



# Journal of the pennsylvania osteopathic medical association

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Due to several unforseen issues, the printing of this issue of the JPOMA was delayed.

— Mark B. Abraham, DO, JD, JPOMA Editor









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# FROM THE EDITOR'S DESK

### Mark B. Abraham, DO, JD



Mark B. Abraham, DO, JD Editor-in-Chief

Before I begin my editorial, I would like to start off by congratulating Dr. Lisa A. Witherite-Rieg for being installed as President of POMA and Dr. Ernest R. Gelb, a Past President of POMA, for being installed as President of the AOA

And now...

The Comedy of Errors

I don't know about the rest of you, but nothing seems balanced. We (I) have gone through the various difficulties which we have all experienced over these last few years. For one, the burnout is still here. The refresh and recharge just hasn't happened. I know I'm not alone because of how many colleagues and others in the healthcare profession with whom I've spoken readily speak of it.

It's gotten to a point where we start to wonder what we are doing and why.

I reached out to some friends several months ago about picking up a new patient. Since I don't practice traditional family medicine anymore, I needed someone to help a family friend in need of a new PCP. There were a lot of issues surrounding the patient and her family's needs.

One friend told me she couldn't take on any more patients, but then told me she would reach out to a colleague for whom she had taken over care of some of that colleague's patients. My friend thought it would be under the auspices of the other doctor "owes her a favor." The problem there was that particular physician wasn't taking new patients at all. In fact, that physician was actively transferring patients to other PCPs. I already knew people who were turned away.

I worked my best charm (believe it or not, I can do that) but to no avail. My friend was too busy (she does a lot of advocacy work in addition to practicing medicine). The conversation turned to my burn out. She then told me how I wasn't "allowed" to stop practicing since too

many "good docs" were leaving the profession. Retirement or otherwise.

Ah, the irony. She didn't want to take on a patient who would need more help than she could provide; she spends a lot of time on advocacy work for the profession (which of course reduces her ability to have a larger patient load), and she then tells me that even if it might be in my best interest to stop practicing medicine, I wasn't allowed. I wasn't allowed.

I don't expect to stop practicing any time soon. But, there are days, many days, when it is more of an effort than I ever imagined.

Patients can't get in to see their PCPs and sometimes even their specialists. The kneejerk reaction is "go to urgent care." (N.B. to the PCPs and specialists. We don't have CT scans in urgent care. We don't do endoscopic procedures in urgent care. We don't titrate and adjust medications for chronic conditions.) Having to then explain to a patient that I can't do certain things because I'm not the PCP or specialist often goes down the path "but my doctor sent me here." Now, who is the bad guy? Of course, it's the person who is saying "no" and not the person who should be managing the case.

I'm not pouncing on PCP's and specialists. You are all worn thin as well. COVID took its toll in many ways. How many of us are having issues with not just having enough providers in our practices/hospitals/health systems but also struggling to find good support staff? It means the workload is increased on the staff we do have. It drives their burnout.

At times, all you can do is laugh lest you cry. A Comedy of Errors.

Even with all of that, there is some good news and sunlight at the end. We are lucky to have Drs. Witherite-Rieg and Gelb ready and able to guide our profession through these challenging times. Best wishes for successful and rewarding tenures.

## OUT OF MY MIND

### Samuel J. Garloff, DO, WGRP

### Not a Cough in a Carload!

WGRP here. I remember when the onset of Spring meant celebrating things such as May Day, April Fool's Day, Religious Holidays and of course baseball spring training followed by opening day! Of course there was also mention of a young's man fancy, but modesty prevents me from commenting further.

Today, all that pales in comparison to the celebration of White Coat Day. If you are old enough to think that gray hair, facial wrinkles and ambulatory assist devices make you look not only mature, but wise, you may find this disturbing. If memory serves me correctly, and it does, after we completed the first two years of school, we were given a plastic name tag, told where to report for our first clinical assignment and informed of the locations of uniform supply stores that sold short white coats. Dutifully, we left the auditorium, drove to the aforementioned supply stores, purchased a coat or two, took them to our apartment and washed and ironed them before reporting to our assignment the following Monday. Oh yes, we proudly pinned our name tag on. We then became student doctors!

Not anymore. Somewhere along the line, it was decided that taking classes and passing tests for two years was cause for celebration. It was also decided that never before in the history of medicine had student doctors passed tests! Hosanna! The small, insignificant task of education was then halted so medical schools could rent auditoriums, invite guest speakers, and of course have these incredible scholars gifted with white coats. Additionally, in Pennsylvania, stethoscopes previously used only by cardiologists, were gifted. It is the least that can be done for this remarkable achievement. Obviously, clinical education will now be relegated to simply another hurdle, obstacle if you will, slowing these scholars on their way to success. Of course, internships, residencies, possible fellowships, licensing and board exams will need to be completed, but they are of little importance in contrast to earning a white coat. It is rumored that after entering practice, many have their white coats bronzed and displayed in waiting rooms. Who can blame them?

The localities where these ceremonies take place are immensely grateful. Hotels, restaurants, and caterers all take part in congratulating these students. Audience members consisting of parents, spouses, other family members and friends are thrilled by the opportunity to

miss work, spend money and be regaled by speakers they will most likely never hear again. In fact many will skip graduation ceremonies entirely knowing that it is a secondary event to White Coat Day! Oh the humanity!

My spies inside the AOA tell me that they are secretly financing the production of "White Coat, The Musical", scheduled to premiere at the Winter Garden Theater in NYC. Negotiations are currently taking place with Spinal Pop and the Dysfunctions. The musical will also introduce the Dancing DOs to theatre audiences! Exciting times my friends. Remember, you read it here first.

[Unfortunately, rumors abound that the AMA is planning to undermine this production by incorporating it into their five year theater take over plan. Those inside the AOA who favor this collaboration assure me that we can separate anytime during the first five years without any lasting adverse effects. Remnants of a faded memory leave me with doubt. I wish I could remember details.]

Assuming success of the musical, it is rumored that Spielberg has expressed interest in producing, directing and bringing this incredibly important cultural phenomenon to the big screen. Me? I will wait until the director's cut will be available. Home theater viewing. No need to expose myself to an unwanted virus or two.

I know what you're thinking. Forget it. My agent has secured an exclusive deal with Hallmark for the sale and distribution of WCD greeting cards. The first printing will feature my copy-written poem, "Roses are Red, Violets are Blue, I have White Coat, Now, so do you!" This is going to be big people. I'm on the ground floor. Boy, oh boy! I suspect this venture will be inflation proof. More money to spend in my retirement!

White Coat Day, a day that will live in infamy! I mean a day that will live eternally, at least until "Half Way through Clinical Training Day" makes us all feel old...

Author's note: I hope you enjoyed reading this submission as much as I did writing it. Humor is a healing balm and self-deprecating humor can be rib-splitting. But, I wish to end on a serious note. This piece is submitted in loving memory of John Callahan, DO. John was POMA's gentleman president. He loved his family, his profession, his patients and his faith. John's kindness, wisdom and humor was refreshing and healing. He is missed.



Samuel J. Garloff, DO

# Lisa A. Witherite-Rieg, DO, Installed as 111th President of the POMA



Lisa A. Witherite-Rieg, DO POMA's 111th president

Lisa A. Witherite-Rieg, DO, FACOFP, was installed as POMA's 2022-2023 president on April 29, 2022 at the Valley Forge Casino Resort in King of Prussia, Pennsylvania. The installation was the culminating event of POMA's first statewide hybrid conference in over two years.

Dr. Witherite-Rieg has been a member of the association for 29 years. Prior to being elected president, Dr. Witherite-Rieg served as a trustee-at-large and chair of POMA's District 12, as well as chair of the Curriculum Committee and the Committee on Young Physicians-West Region. She also represents POMA as a delegate to the American Osteopathic Association House of Delegates.

Board-certified in family medicine and osteoapthic manipulative medicine, Dr. Witherite-Rieg recently retired as director of medical education and diretor of the family medicine residency program for Penn Highlands Healthcare in DuBois, Pennsylvania.

