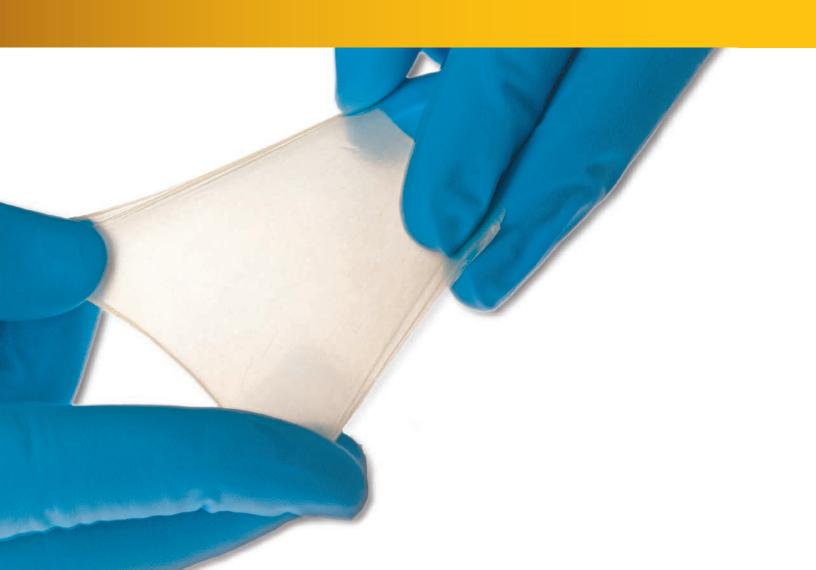


AlloWrap DS surgical barrier case study:

proliferation phase of the healing process



Case study: AlloWrap DS surgical barrier remains in the body through the cell proliferation phase of the healing process while other surgical barriers are resorbed

A review by Samaniego, Adrian, B.Sc., AlloSource, Centennial, CO

Abstract

Soft tissue adhesions due to traumatic injury, chronic inflammation or surgery are very common and have adverse clinical effects on nerve function and limb range of motion. These adverse effects can lead to ongoing pain, dysfunction and ultimately additional surgeries.

The basic healing process involves three primary phases: inflammation, proliferation and remodeling. The cell proliferation phase occurs when new cells are produced to close the wound. However, during this process, these cells contract as they mature, causing adhesions. The prevention of soft tissue adhesions through the use of surgical barriers is often used by surgeons. These barriers are ineffective if they degrade prior to cell proliferation. AlloWrap DS (AlloSource, Centennial, CO) has been shown to persist through this phase. 5,6

Introduction

Adhesion formation around soft tissue can be a major complication after injury, chronic inflammation, or surgery. Adhesions can lead to loss of excursion in tendons and/or peripheral nerve compression including potential loss of nerve function. Surgical intervention to remove scar tissue in these areas involves additional trauma

to these tissues and often results in recurrent scarring and undesired consequences.

The healing process

The healing process following soft tissue injury or surgery is an intricate biologic cascade of different phases (Figure 1).

Inflammation phase

Inflammation is a normal and necessary prerequisite to healing. Changes in vascular flow are responsible for the clinical symptoms we use to detect an inflammatory response. The majority of the specialized cells involved in this phase of the wound healing process come from the circulating blood. With the initiation of inflammation, hundreds of enzymatic factors interact with the local tissues, ceasing bleeding, enhancing local immune factors and providing necessary nutrients. Under normal conditions, these events happen within the first four days after injury.1

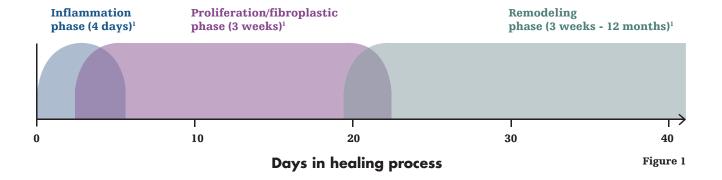
Proliferation/fibroplastic phase

With the inflammatory phase completed, rebuilding begins. This phase is named for the primary cell of scar production—the fibroblast. Although many different cells are involved in the inflammatory phase,

fewer types of cells operate in the fibroblastic phase, with their work lasting approximately three weeks. The purpose of these cells is to provide a matrix and impart strength to the wound.¹

