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The Osteobiologics Contracting Process

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Panelists: Christopher Kauffman, M.D., Todd Lockhart, William Payne, M.D.

Disclosures / Potential Conflicts of Interest

- Dr Payne has a vested financial interest in Myowndocor/Black Telehealth. All financial relationships have been mitigated.
- Todd DeVree & Dr. Huntsman have no financial relationships to disclose.

Note: This program may contain the mention of suppliers, brands, products, services or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, brand, product, service or drug.

Learning Objectives

At the end of this session, participants should be able to:

1. Recall osteobiologic product categories and current market trends
2. Describe a physician's decision-making process around osteobiologic product selection
3. Identify best practices for managing the utilization of osteobiologics within your facility

Moderator & Panelists



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Introduction

Osteobiologics: Definition

1. Products or tissues that promote the healing of fractures or bone defects

- Bone void fillers
 - Indicated for use in the treatment of surgically-created osseous defects or osseous defects created from traumatic injury to the bone
- Human tissue transplants

2. Structural bone grafts

- Donor bone grafts
 - Machined/non-machined

Cornell CN. Osteobiologics. *Bull Hosp Jt Dis.* 2004;62(1-2):13-17.

<https://www.spineuniverse.com/treatments/surgery/role-bone-graft-spinal-fusion-surgery>

FDA Applications & Approvals

Class I or II, exempt

- Register with FDA, follow GMP, general controls
- Example: Scalpel

Class II, non-exempt

- Register with FDA, follow GMP, general controls
- 510(k) notification
- Special controls – guidance document
- Example: Beta Tricalcium Phosphate

Class III

- Register with FDA, follow GMP, general controls
- Premarket approval application (PMA)* *If not S.E. to a pre-amendment device
- Example: **Intraspinous process spacer**

| Osteobiologics: Characteristics & Areas of Use

Characteristics

Osteoconduction (Serves as a scaffold)

- **Scaffold** to support new bone formation: cancellous bone matrix.

Osteoinduction (Capable of inducing new bone formation)

- **Signals** to initiate the bone fusion cascade: cell signalling and demineralized **bone**.

Osteogenesis (Producing new bone)

- **Cells** for direct bone formation, including: mesenchymal stem cells and osteoprogenitor cells.

Areas of Use

- Orthopedic Surgery
- Neurosurgery
- Plastic Surgery
- E.N.T Surgery
- Oral Surgery
- Craniofacial Surgery
- Periodontal Surgery
- Podiatric Surgery

Zhang H, Yang L, Yang XG, et al. Demineralized Bone Matrix Carriers and their Clinical Applications: An Overview. *Orthop Surg.* 2019;11(5):725-737. doi:10.1111/os.12509

Gold Standard: iliac crest bone graft (ICBG)

- Osteoconductive, osteoinductive and osteogenic
- High fusion rates reported in the literature

Why use an Osteobiologic?

