



MALAYSIA ASSOCIATION FOR CELL THERAPY
PERSATUAN SEL PERUBATAN MALAYSIA



UNIVERSITY
OF MALAYA

REGENERATIVE MEDICINE VIRTUAL SYMPOSIUM 2021

Cell and Gene Therapy Products:
Research to Product Registration

13 NOVEMBER 2021

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INTRODUCTION

REGENERATIVE MEDICINE VIRTUAL SYMPOSIUM 2021 **Cell and Gene Therapy Products: Research to Product Registration**

Regenerative Medicine is an emerging field aimed to restore both structure and function to the musculoskeletal system. This field has great potential to transform the current practices and standard-of-care in Medicine. It integrates a multidisciplinary approach to address patient needs. To ensure that regulated advanced therapies are provided at clinical point-of-care (POC), adherence to current regulations and legislations need to be emphasized in tandem with the research and development of regenerative medicine products. In our local regenerative medicine landscape, the National Pharmaceutical Regulatory Agency (NPRA) in Malaysia ensures the quality and safety of pharmaceutical products, including Cell and Gene Therapy Products (CGTPs). The Regenerative Medicine Virtual Symposium 2021 with the theme of “Cell and Gene Therapy Products: Research to Product Registration”, aims to provide a platform for the various stakeholders in the regenerative medicine industry to share their experience in meeting the requirements by the international regulators (i.e. Food and Drug Administration (FDA)) and local regulators i.e. NPRA and Medical Device Authority (MDA), to register their CGTPs as practical products for patient use. This symposium aims to gather all stakeholders including industries, researchers and regulators to exchange their views in this challenging transition time. This meeting also serves as a platform for your researchers, including postgraduate students and postdoctoral research fellows to present their research work related to regenerative medicine.

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Message From
ORGANISING CHAIRMAN
MR WIJENTHIRAN KUNASEKARAN

It is my great pleasure to welcome you to the annual Regenerative Medicine Virtual Symposium 2021 jointly organized by Malaysia Association for Cell Therapy (MACT) and University Malaya. I would also like to congratulate the organizing committee for taking up the challenge of hosting this event during this unprecedented time due to the COVID-19 pandemic.

I would like to convey my heartfelt gratitude to MACT president Dr Lim Teck Onn, Dr Tan Sik Loo (NOCERAL, University of Malaya), Cytonex Sdn Bhd, National Pharmaceutical Regulatory Agency (NPRA), Industrial Biotechnology Research Centre-SIRIM Berhad, Malaysian Bioeconomy Development Corporation, MEDIPOST America Inc., Advanced Medical and Dental Institute, Universiti Sains Malaysia, Kuala Lumpur Sports Medicine Centre (KLSMC), StemLife Berhad, NiSCCELL, INTRAN Technologies, Cryocord Sdn Bhd, CytoMed Therapeutics Pte Ltd (Singapore), China Medical University Hospital (CMUH) (Taiwan), Taiwan Medical Tourism Development Association, Taiwan Medtour Organization, GSBC-Gene & Stem cell Biomedical Company (Taiwan) and not forgetting our platinum sponsor BD Life Sciences (Malaysia) and Bio-Med Global for their support to organize this symposium.

The Regenerative Medicine Virtual Symposium 2021 with the theme of Cell and Gene Therapy Products (CGTPs): Research to Product Registration, aims to provide a platform for the various stakeholders in the regenerative medicine industry to share their experience in meeting the requirements by the international regulators and local regulators to register their CGTPs as practical products for patient use. This symposium aims to gather all stakeholders including industries, researchers, and regulators to exchange their views in this challenging transition time.

I really hope that this symposium will serve as a platform to accelerate the growth of R&D and CGTPs based industry to place Malaysia on a global map as a technology producing nation in Regenerative Medicine and Cell Therapy. To all participants and attendees wish you a successful and fruitful symposium.

Thank you.

A handwritten signature in black ink, appearing to read 'Wijenthiran'.

Wijenthiran Kunasekaran

Chairman

Regenerative Medicine Virtual Symposium 2021

Event: MACT-UM Regenerative Medicine Symposium
Date: 13th November 2021
Time: 0800-1730 (Kuala Lumpur time)
Venue: Zoom Virtual Symposium
Theme: Cell and Gene Therapy Products: Research to Products Program

PROGRAM TENTATIVE

| TIME | TOPIC | SPEAKERS |
|---|---|---|
| 0800 - 0815 | Delegates/Speakers/Presenters Log-in to Zoom | |
| 0815 - 0900 | Opening Ceremony | |
| Session 1 Session Chair: Dr Lim Teck Onn / Dr Caroline Jee | | |
| 0900 - 0930 | Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia | Keynote speaker: Dr Evelyn Loh Yun Xi Senior Principal Assistant Director, Biologics Section, Centre for Product and Cosmetic Evaluation, National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia. |
| 0930 - 0950 | Commercialization journey of an allogenic cord blood-derived MSC product CARTISTEM for Knee OA in Korea, US, Japan and Malaysia | Guest speaker: Dr Antonio Lee CEO & Managing Director, MEDIPOST America Inc.; Rockville MD, USA |
| 0950 - 1010 | Oral Presentation 1- Expedited Regulatory Pathways for Cell-based Therapy in Malaysia: The Way Forward | Dr Firdaus M Aziz |
| 1010 - 1025 | Break | |
| Session 2 Session Chair: Dr Caroline Jee | | |
| 1025 - 1055 | GLP Toxicity Test for compliance with MDA | Keynote speaker: Dr Samsulida Binti Abd. Rahman SIRIM-IBRC |
| 1055 - 1115 | The Malaysian Bioeconomy Ecosystem | Guest speaker: Ahmad Fazil Ellias, Assistant Vice President, Industry Development Division, Healthcare, Malaysian Bioeconomy Development Corporation Sdn Bhd |
| 1115 - 1135 | Mending Broken Hearts : The Promise of Induced Pluripotent Stem Cells | Guest speaker: Assoc. Prof. Dr. Tan Jun Jie Advanced Medical and Dental Institute, Universiti Sains Malaysia |
| 1135 - 1215 | Oral Presentation 2- Concept Paper: Composition and Action of Inflammatory Cells that Infiltrate the Synovium in Osteoarthritis, Oral Presentation 3- 3D composite Poly (lactic-co-glycolic acid)-Nano calcium sulfate-Fucoidan (PLGA-Ncs-Fu) induced differentiation of Human Bone Marrow stromal cells for tissue engineering application, | Ms Ti Jia Wei Ms Norshazliza Ab Ghani |

