Bone Grafting Benign Bone Cysts and Tumors

with PRO-DENSE® Injectable Regenerative Graft

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Grafting Benign Bone Cysts and Tumors with PRO-DENSE® Injectable Regenerative Graft

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Introduction

Your doctor or your child’s doctor is recommending that you have PRO-DENSE® Injectable Regenerative Graft applied to his/her bone cyst or tumor. This product, in conjunction with good surgical and post-operative care can help the bone to heal normally over time. Once healed, the bone should be as strong as normal bone, and unless the grafted area involves the growth plate, it should not affect growth of a bone as your child grows.

Benign Bone Cysts and Tumors

Discovering that your child has a bone tumor or cyst can be quite unsettling, creating anxiety and generating great concern over his or her health. It may help to know that most of these cysts and tumors are actually benign (i.e. not considered cancerous) and do not spread to other parts of the body. Surgical treatment can be minimally invasive or require more extensive surgery depending on the size and type of tumor involved. Sometimes benign tumors or cysts will appear when they fracture. This is called a pathologic fracture and is due to the
weakening of the bone. Often, this is the first time the abnormality is identified. Depending on the fracture, the surgeon may elect to treat the fracture, and if the cyst does not heal completely and resolve, a grafting procedure may be required.

**UBCs and ABCs**

There are several different types of tumors that can occur in children and adolescents. The most common of these are the simple or unicameral bone cyst (UBC), aneurysmal bone cyst (ABC), non-ossifying fibromas, and giant cell tumors (GCT).

A unicameral bone cyst usually occurs in the long bones of a growing child (typically ages 5-15), most often in the shoulder and hip area. The cyst itself is a fluid-filled cavity in the bone and has a fibrous tissue lining. Some heal spontaneously, while others tend to grow and must be addressed surgically. These types of cysts can recur and sometimes multiple treatments are needed.

An aneurysmal bone cyst is typically more aggressive. It is a fibrous cyst in the bone that is filled with blood and expands causing pain, swelling and can fracture if not treated. They are more frequent during teenage years and can occur in almost any bone in the body. Because of their aggressive nature, these cysts can damage the bone and potentially cause deformity. While these cysts are typically treated surgically, they too can come back and require additional treatment.
A non-ossifying fibroma is a type of bone tumor that is composed of fibrous tissue and is one of the most common benign bone tumors in children. They are usually found in the thigh or lower leg bones, but also may occur in the arms and hands. They are typically seen as incidental findings when a bone is x-rayed for other reasons. They are usually not painful or symptomatic, and most often the surgeon will follow clinically as they usually will resolve as the child goes through skeletal maturity. However, sometimes they can grow quite large and symptomatic and require bone grafting. They can also fracture and require treatment of the fracture followed by grafting, if needed.

Giant cell tumors are more aggressive bone tumors. They are very rarely seen in children, and typically occur between the age of 20 and 40. They usually occur at the ends of the long bones in your arms and legs near the joint. Treatment generally involves removal of the tumor, treatment of the bone cavity with cauterization, freezing or chemicals and then bone grafting. Surgery is usually successful but some can grow back.

What to Expect

Again, there are many different types of benign bone cysts & tumors each unique in their own way. Regardless, it is important to remember that when treated properly, these cysts/tumors do not spread and the majority can heal normally with no lasting effects, allowing your child to grow and function normally.
Common Treatments

Non Surgical
Conservative or non-surgical treatment of benign bone cysts is dependent on the type of cyst involved. A simple or unicameral bone cyst for example, may heal spontaneously. Conversely, only a small minority of aggressive aneurysmal bone cysts heal on their own. Non-surgical treatment simply consists of observation and may include casting for immobilization if painful or if a fracture is present.

Surgical
Surgical treatment runs a wide gamut from injections to a more extensive procedure where a window of bone overlying the lesion is removed to allow more aggressive removal of bone with specialized tools (curettage) followed by bone grafting. Some of the cysts may cause such weakness of the bone that the addition of plates, screws or rods for stability may be necessary. Injection
techniques typically include a small incision and two large needles that allow the surgeon to aspirate, irrigate, scrape the bone of the lining of the cyst, and then inject the cavity with a substance to help promote the healing of the defect. Open procedures, on the other hand, will require more exposure of the bone and will include removal of the cyst or tumor and the use of additional treatments such as high temperature cautery, freezing or using chemicals on the inside of the lesion to ensure that it does not re-grow.