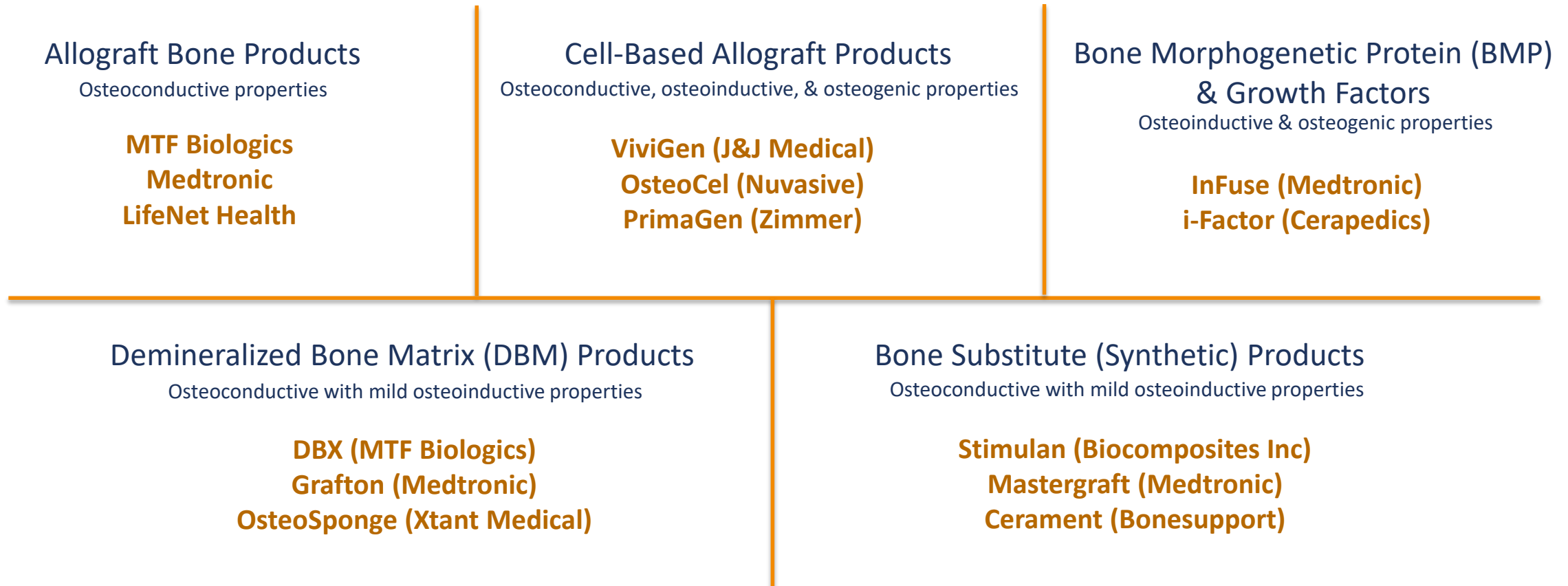
- Limited graft material (revisions)
- Donor site morbidity (depends on technique)
- Patient perception (additional incisions, pain)
- Blood loss (also technique-dependent)
- Time to harvest

Zhang H, Yang L, Yang XG, et al. Demineralized Bone Matrix Carriers and their Clinical Applications: An Overview. *Orthop Surg.* 2019;11(5):725-737.
doi:10.1111/os.12509

The background of the slide features a blurred image of a hospital hallway with a person walking in the distance. In the foreground, an IV drip is visible, consisting of a glass chamber containing clear liquid, a white drip chamber, and clear plastic tubing with blue stopcocks. The overall color palette is a cool, muted blue.

Osteobiologic Product Selection

Biologics by Platform & Product Line Examples*



**Examples are not exhaustive; included above are examples of products and suppliers on HealthTrust supported agreements.*

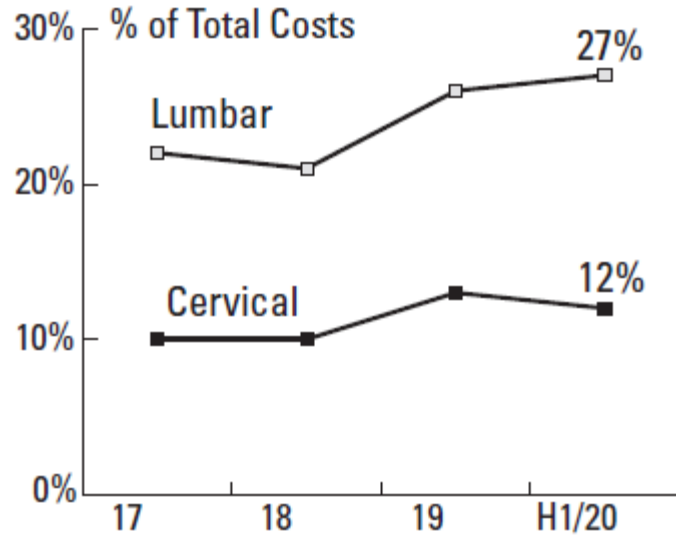
A brief review of the biologics in the H1/2020 yields the following number of manufacturers and product lines, many of which are sold by multiple companies.

| Type of Product | Number of Companies | Number of Product Lines |
|---------------------|---------------------|-------------------------|
| DBM | 32 | 103 |
| Bone Substitutes | 38 | 69 |
| Allograft Bone | 30 | 53 |
| Cell based matrices | 16 | 17 |
| BMP/Growth factors | 2 | 2 |