Dr. Witherite-Rieg is a graduate of Gannon University in Erie, Pennsylvania and a 1992 graduate of the Ohio University College of Osteopathic Medicine in Athens. She completed an osteopathic internship at the former Youngstown (Ohio) Osteopathic Hospital and a family medicine residency at Clarion (Pa.) Hospital. She is a fellow of the American College of Osteopathic Family Physicians

Transcripts of Dr. Witherite-Rieg's presidential speeches follows:

# Inaugural Address to Colleages at the POMA House of Delegates Meeting

It has certainly been a very interesting past two years. I am so happy to see you all here today. Despite a pandemic essentially shutting down the world, your Pennsylvania Osteopathic Medical Association under YOUR leadership has not only survived, but thrived.

Under Gene Battistella's calm direction, our governance activities did not miss a beat, advocacy for all DOs was effective and what could have been a catastrophic loss, proved to be a stimulus for ingenuity in creating exceptional educational opportunities.

When it was time to consider re-establishing human connection, Joe Zawisza (affectionately referred to as "JZ") encouraged POMA to be "on the move". Always taking into account individual and community safety and recommended CDC guidelines, we were able to emerge and begin our search for our "new normal".

"Hybrid" no longer refers only to vehicles and plants. "Social distancing" taught us creative ways to estimate six feet. Zoom meetings allowed greater participation, but often less engagement and we started really looking into each other's eyes but were deprived of the osteopathic hug.

I am more than grateful to say, "We're back." But, we have some real challenges.

The POMA advocates for ALL osteopathic physicians in the commonwealth, in areas like practice rights and integrity, over-regulation

by the General Assembly and over-burdening demands of insurance carriers, HOWEVER fewer than 50% of the licensed osteopathic physicians in the commonwealth are POMA members.

Our state is home to two colleges of osteopathic medicine with three campuses (with a third COM slated to matriculate students in 2024), but with the change in graduate medical education and licensure challenges, many of these graduates leave Pennsylvania after graduation.

This past year there were over 2,300 osteopathic training licenses issued in the state, but since June 2020, with the unified graduate medical education system, our ability to identify and access these residents is limited. Despite the cost of a resident membership being less than an evening out and benefits to residents far exceeding the value of the \$50 price-tag, fewer than 500 osteopathic resident physicians are POMA members.

So, what are we as a professional organization with the mission to promote the distinctive philosophy and practice of osteopathic medicine in Pennsylvania, for our members and their patients to do?

We DO what we DO best — we partner and work together. COLLABORATION is not just something we do — it's WHO WE ARE.

We have all heard the assertion:

"The whole is greater than the sum of its parts."

That accurately describes us — it describes the POMA and our capacity to BE MORE, to DO MORE.

For the next year I envision our efforts as an organization build on the FAMILY FOUNDATION outlined by Dr. Battistella in 2020 and continue ON THE MOVE as motivated this past year by JZ with the ideal of: COLLABORATION: TOGETHER WE CAN DO MORE.

So, what does that mean and what exactly can we do? How can we COLLABORATE?

We can collaborate FIRST with EACH OTHER—collaboration among members and among districts. Sharing ideas, joining our resources, serving in our districts to avoid burn out among members. One of the initiatives recommended by the Member Task Force commissioned in 2021 has a goal of strengthening POMA's presence in our districts. Let's use this to increase our visibility and reach out to prospective members to grow our membership—because together, we can DO more.

Let's collaborate with our COMs — to ensure our osteopathic medical students have the resources they need to successfully complete their studies, like access to learning tools such as Sketchy and scholarships for deserving applicants. Also, we must provide the quality mentorship that was provided to all of us during our journeys to leadership and practice. Paying it forward is very osteopathic.

To ensure our viability, we must collaborate with our osteopathic residents to guarantee that, despite the unified GME system, our osteopathic identity is preserved and maintained AND those young osteopathic physicians who wish to practice in the Commonwealth of Pennsylvania are not presented with unreasonable obstacles to obtaining and maintaining licensure. We need to critically evaluate our outreach to our osteopathic residents to assure we are reaching as many as possible and we are achieving a greater level of engagement. They need us to DO more.

We need to continue collaborating with our LAW MAKERS to make sure they have an accurate understanding and appreciation of who we are and what we DO — so, together with our elected representatives we can preserve our role in the care of and protection of our patients and arrest any attempt for expanded practice rights and misrepresentation of non-physicians.

We need to reinforce our collaboration efforts with the Pennsylvania Department of Health — so that when there is a public health concern, the POMA is of the first entities contacted for counsel, comment and, yes, collaboration to ensure Pennsylvanians have access to the best care possible. By actively contributing to the DOH's Healthy Pennsylvanians initia-

tive, we are recognized as stakeholders in the State of Our Health.

We need to communicate and collaborate with the State Board of Osteopathic Medicine to insure osteopathic physicians who seek initial and renewal of licensure to practice osteopathic medicine in the commonwealth are treated fairly, reasonably, consistently and promptly.

And, certainly not least, collaboration with our OUTSTANDING POMA TEAM!

This phenomenal group of professionals work tirelessly to ensure the POMA's success. By working in concert with our team, we can continue to provide valuable member services, quality publications, effective advocacy, and outstanding educational opportunities. Our employed staff not only work for us, they truly work WITH US. When the opportunity arises, ask them their opinions, ideas and visions. In collaboration with TEAM POMA we can continue building a strong physician-driven professional organization.

I thank you for your kind attention, your friendship and your willingness to lead this profession that has allowed each of us to become physicians.

# Inaugural Address to Attendees at the POMA Installation Gathering

Thank you for being here and being part of our FAMILY REUINION!

I am humbled and I consider myself very blessed to be installed as the 111th president of the Pennsylvania Osteopathic Medical Association.

Yesterday, I was able to address the House of Delegates and present the elected leaders of our fine, member-driven organization my vision for the upcoming year. I talked about working together with the theme: "Collaboration: Together We Can DO More!" That address will be published in an upcoming edition of the *Journal of the POMA*.

Tonight, I would like to briefly share some more personal comments.

Nearly 30 years ago two gentlemen introduced me to the importance of being involved in a professional organization. John Johnston, DO, the 67th president of the POMA, and, funfact, only other president from the AWARD WINNING District 12, introduced me to the then executive director of POMA, Mr. Lanni. I was starting my residency in Clarion, PA. As the only resident in a small rural hospital that was in jeopardy of closing its program, resources were slim. The POMA stepped up and helped. Today that same program is thriving, and the POMA is still supporting. I will forever be grateful to these two gentlemen.

I am proud to have practiced my entire career in the AWARD WINNING District 12.

Though the smallest of the districts, I have received much encouragement and support from the members. I want to thank and recognize all the members from the AWARD WINNING District 12 who traveled across the state to surprise me by being here. Thank you for working together for all we have accomplished. A special thanks to Rick Johnson, DO for his friendship, mentorship and service to the POMA as a trustee and vice speaker of the House of Delegates.

Nearly 20 years ago I met an amazing woman, a strong leader, soft but well spoken and visionary. She saw something in me that I did not see in myself. She mentored me and challenged me. She understood the barriers that being a woman in leadership may present at that time. She broke the barriers. I consider her my "POMA Godmother". Suzanne Kelley, DO, POMA's 89th president and my friend, you are truly remarkable. Thank you for being here and sharing this, and so many other notable moments in my life, with me.

In 2014 I received a call out of the blue from the 91st president of the POMA encouraging me to run for a position on the POMA Board of Trustees. This was not even on my radar. I was perfectly happy working with the POFPS board, minding my own business in the AWARD WINNING District 12 and baking cupcakes. Ernie Gelb, DO saw something in me I didn't see in myself. He continues to encourage and educate me. He is my "POMA Godfather". Barbara Jean did a good job with you. Thank you both for being with us tonight.

Let's all be like Suzanne and Ernie and genuinely look for qualities in people — things they cannot see in themselves — and help them develop and grow to reach their greatest potential.

