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MOFFITT MOMENTUM®

A HOPEFUL TUNE

Trumpeter turns
to clinical trial

TARGETING SOLID TUMORS

Cellular therapy
breakthroughs

PAIN INTO PURPOSE

Pushing through
treatment with exercise



Leadership Message



Patrick Hwu, MD
President and CEO

Dear Friends,

While much progress has been made since opening our doors in 1986, one thing remains the same: We are as committed as ever to the prevention and cure of cancer. As illustrated throughout this issue of Moffitt Momentum, our present and our future are marked by a bold determination to tackle cancer through every avenue possible.

World-renowned trumpet player and Moffitt patient Vincent DiMartino knows firsthand the importance of weighing all your options. Read about his journey and the clinical trial that drew him more than 800 miles from his hometown for treatment of a rare and aggressive form of skin cancer. Then use the camera on your smartphone to scan the QR code to hear him play his beloved instrument and watch him jam with Moffitt's band, The ReMissions.

Since 2015, Moffitt researchers have received more than \$26 million in grants to study tumor-infiltrating lymphocyte, or TIL, therapy. The therapy, which employs a patient's own immune cells to attack cancer, is bringing hope to those with solid tumors. That includes Misty Romine, whose metastatic cervical cancer was initially considered incurable but who is now cancer free.

Exercise may be the furthest thing from the mind of many patients who just received a cancer diagnosis. But researcher Nathan Parker, PhD, is working to understand the impact it can have on improving quality of life during and after treatment. His research focuses on the use of resistance or

strength training in patients with gastrointestinal cancers, and it includes personal training conducted virtually via video conferencing.

Donna and Duane Dunbar shared 65 years together before Donna was diagnosed with metastatic pancreatic cancer. After more than a year of treatment, Christine Sam, MD, had an open conversation with the couple about the realities of the road ahead. With an incurable cancer and limited time, Donna made the decision to spend her remaining months enjoying the people and activities she loved. Read the Dunbars' story and learn about an important initiative focused on aligning cancer care with a patient's personal values and goals.

Innovations in technology, therapies and surgical procedures hold the key to advancing cancer treatment. See how a multidisciplinary team of physicians at Moffitt is working in tandem to perform a delicate surgery to remove certain skull-base tumors. Unlike the traditional open craniotomy, this less-invasive procedure is done through the nasal cavity. The result, as experienced by patient Pedro González Escolá, is a speedier recovery and no external scarring.

We hope you enjoy reading the inspiring stories throughout this issue, which highlight our commitment to the patient experience, the expertise of our clinicians and researchers, advancements to improve outcomes and Moffitt's collective pursuit to save more lives from cancer.

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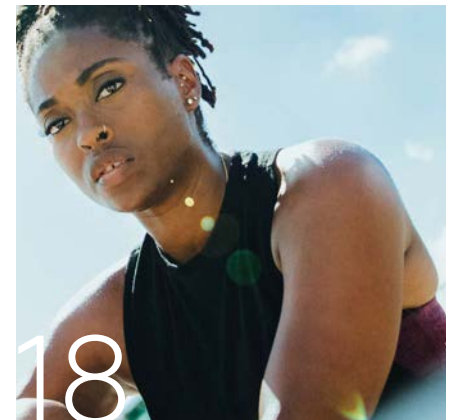
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World-renowned trumpet player Vincent DiMartino came to Moffitt Cancer Center to participate in a clinical trial for Merkel cell carcinoma.



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New Skin Cancer Treatments Hit the Right Notes

Diagnosed with Merkel cell carcinoma, world-renowned trumpet player Vincent DiMartino turned to a clinical trial

By Sara Bondell

Photos by Kevin Kirby

Vincent DiMartino takes a breath. He places his lips around his trumpet's mouthpiece, and in an instant his fingers are quickly moving the valves up and down while his other hand gracefully pumps the slide. The chaotic notes of "Flight of the Bumblebee" fill the room before he effortlessly transitions into a slower jazz song.

Nothing feels more natural than DiMartino playing his trumpet, so it's hard to believe the instrument wasn't always his first choice. But throughout his life, the trumpet has always found him.

When he was young, DiMartino's mother bought him a marimba, a percussion instrument made of wooden bars that are struck by mallets, at a garage sale. But it was too cumbersome for DiMartino to carry around. He wanted to play the drums instead, but his elementary school already had too many drummers. They suggested he try the trumpet.

DiMartino played the instrument for the next decade, but it didn't feel like his future. It was a great hobby, but he had his sights on becoming a dentist.

Then, when DiMartino was a 17-year-old exchange student in Bogotá, Colombia, he wandered into a jazz bar on the wrong side of town and played his trumpet with a local group. He made a deal: He would continue coming back to play if he could bring his 13 friends for some free food.

That summer changed DiMartino. His passion for music was reignited.

"When I went back home, I realized I had missed music," DiMartino said. "I told my mom I don't think I want to be a dentist, I want to be just like my high school band director."

"I told my mom I don't think I want to be a dentist, I want to be just like my high school band director."

VINCENT DiMARTINO
Cancer Survivor



This revelation led DiMartino to the Eastman School of Music in Rochester, New York. After graduating in 1970, he taught at the University of Kentucky for two decades and then at Centre College in Danville, Kentucky, until his retirement in 2012.

During that time, DiMartino built an extremely successful music career and became one of the country's most sought-after trumpet performers. He played alongside jazz greats Lionel Hampton and Clark Terry and backed up legendary singers Tony Bennett and Ella Fitzgerald. He was the first civilian to perform with the United States Marine Band, and he has appeared as a guest soloist with the Boston Pops and many symphony orchestras.

But in June 2021, DiMartino was diagnosed with a very rare and aggressive form of skin cancer. He knew he would need to take some time off from his trumpet during treatment, but would the instrument, like the times before, find him again?



Moffitt's reputation as a world leader in treating Merkel cell carcinoma is what drew DiMartino to travel 800 miles from his home in Kentucky.

MORE AGGRESSIVE THAN MELANOMA

Knee pain brought DiMartino to his doctor. His knee was swollen and it looked like half of a golf ball was implanted under his skin. His doctor sent him for imaging, and the results confirmed DiMartino had Merkel cell carcinoma.

"I had never heard of it before. I had heard of Angela Merkel," DiMartino joked. "But that was all."

Merkel cells are located deep in the top layer of the skin and are connected to nerves. Merkel cell carcinoma is a rare, aggressive form of skin cancer that has a high risk of recurring and spreading within a few years of diagnosis. According to the Skin Cancer Foundation, the disease is 40 times more rare than melanoma, with about 3,000 new cases diagnosed each year in the U.S.

After his diagnosis, DiMartino went to his local hospital in Kentucky, but the prognosis and treatment options presented were not encouraging.

"Merkel cell carcinoma is one of the more aggressive types of skin cancer that we deal with," said Andrew Brohl, MD, a medical oncologist at Moffitt Cancer Center who specializes in the disease. "People think about melanoma being the bad skin cancer, but stage for stage Merkel cell cancer is a more aggressive variety and more likely to grow quickly, progress and ultimately become a life-threatening condition for patients."

Historically, Merkel cell carcinoma has been hard to treat. For advanced cases, where the cancer has spread or metastasized, the prognosis was usually about a six-month life expectancy.

"We used to use chemotherapy, but it was mostly only mildly effective, almost never cured the patient once the cancer got to a late stage and only really slowed it down for a short period of time before the disease became resistant to the treatment," Brohl said.

However, things changed about five years ago when immunotherapies were introduced as a new treatment for Merkel cell carcinoma. Moffitt participated in the clinical trials that led to the U.S. Food and Drug Administration approval of Bavencio in 2017 and Keytruda in 2019 as first-line therapies for advanced or metastatic disease.

"Immunotherapies have been highly successful for Merkel cell cancer in many cases," Brohl said. "Some patients are achieving remissions that are long lasting, and it is now rare that we would try chemotherapy first."

"Immunotherapies have been highly successful for Merkel cell cancer in many cases."

- Dr. Andrew Brohl



In the past, the survival rate for advanced cases was almost zero. Now close to half of patients diagnosed with advanced disease are achieving remissions.

There are a few reasons Merkel cell carcinomas respond well to immunotherapy treatments. A significant percentage of them are caused by a virus that gets integrated into the genome of the cancer cell. Called Merkel cell polyomavirus, it doesn't cause a noticeable infection, but rather sets off a series of events within cells to stimulate cancer growth.

Merkel cell carcinomas that aren't caused by this virus are caused by ultraviolet damage to the skin. Similar to melanoma, the radiation damage upsets cell genomes and causes a lot of differences between a cancerous and normal cell. The more differences from a normal cell, the more opportunities there are for the immune system to react to it.

"Those differences sort of become targets for the immune system, and that's why we think this cancer is more of an immuno-responsive one – because of these either viral proteins and antigens that the immune system might recognize or because of the high burden of changes from chronic UV damage to the cell of origin, which causes possible targets for therapy from your immune system," Brohl said.

A 'GOOD THING'

The next step in Merkel cell cancer research is additional clinical trials to find possible combination therapies that can make treatments even more effective and to investigate if the treatments can be used earlier in the disease before the cancer spreads.

Moffitt is a world leader in Merkel cell carcinoma, treating a large population of patients with the disease due to its location and demographics compared with other cancer

centers. Moffitt treats roughly 150 to 200 new Merkel cell patients a year, and because of this large number the cancer center can successfully run investigator-initiated clinical trials or join a network of trials.

"Right now, I believe we have more active trials in Merkel cell than anywhere else in the world," Brohl said. "Internationally, there are less than 20 open Merkel cell carcinoma trials registered on the national clinical trials website, and at one point recently Moffitt had no less than six to seven open trials."

Moffitt's reputation in the field is what drew DiMartino to a cancer center more than 800 miles from his home in Kentucky. After his diagnosis, he went to teach for a week at the Interlochen Center for the Arts in Michigan while his wife began researching hospitals and treatment options. They would speak every night, and one night she told him about Moffitt's expertise and clinical trial options.

"I hoped that I would qualify for a trial because first of all, I am a teacher and a lifetime learner," DiMartino said. "I said, well, if I can help somebody learn more about this, no matter what happens to me, it's a good thing."

Deciding to get a second opinion at Moffitt turned out to be a very good thing for DiMartino. He qualified for a phase 2 trial investigating the combination treatment of two immunotherapy drugs, Opdivo and Yervoy, already approved to treat other cancers in patients with advanced disease. The trial also added radiation treatment to half of the participants, including DiMartino, chosen at random.

DiMartino and his wife relocated part time to Bradenton to be closer to the cancer center, and he is not the only trial participant to have had a robust response rate.

"I hoped that I would qualify for a trial because first of all, I am a teacher and a lifetime learner."



During his time at Moffitt, DiMartino connected with the cancer center's house band, The ReMissions, and was a guest player at one of their performances.

The trial's results, published in *The Lancet*, showed that 100% of patients who had not received previous immunotherapy – regardless of whether they received radiation therapy – responded to the treatment, with 41% achieving a complete response. Out of the 26 patients who had received prior immunotherapy, eight responded to the treatment, with four having a complete response.

“Since the results are so strong, they will most likely be practice changing even without a follow-up trial. But ideally this approach will be tested in larger numbers to confirm the exciting results we have seen so far,” Brohl said. “There is a good chance this will lead to a change in the National Comprehensive Cancer Network guidelines to suggest that this would be an option to consider for patients as an alternative to single agent therapy.”

Moffitt also has opened clinical trials investigating using additional combination therapies and different therapies prior to surgery for patients with resectable disease.

THE UNIVERSAL LANGUAGE

While DiMartino was at Moffitt for one of his appointments, someone noticed the picture of a trumpet on his face mask. They asked if he played. Word traveled fast and soon he was connected with The ReMissions, the Moffitt band led by President and CEO Patrick Hwu, MD.

“I never thought there would be a Moffitt band, let alone that I would be playing with them,” DiMartino said.

He was invited to a rehearsal and then guest played with the band at one of their performances.

“It was great,” DiMartino said. “Music is the universal language and you take people and put them together and they have this emotional connection of music.”

It's a connection DiMartino is happy to have found again after taking some time off due to his diagnosis. His calendar is once again filled with performances and teaching opportunities, like playing at the Governor's Ball for the Kentucky Derby and guest playing with the Sarasota Jazz Project and the Venice Symphony next season. He also volunteers to play the hymns at a church across from his Florida home and at a home for older adults in Sarasota.

“Just like all the doctors and employees at Moffitt do, you have to be an asset to your community,” DiMartino said. “This isn't a job, it's a life's work. You never get good enough and there's always more you can do where you live.”

He's lost a little bit of breath strength during his cancer treatment, but since he had built it up during his career, it hasn't greatly affected his trumpet playing. Looking back to his initial diagnosis, DiMartino says he never would have thought he would be where he is now: in Florida, at Moffitt, playing with The ReMissions and doing well on a clinical trial.

“It's important for people to take things a day at a time. Don't predict your outcome,” DiMartino said. But the one thing he probably could have predicted is that, like always, the trumpet would find him again so he can share his gift with the world.

Use the camera on your smartphone to scan this QR code and see videos of Vincent DiMartino playing his trumpet.



Infiltrating and Destroying SOLID TUMORS

Engineering a patient's immune cells to attack cancer offers new hope for solid tumor patients

By Sara Bondell | Photos by Nicholas J. Gould





MISTY ROMINE
Cancer Survivor

At age 36, Misty Romine was in so much pain she begged her doctor for a hysterectomy.

She had been diagnosed with HPV with cancerous cells the year before, but follow-up tests found no evidence of disease.

However, when she woke up from surgery, doctors confirmed what Romine already knew deep down: She had cervical cancer.

“It wasn’t that big of a surprise to me,” she said. “I just said, OK, what do we have to do now?”

Romine had both squamous cell carcinoma, the most common type of cervical cancer that develops from cells in the outer part of the cervix, and clear cell carcinoma, a very rare type of the disease that occurs in the lower genital tract. She underwent extensive chemotherapy and radiation treatment in Tallahassee, and while the squamous cell carcinoma went into remission, the clear cell carcinoma had spread to her abdomen and liver.

“They told me I had six months to a year left to live,” Romine said. “I told the doctor I know my body better than you, and I know that I am not going out that soon.”

Extensive research of comprehensive cancer centers across the country brought Romine to Moffitt Cancer Center and a first-of-its-kind trial involving tumor-infiltrating lymphocyte, or TIL, therapy. This approach harvests naturally occurring T cells that have already infiltrated a patient’s tumor, activates and expands them in a lab, then re-infuses those cells into the patient to seek out and destroy cancer.

“They told me I had six months to a year left to live.”

In August 2018, when Romine was enrolled in the trial, TIL had shown success only in melanoma trials and was not approved by the U.S. Food and Drug Administration (FDA) to treat cancer.

“I thought, what do I have to lose?” Romine said. “If it works for me, great. If it doesn’t, at least it will help someone in the future. If you don’t have participants in trials, you won’t find a cure for cancer.”

FIRST SUCCESSES

When the National Cancer Institute began studying TIL in the 1980s, it focused on melanoma because that is one of the most heavily mutated cancers and has the most targets an immune system can attack.

Historically, there hadn’t been many advancements in treatments for patients with advanced melanoma, and in about half of patients the disease ultimately became resistant to traditional therapies. However, the National Cancer Institute trials showed TIL could be a viable option for patients who fail first-line treatments.

In 2009, researchers from Moffitt visited the National Cancer Institute to learn the TIL protocol, and Moffitt became the first cancer center outside of the institute to offer TIL to melanoma patients. Led by surgical oncologist Amod Sarnaik, MD, a phase 2 clinical trial for patients whose advanced melanoma had not responded to other treatments reported a 38% response rate to TIL. The data is currently under review and Sarnaik is optimistic the treatment will soon be FDA approved.

“I am very blessed to be in a position to actually see the genesis of a treatment at our center, carrying it all the way to regulatory approval,” Sarnaik said. “It’s a rare thing and hard to imagine at the time, but patients we treated 12 years ago are still in durable remission from their, at the time, incurable metastatic melanoma.”

So far, Moffitt has treated about 80 melanoma patients on TIL trials, and once the treatment receives FDA approval, the cancer center estimates it will treat 50 to 60 patients annually to start. Sarnaik says the team is also continuing to investigate how to make TIL more successful for melanoma patients, including ways to speed up the cell manufacturing process, selecting more tumor-reactive TILs and combining TIL with other promising treatment options.

NOT ONE SIZE FITS ALL

As Moffitt clinicians and researchers began to see success with TIL in melanoma, they started to study the treatment in other solid tumor types. The biggest challenge with the therapy is that it’s not a one-size-fits-all treatment. Instead of recognizing a defined protein on a cancer cell, a TIL recognizes whatever that specific tumor is expressing. Even if patients have the same cancer type, their TIL product may not recognize the same thing.

“There are some really big outstanding questions, like what are the characteristics of a cell product that are the best? We still don’t know what we want our TIL product to look like,” said Shari Pilon-Thomas, PhD, an immunologist and co-director of Moffitt’s Center for Immunization and Infection Research in Cancer. “Another big question is how do we

measure it? What tests do we do on a TIL product that are the most meaningful and that are going to correlate with a patient response?”

Moffitt researchers have received more than \$26 million in grants to study TIL, and since 2015, they have launched 16 research projects focused on optimizing the cellular therapy.

One of those projects, partially supported by the Suzie Q Foundation and led by Pilon-Thomas and immunologist Daniel Abate-Daga, PhD, is focused on finding ways to stimulate TILs to grow more efficiently for lung cancer and melanoma patients. When a tumor is taken out of a patient, it contains the T cells that will be expanded in the lab for treatment, but also a mixture of other cells, including B cells, which specialize in producing antibodies.

“I told the doctor I know my body better than you, and I know that I am not going out that soon.”



Misty Romine came to Moffitt Cancer Center to participate in a first-of-its-kind trial involving tumor-infiltrating lymphocyte therapy.



“There are some really big outstanding questions, like what are the characteristics of a cell product that are the best?”

– Shari Pilon-Thomas, PhD

“Our work started with the question of whether we can capitalize on the presence of those other immune cells in the tumor to make TILs even better or facilitate the expansion of those TILs,” Abate-Daga said. “Can we indirectly stimulate T cells by directly stimulating the B cell compartment?”

Other research projects are trying to solve the puzzle of timing: when to harvest a patient’s T cells and when to infuse a patient with the TILs so the treatment has the greatest chance of working. Many solid tumor patients have already undergone extensive chemotherapy or radiation prior to TIL, which could damage their immune system and reduce their chances of responding to cellular therapy. Studies are underway to investigate whether TILs can be made from a frozen tumor specimen if immune cells can be collected prior to any treatment and banked for later if needed.

To continue this important research, partnering with pharmaceutical and biotechnology companies is key. This summer, Moffitt announced a new strategic alliance with Turnstone Biologics Corp., a clinical-stage biotechnology

company developing next-generation immunotherapies to treat solid tumors. Through this partnership, Moffitt will collaborate on the development of Turnstone’s pipeline of selected TILs for solid tumor indications, including melanoma, breast and colorectal cancers. The cancer center will also assist Turnstone with TIL manufacturing for upcoming clinical studies.

“It’s a win-win for both of us,” Pilon-Thomas said. “They get data and their trials up and running, and we get a lot of opportunity to do research that will benefit our patients.”

The new alliance’s first task is a Moffitt-sponsored phase 1 clinical trial evaluating a new TIL product in cutaneous and noncutaneous melanoma.

To help prioritize upcoming projects and other partnership opportunities, the TIL working group was established in early 2021. It comprises more than a dozen researchers and providers working in the field who share research ideas and decide which potential collaborations align closest with Moffitt’s goals.

“The industry has exploded – everyone wants to do cellular therapies right now,” Pilon-Thomas said. “We have resources that are limited and we can’t do everything, so the main focus of the group is to talk with the companies interested in partnering with Moffitt and determine where they fall on a list of who we want to move forward with.”

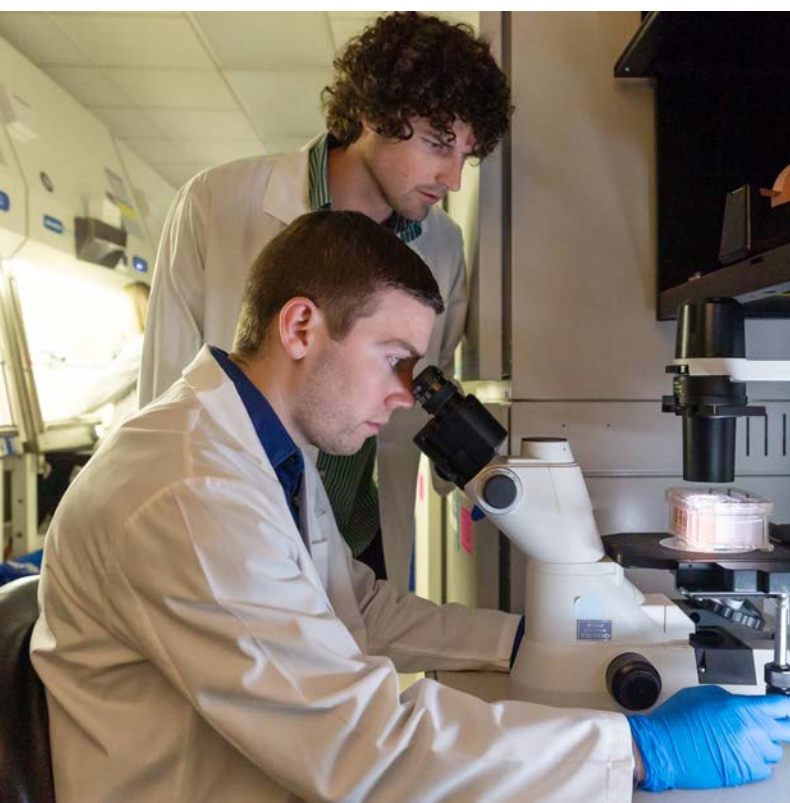
‘WINNING THE LOTTERY’

Since 2009, Moffitt has opened eight TIL clinical trials across multiple disease sites, with three more planned to open in the near future.

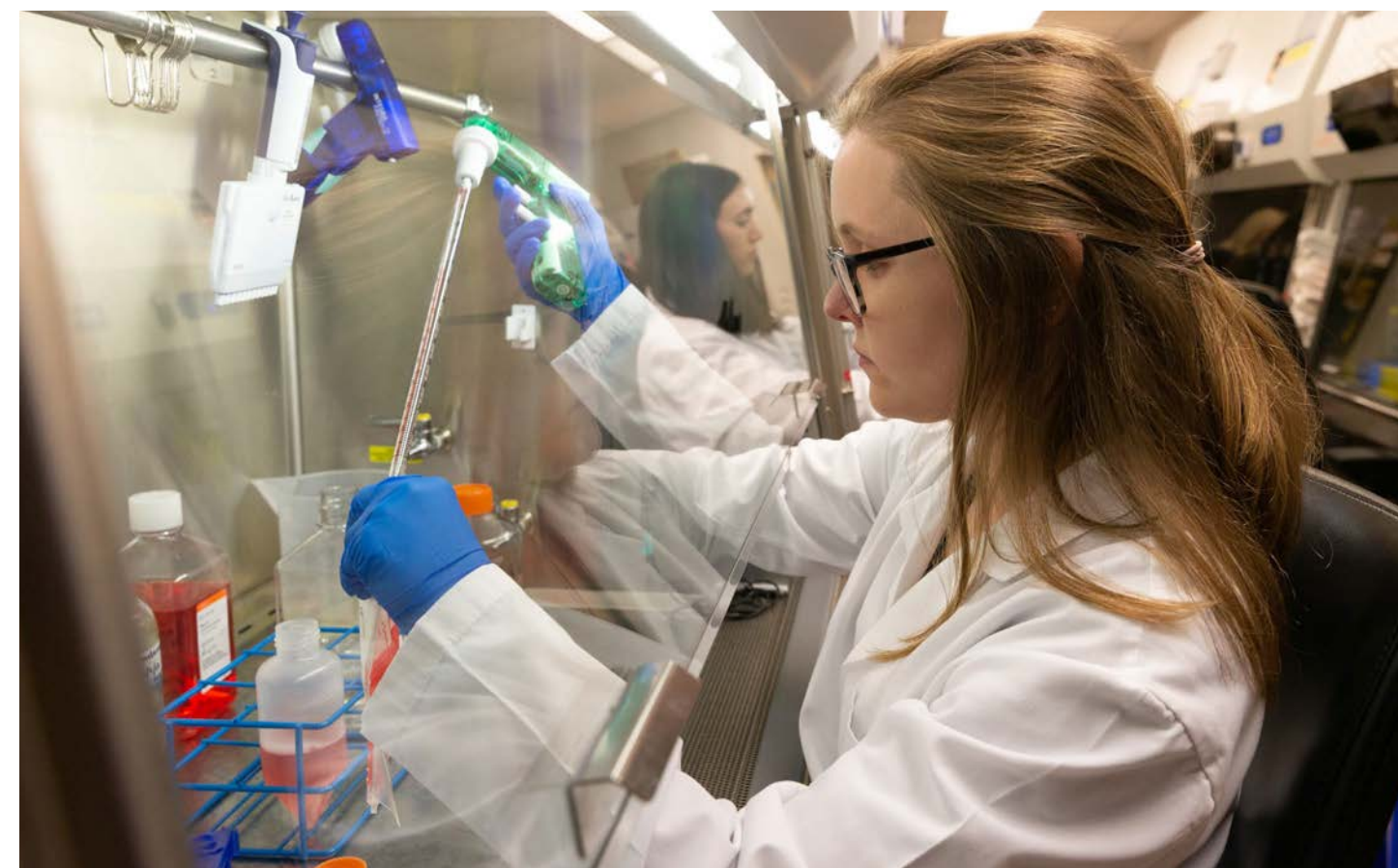
One of those trials is the cervical TIL trial that Misty Romine was part of. After receiving what she calls her “expiration date,” she was more than ready to give the experimental treatment a shot.

“I just knew that I wasn’t going to be gone in a year, I just knew it. I just know my body, and I knew I could keep fighting longer than that,” she said.

At Moffitt, Romine’s T cells were collected, expanded and, after a round of conditioning chemotherapy, reinfused back into her. The treatment came with some intense side effects, but three months later, Romine’s cancer had drastically decreased in size. Three months after that, her cancer was gone.



Researchers in Dr. Shari Pilon-Thomas’ lab at Moffitt are working to determine how to make TIL products more effective. Above, MacLean Hall, standing, and Pat Innamarato work in the lab in 2020.



Across Moffitt, researchers and clinicians are studying TIL as a treatment option for a wide range of solid tumors, including melanoma, cervical cancer, lung cancer and sarcoma. Above, Holly Branthoover in Dr. Pilon-Thomas’ lab in 2020.

“It was like winning the lottery,” Romine said.

While Romine was the only patient out of five on the Moffitt trial to achieve a complete response to the treatment, there were others who achieved partial response.

“Cervical cancer is incurable once the patient has metastatic disease. The median life expectancy from the most recent data we have is at best two years,” gynecologic oncologist and trial co-principal investigator Robert Wenham, MD, said. “The fact that we had a patient, who was heavily pre-treated for years before her infusion, have a complete response makes us think, hey, this is something. We have more details to figure out, such as how and why it works in some and not others and make changes, but it’s pretty exciting.”

One arm of the trial is still open for patients who have never had any other systematic treatment for metastatic cervical

cancer, and there are plans to reopen an arm for patients who have had prior treatment, particularly an immune checkpoint inhibitor.

The first-ever lung cancer TIL trial led by medical oncologist Ben Creelan, MD, has also seen success. Two of 16 advanced non-small cell lung cancer patients on the trial had a complete response after receiving the immunotherapy drug nivolumab prior to their TIL infusion.

Moffitt was also the first in the country to open a TIL trial in sarcoma for adolescent and young adult patients between ages 18 and 39 with metastatic sarcoma who have failed at least one other standard treatment therapy. While results are still pending, the team, led by surgical oncologist John Mullinax, MD, is also focusing on ways to optimize the treatment that patients receive on future trials.

“The fact that we had a patient, who was heavily pre-treated for years before her infusion, have a complete response makes us think, hey, this is something. ... It’s pretty exciting.”

– Robert Wenham, MD



Preclinical work is being done in multiple other solid tumor types, with the hopes of opening more novel trials in the future:

- **PENILE CANCER:** Only about 15% of patients with advanced disease will respond to chemotherapy, and almost half of patients will see disease progression. Early research shows TIL could be highly effective for patients who are HPV-positive or HPV-negative, and patients who have or have not received prior chemotherapy. The goal is to open a small pilot study combining TIL with immunotherapy for patients who are not good candidates for chemotherapy or who did not respond to chemotherapy.
- **BLADDER CANCER:** High-risk stage 1 bladder cancer tumors that fail first-line treatment have a less than 50% chance of responding to a second-line treatment or require surgical removal of the bladder. With funding from the Department of Defense, Moffitt has plans to open a clinical trial treating patients with intravesical TIL for Bacillus Calmette-Guerin-unresponsive bladder cancer. Instead of infusing the TILs back into a patient's bloodstream, the TILs will be directed into the bladder via a catheter, which eliminates the need for preconditioning chemotherapy. This will also be the first time TIL is being used in an early stage cancer instead of metastatic disease.
- **KIDNEY CANCER:** Even though there has been progress with immune therapies, about 90% of advanced stage patients will still relapse. With no other good treatments, researchers are hoping TIL could be an option in the future. Preclinical work is underway to investigate how to optimize TIL for those patients.
- **BREAST CANCER:** Triple-negative breast cancer is considered aggressive because it grows quickly, has usually spread by the time it is diagnosed, and is more likely to come back after treatment. As part of the Turnstone Alliance, Moffitt is planning on using the company's TIL technology in an upcoming trial to see if TIL can benefit these patients.

AHEAD OF THE GAME

There are a lot of pieces of the puzzle that need to be in place for a hospital to offer a cellular therapy like TIL to patients.

“You can’t just go anywhere and get put on a TIL trial,” Pilon-Thomas said. “You have to have open trials, even better if it’s an investigator-initiated trial. You also have to be able to manufacture the cells or be able to get them. We are ahead of the game.”

Moffitt’s Cell Therapies Core is one of only five labs across the country selected by the National Institutes of Health to do diverse cell therapy research. The 10,000-square-foot facility produces more than 700 cellular therapies a year, which can be given to Moffitt patients or cryopreserved and shipped to outside hospitals.

In 2020, Moffitt opened the Immune Cell Therapy (ICE-T) unit to treat patients with cellular immunotherapies like chimeric antigen receptor T-cell therapy (CAR T). The unit has 12 inpatient beds and eight treatment bays for outpatient visits, and while it is usually filled with blood cancer patients, solid tumor patients enrolled in cellular immunotherapy trials are also treated on the floor.



Veronica Mullen, RN, foreground, works with Ivan Ross, RN, to perform a chemo check in the Immune Cell Therapy unit at Moffitt. About a third of the trials done in the unit are for solid tumor patients.

“About a third of the cellular therapy trials we operate in ICE-T are for solid tumor patients,” said Frederick Locke, MD, vice chair of the Blood and Marrow Transplant and Cellular Immunotherapy Department and co-leader of the Immuno-Oncology Program. “The absolute number of patients we treat is lower, but as we get more trials and more FDA approvals we will be able to help more solid tumor patients.”



Moffitt’s Cell Therapies Core is one of only five labs selected by the National Institutes of Health to do diverse cell therapy research. The lab produces more than 700 cellular therapies a year.

The ICE-T unit is also open to solid tumor physicians for rounding, where they can get experience treating both solid tumor and blood cancer patients and learn more about cellular therapies. This, combined with the infrastructure and protocols already in place, will make it easy to ramp up cellular therapy treatment for solid tumor patients when the time comes.

“I think once you get one FDA approval the field explodes, just like in CAR T. One approval and all of the sudden, you are able to test the treatment in multiple tumor types in clinical trials,” Pilon-Thomas said.

Patient Misty Romine agrees: This is only the beginning.

“I don’t think a lot of patients even realize this is an option. I think TIL has a future in cancer treatments, and it’s so amazing to see them learning new things every day and making new discoveries every day.”

Romine is nearing the end of her five-year follow-up period and remains cancer free. She’s not

sure why she responded so well to TIL but is hoping other patients can find the same cure in the future.

“If there’s anything else I can do to help, I will,” she said. “I owe Moffitt my life.”



Expanding Targets for Cell Therapy

Thanks to the infrastructure in place for blood cancers, Moffitt is ready to expand CAR T-cell therapy to solid tumors

By Sara Bondell | Photo by Nicholas J. Gould

Chimeric antigen receptor T-cell therapy, or CAR T, involves collecting a patient's T cells and reengineering them in a lab to recognize and bind to specific proteins, or antigens, on the surface of cancer cells. When infused back into the body, the CAR T cells continue to multiply and, thanks to guidance from their receptors, seek out and destroy cancer cells that have the target antigen on their surface.



Ivan Ross, RN, checks in on patient Daniel Capuano as he receives CAR T in the Immune Cell Therapy unit at Moffitt.

SINCE 2017, SIX CAR T-CELL THERAPIES HAVE BEEN APPROVED by the U.S. Food and Drug Administration for blood cancers, including lymphoma, leukemia and multiple myeloma. However, when it comes to solid tumors, CAR T has been largely unsuccessful. It is difficult to identify antigens on the surface of solid tumors that aren't also on healthy cells, and solid tumors of the same cancer type can be very different from patient to patient. Other obstacles include physical barriers that prevent the CAR T cells from reaching a tumor and immune-suppressing molecules produced by a tumor that can cause CAR T cells to malfunction.



At right, colored scanning electron micrograph of a breast cancer cell (pink) being attacked by a chimeric antigen receptor T cell (yellow). Courtesy of Eye of Science.

At Moffitt, work is underway to address these challenges and identify new targets for solid tumors:

- Researchers have developed a chimeric antigen receptor that introduces follicle-stimulating hormone (FSH) into T cells. The new genetically modified CAR T cells seek out and destroy cancer cells expressing an FSH receptor protein that is found on a large number of ovarian cancer cells. A phase 1 trial, led by gynecologic oncologist Robert Wenham, MD, is now open to test the safety and efficacy of CAR T for ovarian cancer.
- While traditional CAR T uses alpha beta T cells, research led by Daniel Abate-Daga, PhD, is investigating the use of gamma delta T cells in CAR T for solid tumors, particularly prostate cancer that has spread to the bone. Bone metastasis is a frequent complication in advanced prostate cancer and remains incurable. In preclinical studies, gamma delta T cells were engineered to target prostate stem cell antigen, or PSCA, which is overexpressed on prostate cancers but rarely on healthy cells. Combining CAR T with bisphosphonates helped localize the treatment to the bone, which prevented unwanted toxicity, and ultimately resulted in tumor regression and extended survival.

“Gamma delta T cells are a less abundant type of T cell found in blood that have very different biological properties in terms of how they recognize a target cell and how they kill it,” Abate-Daga said. “We have been looking to leverage those specific biological properties in order to maximize the efficacy of the treatment for certain diseases.”
- Moffitt is also participating in a unique CAR T trial for multiple solid tumor types. The trial will start investigating the treatment in colon and pancreatic cancers and expand into lung and head and neck cancers in the future. The therapy uses a dual-signaling receptor to help overcome the major challenge of discriminating between healthy and cancer cells.

