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Archives

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## iStent approved in Japan

The Japanese Ministry of Health, Labor and Welfare has approved the iStent Trabecular Micro-Bypass Stent for use in conjunction with cataract surgery for the reduction of IOP in adult patients diagnosed with mild to moderate open-angle glaucoma who are currently treated with ocular hypotensive medication, developer and marketer Glaukos (Laguna Hills, California) said in a press release. The iStent is now approved for use in 27 countries, Glaukos added.

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## Second phase 3 registration trial on Roclatan starts

Mercury 2, a second phase 3 registration trial of Roclatan (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, a novel once-daily eye drop being tested for its ability to lower IOP in patients with glaucoma or ocular hypertension, has dosed its first patients, developer Aerie Pharmaceuticals (Irvine, California) said in a news release. Roclatan is a fixed-dose combination of Rhopressa (netarsudil ophthalmic solution) 0.02% and latanoprost. Aerie estimates total enrollment of approximately 690 patients in this 3-arm, 90-day efficacy study, comparing once-daily Roclatan for superiority to each of its 2 components, all dosed once daily in the evening. Patients will be evaluated with maximum baseline IOPs ranging from above 20 to below 36 mmHg. The first registration trial, Mercury 1, began in September 2015, and Mercury 3 is scheduled to start in the first half of 2017, Aerie noted.

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## Squalamine/ranibizumab combo phase 3 study on wet AMD initiated



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The first of 2 planned phase 3 global clinical studies evaluating the efficacy and safety of squalamine lactate ophthalmic solution 0.2%, given in combination with ranibizumab, for the treatment of neovascular age-related macular degeneration (wet AMD) has begun, developer Ohr Pharmaceuticals (New York) said. The phase 3 studies will comprise double-masked, placebo-controlled, multicenter, international studies of squalamine lactate ophthalmic solution 0.2%, also known as OHR-102, administered twice a day in subjects with newly diagnosed wet AMD, in combination with ranibizumab injections. The primary endpoint will be a measurement of visual acuity gains at 9 months, with subjects followed to 2 years for safety. The eligibility criteria will include subjects with classic and/or occult choroidal neovascularization (CNV) secondary to AMD.


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## **Moorfields researchers develop eye test to detect early AMD signs**

Researchers at Moorfields Eye Hospital (London) have designed a new test that can spot the early stages of sight loss in age-related macular degeneration (AMD). The Moorfields Acuity Chart (MAC) test features high-pass filtered letters created from fine black and white strips. However, unlike the standard chart, these 2-colored, high-spatial frequency letters appear to vanish when they are too small to be recognized. According to the researchers, VA measurements with the MAC chart appear to be more sensitive to functional loss in AMD compared with conventional letter charts, with similar test-retest variability. Simulations indicate this may be because the high-pass filtered letters are more vulnerable to under sampling as a result of retinal cell loss in the disease process.


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## **CLs can alter ocular bacteria**



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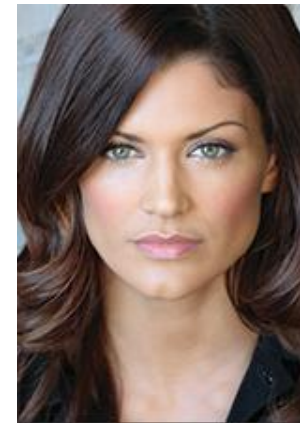
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Contact lenses (CLs) may alter the natural microbial community of the eyes, according to a study published in *mBio*, an online open-access journal of the American Society for Microbiology. In a study of 58 adults seeking outpatient eyecare, researchers at New York University School of Medicine found that CLs make the eye microbiome more skin-like, with higher proportions of the skin bacteria *Pseudomonas*, *Acinetobacter*, *Methylobacterium*, and *Lactobacillus* and lower proportions of *Haemophilus*, *Streptococcus*, *Staphylococcus*, and *Corynebacterium*. Researchers used 16S rRNA sequencing to compare the bacterial communities of the conjunctiva (the eye surface) and the skin under the eye from 58 adults. They also analyzed samples from 20 of the study participants (9 lens wearers and 11 non-lens wearers) at 3 time points over the course of 6 weeks. Looking at 250 samples in the lab (116 from cotton swabs of the conjunctiva, 114 from cotton swabs of skin under the eye, and 20 contact lenses), researchers found a higher diversity of bacteria on the ocular surface than on the skin under the eye or on the CLs. The ocular surface microbiota of those who wore CLs was more skin-like compared to those who did not wear lenses. The study was supported by the Research to Prevent Blindness Foundation.

