

## Q&A with David Hovda, President and CEO of Simplify Medical, Inc. developing a revolutionary Non-Metal Cervical Artificial Replacement Disc as an alternative to Fusion in Spinal Surgery that better Matches the Cervical Anatomy of the Patient



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**CEOCFO:** *Mr. Hovda, what is the vision behind Simplify Medical?*

**Mr. Hovda:** We are developing a cervical artificial disc as an alternative to fusion for patients who would like to retain motion as opposed to locking their joint, which is typically what happens with fusion. Our device has several unique features and benefits that we are evaluating in two clinical trials in the US and we are really pleased with the results we are seeing so far.

**CEOCFO:** *Is the world pretty much in accordance fusion surgery is not really the best option or are people still looking at that as the gold standard?*

**Mr. Hovda:** I think it is in the process of changing but I would say in general, fusion is still likely the gold standard given its long history. However, alternatives are being evaluated. Artificial discs are an excellent option for the appropriate patients and there have been several approved. The long-term data is holding up and the patients who have experienced benefits have now seen them out to 10 years. In general, the revision rates, or explant rates, are lower for disc replacement than fusion. I think fusion will always have a role for patients with certain clinical issues, but I think disc replacement is really starting to take its place as a frontline treatment for many patients who are good candidates.

**CEOCFO:** *What is the new vision for surgical disc replacement at Simplify?*

**Mr. Hovda:** We use different materials than most other artificial discs. Our Simplify Disc is a non-metal disc comprised of a medical-grade polymer called PEEK, which has been used extensively in spinal surgery, for our endplates with a ceramic core. Because we have very little metal in our device, it images very well on MRI. MRI provides a lot

more information for surgeons on soft tissue and it also does not expose patients to ionizing radiation like CT scans do. Importantly, we also offer lower height options that we feel better match patients' cervical anatomy, which we believe is ideal for a motion-retaining device, as opposed to a fusion device. Given these advances, we have no metal wear in the articulation surfaces, and metal has been implicated in some disadvantageous clinical issues, especially in the hip space. In addition, our device provides the advantage that it has no nickel. We are seeing an increasing number of patients who indicate they have allergies to nickel and most metals or metal alloys have nickel in them, so those patients are struggling to find appropriate treatments. We certainly look forward to providing a new cervical disc alternative with these distinct advantages.

**CEOCFO: *How did you know what materials to use?***

**Mr. Hovda:** We have significant experience in cervical motion preservation. We were able to look at other joint replacements, especially in the hip and knee which have had a long, useful life, along with other spinal implants. PEEK was well documented as a medical grade polymer. We also saw a lot of ceramic usage in hips. We liked the softer PEEK articulating on the harder ceramic and we were trying to look for a non-metallic combination. We felt that PEEK-on-Ceramic was really the ideal combination for the cervical application. There has been some work done on PEEK-on-Ceramic hips in Europe, but we took two well-characterized, experienced materials and put them together for the first time in the cervical spine.

**CEOCFO: *One of the things I see on your site is that Simplify Disc is anatomic in design. Is that unusual?***

**Mr. Hovda:** I think it is unusual in the cervical artificial disc space. When we say anatomic, we mean the heights of the implants are designed to better match patients' anatomy. We have a dome on our superior endplate that fits into what is typically a dome in the vertebral body above the disc space. We did a study looking at what is the average disc height of patients. It turns out that, at least for the North American patients in our previous clinical trial, the average disc height was about four millimeters tall. When you look at the other cervical disc replacements, their minimum heights are five and half to six and in some cases seven millimeters or higher. I think the original cervical discs tried to match their height to fusion spacers, but in fusion, you are trying to stop motion and stretch the anatomy, whereas with the motion preserving device, the goal is to retain motion. Our belief is that a cervical disc replacement that better matches the natural anatomy is going to offer patients better biomechanics and, hopefully, better long-term clinical outcomes, which is what we hope to demonstrate with our clinical trials.

