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Case Series

ANTERIOR CERVICAL DISCECTOMY AND FUSION UTILIZING ALLOWRAP® AMNIOTIC MEMBRANE TISSUE BARRIERS

Paul D. Kim, MD
Katherine Lumahan, BS
Janice He, BS

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INTRODUCTION

Anterior cervical discectomy and fusion (ACDF), remains the gold standard for the surgical treatment of patients with radiculopathy and/or myelopathy caused by cervical intervertebral disc herniation or spondylosis.[1] ACDF is a common procedure to relieve pain and dysfunction by decompressing and stabilizing the affected cervical segments. After discectomy, stabilization is achieved by implanting an interbody followed by a fixation plate secured anterior to the vertebrae, stabilizing the spine and supporting bone fusion.[2] Decompression and stabilization may also be accomplished with a stand-alone interbody designed to eliminate the need for anterior plating and subsequently reduce operative time and the amount of soft tissue dissection.[3]

Dysphagia is a common postoperative side effect of ACDF with an incidence rate up to 67%. It is especially common after multi-level procedures.[2,4,5,6] Dysphagia usually presents within the first week following surgery and may persist for more than a year. The incidence of dysphagia two years after anterior cervical spinal surgery is estimated to be 13%.[7] Contributing factors include patient age, gender, smoking status, prior cervical surgery and intraoperative steroid use.[1,8] Additionally, tissue swelling, induced by inflammation near the surgical site, can induce dysphagia (**Figure 1**). Complications include coughing or choking, foreign body sensation in the throat, food remaining in the mouth after swallowing, uncoordinated laryngeal movement, weight loss, and unexplained recurrent nausea and/or vomiting.

Postoperative dysphagia can result in prolonged hospital stay and higher 30-day readmission rates.[4,5,6,8,9,10,11,12] Implementing measures to minimize or prevent dysphagia, may improve outcomes and reduce costs associated with prolonged length of stay and readmissions.

Figure 1. *Post operative soft tissue swelling noted with red arrow (no AlloWrap implanted).*

A human amniotic membrane called AlloWrap® (AlloSource, Centennial CO) may be used as a physical tissue barrier between the esophagus and implants. When placed between the implants and the tracheoesophageal bundle, AlloWrap physically separates scar tissue from the tracheoesophageal bundle, preventing adhesion and thereby potentially decreasing the incidence of dysphagia. It is available in two configurations. AlloWrap, a moist, hydrated amnion format is especially suitable for minimally invasive surgical applications, whereas AlloWrap Dry, a dehydrated format, is optimized for open surgical procedures (**Figure 2**). AlloWrap or AlloWrap Dry may also reduce the occurrence of mass effect (i.e. pressing on the esophagus) due to their thin profile (approximately 50% thinner than placental membranes containing amnion and chorion layers).[13,14]

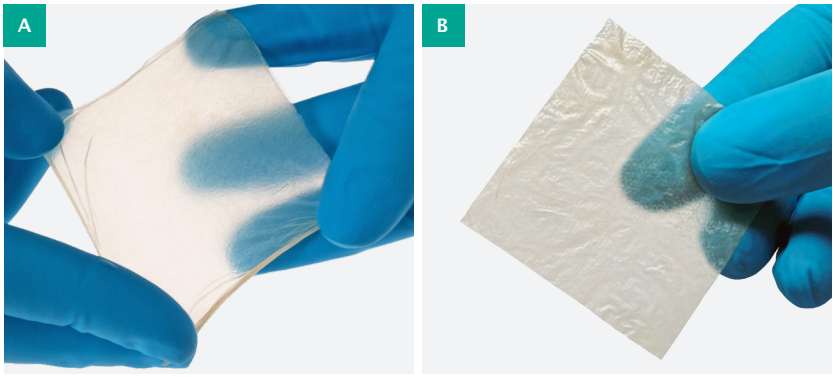

Figure 2. *(A) AlloWrap, available in a moist format. (B) AlloWrap Dry, available in a dry format.*

OBJECTIVE

This analysis presents patient-reported and surgeon-observed outcomes using AlloWrap Dry, for 10 single-and multi-level ACDF surgical patients.

METHODS

Clinical data for this study was retrospectively collected from anterior cervical discectomy and fusion (ACDF) procedures performed between 2022 and 2024. Dr. Paul D. Kim, a board-certified orthopedic surgeon at the Spine and Brain Institute of San Diego, California, USA, utilized AlloWrap Dry as a physical tissue barrier in these ACDF procedures. Dr. Kim employed the standard left-sided anterior cervical Smith-Robinson approach using a cervical stand-alone interbody cage. In this technique, the cage was implanted along the anterior edge of the vertebral body. Since a stand-alone interbody was used, no anterior fixation plate was required. AlloWrap Dry (2 × 4 cm) was placed anterior to the interbody cage in the interval between the medial tracheoesophageal bundle and the carotid sheath, serving as a barrier between the surrounding soft tissue and the implant (**Figure 3**).

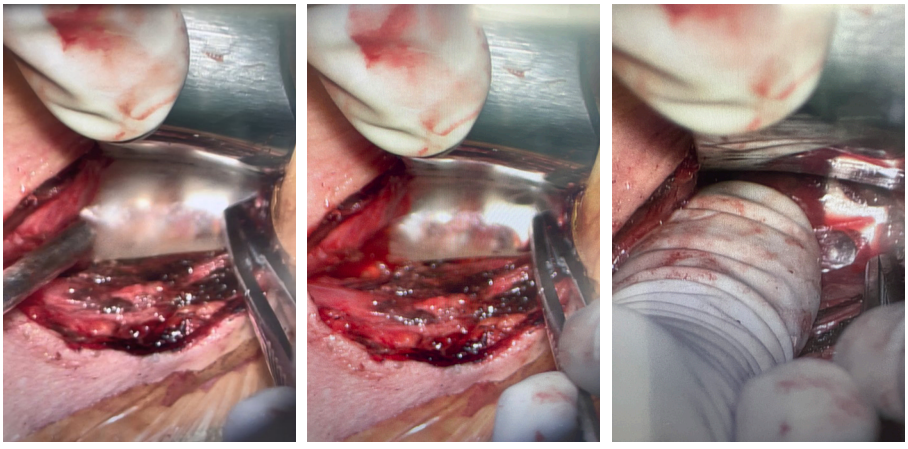

Figure 3. *AlloWrap Dry (2 X 4 cm) placed between the interbody, tracheoesophageal bundle and carotid sheath.*

Six of the ten cases involved high-risk, multi-level ACDF procedures. Patients presented with a range of spinal pathologies, with ages ranging from 40 to 80 years, and an equal distribution of male and female patients. Details of the ten cases are summarized in **Table 1**.

Patient	Age at procedure	Gender	Preoperative symptoms	Preoperative diagnosis	Surgical levels
1	80	Male	Poor balance Weak walking tolerance	Severe cervical stenosis Cervical myelopathy	4 (C3–C7)
2	74	Male	Back and left leg pain	Severe cervical stenosis Cervical degenerative disc disease Right cervical radiculopathy	2 (C4–C6)
3	63	Female	Neck, arm, back, and leg pain	Cervical stenosis Disc herniation Cervical adjacent segment disease Previous C4–6 fusion	1 (C3–C4)
4	40	Male	Left shoulder, neck, and right knee pain	Cervical stenosis Cervical radiculopathy Cervical degenerative disc disease	2 (C5–C7)
5	54	Male	Neck pain	Previous ACDF Pseudarthrosis Cervical stenosis	1 (C4–C5)
6	61	Female	Neck pain	Cervical stenosis Progressive weakness upper extremity Severe degenerative disc disease	2 (C5–C7)
7	74	Male	Back and bilateral buttocks pain	Cervical stenosis Cervical myelopathy Left arm atrophy	1 (C4–C5)
8	64	Female	Back and left leg pain	Cervical kyphosis Cervical degenerative disc disease Spondylolisthesis Cervical stenosis with cervical radiculopathy	4 (C3–C7)
9	55	Female	Back and neck pain Leg numbness	Cervical myelopathy Degenerative disc disease	1 (C5–C6)
10	53	Female	Right arm and leg pain	Disc herniation Degenerative disc disease Cervical radiculopathy	2 (C5–C7)

