

Biological “Packages” in Spine Surgery: Components, Rationale, and Scientific Evidence

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Abstract

A “biologics package” in spine surgery refers to a combination of advanced biological materials and adjunctive products (bone substitutes, growth factors, or blood-derived products) used to stimulate tissue regeneration and enhance the success of spinal fusion procedures. These strategies aim to promote bone healing, accelerate fusion, reduce complications.

Animal-derived barrier membranes (Shield) are resorbable xenogeneic biomaterials increasingly used in spine surgery to reduce postoperative epidural fibrosis, protect neural structures, and facilitate dural repair. Derived primarily from porcine or bovine collagen matrices, these implants function as temporary mechanical barriers and extracellular scaffolds during the critical phases of wound healing. Although preclinical and early clinical studies suggest a reduction in scar tissue formation, high-level evidence demonstrating consistent improvement in long-term clinical outcomes remains limited. Their role is therefore considered adjunctive rather than essential in routine spinal procedures.autologous graft harvesting.

Dual-antibiotic hydrogels (DAB), typically incorporating vancomycin and gentamicin within a bioresorbable carrier matrix, have emerged as adjunctive local antimicrobial strategies in instrumented spine surgery. Designed to prevent bacterial colonization and biofilm formation on implants, these hydrogels aim to reduce deep surgical site infections (SSI) while minimizing systemic antibiotic exposure. Preclinical data demonstrate sustained local antibiotic release and inhibition of biofilm formation. Early clinical series suggest a reduction in infection rates in high-risk populations; however, high-level randomized controlled trials remain limited. DAB represents a promising adjunct in infection prevention protocols, particularly in instrumented lumbar arthrodesis.

Keywords: DBM, DAB , Shiels barrier membrane

Introduction

Common Components Included in Biological Packages

2. Demineralized Bone Matrix (DBM) 2. Animal-Derived Barrier Membranes 3 Antibiotic Hydrogel (DAB).

2. **Demineralized Bone Matrix (DBM)** is a processed allogeneic bone graft widely used as a biological adjunct in spinal arthrodesis. Derived from cadaveric human bone and subjected to acid demineralization, DBM retains the

organic extracellular matrix components—primarily type I collagen and endogenous growth factors, including bone morphogenetic proteins (BMPs)—while removing the mineral phase. This processing enhances exposure of osteoinductive proteins believed to stimulate mesenchymal cell differentiation toward the osteoblastic lineage. (1)

Spinal fusion remains a cornerstone treatment for degenerative, traumatic, deformity-related, and neoplastic

spinal pathologies. Although autologous iliac crest bone graft has long been considered the biological gold standard due to its osteoconductive, osteoinductive, and osteogenic properties, donor-site morbidity, limited graft volume, and increased operative time have prompted the development of alternative biologic strategies (2).

In this context, DBM has emerged as a graft extender or enhancer intended to reduce reliance on autograft while preserving fusion efficacy (3).

Biologically, DBM provides an osteoconductive scaffold and variable osteoinductive potential but lacks viable osteogenic cells. Its clinical performance is influenced by donor characteristics, processing methods, and inter-product variability in retained BMP content. Consequently, while DBM is frequently incorporated into instrumented lumbar and cervical fusion constructs—often in combination with locally harvested autograft or bone marrow aspirate—its standalone efficacy remains a subject of ongoing investigation.(4)

This manuscript reviews the biological rationale, clinical applications, and current evidence supporting the use of DBM in spine surgery, with particular attention to its role in contemporary fusion strategies.

2. Postoperative epidural fibrosis and peridural adhesions are common sequelae following lumbar decompression and discectomy. Excessive scar formation may complicate revision surgery and has been implicated, though inconsistently, in persistent radicular pain. Barrier technologies have been developed to mechanically separate the dura mater from surrounding soft tissues during healing (9).

Among these, animal-derived collagen membranes represent a biologically integrated approach that combines physical

separation with extracellular matrix (ECM) modulation (10).

3. Surgical site infection following spinal instrumentation remains a significant complication, associated with increased morbidity, prolonged hospitalization, reoperation, and potential hardware removal. Biofilm formation on metallic implants is a key pathogenic mechanism, rendering systemic antibiotics less effective (14).

Strategies aimed at achieving high local antimicrobial concentrations during the perioperative period have therefore gained increasing interest. Among these, dual-antibiotic hydrogels have been introduced as a bioresorbable coating or intraoperative adjunct applied directly to implants or the surgical bed (14).

