

Human Gene Therapy With Myoblast Transfer

P.K. Law, T.G. Goodwin, Q. Fang, T. Quinley, G. Vastagh, T. Hall, T. Jackson, M.B. Deering, V. Duggirala, C. Larkin, J.A. Florendo, L.M. Li, T.J. Yoo, N. Chase, M. Neel, T. Krahn, and R.L. Holcomb

CELL THERAPY Research Foundation (CTRF) is completing phase II clinical trials of myoblast transfer therapy (MTT, US Patent #5,130,141) on Duchenne's muscular dystrophy (DMD) under an investigational new drug application approved by the US Food and Drug Administration (FDA). MTT is a platform technology of *in vivo* gene transfer, and cell repair and replacement. As such, it is a combined somatic cell therapy and gene therapy. Begun on February 15, 1990, MTT is the world's first human gene therapy.¹

Myoblasts are muscle-building cells endogenous to the human body. Contained within the nucleus of the myoblast are more than 100,000 normal genes that determine cell normality and cell characteristics.

During myogenesis and muscle regeneration, mononucleated myoblasts fuse spontaneously to form multinucleated myotubes, sharing their nuclei in a common gene pool. On establishing neuronal, vascular, and tendon connections, these myotubes will deposit additional contractile filaments and develop into genetically normal myofibers. When this occurs inside a dystrophic muscle, the process of normal myoblast fusion can replace degenerated dystrophic myofibers with genetically normal ones.

When cultured normal myoblasts are injected into dystrophic muscles, they fuse also with dystrophic myofibers, inserting their nuclei to effect genetic repair at the cellular level.² There is no break-in or breakdown of the nuclear membrane like the sperm and the ovum. There is no tetraploidy formation. Normal myonuclei simply take up permanent residence in the dystrophic myofibers that have now turned genetically mosaic, and transcribe the production of the missing protein which, in DMD, is called dystrophin.

Thus, through natural cell fusion, the donor myoblasts transduce all normal genes within their nuclei into the multinucleated dystrophic myofibers. The transfer of genetic material occurs *in vivo* with the myoblasts serve as the source and the vehicles of gene transfer. MTT is therefore a gene therapy, and because myoblasts are cells, it is also a cell therapy.

Myoblasts can be used as an universal gene transfer vehicle by virtue of their ability to transduce full complement of normal genes instead of a single gene. Besides

being in clinical trials of neuromuscular diseases, basic MTT studies have been published on cardiomyopathy,^{3,4} bone degeneration,⁵ anemia,⁶ human growth hormone deficiency,⁷ hemophilia,⁸ and islet allograft rejection.⁹ Conceptually, MTT can find application in type II diabetes and cancer, and other hereditary degenerative diseases.

According to the FDA, gene therapy is defined as a medical intervention based on alteration of the genetic material of living cells, either cells to be administered to humans, or human cells genetically modified *in vivo*. The practice of MTT using normal, not genetically modified myoblasts pertains to the latter category. MTT using transduced myoblasts qualifies for both.

The FDA is concerned about sterility, endotoxins, identity, potency, and purity of cell cultures used in cell therapy. Cell viability immediately before transplants must be shown in view of nonoptimal conditions encountered in transportation and delay. Most cells do not survive when tightly packaged in shipping media.

Myoblasts are readily identified by their abilities to migrate, divide, align, fuse, and to deposit actin and myosin to form sarcomeres.¹⁰ They lose their major histocompatibility complex-class I (MHC-I) antigens after fusion. Mature myofibers do not express MHC-I antigens. Thus MTT subjects do not require life-long immunosuppression.

CTRF myoblast cultures are at least 98% pure. Viability demonstrated immediately before transplants is 98% using Erythrocin B (Sigma), 0.1%, at pH 7.23.

An often-asked question is how long can myoblasts survive if they succeed in engrafting. To this end, the world's first MTT subject was re-biopsied 6 years after receiving MTT. Dystrophin was present in more than 95% of the myofibers of the myoblast-injected muscle but was absent in the sham-injected muscle.¹¹ The result indicates that donor myoblasts survived, developed, and produced

From the Cell Therapy Research Foundation, Memphis, Tennessee.