Table 1. *Summary of patient demographics and case details.*

RESULTS

Within the first postoperative week following use of AlloWrap, and independent of surgical level, nine of ten patients reported no dysphagia. One patient (Patient #7) reported mild dysphagia without aspiration or choking episodes. During this period, all patients progressed from a soft to a regular diet, and none required outpatient steroid therapy for postoperative swelling. At 1 to 3 months postoperatively, Patient #7 reported persistent dysphagia. Patient #6 was lost to follow-up, and no additional data was obtained for this individual. All patients were discharged on postoperative day 1 or 2, with no extended hospital stays (>2 days) or readmissions. Patient-reported outcomes are summarized in **Table 2.**

Patient	Age at procedure	Gender	Patient-reported outcomes (1 week following operation)	Patient-reported outcomes (1- 3 months following operation)	Surgical levels	Hospital stay
1	80	Male	No dysphagia reported	No dysphagia reported	4 (C3-C7)	2 days
2	74	Male	No dysphagia reported	No dysphagia reported	2 (C4-C6)	1 day
3	63	Female	No dysphagia reported	No dysphagia reported	1 (C3-C4)	1 day
4	40	Male	Coarse voice, no pain or swallowing issues	No dysphagia reported	2 (C5-C7)	1 day
5	54	Male	No dysphagia reported	No dysphagia reported	1 (C4-C5)	1 day
6	61	Female	No dysphagia reported	Patient non-responsive to follow up	2 (C5-C7)	2 days
7	74	Male	Some dysphagia, no aspirations or choking episodes	Some dysphagia, last reported at 3 months following operation	1 (C4-C5)	2 days
8	64	Female	No dysphagia reported	No dysphagia reported	4 (C3-C7)	1 day
9	55	Female	No dysphagia reported	No dysphagia reported	1 (C5-C6)	1 day
10	53	Female	No dysphagia reported	No dysphagia reported	2 (C5-C7)	1 day

Table 2. *Summary of patient demographics and case details.*

DISCUSSION

Postoperative dysphagia is common after ACDF, with an incidence rate up to 67%, which can impact patient recovery.[2,4,5,6] Factors that contribute to dysphagia include the number of fusion levels, patient age, gender, smoking status, prior cervical surgery and steroid use.

In this patient cohort in which AlloWrap Dry was utilized as a physical tissue barrier, nine of ten patients reported no dysphagia within the first postoperative week. At three months postoperatively, one patient reported persistent dysphagia, while one patient was lost to follow-up. No surgical complications or infections were observed during the study period.

CONCLUSION

AlloWrap provides a barrier separating the implant from surrounding tissue physically preventing adhesion which may reduce complications following ACDF. Minimizing the occurrence and complications of dysphagia may reduce length of stay and hospital re-admissions, benefiting patients, surgeons and hospitals.

ADDITIONAL APPLICATIONS FOR ALLOWRAP

As directed by the surgeon, amnion tissue may be used in other surgical procedures as a barrier to separate tissue or tissues, physically preventing adhesion.

- Lumbar spinal fusion in which it may be placed alongside the vertebrae and adjacent structures (e.g. aorta, inferior vena cava, iliac veins) to support vascular mobilization in revision surgeries.[15]
- Spinal cord untethering, in which it may be placed between the spinal cord dura and surrounding tissue to reduce retethering and tethered-cord syndrome.[16,17]
- Spinal laminectomies, in which it may be placed between the spinal cord dura and surrounding tissue, to reduce epidural fibrosis.[16,17,18]

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Dr. Kim completed medical school at Columbia University's College of Physicians & Surgeons. He did his orthopedic surgery residency training at The New York Orthopedic Hospital at Columbia University Medical Center. After his residency, Dr. Kim completed a spine fellowship at The Spine Institute at Cedars-Sinai Medical Center and Saint John's Health Center in Los Angeles, CA.

He is board-certified by the American Board of Orthopedic Surgery (ABOS) and is a member of the American Academy of Orthopedic Surgeons (AAOS).

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The AlloWrap family of products are covered by one or more of the following US patent numbers: 9,358,320; 9,480,549; 9,616,152; 9,795,707

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