

October 2016-2017

Title: Evaluation of Autograft Bone Tissue Recovered with the Hensler Bone Press™

Sponsor: Hensler Surgical Products

Hospital for Clinical Study: University of Alabama at Birmingham.

Medical Director: Dr. Steven Theiss

Type of Study: Qualitative Lab Study, Autograft Analysis from Hensler Bone Press.

Primary Aim

Hypothesis

- i. Intra-operative collection of autologous bone graft using the Hensler Bone Press contains osteogenic and osteoconductive factors for the promotion of spinal fusion.
- ii. These osteogenic and osteoconductive factors can be used to improve the success rate of a complete fusion and reduce pseudoarthrosis from primary spinal fusion surgeries.

Secondary Aim

Hypothesis

- iii. To test the viability of cells and tissue collected using the Hensler Bone Press and to quantify the presence of growth factors.

Study design with description

While performing cervical, thoracic, and lumbar spine surgery, a burr is used to remove the lamina and facets. This morselized bone material mixed in native body fluids will be suctioned to a collection container called the Hensler Bone Press (HBP). The HBP is a sterile 'inline' collection device between the surgical field and the waste container. The HBP is a 510-K exempt, Class II disposable device. The FDA Establishment number for the HBP is: 3009657922 and Regulation number 880.6740. The HBP was designed for the purpose of autologous bone graft collection and separation, and we are using it for this same reason. The method for bone sample collection with the HBP is the same for every surgery, although the procedures themselves may vary. The standard operational procedures will be performed according to normal standards – the only additional step that will be included during surgery is collection of the morselized bone with the HBP rather than a waste container.

For our purposes, bone from only the lamina and facets, minus the articular cartilage, will be aspirated and collected in the HBP. Once collected this autologous bone graft will then be passed off the sterile field in the HBP, placed in a biohazard bag and taken to a laboratory on UAB campus. Once at the lab, the bone press can be used to separate the solid bone matter from its native fluids and blood.

Background Information and Scientific Rationale:

Spinal arthrodesis (fusion) is indicated for several pathologies in the cervical, thoracic and lumbar spine. Briefly, during spine surgery the vertebrae are realigned and neural elements are decompressed. In performing these tasks, the spine is destabilized necessitating internal fixation with various options (pedicles screws, hooks, rods, interbody devices). These devices provide 'temporary' stabilization, however, the ultimate goal is for bony union (fusion) to occur across the operative segments. If complete fusion between the bones does not occur, a pseudoarthrosis will develop leading to fatigue/failure of the hardware, spinal instability, and potential neurologic dysfunction. Spinal fusion is performed by placing bone graft across the motion segments. Two forms of bone graft can be used: 1) Autograft (from the patient) or 2) Allograft (cadaveric or synthetic). Autograft is the gold standard as it contains all the necessary osteogenic factors for bone union to occur. However it does carry the down side of donor site morbidity. Allografts do not have this risk of complications from harvesting autograft bone, but there are concerns about its efficacy in promoting fusion. The idea is to collect and condense morselized bone material that is created during spine surgery and reapply it later in the surgery as an autologous graft source. Normally this bone and tissue gets thrown away, but it could potentially be a valuable source of osteogenic cells and growth factors.

Potential Risks and Benefits:

Risks: None to the patient – there is no change in any component of the procedure that the patient will be receiving. The only difference is that bone/tissue/body fluids that are normally thrown away will be collected and tested at a lab. Even the method of collection is extremely similar to methods that do not involve the HBP.

Benefits: If this study shows that there is osteogenic capability of the autologous bone collected using the HBP, it will be beneficial to orthopedic surgery in many ways:

1. Effective use autograft material (gold standard material) without the morbidity associated with grafting from another location, since it is collected from the same site that it will be applied. Harvesting a graft from another location will cause two points of trauma for the patient and can cause chronic pain or other problems.
2. Faster surgery times since there will no longer be separate graft harvesting when using an autograft.
3. No need for purchasing allograft materials or synthetic growth factors, effectively decreasing the cost of surgery.
4. Promote osteogenesis and complete fusion more effectively than allograft materials can.

Initial Study Results:

... Our analysis of the specimens is complete. We've stained each of the specimens for BMP 2 and 7 as well as routine staining. While the amount of bone varies from specimen to specimen, **there is significant bone present in each. There is also some specimens with prominent staining of BMP 2 and 7, which is very important in bone formation.** This staining predictably is contained in the surrounding blood clot but is certainly present in the graft material. **The photos show positively stained specimens for each of the markers described above.**

HENSLER BONE PRESS™ STAINED BONE SPECIMENS:

