

The Innovative and Safe Implant Treating Pelvic Organ Prolapse

Israeli company Lyra Medical is developing an implant that solves the problems of existing implants which in the US, for example, have been removed from the shelves altogether. "We've monitored our new implant patients for the past four years and the results are excellent," say the founders

Numerous women suffer from pelvic organ prolapse disorder and the reduced quality of life that follows, and they all seek a long-term solution. Dr. Gil Levy, co-founder and Chief Medical Officer of Lyra Medical, which develops innovative implants to treat pelvic organ prolapse, says, "This problem usually occurs in women who have had vaginal deliveries. The births weaken the connective tissue in the pelvis and as a result, a pelvic organ prolapse occurs later in life – whether in the vagina or uterus – in various severity levels."

Levy says that in medicine, this is a familiar disorder that has been well-known for a very long time. In fact, hieroglyphs from ancient Egypt documented solutions used to try and solve this problem. In the past few years many tried to provide surgical solutions, while the oldest treatment, that is still performed in some form or another, is suturing the torn, weakened or stretched connective tissue thus attaching it to the pelvis.

But, the success rates of the traditional treatments were never high and 15-20 years ago synthetic implants started to emerge for the purpose of replacing the damaged tissues and providing support for the pelvic organs. These implants are made of polypropylene mesh and are inserted using a vaginal approach. The mesh is anchored to the tissues in the pelvis and serves as a supportive hammock of sorts for the prolapsed organs. In the past decade, implants have evolved in ways that mainly changed and improved the anchoring techniques. But once those solutions were in wide use many complications emerged; so many that quite a few countries simply stopped using them. "We tried to create an implant that solves the problems and complications of the existing implants, one that provides good results and supports the pelvic organs without the complications caused by the anchoring devices," says Levy. "We began developing this product about six years ago. We successfully progressed through all the necessary stages and obtained approval to use the implant in Europe and Israel. Thus far, the results have been excellent"

What makes your implant unique?

"It is an implant made of a solid frame that holds a thin mesh, which is significantly more delicate than existing implants. The surface of the mesh is coated with titanium dioxide, which creates a hydrophilic environment that improves its compatibility with the surrounding tissue. The frame eliminates the need for anchoring the implant and in doing so, it solves the main problems caused by existing solutions – mesh exposure in the vagina and the pain resulting from the surgery. We have been monitoring women with this implant for nearly four years now and the results are excellent – we have managed to eliminate the complications and pain experienced by many women who were implanted with the older implants."

Iram Levit, co-founder and CEO of Lyra medical, adds that "We know the source of the problem is not the implant itself or the material it's made of, rather it is the need for anchoring the mesh to create a hammock that supports the organs. The anchoring process is complex and could give rise to problems during the procedure. We also assumed that it

could cause problems further down the road, such as chronic pelvic pain and mesh erosion and exposure through the surgical incision.

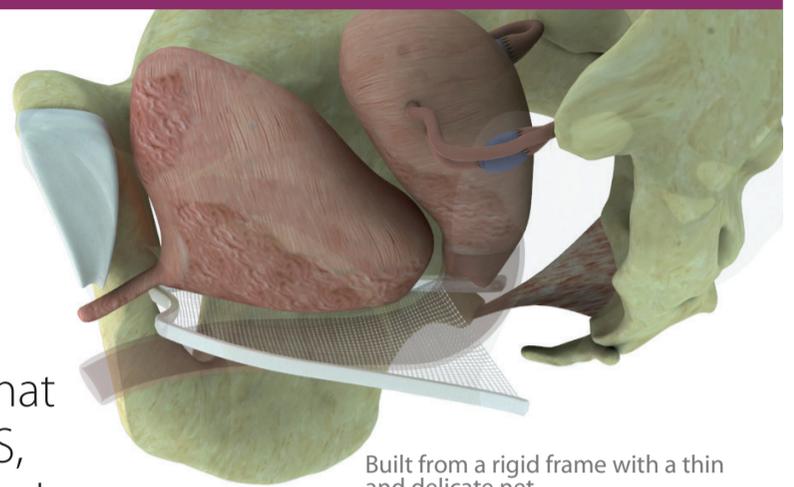
"We had a dual goal – to combine the proven efficacy of existing implants, but eliminate all its issues – namely, to provide an implantable solution that offers the increased safety of the older treatment, of suturing the connective tissues.

"According to our theory, if we eliminate the need to anchor the implant all the problems will disappear, so we started developing an implant that does not require anchoring. In the past few years we have clinically tested about 70 women and we are the only company in the world that received regulatory approval for an implant only after clinical trials were performed. Until now, implants were approved without significant and reliable clinical data. We believe it is important to show significant and reliable clinical data prior to approving the implant for general use.

"In the US, for example, the FDA has stiffened requirements for receiving regulatory approvals for similar implants and the only two companies that decided to reapply for approval of their product, did not manage to provide clinical data that proves their implant is better than the common solution of suturing the connective tissue in the vagina. That's why the FDA has removed all the vaginal approach implants from US shelves"

What is the procedure of inserting the implant you developed?

"The implant is inserted into the pelvis under partial regional anesthesia. It is a relatively short procedure, 20-30 minutes, and the patient can be discharged within 24-48 hours. Within a month, she can return to her usual activities. The implant is permanent, meaning there no need to replace it. In the four years we've been monitoring patients, over 95% success rate has been reported, meaning that the women feel normal, do not sense any pelvic organ prolapse and their sexual activity is not limited. And the implant achieved all that with an impressive safety profile"



Built from a rigid frame with a thin and delicate net. Lyra Medical's innovative implant

Combining Medicine and Engineering

Dr. Levy is a gynecologist who specializes in pelvic floor treatment – a urogynecologist; while Levit is a bio medical engineer with a business and marketing background in the medical device field. After the two met, they came to the conclusion that there is a need for a new product and devised a concept for solving the problems of existing products. "The combination of the two of us – of medicine, engineering and business – is the only way to manifest such creativity," says Levy.

What are your goals for the near future?

"We want to expand our activity in Israel and Europe so that the implant will be accessible to every woman. Naturally, we also have plans to expand to other countries. As I mentioned, the situation in the US at the moment is that there are no good solutions on offer that combine the efficacy of the implant and the safety of suturing the connective tissues. We definitely see this as an opportunity and plan to obtain all the regulatory approvals, including extremely accurate clinical trials that compare our solution with the common solution that exists today, of suturing the connective tissue. "The first company to successfully overcome all the obstacles and obtain the necessary approvals for the rigorous US market will be both the one that presented the superior solution and the only one on the market. By our indications and based on further trials and data, we are certain we can comply with the rigorous US regulatory requirements," concludes Levit.



Iram Levit,
Founder and CEO of Lyra Medical



Dr. Gil Levy,
founder and CMO of Lyra Medical

Lyra Medical

Established: in 2012

Location: Binyamina

Contact:

info@lyramedical.com