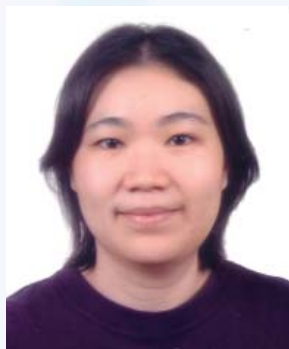
PROGRAM TENTATIVE

| TIME | TOPIC | SPEAKERS |
|---|---|--|
| 1215 - 1235 | Sponsored Talk | Sponsor: BD Sdn Bhd |
| 1235 -1345 | Lunch Break | |
| Session 3 Session Chair: Dato Dr Jai Mohan / Dr Caroline Jee | | |
| 1345 - 1405 | Musculoskeletal Regeneration with Autologous Peripheral Blood Stem Cells - Clinical applications and challenges | Guest speaker: Dr. Saw Khay Yong KLSMC, Malaysia |
| 1405 - 1515 | Oral Presentation 4- The Effect of MSC Exosomes On Insulin Resistant Tenocytes Oral Presentation 5- Effects of Early Passaging on Biological Characteristics and Immunomodulatory Properties of Wharton's Jelly Mesenchymal Stem Cells, Oral Presentation 6- A Systematic Review: Preclinical Findings to The Clinical Applications of the current Gene Therapies for Osteoarthritis, Oral Presentation 7- Evaluation of wound healing stimulatory effects of recombinant human fibroblast growth factor 2 on third-degree burned mouse model, Oral Presentation 8- A systematic review on exosomal piRNA abundance in blood circulation in human diseases, Oral Presentation 9- Cytokine expression on autoimmune disorder after Mesenchymal stem cells treatment, Oral Presentation 10- Patient Outcomes Following Intra-articular Exosome Knee Injections: A Retrospective Review, | Mr Omar Maged Ms Tan Li Jin Ms Atiqah Ab Aziz Mr Khanh-Thien Le Ms Goh Tuan Xin Ms Lee Siew Ee Dr Shankar Lognanathan |
| 15.15-15.30 | Break | |

PROGRAM TENTATIVE

| TIME | TOPIC | SPEAKERS |
|---|---|--|
| Session 4 Session Chair: Dr Lim Teck Onn / Mr James Then | | |
| 1530 - 1615 | Opportunities and Challenges in Regenerative Medicine Industry During the COVID-19 Pandemic: Exploring Collaborative Potentials Between Malaysia and Taiwan | <p>Business Dialogue</p> <p>Panellist: from MACT Malaysia Dr Lim Teck Onn (President of MACT) Mr James Then, Director, Cryocord (Vice President of MACT) Mr Peter Choo, Director , CytoMed Therapeutics (MACT Member) Mr Wijenthiran Kunasekaran, Co-founder, Cytonex Sdn Bhd, Cytonex Sdn Bhd (MACT Member) Dr Saw Khay Yong, KLSMC (MACT Member)</p> <p>from Taiwan: Ms Chang, Yi-Wen, General Manager, Gene and Stem Cell Biochemical Corp Dr. Ooi Hean, Vice director of International Center, China Medical University Hospital (CMUH) , Taiwan Mr Hundred Huang, Taiwan Medical Tourism Development Association Taipei office Director, GSBC- Gene & Stem cell Biomedical Company Sales Director Ms Meiling Chang , Commissioner, Taiwan Medtour Organization Mr Poa-Kai Feng, GSBC, Primary Consultant, Taiwan</p> <p>from Korea: Dr Antonio Lee, CEO & Managing Director, MEDIPOST America Inc.; Rockville MD, USA</p> |
| 1615 - 1630 | Closing Ceremony | |
| 1630 - 1645 | Winner Announcement for the Best Oral Presenters | |
| | End of Symposium | |

KEYNOTE SPEAKER



Dr. Evelyn Loh Yun Xi

Senior Principal Assistant
Director UF54,
Biologics Section,
Centre for Product and
Cosmetic Evaluation,
National Pharmaceutical
Regulatory Agency,
Ministry of Health, Malaysia.

REGISTRATION OF CELL AND GENE THERAPY PRODUCTS (CGTPS) IN MALAYSIA

ABSTRACT

Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia

- The role of NPRA
- Regulatory Framework for CGTPs
- Registration of CGTPs

BIOGRAPHY

Dr Evelyn is a Senior Principal Assistant Director at Biologics Section of National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia. She is currently in charge of the evaluation of biologics for pre-marketing authorization and assessment of variation and additional indication for registered products. She completed her PhD at The National University of Malaysia and Master of Pharmacy (First Class Honours) from a twinning program between International Medical University, Malaysia & University of Strathclyde, Scotland. From 2009-2012, Dr Evelyn is a member in the technical working group to draft the ASEAN Variation Guideline which had officially been adopted in the 19th ASEAN Consultative Committee on Standards and Quality – Pharmaceutical Product Working Group (ACCSQ- PPWG) Meeting in July 2012. She has received TienTe Lee Biomedical Foundation-YSPSAH Excellent Scientific Paper Award in 2019. She has 5 publications.

KEYNOTE SPEAKER



**Dr Samsulida Binti
Abd. Rahman**

Senior Researcher,
Test Facility Manager (TFM)
for GLP Test Facility,
Industrial Biotechnology
Research Centre (IBRC)
SIRIM Berhad

GLP TOXICITY TEST FOR COMPLIANCE WITH MDA

ABSTRACT

A question frequently asked by medical device designers is how and when good laboratory practice (GLP) regulations apply to medical device studies. GLPs are the regulatory standards that define the minimum requirements for planning, conducting and reporting nonclinical safety studies. There is significant confusion about what constitutes “best practices” for applying GLP to medical device studies. This is because the regulations, which were written primarily to apply to nonclinical studies of chemicals and pharmaceuticals, now are being applied to a greater variety of studies—including premarket approval (PMA) submissions to the U.S. Food and Drug Administration (FDA) and medical device biocompatibility studies in support of 510(k) submissions. GLP has been designed to guarantee that results from nonclinical studies could be verified, would be repeatable, and would produce sound, scientifically valid data. This is ensured by requiring that testing facilities conform to standards, have an independent quality assurance unit to assure the integrity of studies and appoint a knowledgeable and trained study director to oversee the study and interpret the test results.

The two most common questions regarding medical device GLP studies are:

- Which medical device studies must comply with GLP regulations?
- What type of medical device characterization data is needed in compliance with GLP?

All the questions will be answered during the presentation

BIOGRAPHY

Dr Samsulida, holds a PhD in Sensor Technology Engineering and a Bachelor of Science (Hons) in Industrial Chemistry from the University Putra Malaysia (UPM). She authored several scientific articles that were published in peer-reviewed journals (in her research area related to sensors and nanomaterials), and authored a book chapter appearing in Biosensors and Chemical Sensors: A Practical Approach and has provided several oral presentations. Dr. Samsulida's timeless experience in the medical device and pesticide/industrial chemicals industry encompasses toxicology, biological safety and, as well as extensive preparation of biological and toxicological risk assessments for submission in countries complying with EU and US FDA regulations. Prior to her current position as Senior Researcher, she has held a variety of positions ranging from laboratory supervision/management, GLP Test Facility Manager, Technical Specialist and project manager for Biological safety and biological risk assessment, and also as a frontliner for testing and services under ISO 17025 and GLP accreditation. She has specific expertise in the evaluation process outlined in ISO 10993-1 (for medical devices) and Toxicology and safety testing according to NPRA and Pesticide Board's Requirements (for pesticide and industrial products).

SESSION CHAIR



Dr Lim Teck Onn

BIOGRAPHY

A graduate of MBCHB University of Glasgow, MRCP (UK), FRCP (Edinburgh) and a Master of Medical Statistics from the University of Newcastle Australia. Formerly director of the Clinical Research Centre Ministry of Health Malaysia, he presently serves as consultant to Government agencies and Universities, as well as the Biotech/ Pharmaceutical and Healthcare industry in variety of areas including Health research, Biostatistics and Healthcare Performance measurement

Dr Lim has been a WHO Consultant for clinical research to China (TCM Research Institute Beijing 2002-2003), consultant on clinical research to the Aga Khan University (2005 and 2006), University Medical Centre HCM & MOH Vietnam (2007, 2008), Ministry of Health Brunei (2007, 2008), King Saud University College of Medicine Saudi Arabia (2009), University of Ruhuna Sri Lanka (2010). His other appointments include as Adjunct Professor at IMU, subject editors for various medical journals. Throughout his career he has been active conducting clinical research and in establishing patient registries. He has more than 60 research publications in reputable international journals.

He has also have contributed to various society and NGOs. Among the current active involvement are as a committee member of Together Against Cancer Association Malaysia (TAC), a cancer health advocacy organisation in Malaysia. Dr Lim is also currently appointed as the President of Hepatitis Free Pahang and Health Malaysia Association. He has also made significant contributions in Malaysia Association for Cell Therapy (MACT) as a President together with his board of committees

SESSION CHAIR



Dr Caroline S. Y. Jee

BIOGRAPHY

Dr Jee manages all applied and fundamental research and development activities in the company. During her time at KLSMC, she has successfully secured a number of government grants and awards. She has 20 years of technical management experience. Prior to KLSMC, she was with Inno Bio Diagnostic, a company set up by the Malaysian Government to develop stem cell related bio-technology. Caroline obtained her PhD degree in 2003 from Queen Mary, University of London, received her B.Eng (1st-class Hons) in Biomedical Materials Science and Engineering from Queen Mary, University of London (1999). She also received numerous awards for outstanding performances throughout her degree. She holds 10 international patents, is a chartered engineer (CEng) and chartered scientist (CSci).



Dato' Dr Jai Mohan

BIOGRAPHY

Dato Dr Jai Mohan was Professor of Health Informatics & Paediatrics at the International Medical University from 2005 to 2018. He continues to teach health informatics part-time at the International Medical University and at Quest International University Perak (where he is Adjunct Professor).

He is Adviser to Nichi-Asia Center for Stem Cell & Regenerative Medicine.

He worked in the Ministry of Health for 30 years from 1971 to 2001 (including being Head of Paediatrics at Hospitals Seremban, Ipoh and Selayang).

Jai Mohan has, to his credit, 36 publications and 10 research reports on paediatrics, health informatics and health policy. He has acted as temporary WHO consultant on telematics and advised on telemedicine development in developing countries.

He is a past president of the Malaysian Paediatric Association and the Malaysian Health Informatics Association.

GUEST SPEAKER



Dr Antonio Lee
CEO & Managing Director,
MEDIPOST America Inc.;
Gaithersburg, Maryland, USA

COMMERCIALIZATION JOURNEY OF AN ALLOGENIC CORD BLOOD-DERIVED MSC PRODUCT CARTISTEM FOR KNEE OA IN KOREA, US, JAPAN AND MALAYSIA

ABSTRACT

Commercialization journey of an allogenic cord blood-derived MSC product CARTISTEM for Knee OA in Korea, US, Japan and Malaysia

BIOGRAPHY

Dr Antonio Lee is CEO & Managing Director, MEDIPOST America Inc.; Gaithersburg, Maryland, USA. He completed his PhD in Developmental Biology & Embryology at University of Otago, Dunedin, New Zealand and Masters of Science in Clinical Anatomy at University of Otago, Dunedin, New Zealand. He has 6 peer reviewed publications.

