

LOCAL, A6

Hundreds show their support during Walk MS at The Villages Polo Club.

SPORTS, B1

'Noles Roll, Gators Fall

LOCAL, C9

Club's spring craft fair set for Monday.

NATIONAL NEWS

The Associated Press

BARR ANALYZING SPECIAL COUNSEL'S REPORT ON RUSSIAN INQUIRY

Attorney General William Barr spent Saturday scouring Robert Mueller's confidential report after receiving it Friday. Barr's summary of the report on President Donald Trump's 2016 campaign could be released today. **A12**

NATION & WORLD REPORT

Nation: Former coal-mining towns in southeastern Kentucky are turning to tourism, counting on their natural beauty, history and culture to help reverse years of economic decline. **A17**

World: Three years of Brexit missteps and mayhem have eroded U.K. Prime Minister Theresa May's image of strength and stability. Many European officials lay blame for the crisis squarely on May. **A20**

INSIDE

Florida NewsA5

LotteryA4

Local NewsA6

World NewsA2

Faces in The News

Liu He

China's vice premier will lead his nation's delegation when it visits the United States next month for talks aimed at ending a trade dispute.

World News, A2

A DAILY SUN SPECIAL REPORT

Stem Cells Met With Controversy, Promise

RESIDENTS SHARE THEIR TREATMENT STORIES

While some regret spending thousands on stem cell treatments that didn't help their condition, others say stem cell therapy changed their lives for the better. The Daily Sun spoke with residents on both ends of the spectrum.

John Mital, Village Rio Grande

Mital said he had exhausted all options to relieve pain that has limited him for about a decade. A partial knee replacement eased some of the damage caused by osteoarthritis, but then his left knee began declining. An ad on stem cells caught his eye, and he later attended a seminar. Mital received injections in one knee in January 2018, and later in one shoulder. Mital said his condition never improved. He still struggles to stand. Stem cells have a lot to offer one of these days, he said, but the therapy is not there yet. "Your hope – don't let it overcome good, solid research," Mital said.

Antoinette Himmelsbach, Village Palo Alto

Six years of steroid shots provided little relief for Himmelsbach's torn meniscus. Her condition worsened over time and eventually, she was walking with a cane. "I was really bad," Himmelsbach said. Since a Sept. 27 stem cell treatment in St. Louis, she said her pain has improved tremendously. "Stem cells have turned my life around," Himmelsbach said. "It's the cutting edge of medicine." Despite her success, she cautioned that many are diving into stem cell treatments without doing proper research on what they do. It's not an overnight cure, Himmelsbach added.

Betty Kayackas, Village of Woodbury

Kayackas' sciatica pain had progressed to the point where she almost couldn't walk. On Dec. 20, she received umbilical cord stem cells intravenously into her arm from a Lady Lake physician. She said she knew it wasn't guaranteed to work but hoped that the cells would travel to the source of pain in her lower spine. "Within three weeks, my pain was gone," she said. Kayackas said she went from taking four opiates a day to half a pill as needed. The \$6,800 treatment was worth every penny and she is considering more, Kayackas said. "You can tell in my face that I'm not in constant pain anymore."

Frank Lomanno, Village of Charlotte

Lomanno wanted to avoid an operation on his hip, where tissue and cartilage have degenerated. "I was feeling pain," he said. Then Lomanno came across stem cell therapy. "It just sounded like if it worked it would be a great solution," he said. "Operations are dangerous." After attending seminars in The Villages, Lomanno received stem cell treatment from an Altamonte Springs clinic on Nov. 19. He said on a scale from one to 100, his pain condition improved zero. "I was very hopeful," he said. "It is a business, and I knew that."

The treatments have been found to help patients with cancer and blood disorders, but funding gaps remain for research.

By CIARA VARONE

Daily Sun Senior Writer

For the future of medicine, scientists are looking to the building blocks of life.

Stem cells, the origin of all organs and tissues in the body, have generated controversy and fascinated scientists since they were first separated from human embryos 21 years ago.