Remodeling phase

Successful wound healing requires more than closing the wound with sufficient tensile strength. The ultimate goal is the return of function. Remodeling requires the fibroblast matrix or scar to mature to replace the lost tissue. As an example, repaired ligaments must have firm, intransigent scar formed with a parallel weave in order to resist deforming joint forces during stretching activities. In these tissues, where tensile strength is important, scar is a functional repair tissue. However, surrounding a tendon or a nerve, scar contracts and inhibits function. "The process of scar remodeling is responsible for the final aggregation, orientation and arrangement of collagen fibers."6 This process will continue throughout the remodeling phase, which may be complete between 6 months and one year after injury. 1

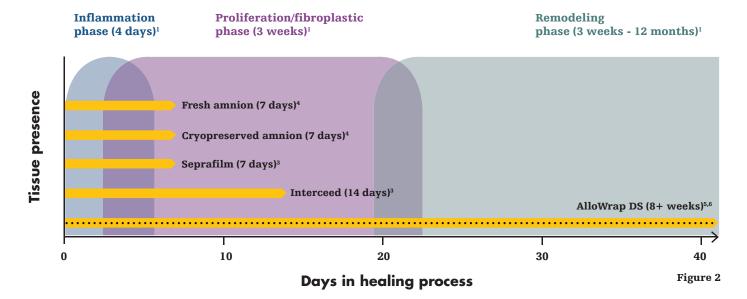




Surgical barriers

In order to prevent adhesions, surgical barriers have been used, but have shown limited results. ⁶ The chart below describes the absorption rates of raw amniotic membrane, cryopreserved amniotic membrane, oxidized regenerated cellulose (Interceed, Ethicon, San Angelo, TX³), chemically modified

sodium hyaluronate/ carboxymethylcellulose (Seprafilm, Genzyme, Cambridge, MA³) and AlloWrap DS amniotic membrane (AlloSource, Centennial, CO⁵) (Figure 2). The ideal surgical barrier should be one that remains at the site of repair long enough to allow mature healing.² "During the cell proliferation phase of the healing cycle, new cell formation effectively closes the wound, but also builds scar tissue to be remodeled later." 6



Discussion

The human body undergoes a complex process of inflammation, cell proliferation and remodeling that can last well over a year in many cases. During this process, scarring and fibrosis may occur as a result of the natural healing process. "However, adhesions often occur due to scarring and fibrosis, resulting in decreased

function, reduced quality of life, and/or reoperation of the affected tissues (Figure 3)." 6

Surgical barriers may be effective in relieving the issue of adhesions, but many barriers on the market dissolve in the body after only a few days and do not remain in the body during the cell proliferation phase. This may result in adhesions occurring despite surgical barrier implementation.

"AlloWrap DS is the only surgical barrier that has been shown to remain in the body through the proliferation phase of the healing process and into the remodeling phase."⁵

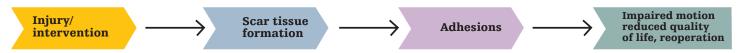


Figure 3 ⁶



References

- Hardy, M. "The Biology of Scar Formation." Physical Therapy 69 (Dec 1989): 22-32.
- Temiz, A., C. Ozturk, A. Bakunov, K. Kara, and T. Kaleli. "A New Material for Prevention of Peritendinous Fibrotic Adhesions after Tendon Repair: Oxidised Regenerated Cellulose (Interceed), an Absorbable Adhesion Barrier." International Orthopaedics 32 (Mar 2007): 389-94.
- Robertson, D., and G. Lefebvre. "Adhesion Prevention in Gynaecological Surgery." Journal of Obstetrics and Gynaecology 243 (June 2010): 598-602.
- Spoerla, E., G. Wollensakb, F. Reberb, and L. Pillunata. "Cross-Linking of Human Amniotic Membrane by Glutaraldehyde." Ophthalmic Research 36 (2004): 71-77.
- Samaniego, A. "Human Amniotic Tissue as an Anti-adhesion, Anti-fibrotic Barrier in an Ovine Spinal Laminectomy Model." AlloSource (2011).
- Samaniego, Adrian. "AlloWrap Surgical Barrier Remains in the Body through the Cell Proliferation Phase of the Healing Process While Other Surgical Barriers Are Resorbed." AlloSource (2013).

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