Medtronic

Dental Bone Grafting Options

A review of bone grafting options for patients needing more bone to place dental implants

Dental Bone Grafting Options

What is bone grafting?

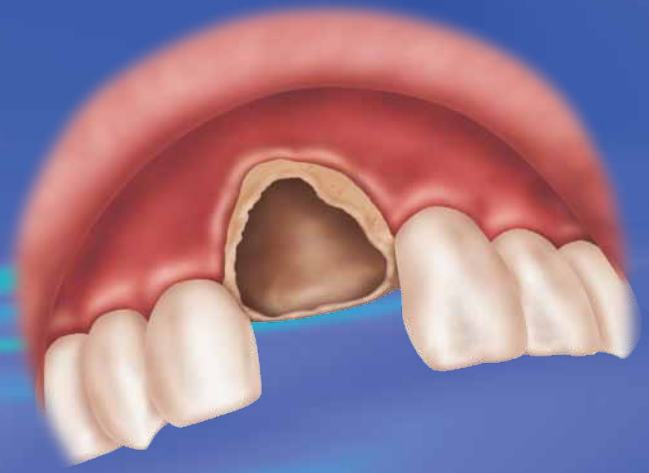
Bone grafting options

- Bone from patient's own body (autograft)
- Recombinant human bone morphogenetic protein (rhBMP-2): synthetically produced, naturally occurring protein that stimulates a person's cells to produce bone
- Bone graft fillers: from other people (allograft), animals (xenograft) or man-made

Patient information resources

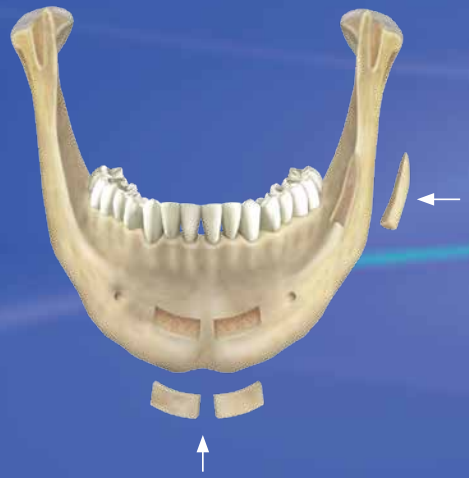
What is bone grafting?

- The replacement of bone in the portion of the jaw that anchors the teeth
- A procedure often performed to replace lost bone due to tooth loss, trauma, ill fitting dentures
- Commonly done to rebuild the bone structure beneath the gums to place dental implants or teeth replacements



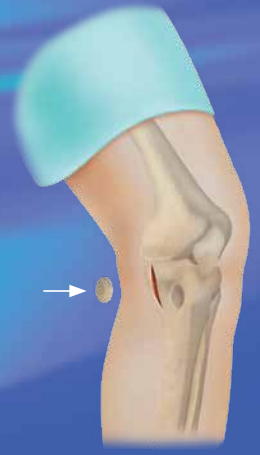
Bone from the patient (autograft)

Surgically harvested from another site in the patient's own body, transplanted into site of the defect



Inside the mouth

Iliac crest harvest site



Tibia harvest site

Bone from the patient (autograft)