Trained developmental biologist with stem cell & molecular biology background and extensive experience in in vitro and in vivo disease-modeling and analysis for establishing preclinical proof-of-concept, under both academic and commercial research settings. Solid analytical skill sets with broad experience across medical science, bio-manufacturing, regulatory affairs and market access, in early- to late-stage commercialization of advanced biological therapeutic modalities throughout multiple geographical/regulatory jurisdictions. Expansive professional network of industry and clinical KOLs, regulators, service/advisory providers and financiers across multiple markets. Strong diplomatic skills and a natural affinity for cultivating relationships and persuading, convening, facilitating and building consensus among diverse individuals. Applies qualities of integrity, credibility and a passion for progress with a strong aspiration for growth through strategic governance, with an industry foresight and long-term vision.

GUEST SPEAKER



Mr. Ahmad Fazil Elias
Assistant Vice President,
Industry Development
Division, Healthcare, Malaysian
Bioeconomy Development
Corporation Sdn Bhd

THE MALAYSIAN BIOECONOMY ECOSYSTEM

ABSTRACT

Malaysian Bioeconomy Development Corporation Sdn Bhd is a Malaysian government agency with a mandate to promote the growth of biotechnology sector in Malaysia. Fazil is responsible to facilitate investment in Healthcare Biotechnology in Malaysia. He joined Malaysian Bioeconomy Development Corporation in 2009 in the Industrial Biotechnology Division where he was involved in the Renewable Energy, Bioplastics and Biobased chemical initiatives and investment in Malaysia. Prior to this, he was with Export-Import Bank of Malaysian Berhad involved in the overseas project financing and strategic planning. He holds an MBA from the University of Nottingham, United Kingdom and a degree in Microbiology and Microbial Technology from the University of Warwick, United Kingdom.

BIOGRAPHY

En Ahmad Fazil Elias is the Assistant Vice President of Industry Development Division of Healthcare Malaysian Bioeconomy Development Corporation Sdn Bhd.

GUEST SPEAKER



Assoc. Prof. Dr. Tan Jun Jie
Advanced Medical and Dental
Institute, Universiti Sains
Malaysia

MENDING BROKEN HEARTS : THE PROMISE OF INDUCED PLURIPOTENT STEM CELLS

ABSTRACT

Heart disease remains the deadliest disease in the world, most of which are due to ischemic heart disease. The blocked coronary artery suffocates a significant number of heart cells, causing cell necrosis and increased cardiac fibrosis. These deleterious events leave the heart with akinetic scars, rendering the heart prone to remodelling. Replenishing the heart cell pool in the ischemic heart to restore the number of contractile units necessary for normal cardiac function can only be achieved by cardiomyocyte therapy judging from the heart being a postmitotic organ. Many types of adult stem cells have been used to address this problem, but the event of neomyogenesis has been low despite the observed improvement in cardiac structure and hemodynamics. Human induced-pluripotent stem cells (hiPSCs) present greater different plasticity. Thanks to the lesson from heart development, the signalling cues directing the differentiation of heart cells are more defined and established than ever, and the production is now possible and reproducible without having ethical controversy like the embryonic stem cells. In this lecture, the advances in cardiac cell therapy, the use of hiPSCs in cardiomyocyte production, the role of non-myocytes cells and the current progress in cardiac tissue engineering and myocardial regeneration will be discussed.

BIOGRAPHY

Dr Tan Jun Jie is a Biomedical Sciences graduate from Universiti Putra Malaysia. He obtained his D.Phil. from the University of Oxford studying the adult cardiosphere-derived cells in 2011. He joined Advanced Medical and Dental Institute, Universiti Sains Malaysia in 2011 and he has recently been promoted to associate professor in the same university. He was a visiting research fellow in King's College London in 2014 and a postdoctoral research fellow in surgery at Massachusetts General Hospital, Harvard Medical School in 2016. Jun Jie has established his laboratory studying the interaction between different types of stem cells, including hematopoietic stem cells, mesenchymal stem cells, cardiac c-kit cells etc. and now his primary focus is on the applications of the human-induced pluripotent stem cells. His interest is to produce functional therapeutic cardiomyocytes for repairing the damaged heart. He is also exploring the use of iPSCs to derive non-myocyte support cells which is essential in cardiac tissue engineering, based on the lessons from heart development. This includes his recent published work on the derivation of chamber specific cardiomyocytes and the pre-epicardial cells, the multipotent cells that make up most non-myocyte cells in the heart.

GUEST SPEAKER



Dr Saw Khay Yong
MCh Orth (Liverpool), FRCS Ed.
Consultant Orthopaedic Surgeon
Kuala Lumpur Sports Medicine
Centre, MALAYSIA.

MUSCULOSKELETAL REGENERATION WITH AUTOLOGOUS PERIPHERAL BLOOD STEM CELLS - CLINICAL APPLICATIONS AND CHALLENGES

ABSTRACT

One of the most common and challenging injuries for physicians to treat is cartilage damage in joints. The structure and function of articular cartilage leads to non-healing lesions or the formation of fibrocartilage following injuries. Well-established arthroscopic methods utilize controlled healing with marrow stimulation or transferring of non-injured cartilage to areas of injury. Historically, these arthroscopic methods as well as open and two-staged procedures have shared common marginal outcomes. Knee joints with massive chondral defects in the younger population represent an 'unmet medical needs' and do not have a satisfactory solution. KART (KLSCMC Articular Regeneration Technology) is a stem cell technology for chondrogenesis (regeneration of articular cartilage). It exploits the innate healing properties of patients' own peripheral blood stem cells (PBSCs) and is capable of treating multiple lesions, including 'bone-on-bone' kissing lesions. The science, surgical technique, harvesting and storage of the PBSCs and the postoperative rehabilitation program that encompasses this innovative technology have been developed to ensure high quality repair and regeneration resembling native hyaline cartilage in the knee joint. Our recently completed US-FDA Phase 2b randomized control trial concluded that arthroscopic subchondral drilling into massive chondral defects of the knee joint followed by postoperative intra-articular injections of autologous PBSCs plus hyaluronic acid is safe and showed a significant improvement of clinical and radiologic scores. This technology is applicable to other joints including other aspects of the musculoskeletal system.