Supported by public donation with US Food and Drug Administration approval for cost recovery.

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Myoblast Transfer Therapy

**F. Koller, Bernhard Ø Palsson, John
Masters**



Myoblast Transfer Therapy:

Myoblast Transfer Therapy Robert C. Griggs, George Karpati, 2012-12-06 I am pleased to introduce this volume on Myoblast Transfer Therapy on behalf of the Muscular Dystrophy Association and all of its Advisory Committees The international conference which led to this volume brought together leading basic scientists and clinical investigators for the purpose of coordinating the development of this new field in the fight against muscular dystrophy The Muscular Dystrophy Association is the nation's most rapidly growing voluntary health agency in terms of its programs of patient care research and professional and public education Success is attributable to its National Chairman Jerry Lewis to its effective corporate membership and to the many physicians and scientists who give their time freely to advise on policies to review grant applications and to participate in meetings such as this I should like to acknowledge a large number of other individuals to whom we are indebted the broad segment of the American public which continually and generously supports our spectrum of services The Muscular Dystrophy Association next year should raise in excess of 115 000 000 These contributions are derived from more than 10 million American families These families are not only pledging their money but expressing their hopes that we will find answers to the tragic problem of neuromuscular disease We are confident that the fruits of this meeting will move the frontier of research forward toward that goal

Handbook of Stem Cell Therapy Khawaja Husnain Haider, 2022-11-07 The handbook comprehensively reviews the therapeutic potential of stem cells and stem cell secretome based cell free strategies in regenerative medicine The chapters in section I and section II respectively discuss the diverse applications of mesenchymal stem cells and non mesenchymal stem cells including skeletal myoblasts endothelial progenitor cells adipose tissue derived stem cells induced pluripotent stem cells and neuronal stem cells in myocardial repair inflammatory bowel disease cognitive deficits wound healing retinal disorders and COVID 19 The subsequent chapters in section III primarily focused on the fast emerging cell free therapy approach in regenerative medicine for tissue repair and regeneration These chapters review the impact of stem cell derived secretome on various biological processes such as angiogenesis neurogenesis tissue repair immunomodulation musculoskeletal pathologies wound healing anti fibrotic and anti tumorigenesis for tissue maintenance and regeneration Lastly section IV summarizes miscellaneous aspects of cell based therapy including the treatment advantages opportunities and shortcomings in stem cell based therapy potentially helping to refine future studies and translate them from experimental to clinical studies Moreover this section also has chapters on cancer stem cells as novel targets in cancer therapeutics This Major Reference Book MRW is a valuable resource for researchers involved in stem cell research to understand the multifaceted therapeutic applications of stem cells and their derivative secretome in regenerative medicine

Myoblast Transfer Peter K. Law, 1994-01-01 *New Growth Factors in Myoblast Transfer Therapy Used as a Treatment in Muscular Dystrophy* Scott Thomas Baker, 1999* **Regenerative**

Pharmacology George J. Christ, Karl-Erik Andersson, 2013-04-15 Regenerative medicine is broadly defined as the repair or

replacement of damaged cells tissues and organs It is a multidisciplinary effort in which technologies derive from the fields of cell developmental and molecular biology chemical and material sciences i e nanotechnology engineering surgery transplantation immunology molecular genetics physiology and pharmacology As regenerative medicine technologies continue to evolve and expand across the boundaries of numerous scientific disciplines they remain at the forefront of the translational research frontier with the potential to radically alter the treatment of a wide variety of disease and dysfunction This book will draw attention to the critical role that pharmacological sciences will undeniably play in the advancement of these treatments This book is invaluable for advanced students postdoctoral fellows researchers new to the field of regenerative medicine tissue engineering and experienced investigators looking for new research avenues The first state of the art book in this rapidly evolving field of research **Cardiovascular Applications of Stem Cells** Khawaja H. Haider,2023-07-05