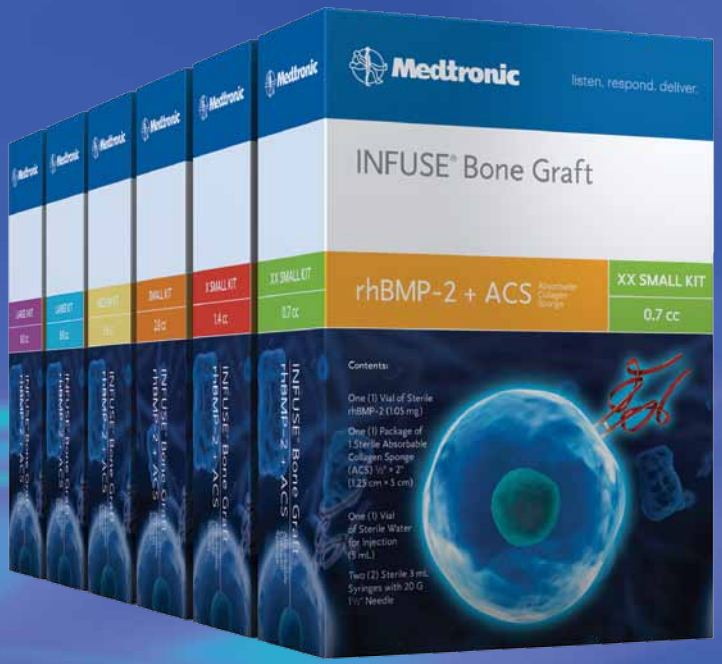
Several drawbacks

- Risk of pain, infection at bone harvest site potentially lasting several months
- Additional surgical time, anesthesia
- Requires second surgical site, longer recovery time
- Not viable option if:
  1. Bone quality/density is poor
  2. Large volume of graft material is required

INFUSE® Bone Graft

Eliminates the need for a second surgery to remove bone from your body

- Potential for decreased surgical time and reduced reliance on anesthesia
- No recovery time from second-site bone harvest



Proven, predictable bone growth for dental implant placement

INFUSE® Bone Graft should not be used in pregnant women. Women of child bearing potential should be warned by their surgeon of the potential risk to a fetus and informed of other possible dental treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

INFUSE® Bone Graft

FDA approvals

- Anterior lumbar spinal fusion indication (2002)
- Acute open tibial fracture indication (2004)
- Certain oral maxillofacial and dental regenerative indications (2007)

Vivian R.
Sinus augmentation patient

INFUSE® Bone Graft

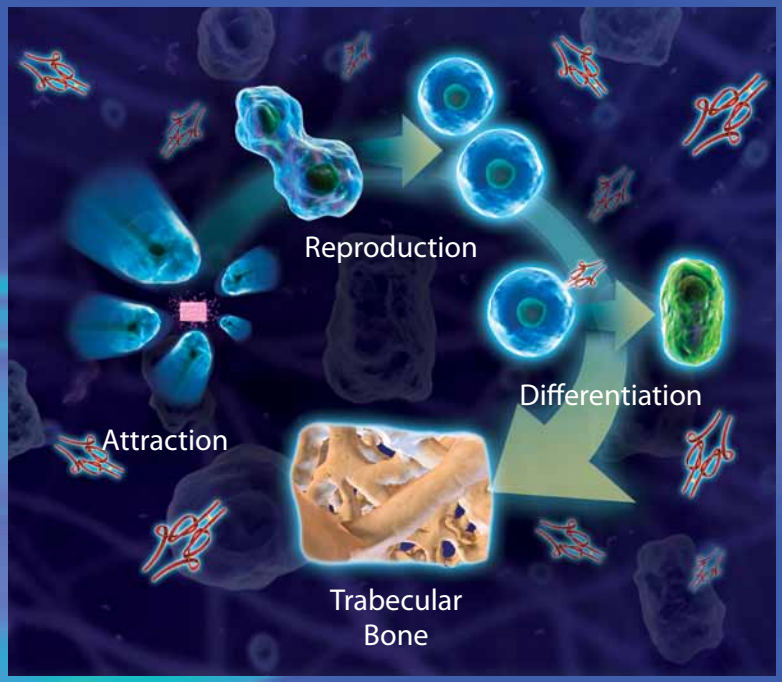
Consists of **two** parts

1. A protein found in everyone's body
2. A natural carrier for delivery: absorbable collagen sponge (ACS)
   - Releases protein over time
   - Provides scaffold for new bone to grow
   - Is absorbed and replaced by bone
   - As the carrier for the rhBMP-2; should be only carrier used for rhBMP-2 as described in the INFUSE® Bone Graft Package Insert
   - Helps prevent soft tissue prolapse into the defect but cannot necessarily resist soft tissue compression

rhBMP-2 + ACS

How does INFUSE® Bone Graft work?

- Surgically placed where new bone growth is needed
- Attracts your body's own bone building cells (stem cells) to the site and over time, new bone is formed
- Bone grows where INFUSE® Bone Graft is placed, for predictable bone-growth results



INFUSE® Bone Graft Mechanism of Action

For what procedure is INFUSE® Bone Graft approved?