In 2001, The White House administration banned federal funding for the development of new embryonic stem cell lines – groups of stem cells grown in a lab – though research could continue on existing ones.

That was reversed in 2009, but a decade later, scientists say the field is still in its early stages.

Stem cells derived from cord blood are proven to help patients being treated for cancer and some blood disorders, according to the Food and Drug Administration. The stem cells help treat these ailments by replacing cells destroyed by disease, injury or aging.

Researchers are now looking into ways of tackling heart disease, replacing neurons in Alzheimer's patients and curing type 1 diabetes through stem cell-derived therapies.

But they're not there yet.

Though the National Institutes of Health funds an active stem cell research portfolio, additional funding would accelerate discoveries, said Dr. Tim Kamp,

Please See **STEM CELLS, A8**

COMMUNITY & CONNECTIONS

Sunday Extras Inside

Grab a cup of coffee, find a comfortable seat and dive into this edition of expanded, comprehensive local coverage.

PARADE MAGAZINE

Find out how chef David Burtka and Neil Patrick Harris make every day a celebration.

SPORTS SPOTLIGHT

A national roundup of all your favorite teams. Plus news from Golf Central. **Section B**

VILLAGES IN DEPTH

A look inside the wide world of target sports in The Villages. **Section C**

EXTRA ACTIVITIES

A full guide to fun in your neighborhood. Plus book reviews and your poetry. **Section D**

NEW DESTINATIONS

Travel far and wide with Villagers and others as they explore the world. **Section E**

ADDITIONAL SECTIONS

On TV this week, "Abby's" premieres on NBC. Plus six pages of color comics.

Neighborhood Roundup

Catch the fun from a recreation center near you. **D2**

Plus: Adopt a pet from an area shelter. **C12**

Plus: Open up your neighbor's photo album. **C8**

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VOLUME 22 | ISSUE 83

from the front page

A DAILY SUN SPECIAL REPORT

STEM CELLS

Continued from A1

professor of medicine and director of the Stem Cell and Regenerative Medicine Center at University of Wisconsin-Madison, where human embryonic stem cells were first isolated.

He is confident in the promise of stem cell treatment, but said availability outside of clinical trials is three to five years away, optimistically.

“I think there are many, many different things under development for many, many different diseases,” Kamp said. “I think we’re just on the cusp of some of these therapies being seriously tested.”

While scientists move toward unlocking their potential with early clinical trials in humans, patients are flocking to clinics offering stem cell treatments the FDA states aren’t shown to work. Still, some local patients say the treatments have saved them from pain, surgery and even death.

More than 100 stem cell clinics are spread across Florida. U.S. Stem Cell Clinic, a Sunrise-based company, opened an office near The Villages in April. More than 100 patients have since been treated there, said Michelle Parlo, medical director for the Weston office.

“We notice improvement across the board, it just may take more than one treatment,” she said.

On The Market

Though the field holds potential, researchers say the rapid increase of stem cell clinics could be endangering patients.

“Since people were hearing about legitimate research on television, they decided to tell people they could give stem cells to anything in the body,” said Bill Allen, professor in bioethics, law and medical professionalism at the University of Florida College of Medicine.

All stem cell uses beyond treatment for diseases of the blood that are outside of a research setting are unproven, Allen said.

Yet some clinics charge thousands for treating ailments ranging from chronic pain to lung disease.

These clinics use cells derived from umbilical cord cells or from a patient’s fat.

Patients are not sedated as fat is extracted from their flanks with a tube and into a syringe. Once the stem cells are isolated, they are inserted into the patient either by injection or through an IV.

A dozen residents responded to a Daily Sun inquiry saying their conditions improved following stem cell treatments.

Antoinette Himmelsbach, of the Village Palo Alto, received her stem cell treatment in Missouri. She said pain from a torn meniscus had progressed to the point where she was walking with a cane.

After injections in both knees, she said her condition improved tremendously, and she’s now walking without assistance.

“I have the energy of a 17-year-old,” she said. “Stem cells have turned my life around.”

Valerie Fulco, of the Village of St. James, said stem cell therapy from umbilical cord cells alleviated her knee pain enough that she could return to work.