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## RESEARCH BRIEFS

- Axial length measurements with the new swept-source optical coherence tomography (SS-OCT) biometer were comparable to the partial-coherence interferometry (PCI) and optical low-coherence reflectometry (OLCR) measurements with a higher axial length (AL) acquisition rate, according to a study published in the *Journal of Cataract & Refractive Surgery*. **H.J. Shamm** and colleagues prospectively evaluated the repeatability and reproducibility of the measurements obtained with the Argos, a new biometer, and compared it to PCI and OLCR in 107 eyes. In this observational study, repeatability and reproducibility of the SS-OCT measurements showed comparable values and a low variation rate, with an interest mean difference of 0.01 mm for AL, 0.01 mm for central corneal thickness (CCT), 0.01 mm for aqueous depth and



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anterior chamber depth (ACD), 0.03 mm for lens thickness, 0.10 mm for pupil size, 0.14 mm for corneal diameter, and 0.02 mm for anterior corneal radius of curvature (RAV). The SS-OCT device correctly measured the AL in 96% of the cases compared with 79% for the OLCR device and 77% for the PCI device.

Comparisons between the PCI device and SS-OCT device were  $-0.01 \pm 0.05$  mm for AL,  $-0.17 \pm 0.20$  mm for ACD, and  $-0.01 \pm 0.05$  mm for RAV. Comparison between the OLCR device and the SS-OCT device was  $0.01 \pm 0.06$  mm for AL,  $0.08 \pm 0.15$  mm for ACD,  $0.00 \pm 0.05$  mm for RAV,  $0.00 \pm 0.01$  mm for CCT,  $0.07 \pm 0.14$  mm for aqueous depth,  $-0.23 \pm 0.22$  mm for lens thickness,  $-0.29 \pm 0.53$  mm for pupil size, and  $-0.34 \pm 0.76$  mm for corneal diameter.

- The mean IOP was lowered by at least 61% after endoscopic cyclophotocoagulation of the ciliary processes and pars plana (ECP-plus), and IOP lowering was sustained over the follow-up period, according to **J.C. Tan** and colleagues. Their retrospective, non-comparative interventional case series at a multicenter tertiary referral academic and clinical practice evaluated 53 eyes (53 patients) scheduled to undergo ECP-plus and who had uncontrolled IOP despite prior glaucoma surgeries and maximally tolerated medical therapy. Diagnoses were primary open-angle glaucoma (32%), chronic angle-closure glaucoma (26%), and secondary open-angle glaucoma (OAG, 42%); 50/53 of subjects had 6 months of follow-up data and 28/53 had 12 months of follow-up data. Preoperative IOP was  $27.9 \pm 7.5$  mm Hg. Postoperative IOP at 6 mo was  $10.2 \pm 5.6$  and at 12 mo was  $10.7 \pm 5.2$  lower than preoperative levels (all  $P < 0.0001$ ). Cumulative treatment success was 81% at 6 mo and 78% at 12 mo. The number of medications fell from  $3.4 \pm 1.2$  pretreatment to  $0.8 \pm 1.0$  at 1 to 6 mo and  $0.7 \pm 1.2$  at 12 mo postoperatively (all  $P < 0.0001$ ). Complications in the initial postoperative period (<3 mo) were hypotony (3/53, 6%), fibrinous uveitis (2/53, 4%), and cystoid macular edema without hypotony (CME; 4/53, 6%). Complications beyond 6 mo occurred in 8/50 (16%) subjects as hypotony (4/50, 8%), choroidal detachment (4/50, 3 with IOP <5 and 1 with IOP  $\geq 5$ ; 8%), CME without hypotony (3/50, 6%), and failed corneal graft (1/50, 2%). The study is published in the *Journal of Glaucoma*.



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- High variation was observed in intravitreal injection rates and in Medicare drug payments per anti-vascular endothelial growth factor (VEGF) injection across the United States in 2013, according to **J.C. Erie** and colleagues. Their observational cohort study using 2013 Medicare claims database evaluated United States fee-for-service (FFS) Part B Medicare beneficiaries and their providers in all 50 states and the District of Columbia. The rate of FFS Medicare beneficiaries receiving intravitreal injections and the mean Medicare-allowed drug payment per anti-VEGF injection was calculated nationally and for each state, using CPT code 67028, and treatment-specific J-codes, J0178, J2778, J9035, J3490, and J3590. In 2013, the rate of FFS Medicare beneficiaries receiving intravitreal injections varied widely by 7-fold across states (range by state, 4 per 1,000 [Wyoming] to 28 per 1,000 [Utah]), averaging 19 per 1,000 beneficiaries. The mean systematic component of variance was 8.5, confirming high nonrandom geographic variation. There were more than 2.1 million anti-VEGF drug claims, totaling more than \$2.3 billion in Medicare payments for anti-VEGF agents in 2013. The mean national Medicare drug payment per anti-VEGF injection varied widely by 6.2-fold across states (range by state, \$242 [South Carolina] to \$1,509 [Maine]), averaging \$1,078 per injection. Nationally, 94% of injections were office based and 6% were facility based. The study is published online ahead of print in *Ophthalmology*.



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**Medical Editors:** Eric D. Donnenfeld, MD, chief medical editor; Rosa Braga-Mele, MD, cataract editor; Clara C. Chan, MD, cornea editor; Reay H. Brown, MD, glaucoma editor; and Steven C.

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For sponsorship opportunities or membership information, contact:

ASCRS\*ASOA \* 4000 Legato Rd. \* Suite 700 \* Fairfax, VA 22033 \* Phone: 703-591-2220 \* Fax:  
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