We are excited to introduce to you the Retina World Congress (RWC) column. Each column will:

- Highlight one of RWC's global activities;
- Introduce a global society partner;
- Discuss a hot topic in the world of retina; and
- Present the RWC Retina Rocks Image Gallery case of the month.

Kourous Rezaei, MD, President
Ashish Sharma, MD, Committee Co-Chair
Lihteh Wu, MD, Committee Co-Chair

RWC GLOBAL SOCIETY PARTNER

BRAZILIAN RETINA AND VITREOUS SOCIETY

The Brazilian Retina and Vitreous Society (BRAVS; https://www.sbrv.org) was founded in 1977 by five ophthalmologists interested in the field of retina. Moving forward, now we have over 1200 members dedicated to the field of retina in Brazil. Our annual Congress usually takes place in April, and it is one of the largest meetings in South America, with more than 1500 attendees, more than 250 speakers from Brazil, and many renowned international speakers. We also have a biannual meeting (BRAMS) to concentrate mainly on clinical and surgical management of retinal diseases.

Our mission is to prevent loss of vision due to retinal diseases by promoting scientific exchange of knowledge among retina specialists and also to strengthen our liaisons with partner societies. Our website contains scientific information such as The Retina E-Book, BRAVS Magazine, BRAVS-tube, BRAVS Image Bank, BRAVS Library, links to several important journals, and much more. The *International Journal of Retina and Vitreous* (https://journalretinavitreous.biomedcentral.com) is the official peer-reviewed journal of BRAVS; it is an open-access publication with high visibility content.

Upcoming meeting:
2023 BRAVS Meeting: 47th Congress of the Brazilian Retina and Vitreous Society
April 28-May 1, 2023
Rio de Janeiro, Brazil
https://retina2023.com.br
Prof. Dr. Arnaldo F. Bordon, President, Brazilian Retina and Vitreous Society (2022-2024).

RETINA WORLD CONGRESS GLOBAL ACTIVITIES

RWC Women Global

The Retina World Congress (RWC) is excited to have formed RWC Women Global as part of its all-inclusive educational efforts around the world. The mission of RWC Women Global is to promote the global representation of female retina specialists in scientific/educational activities and leadership positions around the world, and further, to provide mentorship to young female retina specialists navigating their careers. This goal is accomplished by setting a global interactive network of retina specialists around the world to connect and empower the global community of women in retina. RWC's partnership with 47 retina societies around the world offers a unique forum to help RWC Women Global reach its goals. The Co-Chairs of RWC Women Global are leaders in the field of retina and include Daniela Ferrara, MD, Camille Palma, MD, Jessica Randolph, MD, Maria Berrocal, MD, and Nina Berrocal, MD.

We believe that RWC Women Global will have an immediate positive impact in mentorship and increasing the representation of stellar female retina specialists in the world of retina.

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HOT TOPIC IN THE WORLD OF RETINA

Biosimilar Biologics—Need for Real World Data: International Retina Biosimilar Study Group (Inter-BIOS Group)

Submitted by: Ashish Sharma, MD, Lotus Eye Hospital and Institute, Coimbatore, India

Biosimilar is a biologic that is highly similar (in safety, purity, and potency) to, and has no clinically meaningful differences from, another biologic that has already been approved for clinical use (known as the original biologic or reference product).[1] Approval of the reference ranibizumab (Lucentis, Genentech) expired in June 2020 in the United States and in 2022 in Europe.[2] There has been a series of biosimilar ranibizumab approvals in the last year in multiple countries. The first drug was Byooviz/ranibizumab-nuna (Biogen) that received US Food and Drug Administration (FDA) approval in September 2021 and European Medical Agency (EMA) approval in August 2021.[3,4] The second drug was CIMERLI/ranibizumab-eqrn (Coherus Biosciences) that received US FDA approval in August 2022.[5] It has already been approved by the United Kingdom regulatory authority in early 2022 under the name Ongavia (Teva Pharmaceuticals).[6] Recently it has received EMA approval under the name Ranivisio.[7] India was the first country to approve a biosimilar ranibizumab (Razumab, Intas Pharmaceuticals) in 2015.[8] CIMERLI/ranibizumab-eqrn has received US FDA approval for all five indications [neovascular age-related macular degeneration (n-AMD), retinal vein occlusion (RVO), diabetic macular edema (DME), proliferative diabetic retinopathy (PDR), and choroidal neovascularization (CNV)]. Byooviz/ranibizumab-nuna has not yet received US FDA approval for DME and DR due to the different used doses. However, Byooviz/ranibizumab-nuna has received EMA approval for all five indications. Another major difference between Byooviz/ranibizumab-nuna and CIMERLI/ranibizumab-eqrn is that CIMERLI has received 12 months of exclusivity for interchangeability. An interchangeable biosimilar product may be substituted without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand-name drugs. It is yet to be seen how this will affect clinical practice. Byooviz/ranibizumab-nuna has announced its pricing, which is 40% lower ($1,130 USD) compared with reference ranibizumab. Coherus has announced its pricing, which is 30% lower (USD $1,360 for 0.5 mg and USD $816 for 0.3 mg) compared with reference ranibizumab. CIMERLI is now available with a 30% discounted list price of $1,360.00 and $816.00 per single-dose vial for the 0.5 mg and 0.3 mg dosages, respectively, compared to reference ranibizumab. In the last 2 years, India has approved two more ranibizumab biosimilars (Ranieyes, Lupin Ltd, and Ranizurel, Reliance Life Sciences).[9,10] Japan has approved their first ranibizumab biosimilar (Ranibizumab BS1, Senju Pharmaceuticals) in 2021.[11]

