



Device Name: VersaWrap

Manufacturer: Alafair Biosciences (info@alafairbiosciences.com)

Indication for Use: VersaWrap is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The device may also be used in the management and protection of surrounding tissues such as skeletal muscle and ligament. In these procedures, VersaWrap may encounter a variety of implanted structures such as anchors, grafts, staples, and sutures. VersaWrap is indicated for the management of peripheral nerve (including nerve root) injuries in which there has been no substantial loss of nerve tissue.

FDA Clearances: K160364, K200311, K201631, K203600, K213163, K232029, K240817

Important Note:

- Per FDA guidance, this page must be distributed with the attached article
- Do not distribute this article with promotional material for the device
- This article describes off-label use of VersaWrap to be injected into the joint to prevent pain which is associated with an intended use that is not approved

Surgical Arthroscopy With Intra-articular Hyaluronic Acid/Alginate Adjunct in the Treatment of Ankle Osteoarthritis

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Abstract: Ankle osteoarthritis is a debilitating condition, resulting in severe pain and limited function. Patients who fail conservative management may pursue arthroscopic debridement or advanced reconstructive procedures. Biological adjuncts such as hyaluronic acid can be used alone or in conjunction with surgical intervention. Their use alone has been shown to improve pain and function. We present a surgical technique using a hyaluronic acid-alginate adjunct, VersaWrap, during arthroscopic treatment of ankle osteoarthritis.

Level of Evidence: Level IV.

Key Words: hydrogel wrap, Versawrap, hyaluronic acid, arthroscopy, ankle arthritis

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HISTORICAL PERSPECTIVE

Despite greater weight-bearing loads and higher rates of injuries, the incidence of ankle osteoarthritis lags behind that of the hip and knee.¹ However, ankle osteoarthritis is not without severe pain, limited physical function, and poor quality of life.² Patients who fail conservative management may elect for reconstructive procedures such as supramalleolar osteotomy, arthrodesis, and total ankle arthroplasty.^{3,4} An alternative technique is surgical arthroscopy involving lavage and debridement with or without microfracturing.⁵ Viscosupplementation in the form of hyaluronic acid can be used concomitantly with ankle arthroscopy. Its use alone is associated with improvements in pain, function, and quality of life.⁶

One form of viscosupplementation is VersaWrap (Alafair Biosciences), a plant-based bioabsorbable hydrogel consisting of hyaluronic acid and alginate.⁷ It serves as a semipermeable surface that allows for the diffusion of growth factors needed for physiological remodeling and healing. VersaWrap can be applied as an ultrathin sheet or as a gel, which accommodates its use during surgical arthroscopy. Previous studies mostly describe its use in addressing compressive neuropathies, peripheral nerve transection injuries, and tendon injuries.^{8–10}

However, VersaWrap's smooth gliding surface, semipermeable membrane, and conformable nature make it an

ideal supplement in addressing ankle osteoarthritis. The authors propose a technique for utilizing VersaWrap during surgical arthroscopy for ankle osteoarthritis.

INDICATIONS AND CONTRAINDICATIONS

VersaWrap can be used as an adjunct in the setting of ankle osteoarthritis managed with surgical intervention. Other indications specific to foot and ankle surgery, outside the scope of osteoarthritis, include tendon repair, ligamentous reconstruction, and compressive neuropathies. VersaWrap is contraindicated in the setting of infection and allergy to its polymers-hyaluronic acid and calcium alginate.

PREOPERATIVE PLANNING

Anteroposterior, lateral, and oblique radiographs of the ankle should be performed before surgical intervention to evaluate for sclerosis, joint space narrowing, impingement, loose bodies, and other pathologies within the ankle. Computed tomography can also be used to further assess for osteoarthritis of the ankle joint.

In the operating room, the patient should be placed supine on the operative table. A nonsterile thigh tourniquet is placed on the affected extremity. Padding in the form of foam or towels should be placed under the affected extremity at the level of the thigh to allow for hip flexion to 45 degrees and knee flexion to 90 degrees. This aids in positioning for the ankle arthroscopy portion of the case. All bony prominence is well padded. The operative extremity is prepped and draped under usual sterile conditions.

TECHNIQUE

Ankle arthroscopy using standard anteromedial and anterolateral portals is first performed to evaluate the joint, debride fibrinous tissue and inflamed synovium, and remove any loose bodies. Before the application of VersaWrap, fluid from the joint is evacuated, and the portal sites are closed with 3-0 Nylon (Ethicon).

APPLICATION OF VERSAWRAP

The VersaWrap must first be prepared into a gel consistency before insertion into the ankle joint. The VersaWrap is placed into a 10 mL syringe without the plunger. A citric acid solution is applied to the VersaWrap (Fig. 1) and the solution is mixed using a blunt instrument until the wrap is completely dissolved (Fig. 2). Once dissolved, saline may be added to the solution until a desired consistency is achieved (Fig. 3). Attach an 18 G needle to the syringe and inject the VersaWrap hydrogel into the

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S.G.P. or an immediate family member holds equity in Alafair Biosciences. The remaining authors declare no conflict of interest.

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FIGURE 1. A citric acid solution is placed into the syringe containing the VersaWrap hydrogel.

ankle joint (Fig. 4). The site is then covered with a sterile dressing followed by a bulky Jones splint in neutral dorsiflexion and plantarflexion and neutral inversion and eversion.



FIGURE 3. Small aliquots of sterile saline may be added to the solution to reach the desired consistency.

RESULTS

The aforementioned case describes a 56-year-old female who presented with post-traumatic osteoarthritis of the ankle joint with a loose body along the medial aspect of



FIGURE 2. A, A blunt instrument. In this case, a sterile Frazier tip suction is used to mix the citric acid-VersaWrap solution. B, Mixing continues until the hydrogel is completely dissolved.

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