Then there’s Perry Walton, who has traveled to Mexico for stem cell treatment since 2005 following a diagnosis of idiopathic pulmonary fibrosis, a progressive lung disease.

At the time, Walton couldn’t make it to his mailbox without external oxygen, and he didn’t think he’d live past the spring.

His accountant recommended Walton visit Dr. Jose Antonio Calzada, who said he couldn’t cure him, but he could extend his life.

“He saved my life,” the Village of Bridgeport at Lake Sumter resident said.

Walton continues to return to the clinic periodically.



Bill Mitchell | Daily Sun

Perry Walton, of the Village of Bridgeport at Lake Sumter, tees off on the Kenya nine at Havana Country Club. Walton has been traveling to Mexico since 2005 to receive stem cell treatments for ideopathic pulmonary fibrosis, a progressive lung disease.

Neighbors John and Joan Bennesh have both traveled with Walton to receive treatments.

Joan, once unable to sleep through the night without choking, said she now breathes freely, and John said his rotator cuffs healed so he no longer needs surgery, to the approval of his local primary care physician.

“He says, ‘Whatever you’re doing down there, it’s working,’” John said.

But insurance does not pay for any of the costs.

Walton said his treatments in Tijuana average \$900. On the low end, one respondent said she paid \$3,500 for a single stem cell treatment in the U.S. The majority paid \$7,000 or more.

Though the expensive therapy has helped some, other local patients found no relief.

Kamp said it’s possible some felt better after stem cell treatment, but with a lack of research-based evidence, he cautions against seeking out these treatments because it could be attributed to the

placebo effect.

“Typically if it’s a magic cell therapy that will cure every ailment known to man and it costs a lot of money, those are all bad signs,” he said.

Cracking Down

Erich Flesch, of the Village of Bonita, said he knew it was a gamble when he sought stem cell therapy.

Though he said it did drastically improve his knee pain, he said anyone getting stem cell treatments should have realistic expectations.

“It’s not a miracle cure,” he said. “You’re not going to be like new.”

Researchers warn patients these treatments are unproven and may cause harm. Last year, patients sued the company U.S. Stem Cell Clinic saying injections into their eyes to treat macular degeneration left them blind.

Frank Lomanno received injections from a Central Florida clinic in November. The Village of Charlotte resident said his hip pain has not improved.

“In fact, I’ve gotten worse,” he said.

Lommano said he can’t sleep at night because of the pain caused by bone rubbing on bone.

“It is a business, and I knew that,” he said. “I was buying hope that I could avoid this operation.”

Please See NEXT PAGE

Patrick L. Smith, Attorney at Law
Joseph F. Pippen, Jr. & Associates

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from the front page

A DAILY SUN SPECIAL REPORT

Continued from Previous Page

Peggy Wedel said a South Florida clinic promised improvement for her late husband, John, after a stroke left him unable to speak or walk.

“We called and they said, ‘We can help him,’” the Village of Sabal Chase resident recalled.

The clinic wanted thousands in advance. John did not show any signs of improvement before his death a year later.

Wedel said she knows stem cells have potential and that they’ve helped cancer patients. But the current clinics are making money from unproven treatments.

“I think they prey on people,” she said. “It was a crying shame, that’s all I can say.”

Allen, who has spoken with patients who invested thousands in therapies that didn’t work or caused more damage, said the industry is a terrible way to exploit people.

“Not that there are any good ways to exploit people, but this is one of the most cruel,” he said.

The FDA has issued warnings to some companies including U.S. Stem Cell Clinic, which said in a response to the FDA that it was in compliance because its clinics do not manufacture a drug, instead using a patient’s own fat cells for the therapies.

“If the federal government were to interfere with a person’s ability to obtain and utilize their own cells in their body to heal themselves, this could be a gross violation of the constitution,” the letter said.

Allen said the FDA doesn’t prioritize cracking down on these clinics unless patient safety is compromised.

“I really feel like the FDA should move it up on their priorities, even if they have to hire new people to pursue it,” Allen said. “I think the general medical community should do more to organize and put the word out.”

