CONCORDIA

SERVING WITH A SPIRIT OF COMPASSION AND GRACE

ARTHROPLASTY RESEARCH CHAIR

Report to the 2022 Annual General Meeting

Submitted by
Anupam Kothari, Chair

Contents

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Summary and Purpose Statement

The Concordia Clinical Research team is dedicated to advancing patient outcomes, improving patient experiences and access to health services through clinical research.

Throughout a person's life, they face many health challenges. The advancement of medicine through research directly results in breakthroughs to solve these health challenges. Each year, more and more Manitobans are being affected by joint diseases – many of whom are still working, raising a family, and playing an active role in their community.

The goal of orthopedic research at the Concordia Campus is to continue pushing the boundaries of how medicine improves the lives of people suffering from joint pain, poor function, and limited mobility.

The research we conduct helps us to meet the growing needs of our patients while invigorating the community, growing Manitoba's economy, and advancing orthopedic care on a global scale.

The need for arthroplasty research will persist beyond where we are in 2022.

There will be new technologies, procedures, devices, and care delivery methods, and external pressures that will continually arise as arthroplasty volumes continue to grow and patients continue to live longer and more active lives.

We expect to meet new challenges and address them with science, developing the data and evidence to inform our best practices.

In the next 3-5 years one of our focus will be on achieving additional grant funding and industry support to sustain the continuation of Concordia's research program.

The need for arthroplasty research will persist beyond where we are in 2022.

Statement of the Problem and Gap: What are we studying and why?

The effectiveness of hip and knee arthroplasty in improving quality of life is extensively documented in adults of all ages.

MISSION AND MANDATE

Some arthroplasty patients do not receive the same benefit from these surgeries, resulting in persistent pain, dysfunction, and reduced quality of life. With an increasing prevalence of arthritis, an ever-expanding and aging population, and increasingly strained healthcare resources, the importance of efficient and effective hip and knee arthroplasty demands cutting-edge research and innovation.

MAJOR ACTIVITIES 2020-2022

1. Trials were initiated as part of our radiostereometric analysis (RSA) program, studying: a novel hip stem (ACTIS) designed to be used with a broader range of surgical approaches for hip arthroplasty; a novel dual-mobility hip system (Pinnacle DM) which may increase patient range of motion and reduce dislocation events;

2. A novel total knee replacement (Porous) which eliminates the use of bone cement for implantation; and a novel partial knee replacement (Engage) designed to enhance initial bone fixation and eliminate the use of bone cement.

3. Introduction of Manitoba's first surgical robotics platform (pending formal roll-out in 2023), which entails a handheld robotic bone mill and infrared navigation to deliver greater surgical precision and intra-operative flexibility to optimize surgical results.

4. Publication of two studies (listed below) and significant progress on three additional studies. Two medical writers and additional resources were identified for assistance in publishing six more studies;
    a. Legion Porous long-term analysis, Legion Hinge mid-term analysis, Legion Constrained mid-term analysis, suppressive antibiotic therapy, varus knee alignment outcomes, hip stem metaphyseal debonding.
    b. Updates to the patient database, including the integration of pre-operative health and function data via the pre-consult questionnaire system (completion expected 2023).

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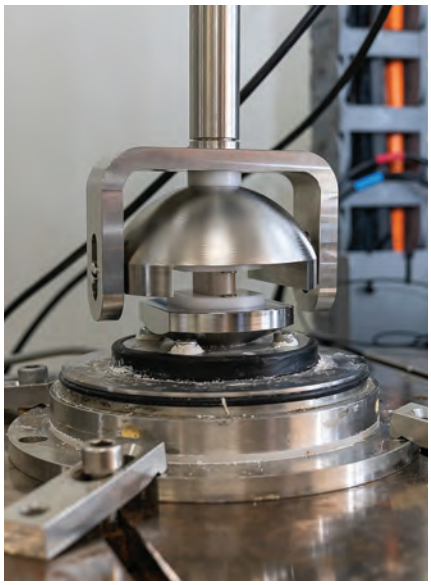
Launch of an updated website (www.cjrg.ca) as a better platform to inform patients and caregivers about their surgery and the research at Concordia.



