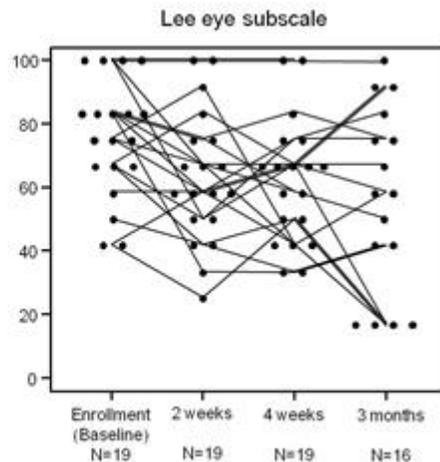


BSCL therapy for ocular GVHD - a sight for sore eyes

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Lee eye subscale score over time. P-values were 0.01, 0.005, and 0.02 after 2 weeks, 4 weeks, and 3 months, respectively, as determined by paired t-tests compared with baseline.

Image provided by Dr. Yoshihiro Inamoto

Graft-versus-host disease (GVHD) is a condition that may affect recipients of allogeneic hematopoietic stem cell transplants, with effects that range from manageable to life-threatening. Among patients with chronic GVHD, 40% to 60% develop symptoms in the eyes, referred to as ocular GVHD. All layers of the eye are at risk, and manifestations include milder "pink eye" (conjunctivitis) and dry eye syndrome, as well as more severe scarring or penetration of the conjunctiva and cornea. Keratitis - inflammation of the cornea - is the most common cause of eye pain, light sensitivity, and vision loss in affected patients. Although symptoms may be partly alleviated through suppression of the immune system, additional care is often required in the form of eye lubricants, immunosuppressive eye drops, and moisture-preservative eyewear. However, the efficacy may be limited depending on the clinical manifestation.

An alternative treatment of severe ocular GVHD is fluid-ventilated gas-permeable (PROSE) lenses that cover the white of the eye (sclera), thereby providing a liquid "bandage" that protects the cornea. For reasons of accessibility and expense, PROSE lenses are unfortunately not available to many patients, but there are other options; bandage soft contact lenses (BSCLs) can be easily fitted and dispensed at a much lower cost, possibly providing relief of ocular GVHD symptoms. This hypothesis was tested by Drs. Yoshihiro Inamoto and Stephanie Lee from the Clinical Research Division in collaboration with a University of Washington ophthalmologist, Dr. Tueng Shen. The

results of this small clinical trial were recently published in *Biology of Blood and Marrow Transplantation*.

A total of 19 patients were included in the analysis, all of whom had already tried most other conventional options, e.g. artificial tears, viscous ointment, cyclosporine eye drops, punctal plugs, steroid eye drops, and systemic immunosuppressants. None had used scleral lenses. At the time of enrollment, 14 of the 19 subjects had moderate ocular GVHD; 5 had severe ocular GVHD. The lenses were used continuously - even during nighttime - with exchange every two to four weeks. Treatment results were evaluated in terms of three scores: Lee eye subscale score, which is a validated symptom scale for chronic GVHD including 3 items (range 0 to 100); ocular surface disease index, which measures dry eye symptoms (range 0 to 100) using a validated survey consisting of 12 items; and a 11-point rating of eye symptoms recommended by the National Institutes of Health consensus (range 0 to 10). These standard questionnaires were completed by patients at enrollment and then after 2 weeks, 4 weeks, and 3 months; in all cases higher scores indicated worse symptoms. In addition, ophthalmological assessments were made at enrollment and at 2 weeks, and beyond that as medically indicated.

The investigators reported statistically significant, clinically meaningful improvements in all measures. At enrollment, the mean Lee subscale score was 75.4, which was lowered to 63.2 after 2 weeks of BSCL therapy, 61.8 at 4 weeks, and 56.3 at 3 months. For ocular surface disease index the corresponding mean scores were 54.5, 36.8, 32.9, and 35.6; the mean 11-point eye symptom rating decreased accordingly, from 7.11 at enrollment to 5.00, 4.37, and 3.94 at 2 weeks, 4 weeks, and 3 months, respectively. During the 3 months of study, relief of symptoms was experienced in 47% to 68% of the participants; clarity of vision and corneal effects were also significantly improved, already after 2 weeks. Adverse events from BSCLs were mild, and did not cause patients to quit using the lenses to any great extent.

The mechanism behind these dramatic effects is quite simple: by protecting the surface of the GVHD-injured cornea wounds are stabilized, facilitating the epithelial healing. Dr. Lee explained that an injured cornea is very bothersome, just like a scratch on the eye: "The bandage lens covers the area and protects it - like a band aid for the eye." Drs. Lee and Inamoto agree that the promising results need to be validated in a larger multicenter trial. "This was a very small study of 20 people who already had pretty severe eye GVHD," Dr. Lee said, who now wants to explore earlier intervention with BSCLs to see if it can help prevent permanent damage. In addition, Dr. Inamoto underlined that long-term safety and efficacy remain to be determined. Keep an eye out for these studies in the future.

[Inamoto Y, Sun Y-C, Flowers MED, Carpenter PA, Martin PJ, Li P, Wang R, Chai X, Storer BE, Shen TT, Lee SJ](#). 2015. Bandage soft contact lenses for ocular graft-versus-host disease. *Biol Blood Marrow Transplant*. [Epub ahead of print]

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