Material and Methods

We conducted a **retrospective study between two well-defined groups**. One group consisted of **300 patients treated from 2020 onward who underwent spine surgery**, in whom the full set of biologics was used. This group was compared with another group with **the same number of patients**, in whom **not all biologics were included**, which we will refer to as the **Historical group**.

Resultados

In the first **biologic analyzed**, DBM, no significant difference was observed in the **rate of fusion regarding the occurrence of pseudarthrosis**. However, a **significant difference was noted in the time required to achieve fusion of the treated segment**.

In the cases in which **DBM was used**, fusion occurred **between 3 and 6 months (Fig I & II)**, whereas in the **Historical group**, fusion began to appear from **6 months onward**, and **pseudarthrosis was observed in 15 patients**.



Figure I: RX fibroblast and vertebral fusion at the L4-L5 level



Figure II: DAB presentation for surgery

Although there are **diverse opinions among spine surgeons regarding postoperative fibrosis after spinal surgery**, and some even question its existence, different criteria and interpretations remain. In **my more than 32**

years of experience in spine surgery, since I began using an **anti-fibrotic barrier membrane in 2002**, my results have **decreased exponentially**. Figure III & Fig IV



Figure III: MRI Fibrosis Post-spinal surgery

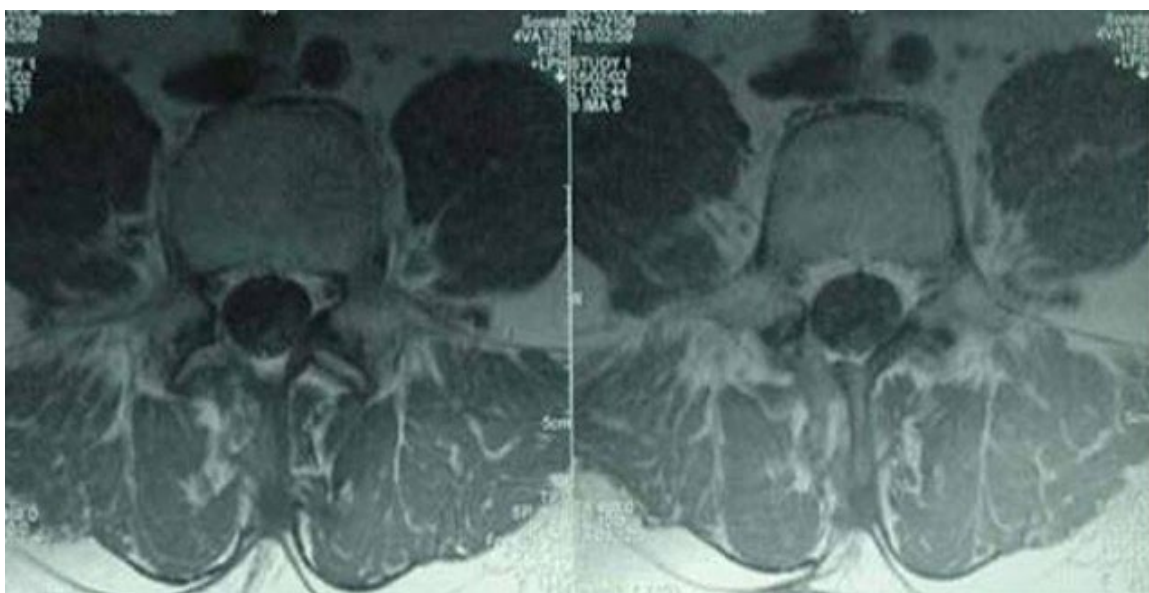


Figure IV: Shield that prevents contact of the muscle with the root and dural sac

Before the use of such membranes, **postoperative fibrosis occurred in approximately 12% of my patients**. After I started using this **protective barrier**, and having used **different types over the years**, this percentage **decreased to about 3%**.

It is also true that **both pseudarthrosis and postoperative fibrosis are not influenced solely by the use of biologics**, but also by **other well-known variables**.

DAB is a relatively new product whose main function is to **prevent the formation of biofilm on transpedicular screws**, thereby reducing the risk that a deep infection will require **removal of the osteosynthesis hardware**.

DAB is a **hydrogel composed of vancomycin or gentamicin**, which is applied to the **entire screw as well as to the nuts and rods** of the instrumentation.