There are many biosimilar aflibercept molecules in the final stages of clinical trials and approvals are expected once the aflibercept patent expires in 2023 in the US and 2025 in Europe. Regeneron has multiple patents on aflibercept and some of them will last until 2032; it will be interesting to see how the biosimilar battle will shape up for aflibercept.[12]

Except for real-world data from India, there is a paucity of understanding about these molecules and real-world data in this field. I felt a need for the formation of a group to understand these molecules better with the help of colleagues across the globe. To begin, we have designed a survey entitled "Biosimilars for Retinal Diseases—United States–Europe Awareness Survey (Bio-RUSE–Survey)." Findings of this survey were recently presented at the American Academy of Ophthalmology (AAO) 2022 in Chicago, Illinois, USA, and the Euretina 2022 meeting in Hamburg, Germany.[13,14] We requested retina colleagues who have actively participated and showed interest in this survey to be part of the proposed group entitled the International Retina Biosimilar Study Group (Inter-BIOS Group).

Biosimilar anti-VEGF agents may have different impacts in different parts of the world due to variations in health care policies. The aim in forming the Inter-BIOS Group is to study the impact of biosimilar anti-VEGF in various countries in isolation and also as an overall influence on retina practice. We would be initiating various real-world studies related to biosimilar anti-VEGFs, as the major outcome revealed from the Bio-USER Survey was that most of the clinicians surveyed were concerned about the safety and efficacy of biosimilars and felt a strong need for more real-world data. The Inter-BIOS Group will also perform various surveys in different countries to assess the awareness and knowledge about these molecules in different geographical regions.

Biosimilars go through smaller clinical trials and receive extrapolation of approval in multiple indications based on the data of one disease. Retina specialists are habituated to large amounts of data before any drug is approved for clinical use, and biosimilar clinical trial design is something new to most. Real-world study results performed under the Inter-BIOS Group could be of great help in the long term in uncovering various facts related to the safety and efficacy of these molecules. Historically, uptake of biosimilar molecules is always slow due to these initial concerns. However, over time the uptake improves and helps patients in accessing these treatments at a more affordable price.

The Inter-BIOS effort is being coordinated by Dr. Ashish Sharma from Lotus Eye Hospital and Institute, Coimbatore, TN, India; Dr. Baruch Kuppermann from Gavin Herbert Eye Institute, Irvine, CA, USA; Dr. Ramin Tadayoni from Université de Paris, AP-HP, Lariboisière, St Louis and Fondation Adolphe de Rothschild hospitals, Paris, France; Dr. Francesco Bandello from University Vita-Salute, Scientific Institute San Raffaele, Milano, Italy; and Dr. Ant Loewenstein from the Division of Ophthalmology, Tel Aviv Medical, Tel Aviv University, Israel. US FDA and EMA are the major regulatory bodies for biosimilar approval, and we hope that efforts with the help of colleagues from Europe and the USA will be able to bring the global data under one platform. The Inter-BIOS Group will not only be limited in performing real-world biosimilar studies but also in publishing educational content about biosimilar molecules, which is the key area of effort of the US FDA and EMA.[12] Retina has various focused groups that have helped in improving the understanding of various diseases in the past.

CURRENT STATUS OF INTER-BIOS GROUP ACTIVITIES

At present, the Inter-BIOS Group has begun contacting sites and investigators in the US, Europe, UK, and Canada who are using or are willing to use Byooviz that have received US approval and are available for clinical use. Initial contact is also being made to sites and investigators from the US and UK who might be willing to use CIMERLI in their clinical practice once available. Regarding international efforts, the Inter-BIOS Group is initialing real-world data collection from India and Japan related to the biosimilar anti-VEGF approved for local usage.