“One is a blocker, the other is an activator,” said medical oncologist Kedar Kirtane, MD, who is heading up the trial at Moffitt. “The blocker recognizes normal cells, so if you engage the blocker, you don't kill it. If the activator is engaged, you kill the cell. It's a unique way to avoid the pitfalls of killing normal tissue.”
- Researchers have identified a target protein called OR2H1, which is expressed in a variety of solid tumors, including lung and gastrointestinal cancers. Initial studies showed CAR T cells specific to the OR2H1 protein killed cancer cells that expressed the protein but had no effect on healthy cells. The goal is to open a phase 1 trial for patients with intrahepatic cholangiocarcinoma, which occurs in parts of the bile ducts within the liver, because OR2H1 is expressed in about 80% of those tumors.
- Moffitt is also one of only a handful of sites across the country participating in the first phase 1 CAR T trial for advanced kidney cancer. While the data is still being collected, early results look promising and next steps could include a phase 2 trial combining CAR T with another therapy or using it earlier in treatment.
- Other trials that are open or planned to open investigate the use of CAR T in gastrointestinal tumors such as gastric, pancreatic, biliary and colorectal cancers, as well as triple-negative breast cancer.

TURNING PAIN INTO PURPOSE

The science and stories behind how exercise can brighten cancer's darkest days

By Pat Carragher

Photos by Ray Reyes and Nicholas J. Gould

As Amanda Brunson approaches the track, the beating summer sun doesn't seem to faze her. It's July in Florida and it's already 85 degrees by 10 a.m. It doesn't matter.

"It brings back memories," she says.

Brunson, a born and raised Floridian, ran 13 years of competitive track. Going for a run in 88% humidity is nothing new for her.

As a group of football players prepares for the upcoming season on the track's infield, Brunson is running circles around them only breaking a minor sweat.

The run on this particular day is just for fun though. She places her hands down on the ground in a sprinter's pose. There are no starting blocks to work with so she uses her imagination. With 13 years of muscle memory on her side, her feet find their position. If you've ever spent five minutes with her, it would be easy to see that this is about as still as she gets. Once she starts moving there's no stopping her. On or off the track, she's constantly in motion. Walking, talking, moving, dancing. It's as if there's a constant soundtrack that she's swinging side to side to.

If there's anything that could slow her down, she's yet to see it.

Cancer tried twice.

Cancer failed twice.



AMANDA BRUNSON
Cancer Survivor



“I knew being in shape during treatment would help tremendously.”

“I was running track in college when one day my shoulder was really bothering me,” Brunson said. “I had chest and back spasms that took my breath away. I went to see a doctor, but I was told I was pushing too hard while working out and just needed to take it easy.”

Weeks later, the pain was getting worse. On top of that, she started noticing bruises and pink rashes all over her body. This time she found herself racing to the hospital.

“When my bloodwork came back, the ER doctor tugged on my foot to wake me and told me, ‘I think you have leukemia.’”

Brunson was diagnosed with acute lymphoblastic leukemia (ALL). What followed was three and a half years of chemotherapy, bone biopsies and spinal taps, but she kept moving. Brunson found herself in remission and was back on the track working toward an Olympic tryout. She managed to finish her senior year and graduate from the University of Central Florida despite an intense chemotherapy regimen.

Just when things were starting to look up, her ALL had recurred. Brunson found herself back at the starting line less than two years after her first bout. She underwent another round of intensive chemotherapy, but this time her doctors called for an allogeneic bone marrow transplant.

“Treatment was harsh but I tend to keep in shape,” Brunson said. “I knew being in shape during treatment would help tremendously. I really like to work out. Just because I had cancer at the time, I didn’t want to let it stop me. It honestly pushed me more.”

“I would work with resistance bands in my hospital room, and I would just go for walks in the hallway.”

Brunson’s bone marrow transplant was successful. The treatments took a toll on her body, though. She was especially weak after her transplant. Despite going back and forth from the hospital because of fevers and other complications, she still found a way to push through.

“I would still go for walks whether it was just in my room or down the hallway,” Brunson said. “I was still walking, and then I was encouraging other patients who were in the same wing to come walk with me.”

EXERCISE’S ROLE IN THE CANCER JOURNEY

It was Brunson’s inpatient nurses at Moffitt Cancer Center whom she credits for pushing her to get up and move even if that was the last thing she felt like her body could do.

“I remember my nurse telling me that I would get out of here faster than if I just sat in bed,” Brunson said. “Even for the weeks at a time when I was in inpatient treatment, I was still active. I would work with resistance bands in my hospital room, and I would just go for walks in the hallway.”

Brunson’s nurses were on to something when they told her to stay active during her treatment. A growing amount of research shows that regular exercise can greatly improve physical and mental health during the cancer journey.

Nathan Parker, PhD, is one of the leading experts in this field. Currently serving as an assistant member in Moffitt’s Department of Health Outcomes and Behavior, Parker first took an interest in the subject as a graduate student studying public health and kinesiology. A graduate research assistantship with Matthew Katz, MD, in the Department of Surgical Oncology at The University of Texas MD Anderson Cancer Center led to a chance to explore what the world of exercise had to offer for patients.

“Dr. Katz became really interested in his older patients who were coming into clinic and approaching pancreas surgery,” Parker said. “These incredibly complex operations require patients to be in pretty robust order to handle these procedures and come out on the other side with the quality of life and the function that they had before.”

What started as interest then turned into opportunity.

“I started to learn and realize that there is a huge role for exercise research in cancer treatment and survivorship,” Parker said. “I worked with clinicians to design a home-based exercise program because we had patients coming from far and wide for surgery. We were trying to gradually increase their aerobic exercise, mostly walking, and we gave them guidelines for intensity and how much they should be doing each week.”

They were also given a set of resistance tubes and received instruction on how to do specific exercise movements along with guidance on how to increase resistance when they felt up to it. The initial study results came as a bit of a surprise.

“What we found was that most patients walked like crazy,” Parker said. “They were very motivated to walk and far surpassed our recommendations for aerobic exercise, but they really struggled to meet the strength training aspect.”

Follow-up interviews found that many of the participants felt they lacked the confidence to feel like they were training effectively, as it was the first time many had embarked on a formal strength training program.

“It was new to most people,” Parker said. “Everybody’s pretty familiar with aerobic exercise, but getting into a structured strength training program isn’t something that a lot of people stick to without guidance and support, especially at the onset. We started to think about ways where we could take an in-person exercise program, which is the gold standard, and bridge that to the comfort and convenience of home-based training where more patients would want to and be able to participate.”

That’s where technology comes in.

A BREAKTHROUGH OVER ZOOM

Fast forward to 2022. Video conferencing was something once reserved for the workplace, but nearly three years into the COVID-19 pandemic, Zoom calls have become second nature for almost everyone.

Now, with that technology on his side, Parker is launching another exercise study. This time technology will allow him to offer a personal trainer in the comfort of a patient’s living room with Zoom, an iPad and a Fitbit.

“We call it ‘tele-resistance training’ because we meet with the participants via Zoom,” Parker said. “We use tablets or smartphones and try to position the devices in the right spot where we can see the patients’ bodies to make sure that they’re doing the exercises properly. It’s also important for them to see us if they need some examples or to mirror what we’re doing.”

The National Cancer Institute-funded study will be open to 100 patients who have advanced, upper gastrointestinal cancers. According to Parker, muscle loss is a major concern due to the older age of patients with these diagnoses.



Dr. Nathan Parker is launching an exercise study where patients receive “tele-resistance training” over Zoom.

RESISTANCE TRAINING EXERCISES

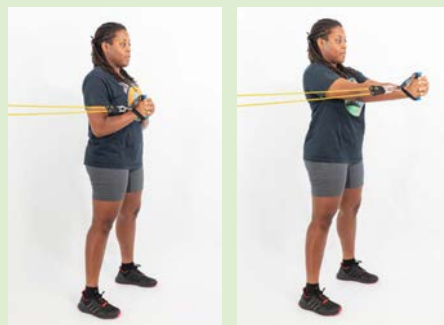
Nathan Parker, PhD, MPH, put together a routine of six resistance training exercises targeting major muscle groups to help maintain strength and muscle mass during cancer treatment. These exercises can be done from the comfort of a patient's home using a basic set of resistance tubes with handles and a door anchor strap, plus a chair for balance and support. Though resistance training with gradual progression is safe and beneficial for most, all patients should discuss exercise plans with their medical providers to ensure appropriate selection and supervision of exercises. Patients should seek professional guidance to identify alternatives for exercises that are challenging due to functional or mobility limitations.

For all exercises, start with light resistance and longer sets (10-15 repetitions) until you are comfortable with the exercise. Then progress to resistance levels that require medium to hard effort for sets of 8-12 repetitions. Gradually increase resistance as you become stronger and feel that sets with a given resistance level are getting easier. Aim for 2-3 sets of each exercise, 2-3 days per week.



