Effect of 10.0 Nylon Ripcord on Outflow Facility of the PreserFlo® MicroShunt

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Introduction: The PreserFlo® MicroShunt gained Health Canada approval in 2021 and is currently approved for the treatment of primary open angle glaucoma in patients on maximally tolerated medical therapy. Despite a more desirable safety profile then traditional bleb forming glaucoma intervention, hypotony remains a common complication. Inserting a 10-0 Nylon ripcord suture into the Microshunt has been hypothesised to reduce outflow reduce postoperative hypotony.

Methods: The PreserFlo® MicroShunt was inserted into a 26G cannula and sealed with cyanoacrylate gel glue. The cannula was then attached to iv tubing and attached to a fluid reservoir at fixed perfusion heights equivalent to 10 and 20 mmHg, perfusing ~1000 ul for multiple timed runs. The perfusion time and volume were then measured to determine outflow facility. A 10.0 nylon suture (Ethilon® CS160-6) was then inserted into the MicroShunt spanning the full length of the MicroShunt and at half length. The outflow facility was again measured at 10 mmHg and 20 mmHg.

Results: The outflow facility of the MicroShunt without a ripcord was 0.87 ± 0.03 ul/min/mmHg at 10 mmHg and 0.78 ± 0.12 ul/min/mmHg at 20 mmHg perfusion pressure. With the 10.0 nylon ripcord in place at full length, the outflow facility was significantly reduced to 0.30 ± 0.03 ul/min/mmHg ($p<0.001$) at 10 mmHg and 0.29 ± 0.02 ul/min/mmHg ($p<0.001$) at 20 mmHg perfusion pressure. With the ripcord at half length the outflow facility was measured at 0.43 ul/min/mmHg($p<0.001$) at 10mmhg and 0.41 ul/min/mmHg($p<0.001$) at 20mmhg. There was no significant difference in outflow facility between 10 and 20 mmHg perfusion pressure ($p=0.51$). Clinically observed IOP and early hypotony rates of the MicroShunt with ripcord placement will be presented.

Conclusion(s): The PreserFlo® Microshunt is an incisional glaucoma procedure developed with the intent of providing substantial IOP-lowering efficacy while reducing many of the adverse events and postoperative management requirements associated with trabeculectomy and tube shunt implantation. The introduction of a 10.0 nylon riprcord can reduce the ouflow facility by a factor of ~3.0. As the designed outflow facility of the MicroShunt will produce ~1.5-2.0 mmHg of pressure drop along the device at human physiologic aqueous flowrates of ~2.4 ul/min, the placement of a removable 10.0 nylon ripcord during surgery could raise the pressure drop along the device to ~4.5-6.0 mmHg. This procedural modification could mitigate the risk of early hypotony, the most commonly observed adverse event associated with the MicroShunt.