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Early engagement with Queen's University researchers to implement a markerless gait and motion capture of arthroplasty patients before and after surgery to characterize gait patterns, assess disease and disability severity and identify surgical factors to optimize postoperative outcomes.

SPECIFIC OBJECTIVES WE PURSUED

- Increase medical publications
- Initiate randomized controlled trials and RSA trials
- Conceptualize and initiate novel research studies, pan-Canadian studies
- Ramp up research activities to help address increased arthroplasty volumes and tight resources
- Initiate collaborative studies and new programs of research
- Better utilize databases and large datasets
- Increase the quantity and quality of education and training of orthopedic residents and fellows

The effectiveness of hip and knee arthroplasty in improving quality of life is extensively documented in adults of all ages.

Future Plans and Goals 2023-2024

We will broaden our eligibility for large, tri-council grants and in partnership with the Concordia Foundation, we seek to raise up to $5 million from private donors in the next five years as part of Concordia's Centennial (2028) Campaign. These funding sources will sustain our research program in perpetuity.

BUILDING CAPACITY AND TEAM

The Research Committee and members of the Arthroplasty Chair team have focused on increasing research capacity, which begins with a strong team and leadership. The first 18 months have been focused on getting organized, setting priorities and working with our volunteer committee.

RESEARCH CAPACITY BUILDING AND INNOVATION

In March 2020 we laid out a series of objectives that were needed to build a strong infrastructure that can support the research for at least the next five years and longer.

One of our first objectives was capacity building which began with the national recruitment of a Director of Clinical Research, who will escalate and facilitate the research goals of the Chair and bring new perspectives and questions to the research program.

REVIEW OF KEY GOALS

2020-2022

1. Appointment of Dr. Chrisiann Righolt to the Director of Clinical Research as of November 21, 2022 after a yearlong national search to fill this pivotal position.
2. Funding for this position acquired for five years by a private grant.
3. Continue to increase the membership of the committee to build support and make use of the considerable expertise that is available to us from professionals, experts and supporters.

2022-2024

4. Forge stronger connections with the University of Manitoba and engage new talent in research through the Masters and Doctoral studies.
5. Establish external resources such as medical writers and statisticians who will accelerate the dissemination of research and free up the Research Chair's time to focus on pushing the boundaries of the program.

6. Maintain the financial viability of the Chair with a view to establishing an endowment and continue to pursue financial support through private donations, grants and funding opportunities in partnership with the Concordia Foundation.
7. Form a Centre of Excellence for Arthroplasty. With a $2 Million endowment we anticipate establishing the "Bergen Centre of Excellence for Arthroplasty" in 2023.

PROJECT COLLABORATIONS

The Research Team

The clinical research team consists of health care and research professionals who work closely and collaboratively with other researchers across Canada. They are an essential part of the Arthroplasty Research Chair that was founded by the Concordia Foundation in 2020 with grants from a number of funders and generous donors.

The purpose and mandate of the Arthroplasty Chair and research committee (managed by the Concordia Foundation) has been to create and administer the Arthroplasty Research Chair which was responsible for raising endowment and operational funds for the newly formed Chair. The Research Chair hired the first Director of Clinical Research funded by the Foundation with three major gifts from benefactors. The members of the committee include funders, donors and community members who are influential.

About Dr. Christiaan Righolt

Dr. Righolt is a senior data scientist and epidemiologist with an engineering background with vast experience in quantitative imagine, machine learning, big data and quantitative health research methods. He has been with the University of Manitoba as an Analytics Manager and Assistant Professor in the Department of Community Health Sciences, College of Medicine and Faculty of Health Sciences. He is an alumnus of Delft University of Technology in Philosophy and Applied Physics, Red River Polytech in Business Analysis as well as University of Manitoba.

He has authored the first comprehensive study and report on the risk factors of COVID-19 which examines the factors that affect people who live in Northern Manitoba, those who have a lower income, or people who live in long-term care facilities are the most vulnerable to COVID-19 in Manitoba.