The cyst/tumor type, its aggressive nature and size will all impact the non-surgical or surgical treatment plan. Your child’s surgeon will then dictate a post-treatment protocol that is designed to allow for the body to heal and monitor for recurrence.
Is PRO-DENSE® Right For You?

PRO-DENSE® Injectable Regenerative Graft is a bone graft substitute that is a purely synthetic composite of calcium sulfate and calcium phosphate. These two materials are highly biocompatible and have been used in orthopedics for over 100 years. The formulation in PRO-DENSE®, however, is unique and has demonstrated excellent results in benign bone cysts and tumors.

PRO-DENSE® bone graft has been used clinically for almost a decade and now is the only bone graft substitute to be indicated specifically for use in benign bone cysts and tumors in patients 6 years and up. The product allows for an injection technique in simple or unicameral bone cysts, or as a backfill in more aggressive tumors/cysts in open techniques.
How is PRO-DENSE® Applied?

A generalized surgical technique is demonstrated below:

**STEP ONE**
Localize the lesion under fluoroscopy. Create cortical access to facilitate curettage.

**STEP TWO**
Using an image intensifier, excise the lesion using a curette to debride defect margins. Excised tissue should be sent to pathology for routine histological examination and culture.

**STEP THREE**
Having debrided the defect area, use the included delivery needle to inject PRO-DENSE® Graft into the defect.
What Happens After Application?

After implantation, the bone graft resorbs over time and allows the body to lay down dense, new bone. This is different than other bone graft materials that take much longer (sometimes years) to resorb and be replaced by bone. In most cases, PRO-DENSE® can be seen radiographically (i.e. on x-ray or CT) as your child returns for post-operative visits. Your child’s surgeon will define healing and post-operative activity level as the material resorbs and new bone heals and replaces the graft.

The below case examples demonstrate how the material can be seen on x-ray and be replaced by dense, new bone as the material is resorbed.

TWELVE YEAR-OLD MALE with a recurrent unicameral bone cyst of the right proximal humerus. Approximately 50cc of PRO-DENSE® graft were used to completely fill the lesion. No complications were reported. New bone formation was detected at 7 weeks, and at 7 months, a small amount of the residual graft was left. At 3 and 12 months, radiographs show dense new bone formation. Patient was fully active at 10 weeks and remains at full activity at present.

PRE-OP

POST OP
2 Weeks

POST OP
1 Year
EIGHT YEAR-OLD MALE with a giant cell tumor of the third metatarsal. Approximately 8cc of PRO-DENSE® graft were used after surgical removal of the tumor. Healing of the bone can be seen as the graft resorbs and is replaced over time. By six months the graft appears to be fully resorbed and the bone has healed and remodeled. The patient was at full activity at 3 months, and there has been no recurrence of the tumor at the two year post-operative visit.

Images courtesy of Matthew Seidel, MD, Phoenix AZ
How Well Does PRO-DENSE® Work?

The PRO-DENSE® material has been used clinically for almost a decade with over 45,000 implantations world-wide. There are several peer-reviewed published reports on the use of PRO-DENSE® in benign bone cysts and tumors.¹⁻³ Complications and recurrence was on par or better than historical experience with bone graft obtained from the patient’s own body, allograft, or other synthetic bone graft. A brief summary of three is below:

Gentile article¹: “Treatment of Unicameral Bone Cysts in Pediatric Patients With an Injectable Regenerative Graft: A Preliminary Report”

This was a review of 16 patients with unicameral bone cysts (UBC) with radiographic (e.g. X-ray) endpoints. 93.7% (15/16) of patients demonstrated radiographic healing after a single procedure and 87.5% (14/16) of patients developed complete radiographic healing. Patients returned to full activities at a mean of 3.1 months (range, 1-6) and all patients were fully functional and pain-free at the last follow-up. One patient healed with defects and one patient had a persistent cyst, which was asymptomatic and requested no further treatment. No patients experienced a postoperative fracture or infection. The authors concluded, “The treatment of UBC in pediatric patients with curettage, decompression, and injection of a CaSO4-CaPO4 composite (PRO-DENSE®) is a safe and cost-effective treatment with a low recurrence and complication rate when compared with conventional methods.”
Evaniew article: “Use of a Calcium Sulfate–Calcium Phosphate Synthetic Bone Graft Composite in the Surgical Management of Primary Bone Tumors”