The book covers multifarious aspects of stem cell based therapy for cardiovascular diseases In addition to stem cells from different sources for cell based therapy it covers stem cell organoids and stem cell derived exosomes in regenerative medicine The book also encompasses advances in state of the art infrastructure to improve the maturation aspects of pluripotent stem cells derived cardiomyocytes using a novel scaffold based cell culture system for cell delivery in experimental animal models and clinical settings Besides the use of mesenchymal stem cells the book includes chapters on the use of cardiac progenitor cells CPCs microtissue implantation use of PSCs for valvulopathies application of decellularized organ arrays as natural scaffolds for cardiac tissue engineering use of epicardial stem cells and skeletal myoblasts in cell based therapy for myocardial regeneration Besides the cell based therapy approach the book also reviews the stem cell derived exosomes their characteristics and engineering strategies to enhance their therapeutic potential via targeting and drug loading and use in disease models Additionally the book also discusses the latest research on injectable hydrogels for cardiovascular regeneration and how hydrogel based delivery protects the cells and their retention post engraftment in the heart a problem which significantly reduces the efficacy of cell based therapy **Tissue Engineering** John P. Fisher,Antonios G. Mikos,Joseph D. Bronzino,2007-05-30

Increasingly viewed as the future of medicine the field of tissue engineering is still in its infancy As evidenced in both the scientific and popular press there exists considerable excitement surrounding the strategy of regenerative medicine To achieve its highest potential a series of technological advances must be made Putting the numerous *Regenerative Medicine for Degenerative Muscle Diseases* Martin K. Childers,2015-12-19

This book compiles and explores cutting edge research in degenerative skeletal disorders such as Duchenne muscular dystrophy and congenital myopathy and new stem cell based therapies and gene replacement therapy Twelve expertly authored chapters navigate the nuances of these treatments in an array of contexts and biological systems The topics covered include How are urine cells from a patient with Duchenne muscular dystrophy transformed into beating heart cells What can reprogrammed cells tell us about heart muscle failure What do gene mutations mean for those born with a muscle

disease How are manufacturing methods applied to human stem cells Does therapeutic exercise benefit those patients who receive engineered limb muscle Is there practical advice about nutrition to enhance muscle function for the Duchenne patient Can microRNAs be useful to regenerate diseased muscle Regenerative Medicine for Degenerative Muscle Diseases is ideal for scientists and clinicians from varying disciplines in genetics cell biology virology cell based manufacturing rehabilitation medicine nutrition veterinary medicine and neurosurgery The reader will see how transformative changes occur in medicine that can powerfully impact the future for patients suffering from inherited disorders affecting muscles of the body including the heart Molecular and Cell Biology of Muscular Dystrophy T. Partridge,2012-12-06 Molecular and Cell Biology of Muscular Dystrophy gives a series of accounts of various aspects of the remarkable breakthrough which has been achieved in our understanding of the Duchenne Becker muscular dystrophies and of the consequences and ramifications of this breakthrough Potential Therapeutic Strategies for Muscular Dystrophy Gisela Gaina,2023-11-02 The book provides a comprehensive overview of the different forms of muscular dystrophy MD including potential therapeutic interventions and the advantages associated with repurposing pharmaceuticals for treating these conditions In addition the book examines the effects of physical training on improving symptoms as well as patient quality of life and life span The target audience of this book comprises students researchers and doctors with an interest in the field of muscular dystrophy

Essentials of the Adult Neurogenic Bladder Jaques Corcos,Gilles Karsenty,Thomas Kessler,David Ginsberg,2020-10-16 This book summarises the entire field of adult neuro urology in a concise well illustrated and practical style Contents include epidemiology lower urinary tract anatomy and physiology This is followed by coverage of the pathophysiology of various types of voiding dysfunctions and a clinical section focusing on practical evaluation and treatment A range of treatments from behavioral pharmacological intra vesical tissue engineering and surgical are explained and reviewed Other topics such as complications sexual function fertility maternity aspects and prognostic factors round off the book Each topic is covered in detail and well illustrated The reader will gain a full understanding of every aspect of adult neuro urology Facilitates improved clinical knowledge and practice Provides an essential and complete reference tool for students and established urologists neurologists physiotherapists and nurses and technicians involved in the care of patients with neurogenic bladder dysfunction Molecular Mechanisms of Muscular Dystrophies Steve J. Winder,2006-01-26 There is no doubt that the study of the muscular dystrophies in recent years has been exciting and rewarding It has attracted the attention of many investigators of international repute and this is reflected in the various contributions to this volume Molecular Mechanisms of Muscular Dystrophies represents a personal collection of chapters cover **Stem Cells - From Hype to Real Hope** Khawaja Husnain Haider,Salim Aziz, MD,2018-12-17 This book is a compilation of the bench experience of leading experts from various research labs involved in the cutting edge area of research The authors describe the use of stem cells both as part of the combinatorial therapeutic intervention approach and as tools disease model during drug development highlighting