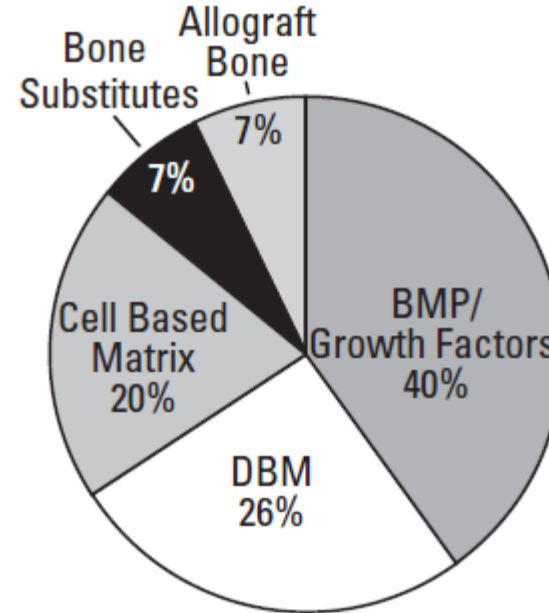
Source: Orthopedic Network News, Vol 31, No 4, October 2020

Biologics Usage in Lumbar Fusions, ORN H1/2020

Biologics Usage in Spinal Fusions

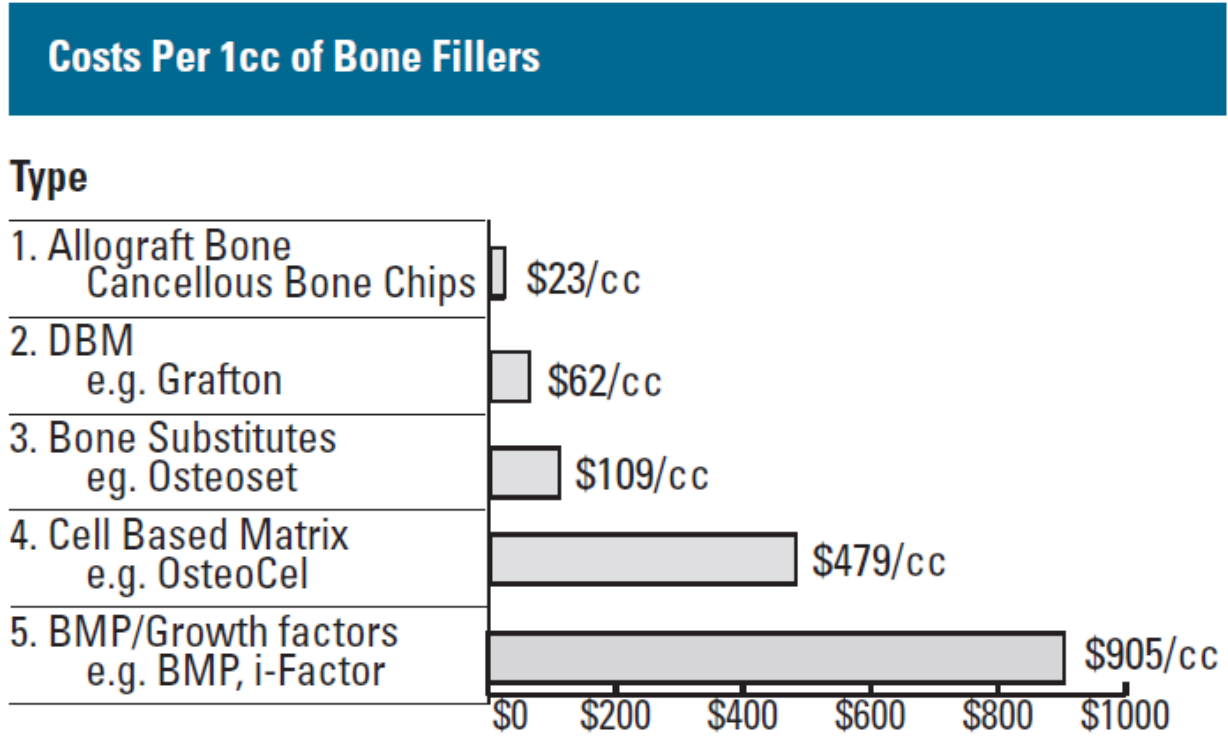


Biologics Used in Lumbar Fusions, by Type



Source: Orthopedic Network News, Vol 31, No 4, October 2020

Costs per 1cc of Bone Fillers



Source: H1/2020 ORN

Definitions of categories:

Allograft bone: GIC 62 and type1=Allo bone

DBM: GIC 62 and type1=DBM

Bone Substitutes: GIC 62 and type1=Bone subs

Cell based matrix: GIC 62 and type1=CB Matrix

BMP/Growth factors: GIC 62 and type1=BMP

Assessment Question #1 of 3

Which of the following is NOT an osteobiologic product group?

