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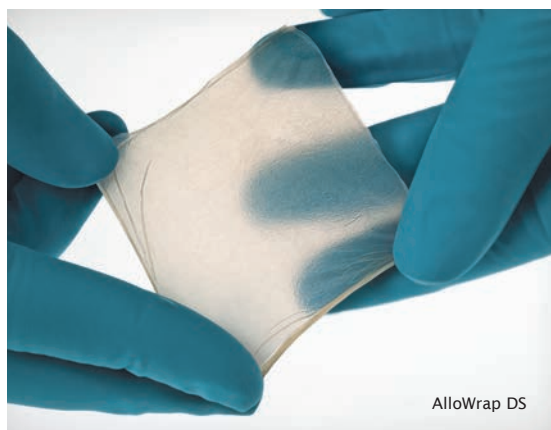
SPINAL UNTETHERING AND USE OF ALLOWRAP® DS BARRIER

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ABSTRACT

Spinal cord tethering is a neurological condition in which the spinal cord adheres to the spinal dura, impairing its longitudinal movement within the spinal canal. The resulting stretching between points of adherence can lead to syringomyelia, spinal cord dysfunction and permanent spinal cord damage. Surgical procedures can untether or free the cord, but these often must be repeated as the adherence has a strong tendency to recur.



This neurological dysfunction is called tethered cord syndrome (TCS). It is most commonly diagnosed in early childhood as a developmental abnormality related to spinal dysraphism or fatty filum, but can also develop in adult patients. The relatively low incidence in the adult population is often a critical factor in the delay in diagnosis and therapy for older patients.¹

We present a case of a TCS detethering procedure accompanied by the placement of AlloWrap® DS (AlloSource®, Centennial, CO) between the nerves and dura, creating a barrier intended to inhibit retethering. Recurrence of the tethering condition in this adult patient has not been apparent in the 18 months following the procedure.

Introduction

Tethered cord syndrome (TCS) refers to the pain and neurological dysfunction caused by elongation and stretching of the spinal cord when the cord and/or nerve roots adhere to the dura. Tethering occurs when the normal pia of the spinal cord and nerves is breached, allowing the spinal tissue to come into direct contact with the dura. It is typically encountered and surgically repaired in early childhood, often in conjunction with treatment for myelomeningocele, the most common form of spina bifida.

Nonetheless, the need for TCS detethering procedures in adults is growing. A spina bifida patient can be expected to live into adulthood,² and with that comes the need to repeat the procedure over the patient's lifetime. Additionally, diagnoses of adult onset TCS are increasing, often triggered by spinal cord injury due to trauma, intramedullary spinal tumors or spinal stenosis.³ In the adult population, recurrence of TCS following detethering has been noted to be as high as 25 percent.⁴

Both age and surgical complications have been identified as predictors of problematic outcomes of TCS detethering procedures.⁵ Additionally, repeated TCS surgeries over a patient's lifetime correlates with a higher likelihood of complicating neurological deficits such as nerve root damage, scarring and persistent cerebrospinal fluid fistula. Risks and procedural difficulties increase with each subsequent procedure.^{6,7} Therefore, minimizing the frequency of spinal cord detethering surgeries is an important public health goal for TCS patients of any age.

We present a case of TCS surgery accompanied by placement of AlloSource's AlloWrap DS, with properties designed to inhibit re-adherence of the cord and nerves to the dura. The adult patient has not had a recurrence of TCS symptoms in 18 months subsequent to the surgery.

Case Presentation

A 54 year old female patient, two years following her most recent detethering procedure, presented with TCS-related symptoms: progressive, intense burning in her right thigh; burning sensations in her lower leg; right leg weakness and falls; patchy numbness extending from her mid-abdomen to toes; and enuresis. Motor testing showed 4/4 strength in proximal groups.

The patient had a history of small meningocele at birth that had been repaired, and subsequently underwent eight detethering procedures over her lifetime. Baclofen pump therapy had been attempted but was discontinued due to pump failure. The patient also experienced urinary incontinence and had an ileostomy stemming from previous untethering and related procedures.

In November 2012, the patient underwent an L2 - L5 laminectomy with lumbar cord detethering. An AlloWrap DS Amniotic Surgical/Wound Barrier was sutured at the top and bottom between the spinal cord nerves and the dura and tucked over the tethered segment (*Figure 1*).

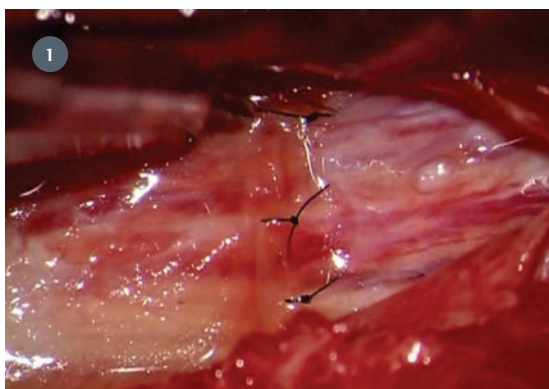


Figure 1. Wrap in place with tacking sutures. AlloWrap DS is to the left of the suture line, normal pia to the right.

Postoperatively the patient was non-weight bearing for two weeks, and the patient started physical therapy at three weeks. The patient had complete resolution of the paresthesias on her first postoperative visit, which continued through the most recent follow-up five months later. Subjectively, postoperative results using AlloWrap DS tissue were much improved as compared to the previous procedure.