Use the camera on your smartphone to scan this QR code and watch videos of the exercises.

PALLOF PRESS



Loop a resistance tube through the door anchor strap with the anchor at abdomen level. Connect both ends of the tube to a single handle. Stand sideways so that shoulders are parallel to the path of the tube coming from the door anchor, and stand far enough from the door so that there is tension in the tube. Grasp the handle with both hands at your chest. Keeping your shoulders square and back steady, push the handle straight out slowly, pausing slightly when arms are fully extended. Keep your lower back and abdominal muscles tight to avoid rotating toward the door. Repeat for 8-12 repetitions. Change your stance and repeat facing the opposite direction. Both directions is one set.

SQUAT OR CHAIR STAND



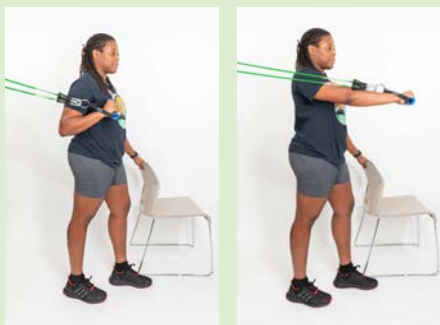
Start seated, with your feet chair-width apart and the resistance tube anchored under both feet with a separate handle attached to each end. Position the tube behind the shoulders, with handles held still slightly in front of the shoulders. Starting with a slight forward lean, stand straight up, driving from the heels and keeping your back as straight as possible. Lower your body back to the starting position slowly and under control. Repeat for 8-12 repetitions.

ROW



Loop a resistance tube through the door anchor strap with the anchor at chest level. Connect both ends of the tube to a single handle. Face the door with feet staggered, left foot in front. Start with the right arm extended straight out in front. Hold a chair with your left hand for stability if needed. Keeping your shoulders square and back steady, pull backward until the handle reaches your body and then slowly extend back to the starting position. Repeat for 8-12 repetitions. Change foot position and repeat with the opposite arm. Both arms is one set.

CHEST PRESS



Loop a resistance tube through the door anchor strap with the anchor slightly above shoulder level. Connect both ends of the tube to a single handle. Face away from the door with feet staggered, left foot in front. Start with the right arm, holding the resistance band in front of the right shoulder. Hold a chair with your left hand for stability if needed. Keeping your shoulders square and back steady, push forward slowly until the arm is fully extended. Then slowly return to the starting position. Repeat for 8-12 repetitions. Change foot position and repeat with the opposite arm. Both arms is one set.

RESISTANCE TUBE DEADLIFT



Attach each end of a resistance tube to each end of a bar or two separate handles, and anchor the tube under both feet. Start from standing. With feet wide, bend slightly at the knees and hinge the hips backward, allowing the bar or handles to drop straight down until just below the knees. Keep the back flat in its neutral position the whole time, being especially careful to avoid rounding it outward. Drive your chest upward and your hips forward as the bar or handle approaches the hips, standing fully upright. The bar should move in a straight vertical path for each repetition, and the arms remain straight. Repeat for 8-12 repetitions.

LATERAL RAISE



Stagger feet with the tube running under the front foot and with a handle attached to each end of the tube. Stand straight up. Keeping arms straight and out to the side, slowly lift the handles up to shoulder height. Slowly lower the arms back to sides. Repeat for 8-12 repetitions.

“Exercise can give patients something within their control at a time when everything feels out of control.”

– Dr. Nathan Parker

“The cancers themselves and the treatments that patients undergo, they can take a toll on body composition in a number of different ways,” Parker said. “Metabolic changes can lead to the deterioration of healthy body tissues. Chemotherapy and other treatments can cause fatigue and other side effects that make people less physically active and more sedentary. Both the cancer and treatments can cause nutritional issues where patients aren’t getting the calories that they need to maintain their muscle mass.”

Parker’s study will focus on the feasibility and acceptability of the exercise intervention in this clinical population, with exploratory outcomes including maintenance of muscle mass and fitness measured pre- and post-intervention. Patients in the intervention will be given a set of resistance tubes as their primary form of strength training.

“We’re using resistance training or strength training exercise for mitigating muscle loss or regaining lost muscle,” Parker said. “The goal of the training is to help keep patients as robust and strong and fit as they can be during chemotherapy. Keeping them strong and better able to tolerate their treatments might improve treatment outcomes, help them keep their energy levels up, reduce fatigue and improve quality of life.”

Donneisha Smith, a research coordinator at Moffitt, was Parker’s first hire to join his new research team, called the MPROVE (Moffitt Promotes Resilience in Oncology Via Exercise) Lab. Smith recently became a certified exercise trainer while pursuing a Master of Health Administration at the University of South Florida. The MPROVE team will keep close track of participants’ sets and repetitions, helping patients safely increase their workload and progress their program as sets at a given resistance become easier.

“We use our beautiful new exercise lab to do baseline and follow-up testing, giving us objective data to evaluate how fitness changes over the course of the program and chemotherapy,” Parker said.

For the next three years, Parker will track a number of patient-reported outcomes like quality of life, fatigue and peripheral neuropathy. These can all worsen with chemotherapy, but the belief is that exercise can help to alleviate some of the side effects.

But how do you tell a patient who is experiencing nausea, fatigue and neuropathy that they need to move more and start a strength training program?

“It can definitely be a hard sell for some people,” Parker said. “But there are far more for whom it registers quickly, revealing

striking motivation. Exercise can give patients something within their control at a time when everything feels out of control, empowering them to improve their trajectories and outcomes.”



Dr. Nathan Parker and Donneisha Smith, a certified exercise trainer, will help patients safely increase their training regimen.

‘FIND LITTLE GOALS TO SET’

Amanda Brunson is now in full remission seven years after hurdling over ALL a second time. Looking back, she knows that her drive to be active during her treatments made a big difference in the long run, even if she couldn’t feel it at the time. Her advice to newly diagnosed patients who may be facing an uphill battle is simple: Listen to your body.

“Whether it’s just a walk or riding a bike to stay active, just listen and be as active as you can,” Brunson said. “Find little goals to set and put them on your chart. It helps tremendously with your mental health.”

Today, Brunson says she’s in remission, cancer free, back in shape and giving back to the cancer community. You can catch her volunteering for Be The Match, Ronald McDonald House, Livestrong, and as a peer advisor for Moffitt’s Adolescent and Young Adult Program. That’s if you can catch her.

“Young adults dealing with cancer have become a deep passion of mine to help, but also to help cancer patients and survivors in general,” Brunson said. “I want to use my own cancer experiences and turn my pain into purpose. To reach out and be what I needed when I was in active treatment.”



The Gift of Time

Moffitt initiative empowers patients to speak openly with providers about treatment decisions

By Amanda Sangster

Photos by Kevin Kirby

The 65-year love affair between Donna and Duane Dunbar is the kind of story that movies are made from. Two kids from a small, rural town meet at school in ninth grade. He spots her from across the classroom. He asks her to join him on a field trip to a local roller-skating rink and she says yes. They spend the day holding hands and flirting.

“And we kissed on the back of the bus the entire way home,” Duane Dunbar said. “I kissed her the first day I met her, and the last thing she did on Earth was give me a kiss.”

They would go on to have a relationship that spanned the better half of a century. Duane joined the Air Force and the couple married on base. Three children later and their family was complete. They would go on to have one adventure after another and live a full life.

The Dunbars were no strangers to tragedy, though. They lost their only daughter to an accident when she was 9 years old. They later lost their younger son, Ken, to brain cancer.

After losing their son, the Dunbars planned an adventure out West in 2020. “Donna and I loved to travel,” Duane said. “Not only that, but we liked to get lost.” When given the opportunity, the couple always took the road less traveled. But when the time came for their trip, Donna was experiencing trouble with her bladder.

She went to her doctors, who ordered scans. A day later, the Dunbars began getting phone calls. The scans showed an abnormality in her pancreas. Her doctors said a huge mass had formed – and it was likely cancer.

‘WE WERE IN FLORIDA TWO DAYS LATER’

“We’re going to a top 10 cancer center – that’s what I told her,” Duane recalled. The couple lived in Pennsylvania but reached out to Moffitt Cancer Center for an appointment. When they mentioned pancreatic cancer, the Dunbars noticed a shift in the woman’s tone over the phone.

“We’re going to a top 10 cancer center – that’s what I told her.”

“We don’t need any more information. If you’re ready, we can see you next Wednesday.’ That’s what she told us,” Duane said. “We were in Florida two days later.”

After arriving at Moffitt, Donna was diagnosed with metastatic pancreatic cancer. They were told that she might have as few as four months to live. The couple were waiting for the elevator while processing the news when Donna collapsed. A stranger immediately began rendering aid to Donna.

“She came out of nowhere – it was instantaneous. She started barking orders at everyone,” Duane said. “Within seconds, first responders were there. Within a minute, everyone was helping Donna.”



Family photos reflect the loving wife and mother Donna Dunbar was. When Donna chose to stop treatment, she prioritized spending her time with those she loved.

