CHAPTER 6

GENERAL CONCLUSION

In this thesis, a dual-valved GDD to fulfill the "band-pass" flow regulation has been developed and *in vitro/ex vivo* tested. Our GDD has been verified capable of draining out eye fluid when IOP is higher than 20 mmHg, and stopping the drainage when IOP is lower than 20 mmHg to prevent hypotony. A new IOP sensor is proposed with a new implantation location so that the quality factor can be retained and also the concern of water filling the capacitor chamber is solved. To accurately design the desired cracking pressure and also predict the life-time of a NC check-valve, parylene-C's mechanical, thermal and polymer properties are investigated. The results show that paryelne-C is a highly temperature-sensitive material, and therefore it can be tailored by thermal annealing to obtain the desired properties.

In chapter 2, a paradigm of NC check-valve is proposed with several slanted tethers to transmit the necessary downward force and therefore the NC check-valve is capable of supplying the desired cracking pressure. The desired residual tensile stress can be achieved by stretching the tethers based on several mechanisms such as: pop-up/self-stiction mechanisms; or by thermal annealing the tethers at the elevated temperature, and then quenching them down to room temperature to introduce the high thermal tensile stress. Therefore, three different approaches are developed to create the slanted tethers: generating and adopting sloped sacrificial photoresist, using pop-up mechanism, and using the self-stiction bonding which inevitably happens after the drying process. The cracking pressure of the NC check-valve can be controlled by several parameters such as the number of the slanted tethers, the sloping angle of the slanted tethers, the geometry of the slanted tethers (the width and the thickness), and also the residual stress of the slated tethers which can be manipulated by the annealing temperatures. The testing results show that the residual thermal tensile stress is the most controllable method among all, and can introduce the highest cracking pressure.

In chapter 3, a new dual-valved glaucoma drainage device with "band-pass" flow profile regulation capability is proposed by integrating four crucial components: one self-stiction bonding NC check-valve developed in chapter 2, one NO valve, one parylene-C fixation anchor, and one all parylene-C protective hollow tube. Our GDD is designed with the form factor that can be put in a #19-gauge needle to fulfill the minimally invasive implantation surgical procedure and the implantation can be done in a 15 minute surgery. The #19-gauge needle creates a wound less than 2 mm in diameter, and therefore it will seal by itself after the surgery and the suture is never needed. Two types of GDD integration approaches are proposed to facilitate the capability of optimizing the check-valves' position. The GDD is placed in the translimbal area with one end staying in the anterior chamber and the other end staying subconjunctivally. The cracking pressure of the NC check-valve of the GDD is designed as 10–20 mmHg. Therefore, the dual-valved GDD is capable of draining away the excessive aqueous when the IOP is in the range of 20–50 mmHg. The NC check-valve also protects the eye from postoperative hypotony as it closes when IOP is lower than 10 mmHg. In addition, the GDD also has a benefit of closing at the sudden unexpected high IOP to prevent hypotony.

In chapter 4, two methods are proposed to improve the performance of the IOP sensor, whose quality factor was reported to degrade during the *ex/in vivo* implantation due to the high loss tangent of the aqueous humor. The first approach is to mount an implantation tube on the accessing hole on the back side of the sensing part. The new IOP sensor is implanted at the pars plana with the implantation tube penetrating through the choroid, while the sensing part is still left outside the eyeball but covered under the conjunctiva. The sensing coil, therefore, can skip the influence of the aqueous humor by this new approach which is also used by Ahmed Glaucoma valve [70]. The *in vitro* characterization experiment demonstrates its feasibility and the capability of preventing the sensing coil from immerging in the aqueous humor. The other approach is to cover the sensing part with thicker low loss tangent materials such as parylene-C to isolate the sensing coil and the surrounding lossy solution. The benchtop tests prove the concept of using low loss tangent materials to preserve the quality factor of the IOP sensor while submerging in the saline solution. Among all the tested low loss materials, the experiments using parylene-C film as the passivation layer shows that the quality factor can be recovered by covering the sensing coil with extra 20 μm parylene-C film, which results in an IOP sensor with 27-μm-thick parylene-C film above the coil metal. The 27-μm-thick parylene-C film can be easily deposited and patterned with the regular surface micromachining techniques. Therefore thickening the IOP sensing coil by depositing thicker parylene-C film during the clean room fabrication is a practical and feasible concept to enhance the electromagnetic coupling between the sensing coil and the external reader to enable the telemetric IOP sensing.

Several important parylene-C properties related to the development of GDD and IOP sensor are measured and demonstrated in chapter 5. Those properties include: polymer properties such as densification, glass transition temperature measurement, and crystallization; thermal properties such as oxidation; and mechanical properties such as Young's modulus, tensile strength, yield point, percentage of elongation, creep, stress relaxation, and viscoplasticity properties, etc. As parylene-C has been widely used in bioMEMS development, those properties mentioned above become very important in developing the bioMEMS devices, especially the implantable ones. Wrongful using of the parylene-C can lead to cracking of the device, short lifetime, or even unpredictable malfunctions.

As for densification, parylene-C starts to shrink when the surrounding temperature gets higher than ~ 50°C, implying the occurrence of the crystallization and also the T_g of ~ 50°C.

When annealed at 100°C, oxidation of parylene-C is not observable by FTIR, implying that very little oxidation happens during the annealing at 100°C. Therefore, soft baking of parylene-C film in the convection oven during the lithography process should not seriously deteriorate the parylene-C within couple of hours. For high temperature annealing, vacuum system is suggested to preserve the parylene-C properties.

The XRD scanning results show that the parylene-C crystallizes rapidly once the temperature goes beyond T_g. The crystallinity and the crystallite size increase as the annealing temperature increase and the annealing time gets longer. The time constant of parylene-C crystallization at 100°C is found as 0.845 min.

The glass transition temperature highly depends on the pre-annealing temperature of the tested parylene-C samples. T_g of as-deposited parylene-C is found in between 50.2-57°C, while T_g of pre-annealed parylene-C samples changes depending on the pre-annealing temperatures. It is assumed that the crystallization during the parylene-C annealing could be the major effect causing the T_g shifting.

As different annealing condition corresponds to different crystallinity of parylene-C films, uniaxial tensile test are performed onto differently pre-annealed parylene-C samples to study the relationship between the crystallinity and its mechanical properties change. It shows that parylene-C with higher crystallinity behaves stiffer, stronger and more brittle than as-deposited parylene-C film.

The creep and stress relaxation behavior are significantly influenced by the glass transition temperature. For the creep and stress relaxation tested at the temperature lower than T_g, the parylene-C behaves similar to elastic material. On the other hand, parylene-C behaves like viscoelastic material when tested at a temperature higher than T_g. Therefore, in order to have more stable mechanical properties at its operating temperature, the parylene-C properties can (and have to) be tailored to a proper T_g by pre-annealing the praylene-C at the appropriate temperature. In addition, the stress relaxation results of parylene-C provide very important information for people to predict the lifetime of the slanted tether parylene-C NC check-valves.

The preliminary viscoplastic results of parylene-C tested at 37°C concludes that parylene-C is a viscoplastic material when operated in human body temperature. That is, the parylene-C's mechanical properties might not be the same as the as-deposited parylene-C that people have studied and reported in the past. Therefore, more detail researches need to be done to understand parylene-C’s properties at 37°C so that a more reliable and safer parylene-C-based implant can be developed and implanted in the human bodies.

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