the shift from a conventional symptomatic treatment strategy to addressing the root cause of the disease process The book is a continuum of the previously published book entitled Stem Cells from Drug to Drug Discovery which was published in 2017

Children in Medical Research Lainie Friedman Ross, 2006-02-09 Lainie Ross presents a rigorous critical investigation of the development of policy governing the involvement of children in medical research She examines the shift in focus from protection of medical research subjects enshrined in post World War II legislation to the current era in which access is assuming greater precedence Infamous studies such as Willowbrook where mentally retarded children were infected with hepatitis are evidence that before the policy shift protection was not always adequate even for the most vulnerable groups Additional safeguards for children were first implemented in many countries in the 1970s and 1980s more recent policies and guidelines are trying to promote greater participation Ross considers whether the safeguards work whether they are fair and how they apply in actual research practice She goes on to offer specific recommendations to modify current policies and guidelines Ross examines the regulatory structures e g federal regulations and institutional review boards the ad hoc policies e g payment in pediatric research and the role of schools as research venues the actual practices of researchers e g the race ethnicity of enrolled research subjects or the decision to enroll newborns as well as the decision making process both parental permission and the child's assent in order to provide a broad critique Some of her recommendations will break down current barriers to the enrolment of children e g permitting the payment of child research subjects allowing healthy children to be exposed to research that entails more than minimal risk without requiring recourse to 407 panels whereas other recommendations may create new restrictions e g the need for greater protection for research performed in schools restrictions on what research should be done in the newborn nursery The goal is to ensure that medical research is done in a way that promotes the health of current and future children without threatening to use the words of Hans Jonas the erosion of those moral values whose loss would make its most dazzling triumphs not worth having *Lovell and Winter's Pediatric Orthopaedics* Stuart L. Weinstein, John M. Flynn, 2013-11-14 Now in its updated Seventh Edition Lovell and Winter's Pediatric Orthopaedics remains a must have for physicians and residents treating infants children and adolescents with orthopaedic problems This classic comprehensive reference covers the basic science clinical manifestations and management of orthopaedic problems in children Now in full color the foremost orthopaedists examine normal musculoskeletal development and the causes diagnosis and treatment of the entire range of abnormalities with emphasis on evidence based decision making in treatment selection The clinical chapters include pearls and pitfalls and a description of the author's preferred approach The book will now cover surgical techniques of management with step by step illustrations from the Atlas of Pediatric Orthopaedic Surgery Primary Mesenchymal Cells F. Koller, Bernhard Ø Palsson, John Masters, 2006-04-11 The human body contains many specialized tissues that are capable of fulfilling an incredible variety of functions necessary for our survival This volume in the Human Cell Culture Series focuses on mesenchymal tissues and cells The in vitro study of

mesenchymal cells is perhaps the oldest form of human cell culture beginning with the culturing of fibroblasts. Fibroblasts have long been generically described in the literature arising from many tissue types upon in vitro cell culture. However, recent studies many enabled by new molecular biology techniques have shown considerable diversity in fibroblast type and function as described within this volume. Mesenchymal tissue types that are described within include bone cartilage tendons and ligaments muscle adipose tissue and skin dermis. The proper function of these tissues is predominantly dependent upon the proper proliferation differentiation and function of the mesenchymal cells which make up the tissue. Recent advancements in primary human mesenchymal cell culture have led to remarkable progress in the study of these tissues. Landmark experiments have now demonstrated a stem cell basis for many of these tissues and furthermore significant plasticity and inter conversion of stem cells between these tissues resulting in a great deal of contemporary excitement and controversy. Newly developed mesenchymal cell culture techniques have even lead to novel clinical practices for the treatment of disease.