This was a review of 24 patients with different benign bone tumors in a more simplified functional outcomes study. In these 24 patients, the mean time to full weight bearing (e.g. walking unassisted) was 7.3 weeks (8.3 for upper extremity, 6.9 for lower extremity). There were two patients that sustained local recurrences, but no other complications related to the graft were reported. The authors stated, “The use of CaSO4/CaPO4 synthetic bone graft composite (PRO-DENSE*) was associated with rapid biological integration and early functional return to activities of daily living with no complications related to the use of the synthetic bone graft.”

Fillingham article: “Function After Injection of Benign Bone Lesions with a Bioceramic”

This was a review of 56 patients with different benign bone tumors with the intent of understanding functional outcomes, which is a measure of normal function and pain, such as walking, dexterity, lifting, etc. The average score across these 56 patients was 29/30, which suggests good to excellent function. There were two postoperative fractures and 3 local recurrences. The investigator additionally stated, “In the current series…only one of the 13 (8%) unicameral bone cysts treated percutaneously has required a second injection…Although it was not an intended outcome, PRO-DENSE® appears to result in a lower recurrence rate after percutaneous treatment as compared with alternative treatment modalities.”
Q. What is a benign bone cyst or tumor?

A. This is a condition in which bone is replaced with fluid or abnormal tissue resulting in a bone void. There are many different types of cysts or tumors that present in different places in the skeleton and are common to different age groups in children and adolescents. These voids can lead to weakened bone and result in pain and/or fracture. It is important to understand that most of these tumors are actually benign (i.e. not cancerous) and do not spread to other parts of the body. They can often be treated non-surgically, and surgical treatment can be minimally invasive depending on the type of cyst involved.
Q. How do bone cysts and tumors form?
A. Unfortunately, this is not entirely well understood for some cysts and tumors. There are different causes for the different lesions which can make it difficult to determine how and where they come from. Your child’s surgeon will discuss your child’s condition with you for better understanding.

Q. Is the cyst/tumor cancer?
A. Benign bone tumors/cysts are not cancers and never metastasize or spread to other parts of the body. These tumors are typically localized and can be healed with the right treatment, although some can be persistent or recur.

Q. Which cysts/tumors are treated conservatively and which are treated with surgery?
A. The answer to this question is likely dependent on several factors, such as the type of cyst/tumor, the size and location, and aggressive nature among others. However, in general, if the lesion is relatively small and not in danger of fracture, and appears to have a more latent appearance (i.e. isn’t growing fast), a conservative treatment option may be available.
Q.  How is a cyst/tumor treated surgically?
A.  Again, depending on several factors, the cyst/tumor may be accessed with a small incision and injected, or may require more exposure of the bone with removal and bone grafting. Your child’s surgeon will assess these various factors and will choose the best approach based on his or her experience.

Q.  What is PRO-DENSE® and how does it work?
A.  PRO-DENSE® is a synthetic composite of calcium sulfate and calcium phosphate, two biocompatible materials that have been used in bone grafting for over 100 years. The composite is unique in how it resorbs in the body, and how the body responds by laying down dense, new bone. Pre-clinical work and clinical experience demonstrate that the rate at which the body resorbs the PRO-DENSE® graft and replaces with newly regenerated bone seems to be timed just right.

Q.  What are the risks of PRO-DENSE®?
A.  Along with the risks inherent in any surgical procedure, patients with severe vascular or neurological disease, or patients who are pregnant may not be the best candidate for PRO-DENSE®.
Indications

PRO-DENSE® resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure in situ. These open bone voids may be the result of benign bone cysts and tumors (in adult and pediatric patients ≥ 6 years old), surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The PRO-DENSE® paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process. PRO-DENSE® is provided sterile for single use only.
Contraindications

The PRO-DENSE® Bone Graft Substitute injectable paste is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Closed bone void/gap filler
- Pregnancy
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Hypercalcemia
- Renal compromised patients
- Patients with a history of or active Pott’s disease

See package insert for additional risk information.
References

