HumeurVitrée : Revolutionizing Retinal Detachment Surgery

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Technology: We have developed a novel, patented gel whose use as a vitreous substitute has the ability to transform the retinal detachment space. The polymer is a combination of hydrophobic N-isopropyl acrylamide (NIPAM), hydrophilic polyethylene glycol (PEG) and acrylic acid (AA), and a monomer containing a hydrolysable lactone ring. Poly(NIPAM) has unique thermal properties, giving our polymer combination a lower critical solution temperature near the body's temperature of 37°C. Practically, this means our polymer is a liquid at room temperature, allowing for easy injection into the eye, and will self-assemble into a gel at body temperature in an aqueous environment, such as the vitreous space. While poly(NIPAM) is typically opaque upon gelation, our formulation including hydrophilic PEG allows the material to maintain transparency. This would allow patients to see through the material, a feature not currently available with existing vitreous tamponades. allowing them to resume normal activities shortly after surgery instead of potentially weeks of downtime. Additionally, the lactone ring incorporated into the polymer backbone aids in polymer degradation over time, allowing the gel to be naturally cleared by the eye over many months. Patients could then be treated with a single surgery, instead of the multiple surgeries currently required to place then subsequently remove the tamponade material. Furthermore, as our material has a tailorable density, the gel formulation would not require patients to be "positioned" to increase the likelihood of a successful procedure. While this is a helpful for all patients, it is especially advantageous to those with inferior retinal tears or pediatric patients. Since this material is a gel, there would also be no limitations to air travel, which again would minimize the disruption to the patient and reduce the economic costs associated with these conditions. To date, we have tested this material in animals and it shows no toxicity to the ocular tissues, allowing it to remain in the eye for many months; some current products must be removed after a few weeks due to toxicity issues.

Market: Retinal detachment, which can cause vision loss, affects approximately 12 per 100,000 individuals in the United States alone. However, it is far more common following cataract surgery, when the rate jumps to 1 in 100 patients. The retinal detachment market is expected to reach nearly $2.7B by 2023 and has a CAGR of ~5.9%. Of that, the vitreous tamponades market specifically is expected to reach almost $90M by 2025 at a CAGR of 3.0%. The steady growth of this market is in part due to the increasing incidence of diabetic retinopathy, which exclusively requires vitrectomy and thus vitreous tamponades. Specifically, liquid tamponades, with which we will most directly compete, have emerged as the lucrative segment of the market, holding 53.9% of the market in 2016, as their use has become widespread over gaseous tamponades. This market is highly fragmented with the presence of small and medium sized players, with different regions dominated by a select number of players.

Commercialization Strategy: Our regulatory approach begins with completing animal trials with our materials. We are initially using rabbits for the testing, and as necessary, will move to larger animals if required. We have equipment that is uniquely able to track the post-surgical rabbits and determine in real time any changes to the retinal tissues without sacrificing them. Once these animal trials are complete, we will determine the best approach for human trials with the regulatory bodies. While we are able to manufacture this material and sterilize it in the lab for the preliminary animal studies, we are seeking a contract manufacturer for GMP-grade materials for clinical use. Given that the market is segmented but has key leaders in geographical regions, we are looking to partner with some of these local leaders to develop a partnership that would allow us to use their marketing and distribution channels. In tandem with the regulatory studies, we will begin discussions around reimbursement, looking to be covered in a manner similar to existing tamponades on the market. Ultimately we hope to license this product to a series of leaders who can distribute it in their various jurisdictions, leveraging their existing relationships with physicians and key opinion leaders.

Figures:

Figure 1. Example of the gel forming in warm water, showing its excellent transparency.