Sinus Lift (Sinus Augmentation)

Existing bone in maxillary sinus cavity may be insufficient for dental restoration

INFUSE® Bone Graft

1. Placed into the upper jaw to promote bone growth in the floor of the sinus cavity
2. To anchor dental implants to allow for dental restoration

Sinus lift

For what procedure is INFUSE® Bone Graft approved?

Localized Alveolar Ridge Augmentation

- Involves placing INFUSE® Bone Graft directly into the empty socket where a tooth's roots once were
- Helps create the natural shape of the gums and jaw that may have been lost following tooth extraction

Ridge augmentation

Why use INFUSE® Bone Graft

Eliminates the need for a second surgical site to remove bone from your body

- Potential for decreased surgical time and reduced reliance on anesthesia
- No recovery time from second-site bone harvest

Proven, Predictable bone growth for dental implant placement

Important Things to Know About INFUSE® Bone Graft

Due to the chemotactic properties of INFUSE® Bone Graft and the angiogenesis associated with new bone formation, facial edema may occur in some (but not all) patients.

INFUSE® Bone Graft has not been studied in IDE trials with patients who:

- Are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure)
- Currently are or may become pregnant

INFUSE® Bone Graft should not be used:

- In patients with a known hypersensitivity to rhBMP-2, bovine Type I collagen or to any other components of the formulation
- In the vicinity of a resected or extant tumor
- In patients with any active malignancy or in patients undergoing treatment for a malignancy
- In patients with an active infection at the operative site
- In pregnant women

Bone from human source (allograft)

- Human, non-vital (dead) bone harvested from a cadaver that is tested, cleaned and processed for transplantation
- Though highly tested and processed, the chance for disease transmission exists
- Cannot produce new bone on its own (unlike autograft or INFUSE® Bone Graft)
- Serves as a framework or scaffold over which bone from the surrounding bony walls may grow to fill the defect or void
- Compared to autograft, allograft may take longer to remodel and be replaced by patient's own bone[1]

Bone from animal source (xenograft)

- Similar to allograft, non-vital highly processed and sterilized bone derived from another species (animal bone)
- Also serves as a framework or scaffold over which bone from the surrounding area may grow to fill the defect
- Like allograft, lacks autograft's bone-forming properties; does not cause bone to form
- Therefore, bone regeneration may take longer than it does when using patient's own bone and outcome may be less predictable
  - May take years for graft material to remodel and be replaced by patient's own bone[2]

What to expect after treatment with INFUSE® Bone Graft

- Potential for prolonged swelling due to cellular activity (chemotaxis)
- Similar function to autogenous bone without the pain and life disturbance of autogenous grafting
- Proven, predictable bone to support dental implants

Resources for Patients

- www.aaoms.org
  The official Web site of the American Association of Oral and Maxillofacial Surgeons. Here you will gain a better understanding of the many ways these surgical specialists can aid your oral and overall health.

- www.perio.org
  The official Web site for periodontists specializing in the prevention, diagnosis, and treatment of periodontal diseases and in the placement of dental implants.

- www.infusebonegraft.com
  This Web site contains product information, including clinical research, news, and articles about bone morphogenetic proteins, your oral health, and patient stories.

Brief Summary for Professional Literature

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, WARNINGS, AND PRECAUTION FOR INFUSE® BONE GRAFT FOR CERTAIN ORAL MAXILLOFACIAL AND DENTAL REGENERATIVE USES

INFUSE® Bone Graft is indicated as an alternative to autogenous bone graft for sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets.

The INFUSE® Bone Graft consists of two components – recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) placed on an absorbable collagen sponge (ACS). **These components must be used as a system for the prescribed indication. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in the package insert.**

INFUSE® Bone Graft is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with any active malignancy or patients undergoing treatment for a malignancy, in pregnant women, or patients with an active infection at the operative site.

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible dental treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

INFUSE® Bone Graft has not been studied in patients who are skeletally immature (<18 years of age or no radiographic evidence of epiphyseal closure).

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

1. Lynch SE, Marx RE, Nevins M, Wisner-Lynch LA, eds. Tissue Engineering: Applications in Oral and Maxillofacial Surgery and Periodontics. Hanover Park, IL: Quintessence Publishing; October 31, 2007.

2. Jensen OT, ed. The Sinus Bone Graft, 2nd edition. Hanover Park, IL: Quintessence Publishing; March 30, 2006.

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