Donna was rushed into an exam room while Duane paced back and forth down the hallway. The stranger stayed quietly by his side. “She really didn’t say anything, but she just walked with me,” Duane said. “She was so calm and caring.”

Kris Lombardi has been a clinical pharmacist for nearly 27 years. She helps patients with chemotherapy treatments and often develops deep connections with them and their families. Patients in the Senior Adult Oncology Program turn to her for help when they experience negative side effects or need modifications to their medicines.

On the day that Donna collapsed, Lombardi was the stranger who comforted Duane while he paced. “I call her my angel. Every time we got in trouble, every time Donna had a problem, there she was. It was like Kris was wandering around looking for us,” Duane joked.

Despite meeting only a handful of times, Lombardi remembered them. During the pandemic when visitor restrictions were in place at Moffitt, Lombardi would find Donna in the hallways and lead her to the clinic while Duane waited in the car. Lombardi eventually treated Donna while she was undergoing chemotherapy, going as far as consulting pharmacology textbooks when Donna began experiencing rare complications.

“I call her my angel. Every time we got in trouble, every time Donna had a problem, there she was. It was like Kris was wandering around looking for us.”



Kris Lombardi, a clinical pharmacist at Moffitt, developed a special relationship with the Dunbars during Donna’s treatment. They never wasted a chance for a selfie.

THE REALITIES OF CONTINUING TREATMENT

Donna initially responded well to chemotherapy. She was able to return to her normal life and some of her favorite activities, such as gardening. Donna loved flowers. She had an acre and a half that she tended to daily back home in Pennsylvania. She would wake at dawn and work in her flower beds until dusk. When not working in her garden, she was volunteering at her local garden club.

Donna was in treatment for more than a year before her kidneys started failing, requiring multiple hospitalizations. Donna’s providers changed the formula of her chemotherapy, but she fell violently ill in response.

It was at this point that Christine Sam, MD, a medical oncologist in Moffitt’s Senior Adult Oncology Program who was treating Donna, had a conversation – one of many – where she spoke openly and honestly with Donna about the realities of continuing treatment.

“I had noticed she wasn’t as joyful,” Sam explained. “She was so focused on her next treatment, but I could tell she was not the same person.”

Sam and Donna spoke about what was most important in Donna’s life. “Sometimes we miss the forest for the trees,” Sam said. “Donna felt isolated – their family was up North, and they were stuck here. She would talk about her garden and how it was probably full of weeds. She wanted to get back there.”

Sam explained to Donna that she had an incurable cancer, and her time was limited – two things that Donna understood well. Donna responded that she wanted to spend her remaining time with her family, traveling with her husband and tending to her garden.

“That’s when Donna said, ‘No, we’re not doing any more treatment,’ ” Duane said. “It was her decision, and Dr. Sam was very supportive.” Even though Donna was in a physical place where she could still receive treatment, more treatment did not necessarily mean that she would live longer, especially as more complications began manifesting.

Throughout Donna’s treatment, Sam had spoken to her about her goals and hopes for the future. Because of this open dialogue, Sam believes that Donna was able to feel at peace in her decision to discontinue treatment. With her decision made, Donna began hospice care in their home. The average time in hospice is less than a week, but Donna stayed under hospice care for almost a year.

IMPROVING GOAL CONCORDANT CARE

Donna’s story is a testament to a larger conversation happening across America’s leading cancer centers. In 2020, the Alliance of Dedicated Cancer Centers (ADCC)

launched a collaborative project called the Improving Goal Concordant Care Initiative. The initiative is a three-year plan designed to address goals of care for patients with advanced cancer. It is a call to action that all patients with cancer and their families should receive care that aligns with their unique values and priorities.

In a commentary published in *The Oncologist*, the ADCC noted that designing care environments in which patient values and goals are defined and honored is critical. The ADCC also recognized that physicians should be consistently and regularly speaking with their patients about their prognosis, personal preferences and goals of care. When conversations about goals of care happen, they should be well-documented throughout a patient’s electronic health record. The ADCC noted that cancer centers also need a measurement framework for these care discussions, like patient surveys and hospitalization data.

There are four core components to the ADCC’s Improving Goal Concordant Care Initiative:

- **Implement a formal training program for communications skills to ensure providers are prepared to have these important conversations**
- **Create structured goals of care documentation in electronic health records so a patient’s team of providers can keep track of what discussions have been had**
- **Establish expectations regarding goals of care communications**
- **Implement a measurement framework to track how this communication is improving patient care**

As a member of the alliance, Moffitt has taken steps to implement the core components of goal concordant care. The center is providing advanced communications skills training to all oncology and hematology providers, in addition to advanced practice professionals. By September 2023, more than 65% of providers at Moffitt will be trained on how to have these conversations early on and more frequently with patients. The initiative is being co-led by Sam and Barbara Lubrano di Ciccone, MD, a psychiatrist with the Supportive Care Medicine Program.

To launch this initiative, Moffitt has focused on the senior adult patient population – a group that generally has advanced stages of cancer. The center has also made changes to the way these conversations are documented in patient records and is developing a measurement framework.

“If we see the hope of living a long life as the only goal a patient can have, then we’re not helping them to see that maybe there are other things they might hope for.”

- Dr. Barbara Lubrano di Ciccone



“These are not meant to be end-of-life discussions. They can happen any time during treatment, including the first day.”

- Dr. Christine Sam



CHANGING WHAT HOPE LOOKS LIKE

“For Donna, we were reevaluating these goal discussions intermittently throughout her therapy,” Sam said. “These are not meant to be end-of-life discussions. They can happen any time during treatment, including the first day. Ultimately, this can benefit any patient with cancer, but to get started, we’re focusing on patients with advanced cancer.”

There is a misconception that these kinds of difficult, honest conversations could deprive patients of hope. “This myth has really been debunked,” Lubrano di Ciccone said. “In reality, we’re depriving patients of opportunity – the opportunity to make decisions about their lives.”

Lubrano di Ciccone says patients’ hopes and goals can transform over time just as the illness trajectory can change. “Hope is not fixed in stone,” Lubrano di Ciccone said. “If we see the hope of living a long life as the only goal a patient can have, then we’re not helping them to see that maybe there are other things they might hope for, like achieving certain milestones or being reunited with a loved one.”

By having goal concordant care discussions throughout their treatment, many more patients could have a better understanding of their treatment options and make decisions based on their evolving values and priorities. “Having these goal discussions can give control back to patients when they’re in a situation that feels out of their control,” Sam said. More patients could feel empowered to make treatment decisions that allow them to make the most of their limited time.



Kris Lombardi kept up with Duane and Donna Dunbar as they traveled and lived life to the fullest during Donna's final year. They often texted Lombardi photos of their adventures.

A Delicate Surgery

A Strong Sense of Hope

Endoscopic procedure allows doctors to remove certain skull-base tumors through the nasal cavity

By Steve Blanchard

Photos by Nicholas J. Gould

'I WOULD DO IT ALL OVER AGAIN'

Chemotherapy had been a blessing to Donna in the beginning. It improved her quality of life and helped her feel better for more than a year. After complications began to occur, her priorities shifted. The way she wanted to spend her remaining time changed. During that year in hospice, Donna thrived.



Donna Dunbar holds her first great-grandson, Paxton, in this family photo.

The Dunbars got to explore again, and Donna was able to tend to her garden. They enjoyed time with family. Most importantly, Donna got to meet her first great-grandson, Paxton. Hospice came every other week to check her vital signs and provided her comfort in the end.

Throughout that last year, the Dunbars shared their photos and adventures with Lombardi and Sam via text messages. Duane made sure to stay in touch with their angel, even sending Lombardi photos of Donna and the newly born Paxton.

"We had a really good year. I'll always be very grateful for that year," Duane remembered. "We did whatever we felt like. ... It was just a beautiful, beautiful year."

It wasn't until her last week of life that Donna began showing signs of deterioration. Her passing surprised even her closest friends because she had been so vibrant until the very end.

Before Donna passed, she wrote Duane a letter that he later found. It detailed their life together. In between the beautiful moments and the heartbreaks that they endured, the page gave life to their epic love affair. In her final words, she wrote to Duane, "If it was with you, I would do it all over again. Love, Donna."

"We had a really good year. I'll always be very grateful for that year. We did whatever we felt like. ... It was just a beautiful, beautiful year."



Dr. Andre Beer Furlan, left, a neurosurgeon with Moffitt's Neuro-Oncology Program, and Dr. Krupal Patel, assistant member in the Department of Head and Neck-Endocrine Oncology, work together to remove a skull-base tumor through endoscopic surgery.

THE TWO DOCTORS OPERATE SIDE BY SIDE, navigating the intricacies of the human skull and nasal cavity to remove rare tumors that can impair a patient's cognitive functions. Andre Beer Furlan, MD, PhD, a neurosurgeon with Moffitt Cancer Center's Neuro-Oncology Program, and Krupal Patel, MD, assistant member in the Department of Head and Neck-Endocrine Oncology, work as a team on these delicate endoscopic surgeries, removing skull-base tumors without having to open the skull itself.