TEAM AND STAFF PARTICIPATION 2021-2022

- **Dr. Thomas Turgeon** – Arthroplasty Chair. Program and project leader
- **Co-Investigators: Drs. Eric Bohm, Colin Burnell, David Hedden** – arthroplasty surgeons and researchers
- **Trevor Gascoyne** – Research Manager (Chair funding, industry funding, local grant funding)
- **Sarah Tran** – Research Coordinator (Chair funding, grant funding, industry funding)
- **Anna Kim** – Research Assistant (Chair funding, grant funding)
- **Amy Yoonju** – Research Clerk (Chair funding)
- **Taranjit Tung** – Orthopaedic Fellow. Lead author on recent publication of Hemi arthroplasty failure modes in Manitoban patients (Chair funding for publication)
- **Austin Moga** – Orthopaedic Fellow. Master's student and physician developing a research project on the impact of Covid-19 on elective hip and knee arthroplasty. (Chair funding, local grant funding)
- **Juan Villa Hernandez** – Orthopaedic Fellow. Leading a review study of the our experience with suppressive antibiotic treatment of chronic joint infections.
- **Rohit Bansal** – Orthopaedic Resident. Leading an implant retrieval and radiographic study looking at debonding a popular hip stem causing loosening and revision surgery.
- **Christine Ngo** – Science Student (co-op, eight months). Assisted with database management and developed an automated system for data entry. (Chair funding)
- **Grace Huang** – Science Student (co-op, four months). Assisted with database management and data entry. (Chair funding)
- **Kevin Stockwell** – Medical Writer (Part-time). Engaged in developing a manuscript for a retrospective study on limb alignment following total knee arthroplasty. (Chair funding, local grant funding)
- **Steven Sheppard** – Medical Writer (Part-time). Engaged in developing a manuscript for a retrospective study comparing patient outcomes following primary versus revision knee arthroplasty. (Chair funding)

PARTNER ORGANIZATIONS

Organization Name: Concordia Joint Replacement Group (CJRG)
Location: Concordia Hip & Knee Institute & Concordia Hospital
Role in the Project: Academic surgeon leadership, the conceptualization of research, the contribution of cases/patients to prospective studies, medical and scientific guidance, writing and review of publications.

Organization Name: Orthopaedic Innovation Centre (OIC)
Location: Concordia Hip & Knee Institute
Role in the Project: Main facilitator of research activities, including protocol writing, ethics submissions, patient enrollment, data collection, data analysis, and some medical writing. Overall administration of CJRG's clinical research program. Hiring and retention of clinical research staff. Discussion with and contracting stakeholders to carry out research projects.

Organization Name: Concordia Foundation
Location: Concordia Hospital
Role in the Project: Administrator of project funds. Established the Concordia Foundation Research Advisory Committee to oversee the Arthroplasty Chair program, outcomes, and spending. A local advocate for arthroplasty research, facilitating numerous fundraising avenues to increase program strength (resources) and longevity.

Organization Name: Research Committee of the Concordia Foundation
Location: Winnipeg – Concordia Hospital
Role in the Project: Acts as a supportive committee to the Chair with representation from a variety of community groups, patients, experts in research or in arthroplasty, and champion of the funding needs that includes private fundraising for the endowment. The committee works with the research team above to provide reporting, stewardship and fundraising for the work of the Chair.

WHAT HAS THE RESEARCH PRODUCED?

Publications

Tung T, **Gascoyne TC**, *Trepman E, Stipelman CH,* **Tran S, Bohm ER, Burnell CD, Hedden DR, Turgeon TR**. Modes of failure of hip hemiarthroplasty for a femoral neck fracture. Can J Surg. 2022 August 12;65(4): E519-E526.

Aragola S, Arenson B, Tenenbein M, **Bohm E**, *Jacobsohn E,* **Turgeon T**. Prospective randomized trial of continuous femoral nerve block with posterior capsular injection versus periarticular injection for analgesia in primary total knee arthroplasty. Can J Surg. 2021 April 28;64(3).