For those that know me on a more personal level, the last seven years have been overwhelmingly challenging for my blood family. When you have the massive brood that we have, challenges are inevitable. I always said our Mom and Dad gave us our seven best friends. Take those eight kids, marry them off and you end up with 16 around the dinner table. Add in 25 offspring and who only knows how many in that next generation, something is bound to be happening. I am proud to introduce the members of what our hometown affectionately calls the "Witherite Nation" that are here this evening. Now I ask you to raise a glass to those who we cannot see here tonight.

Over these past seven years, my family has endured many devastating events: losses,

heartbreaks and significant grief. When the Witherite Nation was struggling, my POMA family stepped up and reached out to me to carry me through. For that I will always be grateful.

POMA looks a little different these days. Our physicians are a little younger, more diverse. We communicate a little differently: podcasts, apps, social media. The way we do education is a little different, more accessible and flexible. Our Team POMA is empowered and encouraged to use their skills to advance our initiatives and our association is truly member-driven. By working together, collaborating, we have accomplished much and we can DO more. During this assembly, your HOD has passed a resolution on Diversity, Equity and Inclusion — just another way we are "reaching out and stepping up" as an association. We continue to support our students and residents — they are our legacy. Some things will never change.

Our celebration tonight looks a little different than in the past. I have asked we put our black ties and sequinned dresses, and Mummers aside, join together in a more casual environment, and celebrate not an individual or a specific position or accomplishment, but, US, OUR POMA FAMILY.

For the past 2 years I have spent nearly two hours every other Tuesday night with two gentlemen who I love, respect, admire and am very grateful for their leadership and guidance. These are two of the most eventempered, composed gentlemen I have ever known. Despite the turbulent and rapidly changing environment and situations of the past two years, the POMA has not missed a beat as far as communications, education, advocacy, and member services. I attribute that to the leadership of Gene Battistella, DO and Joseph Zawisza, DO along with our outstanding Team POMA staff. Gene and Joe did not have the opportunity to celebrate with you as the incoming president have done in the past.

Please join me now in expressing our gratitude for their dedication to our profession. Make sure this evening, when you are mingling, you take the opportunity to connect with these guys. You won't be sorry.

Again, thank you for joining together this evening. Please take the time tonight to talk with someone you have never talked to before. Introduce yourself to someone you do not know. Collaboration starts with INCLUSION and culminates with ACCEPTANCE.

Together we can DO more!

# POMA Past President Ernest R. Gelb, DO Installed as 126th AOA President

On July 16, 2022, POMA past president Ernest R. Gelb, DO, FACOFP, was installed as the 126th president the American Osteopathic Association (AOA) during the AOA's annual business meeting in Chicago, Illinois.

Dr. Gelb has represented Pennsylvania as an AOA trustee since 2011. He currently serves on the Executive and Finance committees. He has chaired the Department of Affiliate Relations, Department of Government Affairs, Department of Professional Affairs, as well as the Ethics Committee, Board of Appeals Committee and Osteopathic Family Relief. He continues to actively serve as a POMA Delegate to the AOA House of Delegates.

During his inaugural address, Dr. Gelb shared his focus for his presidential year is on the "Three Hs: Honor, Humanity and Humor."

As a proud osteopathic physician, he encourages all DOs and osteopathic medical students to incorporate osteopathic principles and practices into patient care, regardless of medical specialty. He said, "We honor our profession by listening to understand, showing compassion, and treating our patients. To us, body, mind and spirit are one." He added that combatting inappropriate scope of practice expansions and confronting misinformation and inaccuracies about osteopathic medicine in the media are other ways to honor the profession.

Reflecting on humanity, he noted the great toll the COVID pandemic has taken on all physicians across the globe. He recalled, "Life-balance became a question rather than an action," and encouraged all osteopathic physicians and students to take care of themselves and recharge. He added, "We must allow ourselves the grace to regain our humanity to become better healers."

And finally, the third H: humor. Dr. Gelb is known for his love of humor. Medicine is serious, stressful and challenging. He said, "We must remember that laughter can sometimes be the best medicine. Our patients need our smile and compassion, and we need to share our smile and compassion with each other."

Following Pennsylvania tradition, the Mummers kicked off the inaugural reception with cheese steaks and pierogies being served in honor of the Keystone State.

Board certified in family medicine with a certificate of added qualification in geriatrics, Dr. Gelb is a graduate of King's College in Wilkes-Barre, Pennsylvania and a 1978 graduate of PCOM. He completed his postgraduate training at Botsford General Hospital in Farmington Hills, Michigan. He served in the United States Public Health Service from 1979 to 1981.

Dr. Gelb served as medical director of the Sullivan County Medi-

cal Center in Laporte, Pennsylvania, and an assistant professor of family medicine at the Philadelphia College of Osteopathic Medicine (PCOM). He also served as core faculty for the Tidelands Health MUSC Family Medicine Residency Program in South Carolina.

In addition to serving as the 2002-2003 POMA president, Dr. Gelb also served as treasurer of the Pennsylvania Osteopathic Family Physicians Society from 2000-2018, and four years prior as a trustee.

He has received numerous awards of distinction over his illustrious career. He was named a fellow of the ACOFP in 2001 and received the POMA Distinguished Service Award in 2007. The POFPS honored him as Family Physician of the Year in 2010 and presented him the Raymond J. Saloom, DO, FACGP Memorial Award in 2000 in recognition of his untiring efforts to promote and preserve the integrity of the osteopathic profession.

Dr. Gelb currently resides in Lewes, Delaware with his wife, Barbara and their springer-doodle, Maggie Mae. They have four children and six grandchildren.

POMA is proud to support Dr. Gelb and wishes him a successful and rewarding tenure as AOA president.



Ernest R. Gelb, DO AOA's 126th President

Fall 2022 / 9

# LECOM DEAN'S CORNER

# Lake Erie College of Osteopathic Medicine

### LECOM Leadership — An Enduring Mission



Silvia M. Ferretti, DO LECOM Provost, Vice President and Dean of Academic Affairs

"A ship in the harbor is safe, but that is not the purpose of a ship."

~Winston Churchill

In serving for a higher good, the mission is the roadmap to success. That enduring mission is rooted in an unshakable commitment to leadership.

When the Board of Trustees of Millcreek Community Hospital founded the Lake Erie College of Osteopathic Medicine (LECOM) in the early 1990s, it became the 16th college of osteopathic medicine in the nation. Since that time, the determined efforts of faculty, staff, and students alike have propelled LECOM to its place as the largest educational institution of its kind.

LECOM educates osteopathic physicians and pharmacists to practice medicine upon a higher level, embodying the credo not for ourselves, but for others. It inculcates the values of inclusive leadership excellence — not solely in educational training, but in community service and through awareness of the human condition. Not only is LECOM a leader in education, but the College and Millcreek Community Health System are partners in providing for the health care needs of the Erie community. LECOM has demonstrated an unwavering and resolute commitment to all of the communities in which it has come to lay its cornerstone.

Noting the first rate medical, pharmacy, and dental schools providing educational training in Erie and Greensburg, Pennsylvania and in Bradenton, Florida and Elmira, New York — the tremendous growth of LECOM is one of the top entrepreneurial success stories in the nation.

To what can we attribute this success? In a word — Leadership. Thus, as an essential principle of the calling of medicine, this POMA segment highlights this key attribute.

Leadership consists of many characteristics: integrity, self-discipline, purpose, preparedness, common-sense, adaptability, and compassion to name a few. Leaders are not born;

they are made — through hard work, through sacrifice, through determination. LECOM students have led the way in medical treatment and care to the suffering in the tattered villages of Haiti and Jamaica, and in the shadows of the inner-cities right here in the United States.

LECOM stands stalwartly in the vanguard of promoting wellness for the communities that it touches.

The principle of leadership has brought LECOM to generously support organizations such as clinics to treat the homeless in Florida and countless outreach programs that work in the areas of health and wellness across the four campus locations. The LECOM Dental clinic proudly serves indigent groups across the spectrum of humanity.

Through the joint leadership of staff and students, the annual LECOM Auction Gala and Dinner raises significant sums annually to aid students in attending medical school. The leadership cycle continues as the students raise thousands of dollars each year by participating in the fundraising efforts of many health service organizations such as the Cancer, Alzheimer's, Heart, Diabetes, and other associations. Leadership is taught by example, a tenet honed by the LECOM President. Leadership begets leadership.