Skull-base tumors, as the name implies, are typically found at the base of the skull or near the top of the spine. They can often form in the frontal sinus cavity near the pituitary gland.

"Skull-base tumors are not formed in the brain itself," Beer Furlan explained. "But all functions of the body can be impaired by these tumors since they press against vital nerves and arteries that control our motor functions and senses."

Historically, these tumors would require an open craniotomy, where doctors physically open the skull above or behind the ear to reach the tumor area. But such intrusive and traumatic surgery is not always necessary, thanks to innovative doctors

such as Beer Furlan and Patel. This multidisciplinary Moffitt team uses endoscopic surgery to remove hard-to-reach skull-base tumors, with better results and speedier recovery times.

Their efforts proved to be a lifesaver for Pedro González Escolá.

EARLY DISCOVERY LEADS TO QUICK ACTION

Fortunately for González Escolá, 40, his tumor was discovered before his motor functions and senses were impacted. A routine blood test showing elevated hormone levels prompted the discovery.

"I went in for a checkup and did blood tests," he said. "They found a high number connected with my hormone level, so he [the doctor] sent me to get an MRI."

That MRI revealed González Escolá had a growth on or near his brain. Even though he was not showing any physical symptoms related to the tumor initially, his doctor suggested he seek out an oncologist's help.

"That MRI was done in September 2021, and I was at Moffitt on Jan. 10 for a follow-up," said González Escolá, who decided to make the trek to Moffitt from his home in Puerto Rico based on advice from his brother, who trained as an oncology surgeon at Moffitt. "On Jan. 11, they told me I had a malignant tumor and suggested I have surgery as soon as possible."



Fortunately for Pedro González Escolá, 40, his tumor was discovered before his motor functions and senses were impacted. A routine blood test showing elevated hormone levels prompted the discovery.

"All functions of the body can be impaired by these tumors since they press against vital nerves and arteries that control our motor functions and senses."

- Dr. Andre Beer Furlan

Moffitt doctors told González Escolá that the two possible tumors with those imaging features were chordoma or chondrosarcoma, both considered slow-growing cancers of tissue found at the base of the skull near his pituitary gland.

González Escolá said his brother, who is a doctor in Puerto Rico, helped keep him calm after his diagnosis and explained that technology had advanced a lot in this area of oncology. "He reminded me that it was 2022 and not the 1990s," González Escolá said. "The technology is so much better now, and I was relieved that they didn't have to go through my skull, which meant less time in the hospital and a faster healing process. It's still a brain surgery, essentially, but it's less invasive."

In the time between his diagnosis and his visit to Moffitt, González Escolá's tumor was pressing against a nerve connected to his vision and eye movement. González Escolá and his wife discussed his options in depth with Beer Furlan and Patel and ultimately agreed to the endoscopic surgery.

González Escolá said he was impressed with both doctors' bedside manner.

"These two doctors explained everything so well and were so caring," he said. "They explained the procedure and how they would remove the tumor through my nose and avoid having to open up my skull. They were straightforward and so respectful."

"These two doctors explained everything so well and were so caring."

González Escolá was admitted into Moffitt on Jan. 21. At the time, he told his doctors he had double vision, which they determined was directly connected to the tumor growing in his skull. He had his surgery on Jan. 28.

AN INTRICATE SURGERY

Removing a tumor can take anywhere from six to 12 hours of surgery, and the doctors physically remove the cancer through the patient's nasal cavity. González Escolá's surgery lasted about 10 hours.

"Pedro's surgery took so long because the tumor was so calcified," Beer Furlan said. "Because the tumor was in a

cavernous sinus area, when you manipulate that you get a lot of bleeding. It was also very close to nerves and the carotid artery, so it's a very delicate area."

Beer Furlan and Patel both worked on González Escolá and used drills to release a block of bone connected to the tumor and extract both the hard and soft tissue through his nasal cavity.

"In a case like this, we work through both nostrils, the right and left side," Beer Furlan said. "Dr. Patel opens the sinuses and makes one larger cavity in the back of the nose. We use a four-hand technique to remove the tumor and to control the bleeding as we extract the cancer."

After the tumor's removal, Patel reconstructed González Escolá's nasal cavity using a nasoseptal flap so the patient could begin to heal.

FASTER RECOVERY WITH NO EXTERNAL SCARS

This procedure is relatively new at Moffitt, and in the program's first year, 38 surgeries were performed. That number will gradually increase as the program grows.

"Skull-base tumors are rare, and a majority tend to have benign behaviors," Beer Furlan said. "But they can cause problems, and recovery is much easier with this new method."



Dr. Andre Beer Furlan, left, and Dr. Krupal Patel, right, meet with González Escolá to discuss his surgery. The procedure is relatively new at Moffitt.



“I didn’t have any headache, which I think is just amazing,” he said. “I can’t smell, but even if that sense doesn’t come back, I’m thankful that I can live a normal life.”

Patel said González Escolá could regain his sense of smell in a matter of months but stressed that each outcome is different.

“I didn’t have any headache, which I think is just amazing.”

Moving forward, González Escolá’s normal life will include continuous monitoring and several trips back to Moffitt throughout the year to ensure he is still healthy. He will start out being monitored every three months, then every six months and eventually, just once a year.

“We don’t fully understand these tumors, and we want to make sure that we continue monitoring to ensure the cancer doesn’t reappear,” Beer Furlan said.

BUILDING HOPE FOR OTHERS

Fortunately, González Escolá has the support of his wife, Yolanda, and family and hopes that his experience can help others.

Beer Furlan said the tumor he and Patel extracted from González Escolá is now part of a database that will help doctors understand their pathology.

“We are building a patient database of tumors and combining those with other centers of excellence around the nation to look at outcomes and impacts to patient survivorship, quality of life, etc.,” Beer Furlan said. “There is so much more to this than just the surgery. These tissues help us understand why some tumors have benign behaviors and others take a different course. That tumor biology will help us learn and have a positive impact on many other patients.”

Knowing his experience can help others gives González Escolá a sense of hope and peace. But even as a cancer survivor, he said it can be hard to know what to say when someone you know is facing their own cancer diagnosis.

“Only the one suffering knows what it’s like in their individual situation,” he said. “But treatment is so important, and you have to focus on the positive. Chemotherapy and treatments are so much more advanced than they used to be, and there are more tools to survive now than before. You must keep the hope. Hope, along with the support of my wife and my amazing doctors, is what saved me.”

“Hope, along with the support of my wife and my amazing doctors, is what saved me.”



Doctors will continue to monitor González Escolá to make sure the cancer doesn’t come back. With the support of his wife, Yolanda, he is back at work and pursuing a law degree.

“The nose acts as a natural corridor to these very complex areas, and the technology of endoscopes allow us to operate in the space.”

–Dr. Krupal Patel

That’s because “the nose acts as a natural corridor to these very complex areas, and the technology of endoscopes allow us to operate in the space and visualize these critical structures that would not otherwise be available,” Patel said. He noted that in addition to the faster recovery times, patients also have no external scars.

Both Patel and Beer Furlan agree that while there are risks associated with an endoscopic surgery, those risks are not as great as traditional surgery, which requires more healing time because of the trauma caused by simply reaching the tumor.

Beer Furlan is quick to point out that not every patient is a candidate for this type of surgery. “It is important to understand that not all tumors in the skull or brain are

removed this way. Each type of tumor has its own treatments, and it’s important to discuss those with your doctor,” he said.

Symptoms and imaging are key to ensuring the correct treatment protocols are followed. “We do that [endoscopic surgery] for tumors that are asymptomatic and have very benign features on the MRI and CT scans,” Beer Furlan said. “Other tumors may require an open craniotomy for resection or a combination of approaches. Radiation therapy may also be needed as an adjunct treatment, depending on the type and grade of the skull-base tumor.”

‘I CAN LIVE A NORMAL LIFE’

As with most cancers, skull-base tumors fall on a scale. A grade 1 chondrosarcoma, which González Escolá had, is a best-case scenario, Beer Furlan explained.

González Escolá recalls waking up in the intensive care unit with a bandage under his nose and his wife at his side. He knew he had come through his surgery, but he was surprised when a physical therapist entered his room and encouraged him to stand.

“I wondered if they knew that I had just had brain surgery 11 hours earlier,” he said. “I was surprised they wanted me to try to stand so soon!”

“I was surprised they wanted me to try to stand so soon!”

González Escolá said he not only stood next to his bed for a few minutes, but he also took a few steps, which showed that he was already on the road to recovery.

Since his surgery, González Escolá has returned to Puerto Rico, is back at work in medical coding and auditing, and is pursuing a law degree. He said he had some minor vertigo after the surgery and just a little pain.

ABOUT MOFFITT CANCER CENTER

Moffitt Cancer Center in Tampa, Florida, has made a lasting commitment to the prevention and cure of cancer, working tirelessly in the areas of patient care, research and education.

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To contribute to the prevention and cure of cancer

VISION

Create revolutionary breakthroughs and innovations that rapidly impact and save more lives

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