If interested in stem cell treatment, Dr. Amir Kashani, assistant professor of clinical ophthalmology at the University of Southern California Keck School of Medicine, said it’s important to do so under the guidance of a clinical trial, which does not charge patients.

Participation is critical for the advancement of these therapies, he said.

“Every major medical treatment in the last two or three decades has been done as part of a clinical trial,” Kashani said.

A Bright Future

Stem cell research was limited to animal models until two research teams simultaneously made a game-changing discovery.

James Thomson, of University of Wisconsin-Madison, and John Gearhart, of Johns Hopkins University, successfully isolated and grew human embryonic stem cells in 1998.

Because stem cells can become any type of cell in the body, they opened the door for researchers across medical fields.

“Any time that you can think of a disease that has a cellular basis, which is most diseases, you can potentially think of a way that a stem cell-derived therapy can either help diagnose it or treat it, manage it in some way or better understand it scientifically,” Kashani said.

Kamp recalled his excitement at seeing beating human heart cells in the lab for the first time.

“What the human embryonic stem cells provided was a way for us, in a dish, to get human heart cells in unlimited numbers that we could study and understand how (they) behave,” he said.

For now, health care applications remain limited for the majority of patients as most stem cell-derived therapies are, at most, entering clinical trials, Kamp said.

Early results for some trials have shown potential beyond researchers’ expectations, however.



Jeff Northrop is comforted by his wife, Debbie, both of New York, as physicians assistant James Hornyak measures fat extracted during a procedure at U.S. Stem Cell Clinic.



Photos by Cindy Skop | Daily Sun

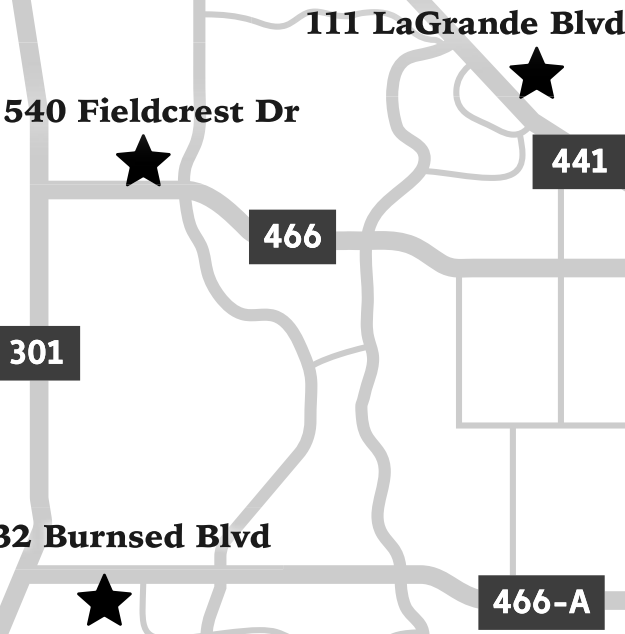
Lab technician Carlin Liggio prepares the extracted fat for separation. The clinic isolates a patient’s stem cells from either their adipose fat tissue or bone marrow.

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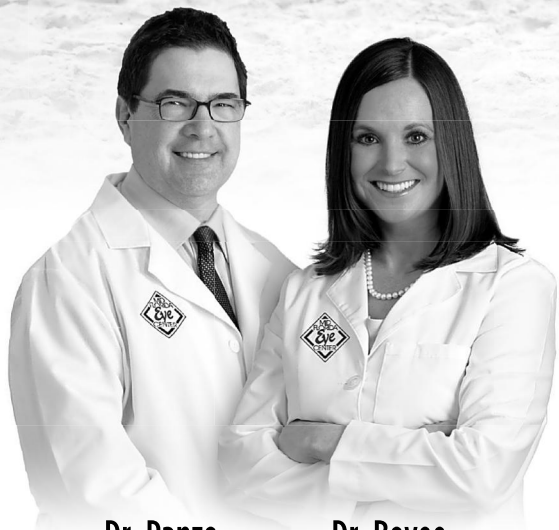


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