Performance has long been the key to successful leadership as students, faculty, and LECOM physicians bear out a community service-focus that directs the footsteps of the LECOM progeny.

People who allow events and circumstances to dictate their lives are not leaders — rather, they live reactively. LECOM is proud of its faculty, staff, and students who lead and who live actively. Leaders inspire others to grow in responsibility and in skills — learning limits by exceeding them and by adopting the concept of continuous improvement as a daily principle.

Leadership is not a one-day activity; rather it is a constant commitment to excellence — a habit and a daily practice.

(continued on page 22)

# PCOM DEAN'S CORNER

# Philadelphia College of Osteopathic Medicine

As we go about our day-to-day lives, the tendency to become caught up in the daily grind of our routines is an easy way to forget what makes us happy. We can quickly lose sight of the parts of life that bring us the most joy — the people and relationships, the daily interactions, the accomplishments — and it can take a conscious effort to remember to pause and celebrate the good things.

I recently spoke with my friend and 1995 Philadelphia College of Osteopathic Medicine alum Jeff Dunkelberger, DO, about the simple joys in life. As a family practice physician for the last 27 years, he has had the opportunity to experience many of our profession's most joyful moments. And as many of us know, one of the most rewarding aspects of our interactions with patients is the chance to form lasting bonds and meaningful relationships. As Jeff told me, "Nothing makes me more satisfied to be a family physician than the relationships I've formed with my patients. I've had, in some cases, four generations of one family come to me," he said. "To be part of their lives and help them to be healthy. It's the most rewarding thing I can think of as a physician."

The doctor/patient relationship is truly one of the most important connections, outside of family and friends, we may have in our lives. The trust and confidence our patients place in us and the honesty with which we must perform our jobs are borne out in the longstanding bonds that are created over the course of our careers. These are some of the rewards of every day that can easily be forgotten if we are not paying attention.

For Jeff, the many rewards of his career are only matched by the opportunity to see his son follow in his footsteps. Matthew Dunkelberger is a current DO student at PCOM and on his way to becoming the next osteopathic

physician in the family. "Having a son who has chosen to live the life of a physician means a lot to me," Jeff told me. "He saw growing up what it was like to help people and the fact that he saw that and wanted to continue in that tradition is a real source of pride for me."

In my many years as dean and provost at PCOM, I have had the unique and privileged opportunity to witness the rewards of many years of hard work and sacrifice our students must make to accomplish their goal of becoming physicians. Each year I have the honor of attending ceremonies recognizing the transition into (White Coat) and out of (Commencement) medical school. These events are incredibly joyful for the students and their families, of course, but also for the faculty, staff, and administrators who have helped them along the way. To experience these formal reminders of the good that can be found in life has been one of the most rewarding parts of my career in medicine and academia.

To be truly appreciated, however, the best moments in life must be accompanied by a certain degree of perspective. A recognition that everyone, every day, is confronting their own challenges and struggles to get where they want to be. As Jeff said to me, "When you are a physician, you realize that people are struggling or experiencing challenges beyond just health. It gives you a sense of perspective and you realize that we receive so many blessings doing the work that we do."

Taking inventory of the rewards of every-day life is not easy. It can take a level of introspection that, despite our best efforts, we are frequently too busy to accommodate. As I so often have to remind myself, I encourage you to take the time, to make the effort, to pause and celebrate all the good in life.



Kenneth J. Veit, DO PCOM Provost, Senior Vice President for Academic Affairs and Dean

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# A STUDENT'S VOICE — PCOM

### Erica Redman, PCOM OMS-III and Navkiran Kaur, PCOM OMS-III

Erica Redman, PCOM OMS-III



Navkiran Kaur, PCOM OMS-III

### **Growing Roses**

When we anticipate the good things, we often look forward into our futures and imagine graduations, the start of clinical rotations, the beginning of new journeys. However, when we reflect on what makes our lives good — the very essence of what it means to be happy, of what makes us hope for continued moments of joy — we find ourselves looking backwards. As two third-year medical students, we have just begun our clinical rotations, a "good thing" we have been eagerly anticipating. We often find ourselves wishing we knew more, could do more, could help more when, honestly, sometimes we feel that the best we can do is try to stay out of the way. But in the small moments, when we can confidently and correctly answer a question from the resident or connect with a patient about their dog they miss dearly, it can help us reflect on how far we have come: from hoping for the acceptance to medical school to online lectures and "Zoom school" alone in our apartments to being a small part of a clinical team caring for real patients.

Looking back and reflecting in these moments is something that drives us forward. Stopping to smell the roses not only gives us a moment to pause and appreciate all the work that went into growing them, but it also compels us to grow more roses for us to enjoy in the future. These reflective moments are

a great motivator — the feeling of achievement that comes with them is what pushes us through the next step and drives us to continue achieving. These reflective moments do not just make you want to stop and smell the roses — they make you wonder why you haven't been cultivating your garden this whole time as opposed to worrying about getting stuck by the thorns (or in my case, encountering one of thousands of microorganisms that could kill you in your backyard — thanks a lot, microbiology).

Being able to celebrate the good things in our lives is often a culmination of appreciating the everyday, absolutely ordinary, subliminally mundane things we often take for granted. This can be a difficult thing especially as the profound weight of all that there is to check off our to-do lists waits for us at the beginning of each day. Nonetheless, it is vitally important to recognize all that we have accomplished and all that there is left to conquer. There is still a lot of learning to do — as there always will be — but the small moments of realization that we made it through the difficulties of the first two years of medical school are a reassuring reminder that we will make it through what is to come as well — and perhaps that is the most important lesson of all.

# ABOUT THE AUTHORS

Alec D. Grossman, DO, received the 2022 POMA Golden Quill Award for his manuscript, "Matrix-Induced Autologous Chondrocyte Implantation (MACI) is Largely Effective and Provides Significant Improvement in Patients with Symptomatic, Large Chondral Defects: A Systematic Review and Meta-analysis." Dr. Grossman is a third-year orthopaedic surgery resident at Millcreek Community Hospital in Erie, Pennsylvania. A 2020 graduate of the Lake Erie College of Osteopathic Medicine (LECOM), he completed his undergraduate studies in chemistry at The College of New Jersey in Ewing and completed his master's in health service administration from LECOM in 2022. A certified podiatric medical assistant, he is a member of the Pennsylvania Podiatric Medical Assistant Association and the American Society of Podiatric Medical Assistants.

Shahida Khatoon, DO, was awarded second place in the 2022 POMA Clinical Writing Contest for her article, "Retrospective Cross-Sectional Study of Rapid Stabilization on Acute Psychiatric Unit Using Risperidone and Fluoxetine Among Patients with Major Depressive Disorder." Dr. Khatoon is a fourth-year psychiatry resident at Millcreek Community Hospital in Erie, Pennsylvania. A 2019 graduate of the Lake Erie College of Osteopathic Medicine (LECOM), she completed her undergraduate studies in biological sciences and is enrolled in the master's in medical education program at LECOM.



Alec D. Grossman, DO



Shahida Khatoon, DO

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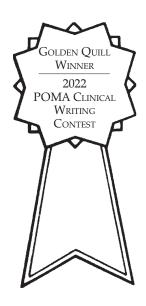


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# Medical Update

# Matrix-Induced Autologous Chondrocyte Implantation (MACI) is Largely Effective and Provides Significant Improvement in Patients with Symptomatic, Large Chondral Defects: A Systematic Review and Meta-analysis

by Alec D. Grossman, DO



### **Abstract**

**Purpose:** The purpose of our study is to perform a meta-analysis for long-term patient-reported outcome (PRO) measures using the Knee injury and Osteoarthritis Outcome Score (KOOS) model.

Materials and Methods: A literature search under the PubMed/Medline database was conducted. Statistical significance was determined between the mean pre- and post-operative scores at each time point (1-, 2-, and 5-years). Cohen's *d* analysis was used to measure the effect size (ES) in each group when compared to pre-operative measurements to determine clinical responsiveness.

