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VERIGRAFT Is Taking A Fresh Approach To Personalized Tissue Grafting

by Barnaby Pickering

The Swedish company has developed a proprietary method of personalizing venous grafts, and plans to bring it – alongside some other products – to the market.

Characterized by edema in the extremities, discomfort and numbness, chronic venous disease (CVD) is an illness that impacts approximately 25m adults in the US.

Mechanically, CVD is expressed as either insufficient or backwards flow of blood in various regions of the body – occurring mostly in the legs. Varicose veins can credit their etiologies to CVD.

When not managed properly, CVD can progress to chronic venous insufficiency (CVI). At this point, patients can lose motion in their extremities and suffer debilitating ulcers – amputation is an all–too–common result.

Of the 25m adults with CVD in the US, approximately 6m have severe disease. A yet smaller subset of these will require tissue grafts to replace their damaged veins and restore blood flow.

But the current options available are inadequate. Gore (the company behind Gore-Tex – which you will likely find in your raincoat) currently dominates the market with its PROPATEN line of products, however these were originally designed to mimic arteries, not veins, and thus have wildly different mechanical properties.

In poorer geographies, this gradient of CVD-CVI can be much more worrying on a population-health basis. A recent paper published in Venous and Lymphatic Disorders looked at adult populations of urban Iranians. It found that CVD impacted almost 40% of patients, with CVI impacting approximately one percent. With a GDP per capita of just $4,000, Iran is ill-equipped to deal with the consequences.

There are start-ups looking to tackle this multi-faceted problem. LimFlow, HumaCtye and Envveno are just some examples of companies working on grafting technologies that allow surgeons to bridge or replace failing vessels.

However, Petter Björquist, CEO of VERIGRAFT believes that his company's approach to the patient-level personalization of grafts will be the way forward.

Speaking to Medtech Insight, Björquist said that there were two major challenges facing the personalized tissue grafting sector: a lack of accurate anatomical matching, and cost.

"The key thing about veins in the groin is that they have valves in them to prevent backflow – most solutions don't consider this," he said, pointing out that the introduction of sub-optimal grafts often leads to thrombosis, infection and, ultimately, rejection.

"And even if they do [consider anatomy], a challenge that is faced with all advanced therapies is the cost-of-goods – the manufacturing," continued Björquist.

"There are cell and gene therapies that have a cost-of-goods of several million Swedish Crowns (1USD ≈ 11SEK) ... Of course, the readiness to pay is about how severe the disease is."

For VERIGRAFT though, cost-of-goods and readiness to pay are almost non-issues. Björquist described the company's method of manufacturing, which sees them submerge decellularized, organ donor-derived tissue in a patient's blood, alongside the utilization of some exclusive "tricks" for approximately ten days, as "lean."

It is through this method that the company produces grafts that are close to the real thing as possible, on a patient-by-patient basis.

"We can do this because we have a really robust set of patents," he explained. "There are other people out there using cells... they harvest cells from places like the bone marrow, identify the correct ones and then grow them. This is a process that takes typically three, four, up to six months, with significant costs and labor associated."

Bypassing this, of course, means that any of VERIGRAFT's future products will likely have some competitive pricing attached.

Future Plans

VERIGRAFT is bold in its ambitions.

Its first product will be a venous graft – of which an early-stage clinical trial is already underway.

Following that, the company hopes to launch an arterial graft, personalized heart valves and then potentially urethral and nerve grafts – the latter of which will see it butt heads with Axogen. (Also see "*Axogen, Dario Health, Biobeat, Immunexpress All Weigh In On 2022 And What Will Succeed In 2023*" - Medtech Insight, 2 Feb, 2023.)

Editor's Note: Attentive readers may spot that, out of the product markets VERIGRAFT is working on, the market for heart valves is one of the most valuable. This is the case, but Björquist explained that the company's current method of personalizing grafts works best for hollow, tubular tissues. Heart valves, which are neither, are trickier to personalize with this particular process.

It also intends to do all of this relatively quickly. Outlining his expectations for the business, Björquist said he hopes to have made serious headwinds over the next four years.

Each of its product types will also undergo an iterative process where their manufacturing methods are improved.

"We see our technology progressing in three steps," he said. "Right now, we use human donor-derived material. We hope to first go to market with this strategy in place."

"But the next step is to use material from large animals – the arteries of cows, pigs and even sheep are very similar to those of humans… you can imagine how much of this material is wasted every day," Björquist continued.

The last step, he revealed, could be to print the graft materials. "Bioprinting is advancing very quickly. I view it as 'humans today, animals tomorrow, printing in the future.'"

Market response to VERIGRAFT's progress has been universally positive, Björquist said. He remarked that competitors are often impressed by VERIGRAFT's technology and are apparently "keen" to learn more.

"Big players are getting worried that by small companies like us turning up and proving that we can take market share. We are still some way off market, but I do not think three years is an unreasonable expectation."

Managing (Great) Expectations

Located in Sweden – not the coastal marshlands of Kent – VERIGRAFT has an international cohort of investors. America's Scientia Ventures, South Korea's IDV Funds and Korean Stem Cell Bank and Switzerland's Alden Holdings are the company's biggest shareholders.

Björquist said that VERIGRAFT's investors have great expectations for the burgeoning start-up.

Some of VERIGRAFT's direct competitors have impressive public-float valuations – Axogen at approximately $250m and Humacyte at approximately $383m. The returns for investors could be significant.

But more money will first need to be raised. The company is currently working to raise $40m – a significant amount for any start-up, let alone one based in Europe – in two tranches.

Investors vary in nature by location, though. Björquist said that, compared with its domestic investors, those in America and Korea are "different."

"Some investors want a quick exit with minimal risk," he continued. "Americans, in particular, can wait to exit, but they want it to be huge. Our hope is that everyone who has invested can make a healthy exit – we may have to replace shareholders over time."

Circling back to the planned cash raise, Björquist said the money should take the company to "first market launch. We take a patient from being sick, to healthy... because it is so black and white, we think we can probably go to market with less than 100 trial patients."

Indeed, there may soon be a precedent for this. Björquist pointed out that, in the pharma universe, advanced therapies are breaking onto the market following smaller and smaller trials.

Questions about trial size directly feed into questions about where to perform them – but VERIGRAFT is close to an answer.

Clinical trials in the US tend to cost orders of magnitude more than those in Europe, but Björquist noted that regulators both in the US and Europe are beginning to consider data derived from opposite each other's sides of the pond.

"Both the FDA and regulators in Europe are saying you can have a mix of data – say 80% US, 20% European, or the opposite. I think our plan will be to do one small trial in the US, and two bigger ones in Europe," he explained.

Willingness To Pay

Questions beget questions; trial location decided, VERIGRAFT must then choose where to first sell its products.

This is an incredibly thorny issue for European medtech start-ups. Naturally, they feel some loyalty to their home bloc, however launching in the US grants access to the bigger budgets of higher payers.

"Willingness to pay and reimbursement – whether it comes from authorities, private persons or

insurance – can both be discussed forever," joked Björquist.

He did note though, that when VERIGRAFT approached potential stakeholders in the US with their initial price – one that was derived from European health economics – the people there described the price as "crazy. They said we could raise the price five times and that if we did not, we would just be losing money."

Raising the price post-launch, though, in either the US or Europe, would be "very hard."

"We will consider carefully where we launch," Björquist said. "Our board sees advantages of both a US and European launch... we will do a vote and decide as a group. People [in our board] are always acceptive of these votes, so we will have to see what will happen."