Since the introduction of this product in **2023**, the incidence of **deep infections has been reduced to approximately 2.5% of the surgeries performed**. In these cases, the infection was successfully managed with a **single deep surgical debridement**, without the need to **remove the implanted hardware** Figure V & Fig Vi.



Figure V: Preparation of the DAC gel with Vancomycin and Physiological Serum



Figure VI: DAC placement on a transpedicular screw in spinal surgery

Discussion

DBM (Demineralized Bone Matrix) is a processed allogeneic bone graft widely used in spinal arthrodesis.

Definition and Biological Composition

DBM is derived from human donor bone obtained from certified tissue banks. It undergoes an acid demineralization process that removes the mineral phase (hydroxyapatite) while preserving:

- Type I collagen
- Bone morphogenetic proteins (BMPs)
- Other endogenous growth factors

Removal of the mineral component exposes BMPs, which are responsible for its osteoinductive properties.

Biological Properties (5)

DBM exhibits:

- **Osteoconductive capacity** (provides a scaffold for bone growth)
- **Osteoinductive potential** (stimulates osteoblastic differentiation)
- **It is not osteogenic**, as it contains no viable cells

Its osteoinductive potency depends on:

- Donor age
- Processing technique
- Residual BMP content

Clinical Indications in Spine Surgery (6)

DBM is commonly used in:

- Lumbar and cervical arthrodesis

- TLIF and PLIF procedures
- Instrumented fusion
- Minimally invasive spinal surgery

It is typically employed as a graft extender or supplement to locally harvested autograft.

Commercial Presentations (7)

- Putty
- Gel
- Paste
- Combined with carriers (glycerol, collagen, hydroxyapatite, cortical chips)

Advantages Compared with Autograft

- Avoids iliac crest donor-site morbidity
- Reduces operative time
- Available in larger volumes
- Useful as graft extender

Limitations

- Biological variability between products
- Unpredictable osteoinductive potency
- Not a complete substitute for autograft in high-risk fusion scenarios
- Higher cost compared to local autograft

In spine surgery, DBM is generally used as a complement to local autograft rather than a stand-alone graft in patients with risk factors such as smoking, diabetes, or multilevel fusion. (8)

2. Animal-Derived Barrier Membranes (shield)

Resorbable membranes of xenogeneic origin are sometimes incorporated to reduce postoperative epidural fibrosis and minimize scar-related complications following decompression procedures (11).

Animal-Derived Barrier Membranes in Spine Surgery

Animal-derived barrier membranes are **resorbable biological implants**, typically of xenogeneic origin (porcine or bovine), used in spine surgery to **reduce postoperative fibrosis**, protect neural structures, and modulate the healing environment after decompression or fusion procedures (12).

Biological Origin and Composition

Most commercially available membranes are derived from:

- **Porcine collagen (Type I and III)**
- **Bovine pericardium**
- Acellular dermal matrices

They undergo decellularization and sterilization processes to remove immunogenic components while preserving the extracellular matrix (ECM) architecture.

Mechanism of Action

These membranes function primarily as **physical barriers**, but also exhibit biological modulation properties:

1 Mechanical Barrier

- Separate dura mater from paraspinal musculature
- Reduce fibroblast invasion into the epidural space
- Limit scar tethering to neural structures

2 Controlled Biodegradation

- Gradually resorbed over weeks to months
- Provide temporary protection during the critical wound healing phase

3 Extracellular Matrix Signaling

- Collagen scaffolding may modulate cellular migration
- Potentially reduce excessive fibrotic response

Clinical Indications in Spine Surgery

Animal-derived membranes are most commonly used in:

- Lumbar laminectomy
- Microdiscectomy
- Revision decompression
- Multilevel decompression
- Situations with high risk of epidural fibrosis

They are also used as **dural substitutes** when primary dural closure is not feasible.

Evidence from the Literature (13)

Epidural Fibrosis Prevention

Studies evaluating anti-adhesion barriers show:

- Reduction in radiographic scar formation in some series
- Mixed evidence regarding improvement in clinical outcomes
- Greater theoretical benefit in revision surgery

High-level randomized trials remain limited. Many studies are:

- Small cohort series
- Heterogeneous in outcome definitions
- Focused on imaging endpoints rather than clinical pain scores

Dural Repair

Collagen-based xenografts used as dural substitutes have demonstrated:

- Acceptable CSF leak rates
- Good handling properties
- Low immunogenic response

They are widely accepted in neurosurgical practice.