- a. Cell-based Allograft
- b. Demineralized Bone Matrix
- c. Non-synthetic
- d. Machined Bone Allograft

Assessment Question #1 of 3: Correct Response

Which of the following is NOT an osteobiologic product group?

- a. Cell-based Allograft
- b. Demineralized Bone Matrix
- c. Non-synthetic
- d. **Machined Bone Allograft**

Utilization of BMP or a Growth Factor

In an analysis of 1,563 of the cases in the ORN for lumbar fusions in the first half of 2020 that used BMP or a growth factor:

| Utilization | Percentage of cases | Cost per case |
|------------------------|---------------------|---------------|
| BMP Only | 17% | \$4,217 |
| BMP + 1 Osteobiologic | 58% | \$5,813 |
| BMP + 2 Osteobiologics | 22% | \$6,933 |
| BMP + 3 Osteobiologics | 2% | \$11,869 |
| BMP + 4 Osteobiologics | 1% | \$32,244 |

Source: Orthopedic Network News, Vol 31, No 4, October 2020

Audience Poll Question: #1 of 2

How many different DBM suppliers are on your hospital's shelves and/or available for use?

- A) 2 or less
- B) 3 - 5
- C) 4 - 6
- D) 6+
- E) Not Sure

Platform & Patient Considerations

- Correct indication/properties
- Patient characteristics/comorbidities
- Timing of application from injury
- Mode of application, e.g.. use of scaffolds, growth factors, composite of osteobiologics
- Size/dose-related efficacy

Approach and Outcomes Considerations

- Approach-based complications
- Label vs. off-label use
- Patient risk
- Adverse events
- Complexity/multi-level

Assessment Question #2 of 3

Selection of osteobiologics should consider all of the following EXCEPT:

- A. Size/dose-related efficacy
- B. One size fits all
- C. Patient characteristics/comorbidities
- D. Timing from injury

Assessment Question: #2 of 3: Correct Response

Selection of osteobiologics should consider all of the following EXCEPT:

- A. Size/dose-related efficacy
- B. **One size fits all**
- C. Patient characteristics/comorbidities
- D. Timing from injury

Identifying Best Practices

| Structuring around a Contracting Strategy

A – E – I – O – U and sometimes Y

- **A**pplication of clinical evidence into prescriptive practice
- **E**valuation of cost impact across process
- **I**dentification of variation within organization
- **O**pportunities for improved efficiencies/performance
- **U**niversal achievement indicators and outcomes measures
- **Y** – engaging physicians and key stakeholders around the **WHY**

Key Tactics for a Successful Contracting Strategy

Engaging Physicians in a Best Practice Approach

1. Understand your **data**

- Where is the variation?
- What is avoidable vs. not avoidable variation?

2. Engage physicians in **evidence, data, and opportunity**

- Patient populations
- Surgical approach
- Patient outcomes
- Variation
- Waste

3. Establish a **plan and track** success

- What is the realistic target for your opportunity?
- Where do you start?
- What risks exist to prevent success?
- Who else needs to be involved in discovery and deployment?
- What governance infrastructure or support is needed? Frequency of engagement? Accountability?

Platform
Selection



Product
Selection



Action



Track

Audience Poll Question: #2 of 2

Do you believe there is an opportunity to lower the cost per case for spine procedures at your **facility through** one of the following methods:

- a. No
- b. Yes, by renegotiating contracts
- c. Yes, through altered surgeon practices
- d. Yes, by both renegotiating contracts and through altered surgeon practices
- e. Not sure

Assessment Question #3 of 3

Which of the following is considered a best-practice for managing utilization of osteobiologics?

- A. Understanding your facility data
- B. Engaging physicians in evidence, data, and opportunity
- C. Establishing a plan and track success
- D. All of the above

Assessment Question #3 of 3: Correct Response

Which of the following is considered a best-practice for managing utilization of osteobiologics?

- A. Understanding your facility data
- B. Engaging physicians in evidence, data, and opportunity
- C. Establishing a plan and track success
- D. **All of the above**

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Thank you...

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