early intervention

Direct hospital costs to achieve union in tibia fractures have been estimated between $7,415 and $27,422 (indexed to 2002 dollars). The IGNITE™ technique is a Low Morbidity, Time-saving procedure:

- Estimated cost-savings potential of over $4,400.
- Minimally Invasive Aspiration and Injection.
- Outpatient, 30-minutes OR time.
- No iliac crest harvest complications and cost (estimated between $2,200 and $5,000).

**REFERENCES**

4. No indirect costs were included in this calculation, such as workers’ compensation, disability, and other non-hospital costs. Cost savings using IGNITE™ technique estimated using more conservative direct hospital cost ($7,415).
7. Sawin PD, Traynes VC, Menezes AH. A comparative analysis of fusion rates and donor site morbidity for autogenic rib and iliac crest bone grafts in posterior fusions.
The IGNITE™ Power Mix combines an injectable cellular scaffold in demineralized bone matrix with aspirated red bone marrow. The combination provides a minimally invasive graft with osteoconductive, osteoinductive, and osteogenic capacity.

The IGNITE™ Composite Graft reinforces and stimulates fracture healing in poorly vascularized areas, such as the long bone diaphysis. Healing with the IGNITE™ Graft proceeds via the normal stages of fracture healing.

**Hematoma phase**
The IGNITE™ Graft is injected to induce hematoma formation. Osteogenic stem cells are transplanted to the defect site.

**Inflammatory phase**
The fracture hematoma clots and elicits a transient inflammatory response. Angiogenesis is an early, critical component at this stage of healing.

**Soft callus phase**
Tissue becomes more organized as new bone (osteoid) is laid down.

**Extra-cortical bridging and remodeling phase**
Tissues continue to organize as osteoid is calcified. Remodeling completes the reparative phase as the bone is stressed.

---

**Case Study**
55 Year-Old Male

Bone marrow is a reliable source of osteogenic cells with little to no morbidity.

**Pre-Injection**
A sub-periosteal envelope is created to receive the IGNITE™ composite. Injection of the graft should bridge the defect to stimulate extra-cortical callus formation.

**Post-op, 2 Months**
Note mature callus bridging the defect site.

**Post-op, 8 Months**
Newly formed bone is remodeled over time.

---

A low morbidity, time-saving, percutaneous treatment for stable diaphyseal fractures has been advanced to include an increased level of proteins to couple with harvested osteoprogenitor cells from bone marrow. The IGNITE™ Power Mix kit features modified instrumentation affording injection of a robust graft to stimulate callus formation in problem fractures.

---

**INDICATIONS**
- Suspect delayed union at 6-8 weeks following index procedure with no sign of callus formation
- Delayed union with well-fixed hardware
- Fresh fractures for “High Risk” patients with one or more comorbidities such as smoking, diabetes, steroid use, etc.
- Stable (well-fixed) nonunions with no prior surgical intervention

**CONTRAINDICATIONS**
- Nonunion with previous infection at nonunion site
- Previous failed grafting for nonunion
- Bone gap greater than 3 mm
- Atrophic nonunion with significant fibrous tissue in fracture gap
- Acute open injury
- Soft tissue defects
- Unstable fracture / defects

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The combination of BMP and BMP has over a decade of clinical evaluation. This large prospective clinical trial demonstrated clinical success comparable to open, autologous grafting in a series of 89 eligible nonunions.

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**CLINICAL COMPARISON OF AUTOGRAGFT, DBM / BMA BIOCOMPOSITE, AND OP-1™**

<table>
<thead>
<tr>
<th># of patients</th>
<th>Clinical Union</th>
<th>Radiographic Union</th>
<th>Time to Union</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autograft</td>
<td>RECKLING, et al.</td>
<td>11</td>
<td>44% 98% - 5-10 months</td>
</tr>
<tr>
<td>DBM and/or BMA</td>
<td>CONNOLLY, et al.</td>
<td>14</td>
<td>90% 20% - 7 months</td>
</tr>
<tr>
<td>OP-1™ (rhBMP-7)</td>
<td>GARG, et al.</td>
<td>15</td>
<td>85% 57% 9 months</td>
</tr>
</tbody>
</table>

---

**SUCCESS RATE BY NONUNION TYPE**

- Hypertrophic: 77%
- Atrophic: 94%
- Total: 88%

---

**TIME TO UNION**

- Autograft: 21 months
- DBM and/or BMA: 8 months
- OP-1™: 6 months

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**Images courtesy of Ross Wilkins, MD**
early intervention

Direct hospital costs to achieve union in tibia fractures have been estimated between $7415 and $27,422 (indexed to 2002 dollars). The IGNITE™ technique is a Low Morbidity, Time-saving procedure:

- Estimated cost-savings potential of over $4400.
- Minimally Invasive Aspiration and Injection
- Outpatient, 30-minutes OR time
- No iliac crest harvest complications and cost (estimated between $2,200 and $5,000)

REFERENCES
4. No indirect costs were included in this calculation, such as workers’ compensation, disability, and other non-hospital costs. Cost savings using IGNITE™ technique estimated using more conservative direct hospital cost ($7,415).
7. Sawin PD, Traynes VC, Menezes AH. A comparative analysis of fusion rates and donor site morbidity for autogenic rib and iliac crest bone grafts in posterior fusions.