BIOGRAPHY

Dr Saw Khay Yong is the founder and a Consultant Orthopaedic Surgeon at the Kuala Lumpur Sports Medicine Centre in Kuala Lumpur, Malaysia. He completed his Masters in Orthopaedic Surgery at Liverpool University Medical School, UK in 1993. He specializes in knee joint arthroscopic surgery with the application of stem cells for chondrogenesis together with bone and soft tissue regeneration. He has presented his work at more than 60 medical/scientific meetings, received numerous awards and has 9 international publications on stem cells related work including five patents granted for this pioneering technology and on his novel medical device.

ORAL PRESENTERS



Mohammad Firdaus Bin Abdul Aziz

Expedited Regulatory Pathways for Cell-based Therapy in Malaysia: The Way Forward

Mohammad Firdaus Bin Abdul Aziz M.F¹

¹ Centre for Law and Ethics in Science and Technology (CELEST), Faculty of Law, Universiti Malaya, 50603, Kuala Lumpur, Malaysia

ABSTRACT

Background: Malaysia has identified a number of chronic diseases that are prevalent among its population, which have created a drain on public healthcare spending. Regenerative medicine based on stem cell technology is seen as a potential solution to provide interventions that may reverse these conditions. In addition, this sector has the potential to play an important part in Malaysia's aspiration to be a hub for medical tourism in this region. Many other countries have already recognised stem cell technology as having viable commercial applications and they have not only heavily invested in this area, but have also revisited their regulatory systems and introduced expedited regulatory pathways to facilitate the advancement of regenerative medicine.

Objectives: This research project aims to examine the current regulatory pathway for cell and cell-based product (CCBPs) in Malaysia and compare it with the selected jurisdictions namely the UK, Japan, and Australia, which are the leading stem cell players.

Methods: A comparative legal analysis was adopted to analyse the regulatory approaches adopted by the countries under study.

Results: The selected countries under study except Malaysia have introduced an expedited regulatory pathway for access to cell-based therapy. Japan's approach could be the best model for Malaysia.

Discussion: Other jurisdictions have recognised that the traditional pathway for regulating new treatment is not suitable for CCBPs. They have implemented dedicated regulatory pathways that can expedite the review process for approving the use of CCBPs to accelerate innovation in regenerative medicine while maintaining the safety and efficacy measures. Malaysia should adopt a similar approach with some ethical and legal considerations.

Conclusions: It can be argued that Malaysia needs to follow suit in order to compete with other stem cell players, properly regulate the current stem cell application in the country, and ensure successful regenerative medicine industry in the future.

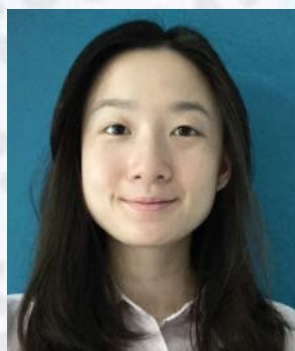
Clinical Implications: Not relevant

Keywords: regenerative medicine, stem cell therapy, cell-based products, stem cell technology, regulation

Conflict of Interest (COI): The author declare that there is no conflict of interest.

Acknowledgements: None

ORAL PRESENTERS



Ti Jia Wei

Concept Paper: Cellular composition and role of inflammatory cells in osteoarthritic synovium

Ti JW¹, Tan SL, Roebusk MM², Kamarul T

¹ Department of Orthopaedic Surgery, Faculty of Medicine, University Malaya, 50603 Kuala Lumpur, Malaysia.

² Department of Musculoskeletal & Ageing Science, Institute of Life Course & Medical Sciences (ILCaMS), Faculty of Health & Life Sciences, William Henry Duncan Building, University of Liverpool, 6 West Derby Street, Liverpool L7 8TX.

ABSTRACT

Background: Osteoarthritis (OA) was traditionally thought of as a “wear and tear” disease that mainly affects the articular cartilage. Over the recent years, it has been established that OA should be considered a whole joint disease that affects not only the articular cartilage but also the surrounding tissues i.e. joint capsule, synovium, subchondral bone, ligaments and tendons. A wide range of disruptions to these tissues has been attributed to inflammation, which is apparent especially in the OA synovium. These cells secrete inflammatory factors and are thought to be one of the main contributors to the progression of OA. Many studies have shown the possible inflammatory pathways of specific inflammatory cells in the OA synovium which lead to the increase in cartilage breakdown. However, there are few systematic reviews of the general cellular infiltration. This is a concept paper for the systematic review that we will conduct on the cellular composition and role of the different inflammatory cells that infiltrate the OA synovium. Following this review, we will identify the major contributors to inflammation in OA joints, as well as propose therapeutic targets that can best slow down OA progression.

Objectives: To identify the cellular composition of inflammatory cells in the OA synovium and to detail the role of these different cell types in the synovium.

Methods: A predefined search strategy will be used to conduct the systematic review. Only studies relevant to the objectives will be included.

Clinical Implications: Following this review, we will identify the major inflammatory contributors of OA and propose the potential therapeutic targets that can delay OA progression. Ultimately, the effects of MSC-derived cell-free products (eg. exosomes) in targeting the inflammatory factors can be further investigated.

Keywords: Osteoarthritis, inflammation, infiltration, synovium, leukocytes

Conflict of Interest (COI): The authors declare that there is no conflict of interest.