Advantages

- Biocompatible and resorbable
- Easy intraoperative handling
- No donor-site morbidity
- Avoid synthetic permanent implants
- May reduce reoperation difficulty in revision cases

Limitations and Concerns

- Limited high-level clinical outcome data
- Added procedural cost
- Variable resorption times
- Rare inflammatory reactions
- Unclear long-term impact on failed back surgery syndrome

Importantly, reduction of radiographic fibrosis does not always correlate with improved clinical outcomes, which is a key point emphasized in systematic reviews.

Current Clinical Interpretation

Most spine surgeons consider animal-derived barrier membranes:

- Reasonable in selected high-risk cases
- Potentially useful in revision surgery
- Not mandatory in routine single-level decompressions

They are viewed as **adjunctive protective devices**, rather than essential components of spinal fusion constructs.

3. Antibiotic Hydrogel (DAB)

Dual-antibiotic hydrogels containing vancomycin and gentamicin are used as local antimicrobial prophylaxis. These hydrogels aim to:

- Prevent bacterial colonization
- Inhibit biofilm formation on instrumentation
- Preserve lumbar arthrodesis integrity
- Reduce deep surgical site infection risk
- Decrease the likelihood of hardware removal

By maintaining high local antibiotic concentrations, they provide targeted protection without significant systemic exposure (15).

Scientific Evidence on DBM in Spinal Arthrodesis

1. General Systematic Reviews

Critical reviews of the literature on DBM in spinal fusion indicate:

- Evidence from both animal models and human clinical studies
- Most human studies are retrospective case series
- High fusion rates are reported when DBM is used as a graft extender
- Very few randomized controlled trials (RCTs) directly compare DBM with iliac crest autograft
- High-level evidence (large, well-controlled RCTs) remains limited

Summary: Current evidence supports DBM as a graft enhancer or extender; however, insufficient high-quality trials exist to endorse it as an independent graft substitute in all scenarios (16).

2. Relevant Clinical Comparisons

DBM + Autograft vs Autograft Alone

Retrospective studies suggest that adding DBM to autologous bone may achieve fusion rates comparable to autograft alone.

DBM vs rhBMP-2

Comparative analyses with recombinant human bone morphogenetic protein-2 (rhBMP-2), commercially produced by Medtronic, indicate:

- Similar overall fusion rates in instrumented lumbar fusion
- Higher incidence of radiographic complications (e.g., ectopic bone formation) with rhBMP-2
- Significantly lower biological cost per level with DBM

These findings suggest that DBM may represent a reasonable alternative to recombinant growth factors in selected clinical settings, particularly when cost and complication profile are considered (17).

3. Common Trends Identified Across Studies

- DBM performs well as a graft extender, especially when combined with local autograft or bone marrow aspirate (BMA).
- Significant inter-product variability exists due to differences in donor source and processing methods.
- When fusion is achieved, clinical outcomes (pain and function) are generally comparable to other graft materials. (18).

4. Limitations of Current Scientific Evidence

- Limited high-level evidence (few large multicenter RCTs)
- Heterogeneity in surgical techniques and fusion assessment criteria
- Variability among DBM products
- Frequent combination with other graft materials, limiting attribution of outcomes solely to DBM (19).

Current Scientific Conclusion of DBM ; Shield & DAB

- DBM can be effective as a graft extender or biological enhancer in spinal arthrodesis, with fusion rates and clinical

outcomes comparable to other graft materials in available studies.

However, high-level evidence remains limited. Large, well-designed randomized controlled trials are still required to define its independent role and to establish clear recommendations based on spinal level, surgical technique, and patient risk profile.

- Animal-derived collagen barrier membranes represent a biologically integrated strategy aimed at reducing postoperative epidural fibrosis and protecting neural elements in spine surgery. While preclinical and early clinical data support their anti-adhesion properties, robust evidence demonstrating consistent improvement in long-term functional outcomes is lacking. Future multicenter randomized controlled trials with standardized clinical endpoints are necessary to clarify their definitive role in spinal surgery practice.

- DAB systems provide targeted local antimicrobial prophylaxis aimed at preventing bacterial colonization and biofilm formation in instrumented spine surgery.

Preliminary evidence supports their safety and potential efficacy in reducing deep surgical site infections without compromising fusion biology.

Nevertheless, definitive conclusions await high-quality randomized controlled trials evaluating long-term clinical outcomes and cost-effectiveness.

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