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BONE MORPHOGENIC PROTEIN (BMP) IN SPINAL SURGERY

WHAT IS BONE MORPHOGENIC PROTEIN (BMP)?

BMP is used to stimulate new bone formation and consists of two parts: a solution containing rhBMP (recombinant human Bone Morphogenetic Protein) and the AC (Absorbable Collagen). The protein is a manufactured (genetically engineered) version of a natural protein normally found in small quantities in the body. The purpose of the protein is to stimulate bone formation. During surgery, the protein solution soaks into the AC. The AC acts as a scaffold for the formation of the new bone that the protein stimulates. It is designed to resorb (disappear) over time.

WHAT ARE THE POSSIBLE BENEFITS?

A potential advantage of having a spinal fusion procedure using BMP is its ability to induce new bone formation and indirectly stimulate the formation of new blood vessels. This will enable Mr D'Urso to perform the surgery without having to harvest bone graft from your hip. By avoiding the harvesting of bone the surgery will be less invasive and quicker. The risk of donor site complications such as infection, blood clot and nerve damage will be avoided and your recovery from surgery should be faster and less painful.

WHAT ARE OTHER OPTIONS FOR TREATMENT?

Autograft bone is bone is taken from one part of your body and placed at the part of the spine being fused. Obtaining bone from a donor site or may lead to increased risks, including but not limited to new or increased pain, fracture of the donor site bone, injury to the nerves or blood vessels in the donor site area, increase in scar tissue, and infection.

WHO SHOULD NOT RECEIVE BMP?

BMP should not be used if:

- you are pregnant or suspect that you might be pregnant
- you are sensitive to bovine (cow) Type I collagen or recombinant human Bone Morphogenetic Protein
- you have an infection near the area of the surgical incision
- you have a resected or existing tumor, an active malignancy (progressive and uncontrollable tumor) or are undergoing treatment for a malignancy
- your bones have not stopped growing

HOW IS THE SURGERY PERFORMED?

The BMP can be implanted through an opening in your lower back. This is known as a posterior surgical approach. You should speak with Mr D'Urso about the risks and benefits of this technique prior to surgery. During your surgery, Mr D'Urso will remove some bone to allow the BMP and implants to be inserted. Rather than taking bone (autograft) from your hip Mr D'Urso will utilize the bone taken during the exposure of the spinal nerves and mix it with the BMP to help stimulate bone growth.

If you have any questions regarding this surgery you should discuss these with Mr D'Urso before you make your decision.

HAS BMP BEEN STUDIED IN HUMANS?

BMP has not been previously tested in controlled human clinical trials for some indications. Data supporting its use in symptomatic, multi-level posterolateral revision procedures has been obtained from a small number of patients who were smokers and/or diabetics. In this analysis, no new adverse events were observed. All patients with fusion data were determined to have a solid fusion outcome. Patients received BMP and a small amount of their own bone. Fusion success was achieved in all cases with sufficient follow up. The combination of BMP with spinal instrumentation has also been evaluated in another study. This study was intended for patients suffering from single level disease requiring surgical intervention at the operative level for the first time. The data provided further evidence supporting the safety and probable benefit of BMP.

BMP has been evaluated in several other human clinical studies resulting in FDA approval for various indications. These indications include: the treatment of acute, open tibial shaft fractures that have been stabilized with intramedullary nail fixation and spinal fusion bone grafting procedures. Specifically, these procedures ("Indications for Use") include Anterior Lumbar Intervertebral Body Fusion (ALIF). ALIF is a surgical procedure that involves approaching the spine from the front (anterior) of the body to remove all or part of a diseased or damaged disc in the lumbar spine. BMP is then placed in a fusion cage which is implanted between the vertebral bodies. As the body heals, the vertebral bone eventually grows together and fuses the spine.

WARNINGS AND PRECAUTIONS

BMP has not been tested to determine if it could harm a developing fetus. Women of childbearing age must not get pregnant for one year following treatment with the BMP. BMP has also not been studied in nursing mothers. When tested in female rabbits that received the BMP, the collagen component of the device, developed an immune response and later became pregnant, the following was seen: antibodies developed by the mother were able to reach the developing rabbit fetus. The effect of these antibodies on the developing rabbit fetus is not currently known. Some bone formation abnormalities were observed in a small number of the rabbit fetuses tested. It is not known if these changes would disappear as the rabbit fetus continued to develop or at some time after birth. BMP should not be used immediately prior to or during pregnancy. Women of child-bearing potential should not get pregnant for one year following treatment with the BMP. BMP plays a critical role during fetal development in humans and other animals. It is not known whether a pregnant woman,

previously exposed to BMP by implantation with the device, might develop a second immune response to BMP from the developing fetus with adverse effects for the woman or baby. In a rabbit pregnancy study to investigate this issue, no increase in anti-BMP antibodies was observed.

In addition, BMP has not been tested:

- to see if there are side effects by using it more than once in the same person
- in people with liver or kidney problems (this might be important because these organs are involved in removing BMP as it resorbs)
- in people with metabolic bone diseases, such as osteoporosis
- in people with autoimmune or immunosuppressive disease, such as lupus or HIV/AIDS
- in people with immune deficiency due to other treatments, such as radiation therapy, chemotherapy, or steroid therapy

Although not seen in studies performed by the manufacturers, there is a possibility that too much bone may form at the implantation site (exuberant bone formation), bone may form at a location away from the implantation site (ectopic bone formation), or the bone that is formed may be abnormal.

Please talk with Mr D’Urso about any of the above warnings and precautions if you have concerns.

WHAT POSSIBLE COMPLICATIONS COULD OCCUR?

As with any surgery, spinal surgery is not without risk. A variety of complications related to the use of BMP can occur. These may occur individually or in combination. Some of these may be severe, affecting your outcome. You may also need to have additional surgery to correct these complications. Some of the possible complications include:

Occasional

- allergic reaction to the implant materials
- ectopic and/or exuberant bone formation (displaced, ectopic and/or profuse bone formation)
- edema (swelling)
- erythematous tissue (abnormal redness of the skin)
- inflammation
- itching
- pain
- scar formation
- seroma (localized swelling from an accumulation of fluid)

Very Rare

- anaphylactic reaction (exaggerated allergic reaction to the protein)
- bone fracture
- damage to blood vessels and cardiovascular system compromise
- damage to internal organs and connective tissue
- death
- development of respiratory problems
- disassembly, bending, breakage, loosening, and/or migration of components
- fetal development complications
- loss of spinal mobility or function
- neurological system compromise
- non-union (or pseudoarthrosis), delayed union, mal-union
- post-operative change in spinal curvature, loss of correction, height, and/or reduction
- tissue or nerve damage

Contact your Mr D'Urso immediately if:

- you get a fever
- your wound starts leaking fluids
- you have trouble breathing
- you have trouble urinating
- you have new or increased back or leg pain or numbness

Mr D'Urso will schedule office visits to check on how you are doing and to see if anything else needs to be done.

TALK TO MR D'URSO

While this information sheet has hopefully provided you with the information you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice. If you have any questions or need additional information about BMP, please call or consult with Mr D'Urso, who is the only one qualified to diagnose and treat your back.

FURTHER INFORMATION

Further information about BMP may be obtained at the following web sites:

<http://www.stryker.com/en-us/products/Orthobiologicals/index.htm>

<https://www.infusebonegraft.com/>