**CEOCFO: *What has been the reaction from the people in the medical community who are aware of what you are doing?***

**Mr. Hovda:** Reactions to date have been very positive. We hear that with most cervical disc replacement options available on the market, that 90-95% of the discs implanted are the lowest height implants offered by manufacturing companies. With any kind of normal distribution, if the lowest height is used 90% of the time, you would say it is probably too tall, but the best currently available. I think surgeons are excited about our lower height options. In addition to disc height optionality, the imaging is also really beneficial because it does not preclude future

imaging of MRI, which is the preferred imaging for patients. With other devices that have metal endplates, you would typically have to get the CT scan, which is more for imaging of bony structures, not soft tissue imaging, and it exposes patients to substantial radiation. Our disc allows surgeons to use MRI to evaluate their patients while avoiding the limitations of CT imaging.

**CEOCFO: *You mentioned clinical trials. What is your timetable?***

**Mr. Hovda:** We are currently conducting two clinical trials, both for one-level and two-level treatments. We completed enrollment in the one-level trial in Q1 of this year and we have just recently completed enrollment of the two-level trial this month – which was quicker than anticipated and a result, we believe, of the exceptional interest we’ve received for our Simplify Disc. For both trials, we then have to follow patients for two years and then we submit that data to the FDA. If all goes well, we are still looking at at least two years out before potential approval in the US.

**CEOCEO: *How do you encourage patients to try something new?***

**Mr. Hovda:** While I’m not a surgeon, I will say that the cervical disc market is now a viable market. There are FDA approved discs and a lot of patients typically tend to opt for the FDA approved product. As more data are generated through clinical trials, the market becomes more mature and I think it comes back to a conversation between the surgeon and the patient to discuss the potential advantages of an investigational or recently approved device and how it may better treat the individual patient. Considerations that arise are: Do patients prefer to opt for a device that is commercially available and their insurance company will pay for it, or do they opt to enroll in our clinical trial because they find the potential benefits that we offer to be more compelling? We have been fortunate, as we enrolled our trials ahead of schedule and I think it is on the basis of our distinct potential benefits.

**CEOCFO: *Is the investment community aware? What do they think? Are you looking at funding?***

**Mr. Hovda:** Actually, at this time we are not seeking funding. We completed a fairly substantial Series B financing, partly in 2017 and partly this year, of \$44 million. Like any private company, we may need money in the future, but for now we are well financed and not raising money. Later in 2019, we expect to raise funds for the company to commercialize our technology, assuming everything goes well with our clinical trials.

**CEOCFO: *What is it you understand about bringing a product to market or will you be taking on additional people when the time comes?***

**Mr. Hovda:** It is a combination of the experience that we already have on the team, and expanding the team to commercialize. The spine market is primarily a distributor-driven market. Even the large spine companies typically have exclusive distributors. Typically, their distributors can work with a company like ours if the parent company does not have a cervical artificial disc. We believe we will have access to very strong professional distribution with our really unique, proprietary Class III device. We would certainly have to add to our team, but we do have members of the team right now who have experience commercializing technology in the spine space and other medical specialties.

**CEOCFO: *Are Simplify discs available in other countries now?***

**Mr. Hovda:** It is available outside the US. We have CE mark, which allows us to sell in Europe and we have commercialized in a very targeted, controlled way in the UK and especially in Germany, with one large hospital clinic group who reached out to us because they really wanted a non-metallic disc option for their surgeons. We are working with them, with a high-level of control and support, in parallel with our clinical trials in the US.

**CEOCFO:** *What surprised you as Simplify Medical and the concept have grown and evolved?*

**Mr. Hovda:** I have been very pleased to see the acceptance and interest in cervical disc replacement continue to grow. I spoke to many of my friends about how thirty of forty years ago, if you had a hip problem, your hip would be fused and most people are shocked to hear that these days. The majority of spine patients who have degenerative disc disease currently are fused. I am excited to see the growing awareness and interest in retaining motion and some of the good work done by companies who preceded us in terms of how durable and excellent the clinical outcomes are for cervical disc replacement. We certainly look forward to being an important option for treating patients with cervical disc disease and are excited about the interest in advancing development of our Simplify Disc.