Handbook of Stem Cell Applications Khawaja H. Haider, 2024-03-25 This handbook reviews the clinical applications of stem cell based therapy. The book covers the clinical applications of stem cells in cardiovascular diseases neurological and ocular diseases pediatrics and the role of cancer stem cell derived exosomal microRNA payload in lung cancer. The chapter reviews emerging stem cell therapy and tissue engineering approaches in neurodegenerative diseases. The book further examines the applications of stem cells in various fields of dentistry and for the regeneration of oral and non oral tissues. The chapters also explore the application of 3D bioprinting in conjunction with bone marrow mesenchymal stem cells for the treatment of bone defects and state of the art technology for bone and cartilage regeneration using mesenchymal stem cells. The book presents stem cell based therapy against renal pancreatic and kidney diseases and examines the advantages of a novel hepatic stem for cirrhotic liver repair and regeneration. Lastly the book provides methodological and procedural advancements in stem cell based therapy including the applications of single cell sequencing in stem cell research. This handbook is a major one stop reference for researchers working in regenerative medicine cellular pharmacology stem cell research in general and those involved in specific areas of adult stem cells as well as embryonic and induced pluripotent stem cells.

Library of Congress Subject Headings Library of Congress. Cataloging Policy and Support Office, 2007

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Current Neurology S. H. Appel, 1997 The goal of the CURRENT NEUROLOGY series is to address the latest advances in the Neurosciences and their application to Neurologic disease. No field is changing more rapidly than Neurology and all Neurologists have an increasing responsibility to use this information to help devise meaningful therapeutic strategies for the patients. To help achieve this goal several areas for in depth discussions are selected. The rapid advances in the muscular dystrophies is addressed with specific emphasis as to how these genetic breakthroughs will impact the therapy of these disorders in the future. Also discussed is therapeutic Neuro ophthalmology which has always been of clinical importance for importance for Neurologists.

Finally the problem of pain is extremely important and the latest understanding of neuropeptides and neuronal reorganization are discussed as the basis for future therapeutic approaches

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Table of Contents Myoblast Transfer Therapy

1. Understanding the eBook Myoblast Transfer Therapy
 - The Rise of Digital Reading Myoblast Transfer Therapy
 - Advantages of eBooks Over Traditional Books
2. Identifying Myoblast Transfer Therapy
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Myoblast Transfer Therapy
 - User-Friendly Interface
4. Exploring eBook Recommendations from Myoblast Transfer Therapy
 - Personalized Recommendations
 - Myoblast Transfer Therapy User Reviews and Ratings
 - Myoblast Transfer Therapy and Bestseller Lists
5. Accessing Myoblast Transfer Therapy Free and Paid eBooks
 - Myoblast Transfer Therapy Public Domain eBooks
 - Myoblast Transfer Therapy eBook Subscription Services
 - Myoblast Transfer Therapy Budget-Friendly Options
6. Navigating Myoblast Transfer Therapy eBook Formats
 - ePub, PDF, MOBI, and More
 - Myoblast Transfer Therapy Compatibility with Devices
 - Myoblast Transfer Therapy Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Myoblast Transfer Therapy
 - Highlighting and Note-Taking Myoblast Transfer Therapy
 - Interactive Elements Myoblast Transfer Therapy
8. Staying Engaged with Myoblast Transfer Therapy

- Joining Online Reading Communities
- Participating in Virtual Book Clubs
- Following Authors and Publishers Myoblast Transfer Therapy
- 9. Balancing eBooks and Physical Books Myoblast Transfer Therapy
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Myoblast Transfer Therapy
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Myoblast Transfer Therapy
 - Setting Reading Goals Myoblast Transfer Therapy
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Myoblast Transfer Therapy
 - Fact-Checking eBook Content of Myoblast Transfer Therapy
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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