**Results:** All subscales of mean KOOS at all long-term post-operative follow-ups measured in this study showed significant (p-value <.001) improvement when compared to pre-operative scores. Furthermore, apart from KOOS Sports and Recreation (KOOS-SR) at 1-year post-operative follow-up that showed a medium ES (ES, 0.761), all KOOS subscales at all long-term follow-up periods showed a large (>0.8) ES on mean pre-operative KOOS.

Conclusion: After an extensive literature review, no large meta-analyses for long-term PRO measures in MACI were found. It was found that all subscales were largely responsive when evaluated at >2 years after surgery. Based on these results, MACI is an effective treatment option for patients with symptomatic, full-thickness cartilage defects about the knee.

**Level of Evidence:** IV; Systematic Review of Level I-IV Studies

**Key Words:** Cartilage repair; Knee injury and Osteoarthritis Outcome Score (KOOS); Orthopaedics; Sports; Arthroscopy; Matrixinduced autologous chondrocyte implantation (MACI); Patient-reported outcomes; Knee

### Introduction

Surgical procedures for articular cartilage defects are a common practice in the United States with an increase in annual incidence by 5% each year.1 Magnetic Resonance Imaging (MRI) is useful for initial evaluation of articular cartilage defects, but arthroscopy remains the most accurate method for visualizing and classifying the pathology. This pathology is often defined using the Outerbridge classification; grade 1 is cartilage softening and swelling, grade 2 is fissuring less than 0.5 inch in diameter, grade 3 is fissuring greater than 0.5 inch in diameter, and grade four is fullthickness cartilage erosion down to bone.32 Previous arthroscopic studies have shown that up to 60% of the general public have evidence of chondral lesions in their knee. For those under the age of 50, up to 9% had high-grade (Outerbridge III or ÎV) cartilage defects.2 Among a more active population, such as athletes, the overall prevalence of full-thickness cartilage tears (Outerbridge IV) was 36%.3 Current surgical options for treatment of larger (>2 cm<sup>2</sup>) cartilage defects in the knee include osteochondral autograft transfer

and matrix-induced autologous chondrocyte implantation (MACI).<sup>4</sup>

Autologous chondrocyte implantation (ACI) was first introduced and described in 1994 by Brittberg et al.<sup>5</sup> This involved a two-part procedure requiring an arthroscopic assessment and cartilage biopsy from a non-weight bearing region of the injured knee. Healthy chondrocytes obtained were then amplified in a laboratory. A subsequent open surgery was performed, where cultured chondrocytes were injected into the defect and covered by a periosteal flap obtained from the proximal medial tibia and sutured into place.<sup>5-8</sup> While the first generation ACI had promising results, there were a few notable disadvantages. The periosteal flap that was harvested had to be sutured into place, causing damage to the surrounding healthy cartilage. Other concerns included the need for open surgery, the risk of uneven distribution of cartilage cells, and post-operative complications such as periosteal hypertrophy.<sup>6,8</sup>

Second generation ACI was then introduced to replace the autologous periosteal membrane with a bioabsorbable porcine collagen membrane.<sup>7-9</sup> Clinical outcomes between first and second generation ACI were similar, but there were fewer complications and lower risk of revision surgery with second generation ACI.<sup>9</sup> Unfortunately, this newer generation did not address the concern of an open surgical procedure and still involved suturing the membrane into place.

The concept for the third generation ACI (MACI) is to expand on ACI by better simulating the normal environment of chondrocytes in hyaline cartilage. Chondrocytes naturally live within an extracellular matrix surrounded by proteoglycans giving them tensile and compressive strength. MACI uses a specialized three-dimensional bilayer collagen scaffold matrix seeded with the chondrocytes that were amplified in the ACI technique. 10 Rather than using sutures to adhere the graft, MACI uses fibrin glue. This membrane conforms to oddly shaped defects more efficiently. The scaffold matrix, embedded with chondrocytes, allows better distribution of these cells throughout the defect. Furthermore, MACI can be performed all arthroscopically, reducing infection rates and other risks that come with an open surgical procedure. All of these adjustments have made MACI a safer and more effective version of ACI.9

MACI has been approved by the United States Food and Drug Administration (USFDA or FDA) since December of 2016 for the repair of single and multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults. <sup>11</sup> Prior to authorization in the United States, MACI had been primarily indicated in patients with

a symptomatic and high-grade Outerbridge III or IV cartilage defect (ranging from 2 to 10 cm²) in the knee that did not have significant osteoarthritis. Those with non-focal, diffuse wear of the joint had poorer outcomes. Most studies have candidates between the ages of 15 to 65, but the status of the articular cartilage is the ultimate criteria to exclude potential MACI candidates.<sup>12</sup>

The purpose of this study is to perform a meta-analysis of long-term patient reported outcome (PRO) measures using the Knee injury and Osteoarthritis Outcome Score (KOOS) model. PRO measures have been well documented to be a reliable part of measuring patient satisfaction and procedural effectiveness. However, despite there being multiple papers published describing PROs for MACI, there are currently no large-scale meta-analyses reviewing the long-term clinical effectiveness of MACI with a specific PRO system. It is also hoped that this will help standardize the KOOS model as the PRO system of choice for future MACI studies.

### **Materials & Methods**

### Literature Search

Published studies were searched for under the PubMed/Medline database. Various combinations in the search were performed including the following search terms: "Matrix-induced autologous chondrocyte implantation", "MACI", "Patient reported outcomes", "Knee injury and osteoarthritis outcome score", and "KOOS".

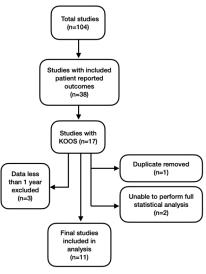
### **Study Selection**

All articles published before 2010 were excluded, as that was 10 years prior to when the literature search was conducted. Only papers written in the English language were evaluated. 104 published studies of interest

were identified. Inclusion criteria were studies investigating long-term patient reported outcomes in matrix-induced autologous chondrocyte implantation using the KOOS system. After literature review, 11 total studies met the defined inclusion criteria as seen in Figure 1.

### **Clinical Outcome Measures**

The Knee injury and Osteoarthritis Outcome Score (KOOS) is a 42-item questionnaire that is divided into 5 subscales. These include pain, disease-specific symptoms, activities of daily living (ADL), Sport and Recreation Function (SR), and knee-related Quality of Life (QOL). Each subscale has a varying number of associated questions, resulting in a total score that ranges from 0 (poor) to 100 (excellent). Unlike most patient reported outcome (PRO) models that combine all sur-



**Figure 1:** Flow chart illustrating the process for study selection\*

\*KOOS, Knee injury and Osteoarthritis Outcome Score.

Summary of MACI Studies Characteristics and Associated Mean KOOS Evaluated*								
Studies	Year Follow- up	Number of Patients	Pam	Symptoms	Activities of Daily Living	Sports and Recreation (Function)	Knee Quality of Life	
Ebert et al. 201014	Pre-operative	69	68.84	71.55	79.40	26.09	33.33	
	1-Year	69	82.57	82.14	90.44	43.17	50.21	
	2-Year	69	84.33	85.45	91.56	58.09	59.17	
Ebert et al. 2011 <sup>15</sup>	Pre-operative	41	57.55	58.75	65.66	20.80	25.13	
	1-Year	41	80.69	84.48	88.58	32.10	50.02	
	2-Year	41	80.50	86.56	88.35	51.90	55.41	
	5-Year	41	83.88	83.60	87.98	57.44	61.52	
Ebert et al. 201216	Pre-operative	20	58.06	59.46	73.24	27.88	24.86	
	1-Year	20	80.07	85.30	89.67	51.05	51.97	
	2-Year	20	86.81	85.94	94.61	67.19	56.25	
Ebert et al. 2013 <sup>17</sup>	Pre-operative	104	63.90	66.40	74.20	23.80	29.30	
	5-Year	104	85.00	84.50	91.80	63.10	58.50	
Edwards et al. 2014 <sup>18</sup>	Pre-operative	41	62.83	64.29	77,38	32.56	31.50	
	1-Year	41	84.49	87.04	93.02	56.73	59.29	
Ebert et al. 2014 <sup>19</sup>	Pre-operative	56	64.87	66.07	-	2	-	
	1-Year	56	83.43	83.73	-	-	-	
	2-Year	56	85.73	86.90	-	-	-	
	5-Year	56	84.33	85.90	-	-	-	
Ebert et al. 2015 <sup>20</sup>	Pre-operative	47	61.40	64.70	69.00	24.60	22.90	
	1-Year	47	79.20	82.90	86.00	32.60	45.40	
	2-Year	47	83.30	86.40	87.50	50.10	53.30	
Akgun et al. 2015 <sup>21</sup>	Pre-operative	7	67.46	67.46	63.24	35.71	37.50	
	1-Year	7	81.75	81.63	82.35	75.00	76.79	
	2-Year	7	82.54	83.67	83.61	77.86	80.36	
Brittberg et al. 20189	Pre-operative	65	37.10	48.40	43.60	15.40	19.90	
	2-Year	63	82.20	83.50	87.30	60.50	55.40	
	5-Year	65	82.20	80.90	86.40	61.90	59.80	
Ebert et al. 2019 <sup>22</sup>	Pre-operative	97	-	-	(#)	27.90	(+)	
	1-Year	97	-	-	-	52.10	-	
	2-Year	97	-	-	3.50	64.80	3 <del>5</del> 3	
	5-Year	97	-	-	-	70.40	15.1	
Ebert et al. 2020 <sup>23</sup>	Pre-operative	150	2	-	-	27.50	121	
	2-Year	150	2)	2	123	61.10	323	

