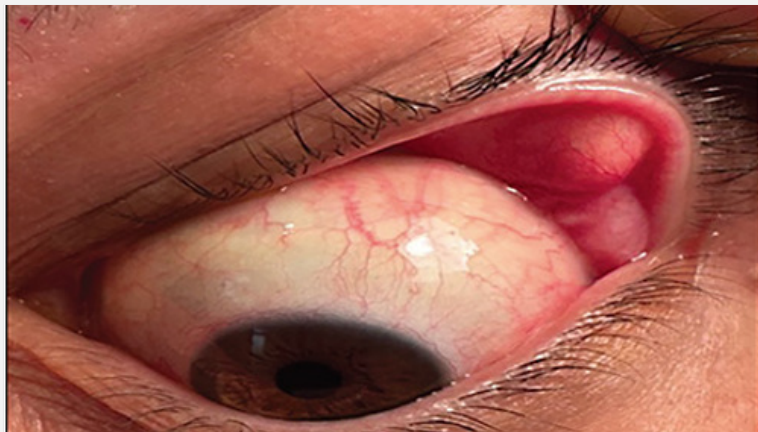
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