The Inter-BIOS group is open to global ophthalmology colleagues who are or will be using biosimilar anti-VEGFs. If you are interested in more information or how to become an investigator, please contact us by email at drashish79@hotmail.com.

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RWC Retina Rocks Image Gallery Case of the Month

Committee Co-Chairs: Steven Bloom, MD; Paulo Stanga, MD; Ashish Sharma, MD

Submitted by: Barbara Parolini, MD; Veronika Matello; Eyecare Clinic, Brescia, Italy

The patient is a teacher who suffered from a wet age-related macular degeneration (AMD) submacular hemorrhage. Despite six anti-vascular endothelial growth factor (anti-VEGF) injections, vision dropped to 20/200. She was 58 years old and unable to read. After a long discussion regarding the pros and cons of surgery, she underwent autologous choroidal transplantation in 2013.

The surgical procedure included (1) complete pars plana vitrectomy, (2) creation of a temporal retinal detachment, (3) peripheral 200 degree retinotomy, (4) macular neovascularization (MNV) removal, (5) feeder vessel endodiathermy, (6) designing the peripheral choroidal patch with endodiathermy, (7) cutting and isolation of a full thickness autologous RPE and choroid transplant (under perfluorocarbon liquid, PFCL), (8) translocation of the patch under the fovea (under PFCL), (9) transfer of PFCL from under to over the retina with retinal reattachment, (10) peripheral laser, and (11) PVCL exchange for 1000 cs silicone oil.

Eight years later, Clarus 500 widefield photography shows the intact submacular choroidal autograft and the white area of bare sclera in the temporal quadrant, which was the autograft harvesting site (**Figure 1**). Canon Xephilio S1 widefield optical coherence tomography (OCT) shows fairly normal retina overlying the graft. Xephilio A1 OCT-angiography shows the intact choroidal graft vessels arranged in a different direction compared to the native surrounding choroidal vasculature (**Figure 2**).

When last examined, near vision was 20/30. The patient recently developed a macular neovascularization (MNV) in the contralateral eye, which is being treated with anti-VEGF injections.

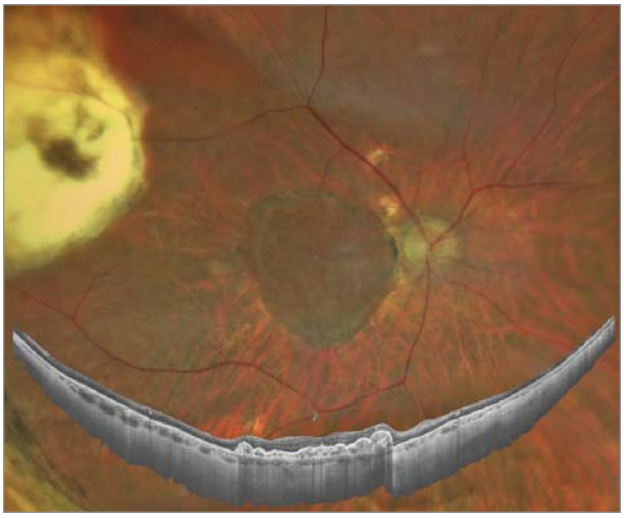

Figure 1. Composite image showing the hyperpigmented submacular choroidal autograft, white area of bare sclera, and widefield OCT with fairly normal retina overlying the graft.

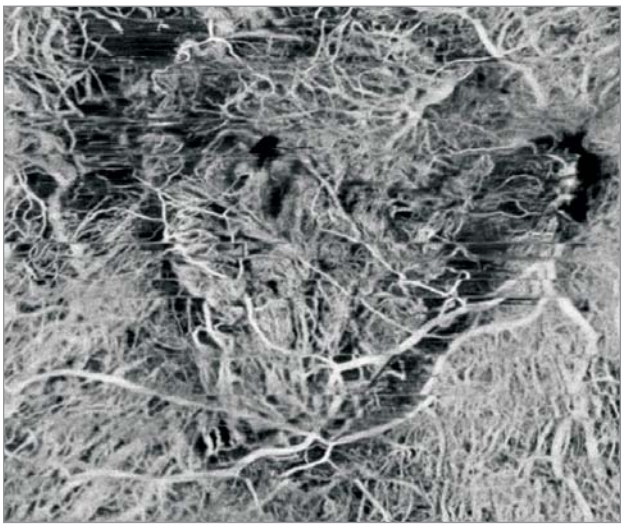

Figure 2. Xephilio A1 OCT angiography shows an intact choroidal graft.

Please visit https://retinaworldcongress.org/retina-rocks/ to view the image gallery.