ORAL PRESENTERS



Norshazliza Ab Ghani

3D composite Poly (lactic-co-glycolic acid)-Nano calcium sulfate-Fucoidan (PLGA-Ncs-Fu) induced differentiation of Human Bone Marrow stromal cells for tissue engineering application

Norshazliza Ab Ghani¹, Krishnamurthy Genasan¹, Megala Jayaraman¹, Sathiya Maran³, Tunku Kamarul^{1*}, Hanumanth Rao Balaji Raghavendran^{1, 2*}

¹ Tissue Engineering Group (TEG), National Orthopaedic Centre of Excellence in Research and Learning (NOCERAL), Department of Orthopaedic Surgery, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia

² Sri Ramachandra Institute of Higher education and Research, Central Research facility, Porur, Chennai India-116

³ School of Pharmacy, Monash University, Malaysia

ABSTRACT

Background: The aim of this study was to functionalize a novel porous PLGA (Poly lactic-co-glycolic acid) composite scaffold in combination with nano-calcium sulfate (NCS), fucoidan (FU) in combination or either of them alone will potentiate osteogenic differentiation of human bone marrow stromal cells.

Objectives: Aim of this study is to analyse the composition and chemical properties of PLGA/Ncs/Fu, PLGA/Ncs and PLGA/Fu as a potential biomaterial for bone tissue engineering and to conduct an in-vitro evaluation of the nano-biocomposite scaffold for biocompatibility, cell viability, cell attachment and cell proliferation as bone tissue regeneration potentials.

Methods: Composite scaffolds such as PLGA-FU, PLGA-NCS, PLGA-FU-NCS were fabricated and characterization was done using Confocal and Energy Dispersive X-Ray Analysis (EDX). In vitro human bone marrow stromal cells adhesion, proliferation, differentiation induction by scaffolds was confirmed using alamar blue, alkaline phosphatase (ALP) and osteogenic gene markers.

Results: Confocal microscopy analysis of scaffolds showed cell attachment in the all three composite materials, however the cell density was relatively high in PLGA-composite with both FU and NCS, than either one of them.

Conclusions: Incorporation of both Fucoidan and Nano-calcium silicate along with PLGA showed a promising improvement in the osteogenic parameters

Clinical Implications: PLGA-Ncs-Fu ideal candidate for next pre-clinical studies for development of successful implant which could induce rapid osteogenic differentiation

Keywords: PLGA (Poly lactic-co-glycolic acid) ; nano-calcium sulfate (NCS); Bone; fucoidan (FU); Bone tissue engineering.

Conflict of Interest (COI): "The authors declare that there is no conflict of interest."

ORAL PRESENTERS



Lee Siew Ee

Cytokine expression on autoimmune disorder after Mesenchymal stem cells treatment

Lee S. E.¹, Tan L. J.¹, Chua K. S.², Loganathan S.¹, Khairuzzaman S. R.¹, Kunasekaran W.¹

¹ Cytonex Sdn. Bhd., Menara UOA Bangsar, A-16-17, No. 5, Jalan Bangsar Utama 1, Bangsar, 59000 Kuala Lumpur

² Gleaneagles Kuala Lumpur, 50450 Kuala Lumpur

ABSTRACT

An autoimmune disease is an abnormal immune response in which the immune systems attacks your own healthy cells and tissues by mistake. These immune responses resulted in inflammation which causes redness, sore and/or swelling. On the other hand, mesenchymal stem cells (MSCs) are well-known for their anti-inflammatory and immunomodulatory properties.

Objectives: This study aims to determine the in-vivo cytokines expression pattern on autoimmune rheumatic disorder after MSCs treatment.

Methods: MSCs was intravenously injected into a child diagnosed with Systemic Juvenile Sclerosis. Blood samples were taken pre-treatment (0 hour) and, 48 and 96 hours post-treatment. Cytokine analysis were performed via qPCR platform on the expression level of TNF, IFNG, IL-6 & IL-10. Antinuclear antibodies (ANA) test results three months prior and after treatment respectively were provided by the participant as supportive data as well as to monitor the condition of the autoimmune disorder.

Results: The expression of TNF- α and INF- γ decreases while IL-6 increases post MSCs treatment. The expression of IL-10 decreases 48 hours post treatment but increases on 96 hours post treatment. ANA test value decreases post treatment.

Discussion: The reduction of proinflammatory markers TNF- α and INF- γ and increment of anti-inflammatory marker IL-10 might indicate a reduction in inflammation. IL-6 has contradictory role of proinflammatory and anti-inflammatory properties under different conditions. The fluctuation of IL-6 indicates the presence of immunomodulatory work. The decreased in ANA test result supports the cytokines expression data, whereby the autoimmune condition decreases post MSCs treatment.

Conclusions: Cytokines analysis showed improvement in the autoimmune disease after MSC treatment. These results were supported by the reduction in ANA test value. These data indicates that MSCs have the potency of immunomodulatory and anti-inflammatory properties.

Clinical Implications: MSCs poses a potential to be explored as a treatment for inflammatory-related diseases.

Keywords: Mesenchymal stem cells (MSCs), autoimmune, inflammation, cytokine, treatment

Conflict of Interest (COI): The authors declare that there is no conflict of interest.

ORAL PRESENTERS



Tan Li Jin

Effects of early passaging on biological characteristics and immunomodulatory properties of Wharton's Jelly mesenchymal stem cellsTan L. J.¹, Talebi S. ¹, Lee S.E. ¹, Khairuzzaman S. R. ¹, Kunasekaran W. ^{1*}¹ Cytonex Sdn. Bhd., Menara UOA Bangsar, A-16-17, 59000, Kuala Lumpur

ABSTRACT

Background: The outcome of clinical studies using human mesenchymal stem cells (MSCs) has been inconsistent, mainly due to variation in type and passage number of stem cells being used. Serial passaging is a common practice in allogeneic MSCs therapy to obtain suitable clinical dose. However, continuous passaging could affect their potency.

Objectives: This study aims to investigate the effect of early passaging on the biological and immunological behaviours of Wharton's Jelly mesenchymal stem cells (WJ-MSCs).

Methods: WJ-MSCs were cultured from passage(p)2 to p6 and their biological properties were assessed for each passage in terms of morphology, trilineage differentiation and expression of surface markers. Their immunomodulatory function was compared by assessing the proliferative activity of phytohemagglutinin (PHA)-activated human peripheral blood mononuclear cells (PBMCs) when co-cultured with WJ-MSCs-p2 to p6 at different ratios and timepoints. To further understand the immunomodulatory mechanisms of WJ-MSCs, cytokines analysis (TNF- α , IFN- γ , IL-4, IL-10) was performed.