Turgeon T, Burnell C, Hedden D, Bohm E, *Lieberman J, MacDonald S, Parvizi J, Zuckerman J.* Introduction of a Novel Reverse Total Hip System to Address Instability. [Article in review @ Journal of Arthroplasty]

Smith TD, Wilson IR, **Burnell C**, *Vernon J,* **Hedden DR, Turgeon TR**. Multi-Center Experience with Outpatient Total Hip Arthroplasty via a Standard Posterolateral Approach. [Article in review @ Hip International]

Turgeon TR, *Vasarhelyi EM, Howard JL, Teeter MG,* **Gascoyne TC**, **Bohm ER**. Randomized Controlled Trial Comparing Traditional Versus Enhanced-Fixation Designs of a Novel Cemented Total Knee Replacement Tibial Component. [Article in development]

Informed Decision Making and Impacts

DAY SURGERY

Research on the safety and efficacy of hip day surgery via the posterolateral approach [Article in review] helped to guide change in practice at Concordia and the Winnipeg region, demonstrating that outpatient total hip replacement surgery is a suitable method of care associated with reduced healthcare spending and burden on resources.

This particular study provided the safety and efficacy evidence for outpatient surgery, which was virtually the only form of hip and knee surgery that occurred during the Covid-19 pandemic and continues to be a highly effective mode of surgery that is still increasing in prevalence today as a method to combat surgical backlogs.

TRAINING AND SKILLS DEVELOPMENT

The program has impacted the training and skills development of several orthopedic residents and fellows. The program has directly influenced recent trainees by involving them in research projects, from data collection to publication.

Trainees include three orthopedic fellows (E Trepman, J Villa Hernandez, I Moga) and four orthopedic residents (J Lyng, R Bansal, M Abuhantash, and D Mulhall). The majority of these trainees are from underrepresented groups and have gained first-hand experience with scientific methodologies, specializing in their learning of a particular aspect of orthopedic surgery, understanding data analysis and statistics, and developing their professional writing and communication skills, all of which will further their career development and desire for continued learning.

With the hiring our Director of Clinical Research, we anticipate an even greater involvement of trainees through supervision and mentoring of students from the medical, science, or engineering faculties at the undergraduate and graduate levels. This will be facilitated by seeking a nil salaried appointment with the University of Manitoba, which will provide eligibility to apply for peer-reviewed grant funding (CIHR, NSERC) and allow the Director to advise multiple graduate students.

OTHER IMPACTS ANTICIPATED

Ongoing research is anticipated to impact the following aspects in 2023-2024

1. cost and patient outcomes efficacy of simultaneous bilateral knee surgery (both knees in one operation),
2. modifications to operating room processes to increase the efficiency of surgery,
3. defining tangible benefits of robotic-assisted orthopaedic surgery,
4. determine how pre-operative gait can guide individualistic treatment to achieve optimal outcomes,
5. examine factors that influence whether to resurface the patella (knee cap) during knee replacement surgery,
6. scrutinize the delivery of care between different patient groups within our region and how this is reflected across Canada.

IMPACT ON OTHER DISCIPLINES: ON SOCIETY BEYOND SCIENCE AND TECHNOLOGY

The investment in research at Concordia demonstrates to the public, especially patients awaiting hip and knee surgery, that they are valued and that our practitioners within our imperfect medical system are stubbornly continuing to advance the quality of their care.

Surgical backlog

While the surgical backlog is on the minds of many, including politicians and decision-makers, this grassroots investment

in research may influence future funding decisions and government priorities toward elevating public health.

Jobs Creation

Two new jobs were created: Clinical Research Clerk (Sep 2022), and Director of Clinical Research (Nov 2022).

Other lessons learned and the value added to aid in fighting COVID-19

The Covid-19 pandemic delayed several aspects of this project through restrictions on future research, the stoppage of elective surgeries, and the challenges of collaborating while working from home or socially distanced.

Throughout the pandemic, our team worked hard to continue future research as much as was feasible, and when facing restrictions, the team pivoted to retrospective research and writing of publications.

Our researchers demonstrated a 'can-do' spirit and inherent value of research during times of need during the height of the pandemic.

During the pandemic's 2nd wave (Nov 2020 – Feb 2021), all orthopedic surgeries were halted, and arthroplasty research was at a standstill.

A local company (Precision ADM) had pivoted to manufacture nasal swabs for Covid-19 testing which was a critical product that was in short supply at the time. The company approached the research team to create a prospective, double-blinded, randomized controlled trial to determine if these locally-manufactured swabs were suitable for Covid-19 testing.