**Table 1:** Summary of MACI Study Characteristics and Associated Mean KOOS Evaluated\* \*KOOS, Knee injury and Osteoarthritis Outcome Score.

Pre-operative, 1-, 2-, and 5-Year Postoperative Mean KOOS for MACI Studies Evaluated*											
Year Follow-up	Pain	Symptoms	Activities of Daily Living	Sports and Recreation (Function)	Knee Quality of Life						
Pre-operative (n=697)	60.22	63.01	68.21	26.22	28.05						
1-Year (n=378)	81.74	83.89	88.34	48.96	55.61						
2-Year (n=550)	83.63	85.49	88.82	61.44	59.98						
5-Year (n=363)	83.85	83.73	88.73	63.21	59.94						

**Table 2:** Pre-operative, 1-, 2-, and 5-Year Postoperative Mean KOOS for MACI Studies Evaluated

	Pain				Symptoms			ADL			SR				QOL					
Comparison	k	Mean	SE	95% CI	k	Mean	SE	95% CI	k	Mean	SE	95% CI	k	Mean	SE	95% CI	k	Mean	SE	95% CI
1-Year to Pre-operative	7	1.133	0.168	(0.802, 1.463)	7	1.237	0.202	(0.842, 1.632)	6	1.105	0.281	(0.555, 1.656)	7	0.761	0.204	(0.361, 1.162)	6	1.220	0.197	(0.834, 1.607)
2-Year to Pre-operative	7	1.780	0.330	(1.132, 2.427)	7	1.626	0.231	(1.172, 2.079)	6	1.701	0.405	(0.907, 2.496)	8	1.413	0.189	(1.043, 1.783)	6	1.602	0.213	(1.185, 2.020)
5-Year to Pre-operative	4	1.581	0.318	(0.958, 2.205)	4	1.320	0.181	(0.966, 1.674)	3	1.542	0.391	(0.776, 2.309)	4	1.539	0.159	(1.227, 1.850)	3	1.558	0.210	(1.147, 1.969)

**Table 3:** Statistical Analysis for MACI Studies Evaluated\*
\*ADL, Activities of Daily Living; SR, Sports and Recreation (also known as Function); QOL, Quality of Life; k, Number of studies; Mean, Mean of study effect sizes using a Cohen's d analysis; SE, Standard error of study effect sizes.

vey results as one overall score, the KOOS system was specifically designed to measure each subscale score separately.<sup>30</sup>

### **Data Analysis**

For statistical analysis, the statistical significance of the improvement in mean PRO scores at each postoperative time point (1-, 2-, and 5-years) from the mean pre-operative score in each subscale was first calculated. Any mean KOOS improvement with a p-value of <.05 would be considered significant enough to reject the null hypothesis. Cohen's *d* analysis was then used to determine what clinical effect this significance had on long-term patient outcomes when compared to pre-operative values in those undergoing MACI treatment. For Cohen's *d* effect size (ES) results, a value of <0.2 was classified as minimal to no effect, a range of 0.2-0.5 would be a small effect, 0.5-0.8 would be a medium effect, and >0.8 would be a large effect. These ES values were derived from Cohen's original terminology for his statistical analysis tool.<sup>13</sup> A random effects model was used for each meta-analysis performed.

### Results

Upon completion of our literature search, 11 studies <sup>9,14-23</sup> were included and underwent analysis. Table 1 presents the 11 studies with the associated mean KOOS subgroup values at each time period. Table 2 subsequently summarizes the pre-operative, 1-, 2-, and 5-year postoperative means for each KOOS category.

The number of studies used in each comparison, mean effect size (ES), standard error of the ES, and 95% confidence interval for the mean ES are given for each subscale comparison in Table 3 as shown below. Cohen's d measurements demonstrated that, apart from KOOS-SR at the 1-year post-operative followup (which showed a medium ES of 0.761), each PRO group at all other post-operative time periods recorded in this study showed a large mean ES compared to the pre-operative measurements. The analysis performed included a p-value for each mean effect size, and in all cases, the p-value was <.001. These results confirm our hypothesis that MACI provides significant improvement and is a largely effective treatment method for patients with symptomatic, large chondral defects.

### Discussion

The principal findings of this study are that patients undergoing MACI report largely significant improvements (p-value <.001) in pain, function, activities of daily living, quality of life, and other symptoms after undergoing treatment with MACI. Taking this a step further, the effect size (ES) of MACI was able to be quantified using the Cohen's *d* analysis tool. With one exception, the ES revealed that PRO scores measured at the 1-, 2-, and 5-year post-

operative time period after receiving MACI treatment had a large ES on the pre-operative mean PRO scores. The one exception was KOOS-SR at the 1-year mark, which showed a medium ES. Of note, KOOS-SR was found to have a large ES with subsequent years. Furthermore, the statistical analysis demonstrated that patients had continued benefit over their pre-operative status, and the grafts showed excellent longevity. Based on this information, MACI is a viable option for the treatment of large chondral defects and it is expected that its use will continue to become more popular in the United States. To date, it is believed that this is the largest meta-analysis of its kind.

MACI is a 2-step arthroscopic procedure that is particularly beneficial for large (>2 cm<sup>2</sup>) cartilage defects in the knee that are not associated with underlying arthritis. As of 2016, MACI was approved by the FDA to be used on adults in the United States. Due to this recent approval, there is very minimal long-term outcome data available in the United States. One limitation of MACI is that it has been far more expensive than its alternative, less effective treatment methods such as debridements/chondroplasties and other marrow stimulation techniques. A retrospective study in 2015 collected data from 2008 to 2010 to analyze total costs regarding the perioperative management of articular cartilage lesions in the United States. They found that the per-patient average charge for autologous chondrocyte implantation was \$16,016.70 whereas the per-patient average charge for microfracture was \$7,258.51.24

It is essential to establish a standardized patient-reported outcome measuring tool. PROs have been instrumental in determining patient satisfaction and the effectiveness of surgical procedures. Although objective data is necessary for assessing surgical techniques, subjective data recorded with PRO scores have been shown to be more important in the timing of the patient's return to sports and regular activity.<sup>25</sup>

Upon searching the literature, 13 variations of PRO scoring systems used for MACI were found. The KOOS model was the most documented instrument related to our topic of interest. The KOOS model was also found to be the most responsive and predictive for patient satisfaction in long-term assessments of MACI treatment.<sup>17</sup> Furthermore, in the pivotal European SUMMIT Trial, the investigators demonstrated superiority of MACI over microfracture, and they evaluated their data using KOOS.<sup>28</sup> This is a critical point because the FDA referenced this trial as supportive evidence for their approval of MACI in the United States. 11 It is reasonable to expect that this formative endorsement will lead other researchers to recognize these conclusions and begin recording MACI PRO measures using

the KOOS system. Additionally, KOOS has the potential to be a universal PRO model because it has been adapted for numerous cultures and languages.<sup>29</sup>

Secondary to approval of MACI on adults, the FDA recently agreed upon an initial pediatric study which began enrollment in October of 2018. The PEAK ("Pediatric Autologous cultured chondrocytes treatment of cartilage defects in the Knee") study is currently the only ongoing randomized control trial studying chondral and osteochondral defect treatment options in children and adolescents, ages 10-17. Similar to the European SUMMIT trial, the PEAK study will also use the KOOS model as their PRO tool.<sup>31</sup> After conclusion of the PEAK trial, further evaluation of the data obtained and assessment of outcomes as compared to the adult population need to be evaluated using the KOOS model.