Results: While WJ-MSCs retained their biological properties from p2 to p6, changes in immunological behaviour were observed. WJ-MSCs-p6 demonstrated lower inhibition of the PHA-activated PBMCs as compared to other passages. Among all passages, WJ-MSC-p4 showed higher suppression of PHA-induced PBMCs and proinflammatory cytokines TNF- α and IFN- γ .

Discussion: The biological properties of early passages of WJSCs did not show significant divergence which agrees with previous works. However, WJ-MSCs demonstrated different degree of immunomodulatory effect across p2-p6. A similar study on bone marrow-derived MSCs found no significant difference between p3, p5 and p7 in terms of their immunological behaviour.

Conclusions: The inconsistency in clinical outcomes warrants more studies to reveal biological pathways involved in such behaviours and the correlation to culture adaptation of these cells in vitro.

Clinical Implications: The outcome of such studies could help researchers select the right cell passage for clinical trials, especially for inflammatory-related diseases.

Keywords: Wharton's Jelly mesenchymal stem cells; serial passaging; immunomodulatory properties; stem cells potency, cytokines

Conflict of Interest (COI): The authors declare that there is no conflict of interest.

ORAL PRESENTERS



Omar Maged Mohammed
Mohammed Hassaballah

The Effect of MSC Exosomes on Insulin Resistant Tenocytes

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ABSTRACT

Background: Diabetic tendinopathy (DT) results in the disruption of tendons in terms of their biomechanical properties, histology and gene expression. Mesenchymal stem cells-derived exosomes (MSC-Exos) are nano-sized extracellular vesicles that promote tissue regeneration, which can potentially be a cell-free therapy for DT.

Objectives: To review existing research reported on MSC-Exos in DT and discuss the potential effects of MSC-Exos on DT.

Methods: Library database search in PubMed (up to 1/11/2021) was conducted with keywords “mesenchymal stem cells exosomes” or “mesenchymal stem cell extracellular vesicles” or “exosomes” or “mesenchymal stromal cells exosomes” or “MSC exosomes” or “mesenchymal stromal cell extracellular vesicles” or “MSC EV’s” AND “diabetic tendinopathy” or “tendon” or “tendon cells”.

Results: The search found 55 articles, of which 20 articles fulfilled the inclusion criteria. Among these 20 articles, MSC-Exos used in the studies were derived from MSCs isolated from adipose (7), bone marrow (6), tendon (3), umbilical cord (3) and amnion (1). These studies were conducted on in vivo models in rats (4), mice (3) and rabbits (1), as well as in vitro models in humans (3), rats (3), equine (1) and swine (1) tendons. The findings showed that MSC-Exos could improve tendinopathies in terms of histological properties (4), balancing ECM synthesis and degradation (3), promoting the proliferation of tenocytes (4), reducing inflammation, enhancing tendon biomechanical properties (3), relieving adhesion (2) and promoting the expression of tenogenic genes (4). No human clinical studies have been reported.

Discussion: MSC-Exos (i) promote proliferation, migration and fibrotic activity in rotator cuff tenocytes through activation of transforming growth factor β 1 signalling; (ii) induce healing of injured tendon; (iii) suppress the synthesis of catabolic cytokines (IL-1 β , IL-6, and MMP-9) and catabolic gene expression (MMP-9 and MMP-13) and increase type I/III collagen gene expression ratio; and (iv) promote tendon regeneration via proliferation and differentiation of TSC. Clinical translation of these results would require further research (e.g. tumorigenicity and toxicity of MSC-Exos).

Conclusion: MSC-Exos have potential curative effects on DT at cellular and molecular levels.

Clinical Implications: MSC-Exos would potentially be applied as a cell-free therapy for DT.

Keywords: Mesenchymal stem cells, exosomes, diabetic tendinopathy, insulin-resistant tenocytes.

Conflict of Interest (COI): The authors declare that there is no conflict of interest.

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ORAL PRESENTERS



Atiqah Binti Ab Aziz

A Systematic Review: Preclinical Findings to The Clinical Applications of the current Gene Therapies for Osteoarthritis(OA)

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ABSTRACT

Background: It has been estimated that about 250 million people all over the world suffer from osteoarthritis (OA). Thus, OA is a major health problem in urgent need of better treatment. Current therapies for OA can temporarily relieve clinical symptoms, rather than preventing or curing OA. Therefore, researchers began to look for alternative treatments which are not just effective but also safe for OA and gene therapy offers to meet this need.

Objectives: This article aimed to shed light on the current gene therapy mechanism of action In OA.

Methods: Articles that demonstrated preclinical and clinical treatments of OA were extracted, categorized, and reviewed through the PRISMA method using PubMed, Web of Science (WoS), and Scopus engine published from 2015 to 2020.

Results: There were 319 articles screened. Articles that fall under the categories of non-English articles, full articles that were not available, articles that cover the expansion of the same experiments, not an empirical article, a report, conference proceedings, book, or a review were excluded. Ultimately, 17 articles were reviewed. The articles reviewed suggested 11 categories of current gene therapies for OA.

Discussion: This review provides information on the introduction and function of selected gene therapy for OA and summarizes their published research on preclinical and clinical findings.

Conclusions: It can be seen that not many studies related to gene therapies of OA are extended to the level of clinical studies. Hence, exposure to clinical application is needed to increase the level of knowledge of its effects in OA.

Clinical Implications: This paper provides valuable perspective to the clinicians on the effectiveness and the potential of using these current gene therapies for the future in OA treatment and management.

Keywords: gene therapies, osteoarthritis, clinical studies, treatment, review, cell and gene therapy

Conflict of Interest (COI): The authors declare that there is no conflict of interest.

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ORAL PRESENTERS



Khanh-Thien Le

Evaluation of wound healing stimulatory effects of recombinant human fibroblast growth factor 2 on third-degree burned mouse model

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ABSTRACT

Background: Fibroblast growth factor 2 (FGF-2) has been thoroughly exploited in burn treatment research due to its crucial functions in wound healing.