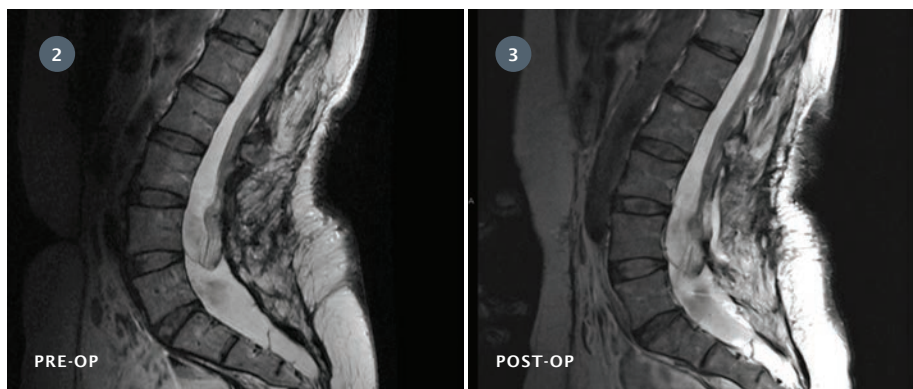


Figure 2. Shows an MRI of the patient prior to surgery.

Figure 3. Shows an MRI of the patient post-op with AlloWrap tissue in place.

Discussion

Barrier wrapping is commonly used to prevent nerve adherence to adjacent tissue. The ideal barrier should be inert so as not to incite an inflammatory response and allow for nerve gliding.⁸

In 2011, Meng investigated the use of human amniotic membranes to wrap sciatic nerves in a rat model and found the membrane decreased adhesions and scar formation.⁹ In 2002, Demirkan evaluated the use of amniotic membranes in flexor tendon repairs and found significantly reduced levels of adhesions. He also noted that three months after the repair, no remnants of the amniotic membrane were present at the tendon repair site.¹⁰

AlloWrap DS is a human amniotic membrane that can serve as a barrier following surgical repair. It is double-sided, with two layers of amniotic tissue oriented with the epithelial layers facing outward. The tissue is packaged wet and stored at room temperature for immediate use. AlloWrap DS constitutes a thin, strong membrane that conforms around the tissue. It still requires care in handling as it can be torn. It can be effectively positioned with or without suturing. Clinically, the tissue is immune privileged and remains in the surgical site longer than eight weeks.^{11,12}

While a single case does not constitute proof, we have found the clinical results in this case to be consistent with the experience of previous studies. We attribute the promising surgical outcome to the ability of AlloWrap DS to form a tissue layer around the spinal cord the spinal cord and exiting nerve roots, isolating and protecting them from surrounding tissues. The amniotic material could therefore provide a barrier which allows the cord to continue to glide freely and thus could significantly reduce the recurrence of spinal cord tethering.

Economic Consideration

Surgery for a tethered spinal cord is very expensive. In addition to the clinical benefits, potentially reducing the rate of re-operations for detethering of spinal neural anatomy could have a significant cost savings for the patient, physician, hospital and the healthcare community at large.

References

1. Shih P, Halpin RJ, Ganju A, Liu JC, Koski TR. Management of recurrent adult tethered cord syndrome. *Neurosurgical Focus*. July 2010. Volume 29. p.1.
2. Ibid.
3. NINDS Tethered Spinal Cord Syndrome Information Page. National Institute of Neurological Disorders and Stroke, National Institutes of Health. Downloaded http://www.ninds.nih.gov/disorders/tethered_cord/tethered_cord.htm.
4. Filler AG, Britton JA, Uttley D, Marsh HT. Adult postrepair myelomeningocele and tethered cord syndrome: good surgical outcome after abrupt neurological decline. *British Journal of Neurosurgery*. 1995, Volume 9. p.659-666. Cited in Shih p.2.
5. Lad SP, Patil CG, Ho C, Edwards MSB, Boakye M. Tethered cord syndrome: nationwide inpatient complications and outcomes. *Neurosurgical Focus*. August 2007. Volume 23. p.4.
6. Shih p.2.
7. Pouratian N, Elias WJ, Jane JA Jr., Phillips II LH, Jane JA Sr. Electrophysiologically guided untethering of secondary tethered spinal cord syndrome. *Neurosurgical Focus*. July 2010. Volume 29. p.1.
8. Sarris IK, Sotereanos DG. Vein wrapping with autologous graft for recalcitrant median nerve compression. *Atlas Hand Clin*. 2002;7:287-9.
9. Meng H, Li M, You F, Du J, Luo Z. Assessment of processed human amniotic membrane as a protective barrier in rat model of sciatic nerve injury. *Neuroscience Letters*. 2011;496:48-53.
10. Demirkan F, Colakoglu N, Herek O, Erkula G. The use of amniotic membrane in flexor tendon repair: an experimental model. *Arch Orthop Trauma Surg*. 2002; 122:396-9.
11. Akle CA, Adinolfi M, Welsh KI. Immunogenicity of human amniotic epithelial cells after transplantation into volunteers. *Lancet*. 1981;2:1002-5.
12. Samaniego AC, Ronholdt CJ, Ryan S, Ehrhart EJ, et al. Human amniotic tissue as an anti-adhesion, anti-inflammatory barrier in an ovine spinal laminectomy model. 2009; AlloSource.



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