### Limitations

Limitations to this study include being unable to obtain specific KOOS data for certain timelines from authors who plotted the results in their literature. This meta-analysis also had a relatively small number of studies (n=11) that reported long-term KOOS data. Due to recent USFDA approval, all long-term PRO data was collected in foreign countries. Given the relatively recent advent of the MACI procedure, patients in this analysis were only followed up to the 5-year mark; longer follow-ups might reveal further information that are not visualized with shorter follow-up time periods.

Demographic data from the studies selected was not recorded, so it is possible that there may be bias in the MACI cohorts. Although this procedure is indicated for those up to 65 years old, it is mostly performed in younger, healthier patients. Measuring patient satisfaction in this population comes with some inherent limitations that are difficult to account for; younger candidates are typically looking to get back to a full, active lifestyle as quickly as possible. Despite not being accounted for in previous studies, expectations can have an impact on outcomes and need to be considered. 17 Furthermore, this is a relatively expensive procedure that some insurance companies may not fully cover.<sup>26</sup> This may also come with increased limitations for the patients considering whether to undergo it or not.

### Conclusions

After extensive literature review, no large meta-analyses for long-term PRO measures in MACI were found. It was found that all subscales were largely responsive when evaluated at >2 years after surgery. Based on these results, MACI is an effective treatment option for patients with symptomatic, full-thickness cartilage defects about the knee.

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# Medical Update

# Retrospective Cross-Sectional Study of Rapid Stabilization on Acute Psychiatric Unit Using Risperidone and Fluoxetine Among Patients with Major Depressive Disorder

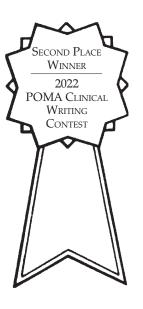
### **Abstract**

Major depressive disorder can be a very debilitating disease and often times challenging to treat effectively in an acute inpatient setting. The purpose of this study is to determine the efficacy of the combination of risperidone and fluoxetine in rapidly stabilizing patients with major depressive disorder in the acute inpatient psychiatric unit. Patients between the ages of 18 to 65 years who were admitted to Millcreek Community Hospital with the diagnosis of major depressive disorder, between the times frames of July 31, 2019 to July 31, 2020, were included in the study. The study was divided into the risperidone and fluoxetine combination group and the comparison group which consisted of all patients who were not tried on the risperidone and fluoxetine combination. A non-parametric t test was used to test whether a significant difference exists between the risperidone and fluoxetine combination group versus the comparison group in terms of average length of stay in the inpatient psychiatric unit. A p value of <0.05 was used to test for significance. The p value was 0.0424, concluding that a significant difference exists. A z-test was used to determine if there is a difference in the percentage of readmissions within 90 days between the risperidone and fluoxetine combination group versus the comparison group. An alpha of <0.05 was used to test for significance. The z score was 11.264 with a p value < 0.00001, thus it can be concluded that a significant difference exists. Based on the results, the combination of risperidone and fluoxetine appears to be effective for rapid mood stabilization among patients with major depressive disorder in the inpatient setting at Millcreek Community Hospital.

### **Introduction**

Major depressive disorder is a common psychiatric condition that negatively impacts one's mood and affects one's ability to function in everyday life. Depression affects roughly 7% of adults every year. There are many treatment modalities for major depressive disorder but antidepressants, psychotherapy (only used as mono therapy for mild to moderate cases), or a combination of both antidepressants and psychotherapy is recommended for acute cases of major depressive disorder with the aim of achieving remission and full return to baseline level of functioning.2 Although patients can see some benefits from antidepressants within a week of initiation, it usually requires a couple of months to see the full benefits.3 Unfortunately, 30-40% of patients with major depressive disorder who are treated with standard antidepressant therapy never achieve symptom resolution.4 Furthermore, only 50-60% of patients with major depressive disorder respond to antidepressants.5

Antipsychotics can be initiated together with antidepressants for major depressive disorder with psychotic features. Otherwise, antipsychotics are typically initiated for treatment resistant depression. Although risperidone is not FDA approved for treatment resistant depression, there have been several studies that have proven the efficacy of risperidone in treatment resistant depression.6 There are two studies that show the superior efficacy of risperidone augmentation to antidepressants in comparison to placebo in response and remission rate among those with treatment resistant depression.<sup>7,8</sup> There is one study showing the efficacy of risperidone augmentation to antidepressants to reduce suicidality among those with treatment resistant by Shahida Khatoon, DO



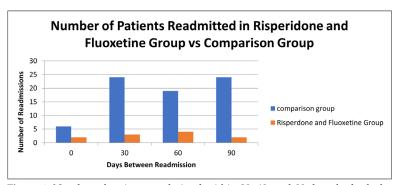
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depression.<sup>9</sup> There are two studies showing the efficacy of risperidone augmentation to antidepressants for maintenance therapy.<sup>4,10</sup> The possible mechanism of action by which risperidone augmentation treats depression is through receptor antagonism at 5-HT2A, alpha-2, and 5-HT7.<sup>6</sup>

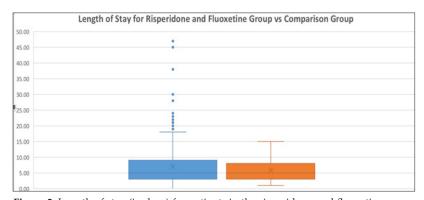
There is a clear benefit to using risperidone for treatment resistant depression, but there aren't any studies showing the combination of risperidone and antidepressants for rapid mood stabilization in the inpatient setting. Risperidone and fluoxetine is often used together to rapidly stabilize patients with major depressive disorder in the acute psychiatric unit at Millcreek Community Hospital. Since antidepressants take time to show an effective response, the theory is to speed up the process of mood stabilization by initiating risperidone along with the antidepressant. The purpose of

ICD 10 DIAGNOSIS	Fluoxetine and Risperidone Combination Group	Comparison Group
MAJOR DEPRESSV DISORDER, RECURRENT, SEVERE W PSYCHOTIC FEATURES	2	7
MAJOR DEPRESSIVE DISORDER, SINGLE EPISODE, UNSPECIFIED	36	198
MAJOR DEPRESSV DISORD, SINGLE EPSD, SEVERE W PSYCHOTIC FEATURES	7	26
MAJOR DEPRESSV DISORDER, RECURRENT SEVERE W/O PSYCH FEATURES	5	53
MAJOR DEPRESSIVE DISORDER, RECURRENT, UNSPECIFIED	5	21
MAJOR DEPRESSIVE DISORDER, RECURRENT, MODERATE	2	10
MAJOR DEPRESSIVE DISORDER, RECURRENT, MILD	0	1

Table 1. Number of patients in each ICD 10 Diagnosis for Major Depressive Disorder



**Figure 1.** Number of patients readmitted within 30, 60, and 90 days for both the risperidone and fluoxetine group (orange) and the comparison group (blue).



**Figure 2.** Length of stay (in days) for patients in the risperidone and fluoxetine group (orange) and comparison group (blue).

this study is to look retrospectively to measure the efficacy of this drug combination. The study will focus on adults 18-65 years of age who were admitted between July 31, 2019 and July 31, 2020 to Millcreek Community Hospital psychiatric unit. The efficacy of the drug combination will be tested based upon length of stay at the hospital and days until readmission (with 90 days being the cut off).