IGNITE™ POWER MIX | 860T-2000 20cc
ALLOMATRIX® CUSTOM BONE PUTTY | 86XC-0500 5cc
ALLOMATRIX® CUSTOM BONE PUTTY | 86XC-1000 10cc

FOR OPEN GRAFTING OF DIFFICULT FRACTURES TRY

ORDERING INFORMATION

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Healing with the IGNITE™ Graft proceeds via the normal stages of fracture healing.

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- **Inflammatory phase**: The fracture hematoma clots and elicits a transient inflammatory response. Angiogenesis is an early, critical component at this stage of healing.
- **Soft callus phase**: Tissue becomes more organized as new bone (osteoid) is laid down.
- **Extra-cortical bridging and remodeling phase**: Tissues continue to organize as osteoid is calcified. Remodeling completes the reparative phase as the bone is stressed.

**Case Study**: 55 YEAR-OLD MALE

Bone marrow is a reliable source of osteogenic cells with little to no morbidity.

**Pre-Injection**: A sub-periosteal envelope is created to receive the IGNITE™ composite. Injection of the graft should bridge the defect to stimulate extra-cortical callus formation.

**Post-op, 2 Months**: Note mature callus bridging the defect site.

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**INDICATIONS**
- Suspect delayed union at 6-8 weeks following index procedure with no sign of callus formation
- Delayed union with well-fixed hardware
- Fresh fractures for “High Risk” patients with one or more comorbidities such as smoking, diabetes, steroid use, etc.
- Stable (well-fixed) nonunions with no prior surgical intervention

**CONTRAINDICATIONS**
- Nonunion with previous infection at nonunion site
- Previous failed grafting for the nonunion
- Bone gap greater than 3mm
- Abscess, infection, or significant fracture instability
- Nonunion in patients with significant bone loss
- Nonunion with failed bone grafting
- Unstable fractures / defects

**Minimally-invasive technique**

**Targeted graft placement**

To stimulate extra cortical bridging

**Powerful osteogenic combination**

of cells, signaling proteins and scaffold

**Stimulate fracture callus formation**

**Enhance diaphyseal fracture healing**

The combination of DBM and BMA has over a decade of clinical evaluation. This composite has demonstrated clinical success comparable to open, autologous grafting in a series of 69 stable nonunions.

**Clinical Comparison of Autograft, DBM / BMA BioComposite, and OP-1™**

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<td>11</td>
<td>92%</td>
<td>92%</td>
</tr>
<tr>
<td>Connolly, et al</td>
<td>14</td>
<td>85%</td>
<td>74%</td>
</tr>
<tr>
<td>Frieda, et al</td>
<td>61</td>
<td>85%</td>
<td>74%</td>
</tr>
<tr>
<td>Wilkins, et al</td>
<td>20</td>
<td>90%</td>
<td>- 7</td>
</tr>
<tr>
<td>Garga, et al</td>
<td>69</td>
<td>81%</td>
<td>88%</td>
</tr>
<tr>
<td>RhOP-1™ (Bmp-7)</td>
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**SUCCESS RATE BY NONUNION TYPE**

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### CONTRAINDICATIONS

- Nonunion with previous infection at nonunion site
- Previous failed grafting for the nonunion
- Bone gap greater than twice the width
- Acute fracture with significant bone loss
- Non-union issues in fracture gap
- Sign of hardware loosening
- Unstable fractures / defects

### Beneficial osteogenic combination

- of donor cells, signaling proteins, and scaffold

### INDICATIONS

- Stimulate fracture callus formation
- Enhance diaphyseal fracture healing

### CONTRAINDICATIONS

- Nonunion with previous infection at nonunion site
- Previous failed grafting for the nonunion
- Bone gap greater than twice the width
- Acute fracture with significant bone loss
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- Unstable fractures / defects

### Proven technique

The combination of BMP and BBM has shown a decade of clinical experience. This protein- and stem cell-based clinical success can be replicated in a series of clinical case reports.
early intervention

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