Key Questions Related To The Use Of The Cartiva® Synthetic Cartilage Implant For The Treatment Of Hallux Rigidus

Interview with Patrick Fisher, President of U.S. Lower Extremities and Biologics at Wright Medical

Hallux rigidus, osteoarthritis of the big toe joint, is a painful condition that causes pain and a progressive decline in mobility and physical activity, which can have a compounding negative effect on a patient's health and well-being.[1] This is a patient population that is more active than ever before, with a desire to remain active for as long as possible, which makes motion preservation a critical consideration for those seeking treatment.[1] The historical gold standard for treatment is fusion surgery, an effective procedure for pain relief but one that also eliminates motion of the big toe in the process. As result, physicians and patients alike are looking for new treatment options that not only address arthritic pain, but also preserve toe and foot movement.

First approved in the United States in 2016, the Cartiva® Synthetic Cartilage Implant (SCI) presented physicians with a new treatment offering for patients suffering from painful hallux rigidus that not only reduces pain, but also preserves motion.[2] New technologies like Cartiva raise a great deal of hope for patients who are seeking pain reduction but are not ready to sacrifice their toe motion. However, without realistic expectation setting on the front end, patients may not have an appreciation for the time it takes to achieve the full benefit the Cartiva procedure offers. In fact, a recent case series raises questions related to the proper use of Cartiva to ensure successful clinical outcomes.[3] Wright Medical, the company behind the Cartiva SCI, is stepping up to answer some of those questions.

A recently published retrospective case series suggests different results for Cartiva than the published Level I evidence from the pivotal clinical trial. Why is there a difference?

We have reviewed this recently published retrospective case series and believe it can provide insight into the day-to-day use of Cartiva in clinical practice. However, reports from this case series have various confounding factors and significant limitations, as noted by the authors, that prevent a direct comparison to the pivotal trial, including concomitant procedures, varied surgical techniques, varied recovery and rehabilitation techniques, dissimilar methods of data collection and a wide range of follow up time points.[3,4] While it is important to learn from real-world experience, it is more scientifically valuable to consider the safety and efficacy data from the MOTION study, which was a Level I, multicenter, prospective, randomized clinical trial.[4] Still, this case series does provide insight into the variables that should be considered to ensure an optimal outcome with the use of Cartiva in clinical practice. We are in full agreement with the conclusion made by the authors of the case series that patient selection, setting patient expectations, following the surgical protocol and post-operative management are key to successful clinical outcomes and patient satisfaction comparison.[3] These important factors have been, and continue to be, the focus of our physician education efforts. To support physicians and patients through the recovery process, Wright Medical produced a patient recovery guide that outlines proper postoperative and recovery care. The guide can be accessed on www.cartiva.net .

Why do you believe there have been differences in some physician and patient experiences with Cartiva?

The technology behind Cartiva is new and as with any medical device, we recognize the importance of educating physicians on the proper use of the device and managing patient expectations. We want to ensure our clinical data is appropriately contextualized to balance highlighting the value of Cartiva with setting realistic expectations for patient recovery and outcomes. Based on our MOTION clinical trial data, we are very confident in the safety and efficacy of Cartiva and believe the procedure can deliver a powerful benefit to patients' quality of life by preserving motion in the first metatarsophalangeal (MTP) joint.[4] We will continue to focus on helping physicians achieve the very best outcomes with Cartiva, including providing educational tools to address patient selection, setting patient expectations, proper surgical protocol and post-operative management.

Why is the Cartiva revision rate observed in the case series higher than reported in the pivotal trial?

The removal and revision rate observed in the retrospective case series is actually on par with what was seen in the clinical trial. While the reported reoperation rate in the case series is 20%, that number included four patients who underwent scar tissue removal, which may not be related to the

device.[3] If we were to look at the reoperation rate against the same measures used in the pivotal trial, the case series observed a 14.5% reoperation rate, which is closer to the 11.2% reoperation rate observed in the MOTION trial.[3,4] As new data becomes available, it is important to recognize that many real-world cases include confounding, concomitant index procedures like debridement, Moberg osteotomy and conversions to an arthrodesis that could impact the reported re-operation rate.[3]

Appropriate patient selection was a big takeaway from the case series. Who is the right patient for a Cartiva procedure?

Patient selection is important and should take into consideration multiple variables. Cartiva is intended for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first MTP joint with or without the presence of mild hallux valgus.[2] When determining if a patient is a good candidate for Cartiva, one should first take into account the inclusion and exclusion criteria from the published MOTION study.[4] It is clear that those patients with good bone stock, advanced arthritis that has failed to improve with non-operative treatment, who are not taking medications that weaken bone, and having daily walking pain at a level of 40 out of 100 on a visual analog scale benefit from Cartiva. A full list of contraindications and precautions can be found in our Instructions for Use (https://www.cartiva.net/ifu/).

What outcome should physicians and patients expect from Cartiva SCI?

Cartiva can provide long-term pain reduction and motion preservation for people suffering from hallux rigidus. However, it is important that patients are aware of the recovery time required to see the full benefit of the Cartiva procedure. On average, patients will start to experience clinically meaningful pain reduction and functional improvement (e.g., activities of daily living) at three months, and this improvement will continue for up to 24 months. On our website, physicians can find a graph that visually demonstrates median improvement in pain reduction from pre-op to 5.8 years. This can be helpful to share with patients to set expectations. In the post-approval, multicenter, prospective, randomized study, the long-term benefit of Cartiva was demonstrated in patients who experienced 97% reduction in pain at 5.8 years post-procedure, and 93% of patients were satisfied and said they would have the procedure again.[5]

In addition to setting expectations around the recovery timeline, it is also important to address what motion preservation looks like. Patients receiving a Cartiva implant can expect to restore movement to their baseline preoperative level of big toe joint motion. This means that the benefit Cartiva provides is to preserve the big toe joint motion the patient currently has instead of losing it completely. The ability to bend the big toe generally returns to baseline within two weeks of surgery and continues to improve over the next 24 months.[4]

What expectations should be set for patients about recovery timeline?

The progression of hallux rigidus occurs over time and taking the time to recover is important to unlocking the long-lasting pain reduction Cartiva can provide. Because Cartiva uniquely preserves joint mobility and is intended to mimic the natural movement of the joint, it will take the joint time to fully heal. It is perfectly normal for patients to experience residual pain during recovery as they begin to move a joint that has been stiff or inflamed due to years of arthritic progression and then subject to a surgical procedure. To ensure proper recovery, patients should follow a strict recovery regimen for six to 12 weeks.[6] For the first two weeks post-procedure, patients should take care by elevating their foot while sitting, avoiding physical activity, and protecting their foot with compression wrapping and a postoperative shoe.[4,6] After sutures are removed, patients can start motion exercises at home or physical therapy as directed by their physician to slowly ease back into movement.[4,6] Every patient is different, so easing back into movement should be contingent upon his or her pain levels at that time. As I mentioned earlier, to support physicians and patients through the recovery process, Wright Medical produced a patient recovery guide that outlines proper postoperative and recovery care. The guide can be accessed on www.cartiva.net .

To summarize, Cartiva is backed by the highest level of prospective, randomized clinical research and has been proven to be a viable alternative to fusion for patients wanting to maintain range of motion. With almost six years of follow up from a rigorously conducted clinical trial, the data supports Cartiva being a game changer in the treatment of patients with painful degenerative or post-traumatic arthritis in the first MTP joint. We look forward to continuing to provide physicians and their patients with this breakthrough technology. ■

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