### Methods

This study identified adults between the ages of 18-65 years who were admitted to the inpatient psychiatric unit at Millcreek Community Hospital with the diagnosis of major depressive disorder between the time frames of July 31, 2019 to July 31, 2020. The diagnosis of major depressive disorder included ICD-10 codes F32.0 to F33.9 and had to be the primary diagnosis for inclusion into the study. Patients with prior admissions were excluded (meaning that this is their first admission to the psychiatric unit). The study was divided into two groups: risperidone and fluoxetine combination group and comparison group. The average dose of risperidone was 0.5mg twice a day and fluoxetine was 20mg daily. The comparison group contained all patients who were not tried on a combination of risperidone and fluoxetine for rapid mood stabilization. The two groups were compared by calculating the length of stay in the hospital for each patient and the days to readmission for each patient. The days to readmission were divided into 0,30,60, and 90 days with 90 days being the cutoff.

A non-parametric t test with alpha of < 0.05was used to test whether a significant difference exists between the risperidone and fluoxetine combination group and the comparison group in terms of average length of stay in the inpatient psychiatric unit at Millcreek Community Hospital. A z-test was used to determine if there is a difference in the percentage of readmissions within 90 days between the risperidone and fluoxetine combination group and the comparison group. A non-parametric t test with alpha of <0.05 was used to test whether a significant difference exists between the risperidone and fluoxetine combination group and the comparison group in terms of average day to readmission to Millcreek Community Hospital.

### Results

A total of 57 patients (29 females and 28 males) were included in the risperidone and fluoxetine combination group. A total of 316 patients (146 females and 170 males) were included in the comparison group. A box and whisker plot was used to compare the length of stay of the two groups. The average length of stay for the risperidone and fluoxetine com-

bination group was 5.82 with the shortest stay being 1 day and longest stay being 15 days. The average length of stay for the comparison group was 7.04 with the shortest stay being 0 days and longest stay being 47 days. A bar graph was used to compare the number of patients readmitted on days 0,30,60, and 90 days from date of discharge from the inpatient unit. Overall, 23.1% of patients in the comparison group were readmitted within 90 days versus 19.3% of patients in the risperidone and fluoxetine combination group. The average day to readmission in the comparison group was 42 whereas the average day to readmission in the risperidone and fluoxetine combination group was 31.

A non-parametric t test with alpha of <0.05 was used to test whether a significant difference exists between the risperidone and fluoxetine combination group versus the comparison group in terms of average length of stay in the inpatient psychiatric unit at Millcreek Community Hospital. The p value was 0.0424, thus it can be concluded that a significant difference exists between the risperidone and fluoxetine combination group versus the comparison group in terms of average length of stay in the hospital.

A z-test was used to determine if there is a difference in the percentage of readmissions within 90 days between the risperidone and fluoxetine combination group versus the comparison group. An alpha of <0.05 was used to test for significance. The z score was 11.264 with a p value <0.00001, thus it can be concluded that there is a significant difference between the risperidone and fluoxetine group in terms of the percentage of readmissions within 90 days.

A non-parametric t test with alpha of <0.05 was used to test whether a significant difference exists between the risperidone and fluoxetine combination group versus the comparison group in terms of average date for readmission to Millcreek Community Hospital. The p value was 0.200, thus the null hypothesis was accepted concluding that there is no difference between the two groups in terms of average date for readmission to the hospital.

### Discussion

Based on the results, it can be concluded that there is a significant difference between using the combination of risperidone and fluoxetine vs using other psychotropic medications for rapid mood stabilization among patients with major depressive disorder in the acute inpatient setting in terms of average length of stay and percentage of readmissions. The average length of stay for the risperidone and fluoxetine group was 5.82 vs comparison group being 7.05, indicating that the risperidone and fluoxetine group

required less days to reach stabilization than the comparison group. About 19.3% of patients in the risperidone and fluoxetine group were readmitted within 90 days of discharge from the acute inpatient setting versus 23.1% of patients in the comparison group indicating that less patients decompensated to the point of requiring readmission in the risperidone and fluoxetine group vs comparison group. The average day to readmission was 42 for the comparison group and 31 for the risperidone and fluoxetine group but the difference was not statistically significant as the p value was 0.200. The combination of risperidone and fluoxetine appears to be effective for rapid mood stabilization among patients with major depressive disorder in the inpatient setting at Millcreek Community Hospital. Further research on this drug combination in other psychiatric institutions will help solidify the findings of this study.

Future considerations: Unfortunately, medication records prior to hospitalization could not be obtained. This might be beneficial data for comparison purposes. There are also many different drug combinations in the comparison group. A post-hoc analysis might be beneficial to compare all the different drug combinations for significance.

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# MACI REVIEW & ANALYSIS (continued from page 18)

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# **LECOM DEAN** (continued from page 10)

Leadership requires adaptability. During the COVID pandemic, LECOM navigated the rules and regulations of three separate states. LECOM leadership facilitated the ability of the schools to remain open and for medical education to continue uninterrupted.

In this uncertain time of turmoil and economic strife, it is important to challenge oneself to lead all the days of one's life. Halfheartedness never won a battle.

The noble principle of leadership is the code of practice that each student finds honed through protracted hours of study and through tireless determination of singleminded purpose; the awareness that to be able to lead others, one often must be willing to go forward alone; the realization that leaders do not wait — they shape their own frontiers, seeing challenge as opportunity rather than impediment.

Recalling the humble beginnings of LECOM, as a once wistful idea that crossed the minds of a few dreamers as they envisaged the future, one can see that all who have accomplished purposeful victories have held a high aim, have fixed their gaze upon a goal which was towering, one which sometimes seemed impossible — for this is the code of leadership, this is the mission of LECOM, and this is the heart of LECOM scholars.

# CME Quiz

Name \_\_\_\_\_ AOA # \_\_\_\_

1. MACI is currently indicated for patients with symptomatic and high-grade Outerbridge III or IV cartilage defect.

a. True b. False

2. MACI is an effective treatment option for patients with symptomatic, full-thickness cartilage defects about the knee.

a. True b. False

3. Third generation MACI now uses suture to adhere the grafts rather than fibrin glue which was used in older generations.

a. True b. False

4. There is a significant difference between using the combination of risperidone and fluoxetine vs using other psychotropic medications for rapid mood stabilization among patients with major depressive disorder in the acute inpatient setting in terms of average length of stay and percentage of readmissions.

a. True b. False

5. There are many treatment modalities for depression but antidepressants, psychotherapy (only used as mono therapy for mild to moderate cases), or a combination of both antidepressants and psychotherapy is recommended for acute cases of depression with the aim of achieving remission and full return to baseline level of functioning.

a. True b. False

6. A non-parametric t test with alpha of < 0.05 was used to test whether a significant difference exists between the risperidone and fluoxetine combination group versus the comparison group in terms of average date for readmission to Millcreek Community Hospital. The p value was 0.200, thus the null hypothesis was accepted concluding that there is no difference between the two groups in terms of average date for readmission to the hospital.

a. True b. False

To apply for CME credit, answer the questions in this issue and return the completed page to the POMA Central Office, 1330 Eisenhower Boulevard, Harrisburg, PA 17111; fax (717) 939-7255; e-mail cme@poma.org. Upon receipt and a passing score of the quiz, we will process 0.5 Category 2-B AOA CME credits and record them in the POMA CME portal and forward them to the AOA.

Complete the CME quiz for this issue of the JPOMA online — www.poma.org/jpoma2022-2

### Answers to Last Issue's CME Quiz

1. d

2. False

3. d

4. True

5. True

6. True

(Questions appeared in the Spring 2022 Journal.)



### POMA District VIII 35th Annual Educational Winter Seminar Seven Springs Mountain Resort, Champion, PA January 26-29, 2023

24 hours of Category 1-A AOA CME Credits Anticipated and 24 AMA PRA Category 1<sup>™</sup> Credits Anticipated

POMA 115th Annual Clinical Assembly & Scientific Seminar Kalahari Resorts & Conventions, Pocono Manor, PA May 3-6, 2023

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