In a manner of weeks, the research team developed a study protocol, obtained all ethical and site-impact approvals at three Winnipeg hospitals, hired external research nurses, and struck an agreement with a local laboratory for PCR analysis. The study proceeded rapidly, with patient recruitment taking less than two months. The laboratory analyzed patient samples the next day, and the data was compiled and reported the same day. Many person-hours, early mornings and late nights went into the study as speed was essential.

The study demonstrated that the locally-made swabs were suitable for Covid-19 testing, which led to Health Canada approval and national distribution to backstop the supply chain of this critical product.

REVIEW:

Timeline from March 2020 to November 2022

FINANCIAL SUSTAINABILITY

The initial funding that established the Chair came from Research Manitoba with a grant of $200,000. Shortly after that a private donor established a personal campaign for the Chair in memory of a family member who had benefited from hip replacement surgery. The Fund continued to grow with two other donors who wished to remain anonymous who made a total of four more gifts that equaled $450,000. The community of former patients, physicians, staff and other people have shown their support through their donations, volunteerism and good will has continue to grow.

RESUMPTION OF RESEARCH ACTIVITIES:

During the pandemic we were hampered in pursuing a lot of our research with a view that by early 2022, with all restrictions on research removed during the spring and summer of 2022, we could resume where we left off in 2020.

APPOINTMENT OF DIRECTOR OF CLINICAL RESEARCH

Appointment of Dr. Chrisiann Righolt to the Director of Clinical Research as of November 21, 2022 after a yearlong national search to fill this pivotal position.

ENGAGE MEDICAL WRITERS

Two medical writers have been identified and will be engaged in the coming months to accelerate the publication of completed studies.

Conclusion

The goal of orthopedic research at Concordia is to continue pushing the boundaries of how medicine improves the lives of people suffering from joint pain, poor function, and limited mobility.

The research we conduct helps us to meet the growing needs of our patients while invigorating the community, growing Manitoba's economy, and advancing orthopedic care on a global scale.

Without a doubt this is a key program at Concordia which is groundbreaking and innovative and has the support and credibility of people from around the world and in our own backyard.

Canada has build an enviable reputation as a leading science-and-technology-development nation with major public investments. We intend to forge a path forward to continue the work that was started over 10 years ago by Dr. Tom Turgeon and others on the team and create the Concordia Centre of Excellence.

FOR MORE INFORMATION:

Thomas Turgeon,
BSc MD MPH FRCSC FAAOS

Orthopaedic Surgeon- Adult Reconstruction

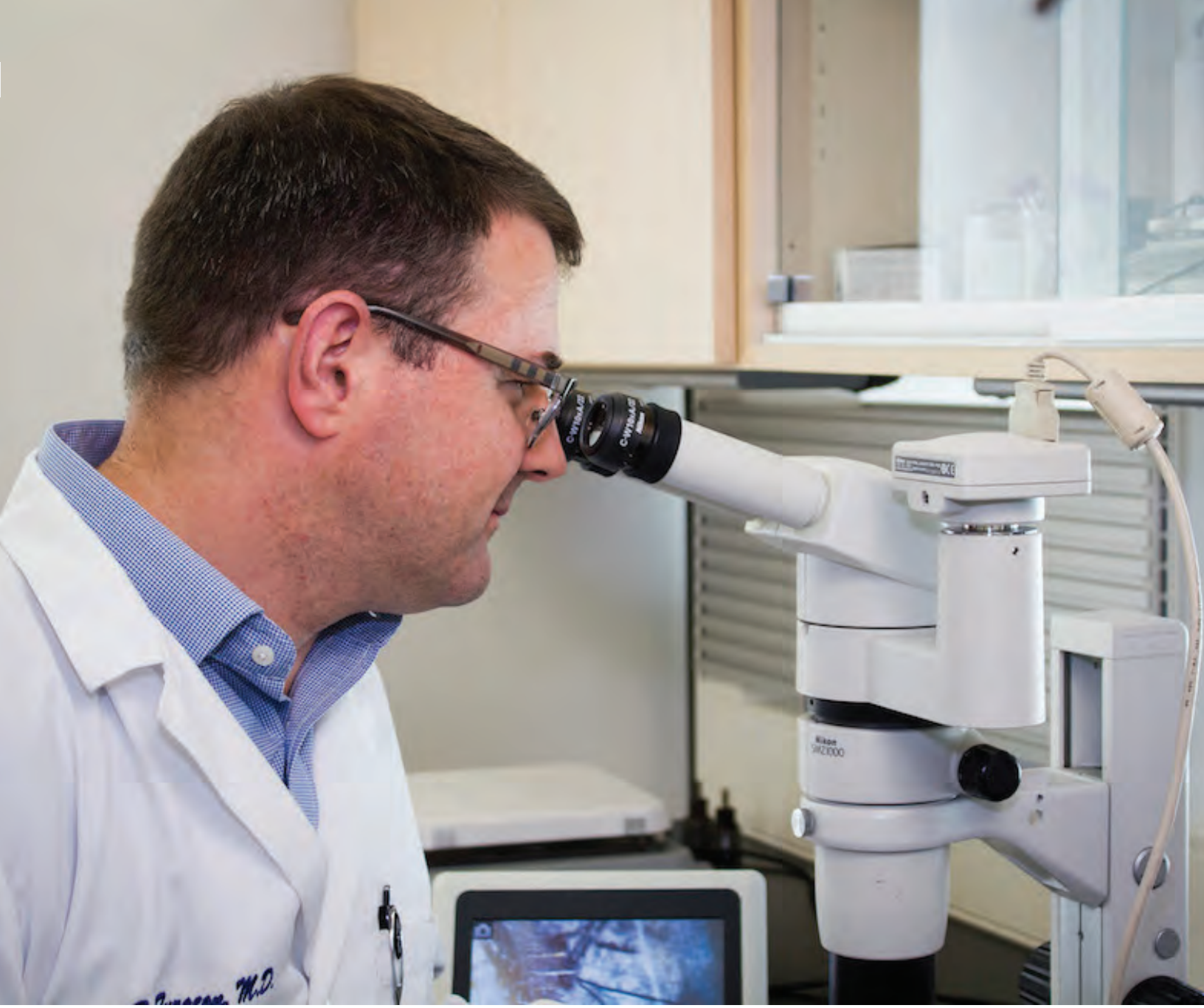
Arthroplasty Research Chair, Concordia Foundation

Director of Arthroplasty Research, Concordia Hip and Knee Institute

Fellowship Director for Hip and Knee Arthroplasty, Concordia Joint Replacement Group

Associate Professor, University of Manitoba

Site Head of Surgery, Concordia General Hospital



Concordia's Research Legacy

Our Orthopaedic Research program began in 2003 and has thrived over the past 16 years, achieving many meaningful goals and milestones. Thanks to donations from our community, we constructed the Hip and Knee Institute in 2009 to house our world-class research program, creating a centre of capability and expertise that is unmatched elsewhere in the world. Over the past 16 years, our research has stretched from the benchtop to the bedside and beyond.

On the benchtop, our engineering staff and machines have evaluated dozens of joint replacement devices for quality and safety before being used in the clinic. At the bedside, our clinical staff and systems have monitored patient well-being and joint replacement success through innovative, proven means.

Chasing what's next, our scientific staff and equipment have assessed joint replacement failures, pinpointing the root cause for future devices to learn from and avoid.

The Concordia Hip and Knee Institute and the Orthopedic Research program were built by Manitobans to be like no other.

Future Research

The focus of the Research Chair will be to continue along these same pathways through the following projects:

- Impact, access to care, and key issues of joint replacement on our Indigenous population;
- Advancing identification, treatment of, and patient outcomes following a joint replacement related infection;
- Improving knee replacement function by comparing surgical techniques, exploring new devices and materials, and enhancing surgical precision through robotics;
- Reducing surgical waitlist and healthcare costs by furthering operating room efficiency, surgical techniques, and post-operative medications and monitoring;
- Ensuring the safety and effectiveness of new and novel joint replacement devices with high-precision assessment methods and innovative clinical research methods.

Concordia Arthroplasty Research Chair funds will be used for operating costs associated with the research projects outlined by the Chair's research directive. Such costs will include; research and engineering staff, project supplies and consumables, laboratory usage.

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