Objectives: In this study, we evaluated burned mouse treatment using our *Escherichia coli*-expressed recombinant human FGF-2 (rhFGF-2).

Methods: Burned mouse model was established using heated brass rod. Burn treatment using rhFGF-2 was evaluated based on wound photo and histological analysis. All experiments on animals were approved by University of Science, Ho Chi Minh City, Vietnam under ethical approval number 09/18-0599-02.

Results: Wound area and wound depth of created burned mouse model were 0.83 ± 0.05 cm² and 573.40 ± 147.82 μ m, respectively. Besides, rhFGF-2-treated burned mice at the dose of 1 μ g/cm²/day showed higher rate of wound closure, granulation tissue formation, re-epithelialization, and angiogenesis than control group.

Discussion: Generally, our rhFGF-2 had an equal biological activity to commercial FGF-2 product named Trafermin with effective dose of 1 μ g/cm²/day.

Conclusions: This study demonstrated that our rhFGF-2 could potentially become therapeutic protein in order to be used for burned patients.

Keywords: burn treatment, fibroblast growth factor 2, tissue repair and regeneration.

Conflict of Interest (COI): The authors declare that there is no conflict of interest.

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ORAL PRESENTERS



Goh Tuan Xin

A systematic review on exosomal piRNA abundance in blood circulation in human diseases**Authors and Affiliations:**

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ABSTRACT

Background: Circulating exosomes are potential biomarkers for human diseases, attributed to their cargo contents that reflect the state of their host cells. As piwi-interacting RNA (piRNA) can regulate gene expression through epigenetic regulation and post-transcriptional gene silencing, investigating piRNA profiles in exosomes derived from human clinical samples could potentially unveil markers that characterize disease stages.

Objectives: To review the abundance of exosomal piRNAs in blood circulation that had been reported in human clinical samples, i.e. plasma and serum, as a supporting reference for further studies on synovial fluid (SF)-derived exosomal piRNAs.

Methods: In October 2021, we searched in PubMed databases, in which a total of 56 articles were identified. According to our inclusion and exclusion criteria, 41 articles were excluded, and a total of 15 articles were included in this review.

Results: Various studies have demonstrated the abundance of piRNAs in circulating exosomes, with the abundance level varies from 4.57% in plasma, and 8.88% in serum. Differentially expressed exosomal piRNAs between patients and controls were also detected in 10 studies.

Discussion: To date, no studies have reported the presence of exosomal piRNA in SF. Mesenchymal stem cell (MSC) has been proposed as a regenerative therapy in cartilage repair in OA. Thus, it is of interest to investigate if the SF-derived exosomal piRNAs could reflect the inflammation condition in the synovium and its potential inhibitory effect on MSC chondrogenic differentiation or stimulatory effect on chondrocyte hypertrophy.

Conclusions: Future work is required to understand the molecular mechanism of SF-derived exosomal piRNA in OA as well as in MSCs, to provide insight into the therapeutic potential of MSCs in OA.

Clinical implications: Since differentially expressed piRNAs could be detected among patients and non-patients, exosomal piRNA could serve as a powerful diagnostic tool for human diseases.

Keywords: piRNA, exosomes, blood, human, diseases.

Conflict of Interest (COI): The authors declare that there is no conflict of interest.

ORAL PRESENTERS



Shankar Loganathan

Patient Outcomes Following Intra-Articular Exosome Knee Injections: A Retrospective Review

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ABSTRACT

Background: Knee osteoarthritis (OA) affects millions of people worldwide. It is caused by progressive loss of knee joint articular cartilage loss. resulting in pain, stiffness, decreased mobility, swelling, and instability. Conventional non-surgical treatments may control OA symptoms but cannot restore the damaged joints.

Objective: This study was thus conducted to evaluate the potential of exosomes derived from mesenchymal stem cells (MSCs) as an alternative method for the treatment of knee OA.

Methods: 10 volunteers (5 males and 5 females) with chronic knee pain and imaging corresponding to Kellgren-Lawrence OA Grades of 2, 3 and 4 were recruited and informed consent was obtained from them. Their baseline WOMAC scores were recorded and each volunteer received an intraarticular injection of MSC-derived exosomes to an affected knee. Each volunteer was followed up on for successive WOMAC scores as well as reports of adverse effects over 12 months following the injection.

Results: Two volunteers reported some swelling in the treated knee which subsided after 48 hours. The treatment showed a significant ($p < 0.05$) improvement in WOMAC scores for Grade 2 and 3 volunteers over the 12-month observation period. However, Grade 4 volunteers did not experience a significant improvement in their WOMAC scores.

Discussion: Exosomes derived from MSCs have been previously shown in-vitro to improve osteoarthritic conditions. These improvements were mainly shown to be due to the ability of these exosomes to induce proliferation of chondrocytes and prevent apoptosis to restore or reduce the severity of the worn cartilage. This correlates with our findings of significant improvements in self-reported WOMAC scores. Volunteers with Grade 4 OA and more severely diseased joints and native chondrocytes were predictably less receptive to this treatment modality. Of note however is the lack of decline in self-reported WOMAC scores over the 12-month observation period despite the progressive nature of OA.

Conclusion: In conclusion, these findings can contribute to the literature on the use of exosomes for knee OA improvement. Furthermore, our study showed that intra-articular MSC-derived exosome injections could be considered a safe and reliable treatment option to reduce pain and dysfunction in less severe knee OA (Grade 2 and 3).

Clinical implication: We believe that this study provides evidence of potentially viable clinical applications of MSC-derived exosomes for the treatment patients with knee OA.

Conflict of interest: This work is funded by Cytonex Sdn. Bhd. The authors affiliated with Cytonex. Sdn. Bhd. are involved in the research and manufacture of MSCs and MSC-derived exosomes.

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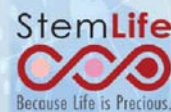
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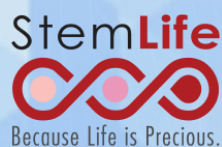
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