In vitro testing of the Device Synergies Self-Grafting Drill Bit technology

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Background

Accessing bone as part of implant fixation for orthopaedic, spinal and sports medicine devices is a fundamental requirement. To this end, surgical drills are often used to create bone tunnels prior to deployment of a device such as screws and anchors. These devices play an integral role in fixation and ultimately clinical success.

To date, all surgical drill bit technologies for either soft or hard tissue have been based on classic machine type designs. Whilst there have been differences in geometries and the number of cutting flutes, to date all spiral flute drills have incorporated standard right-handed helixes. A right-handed drill bit, by design, removes material, often referred to swarf as the drill bit performs its function.

Historically, autograft has been the material of choice used by orthopaedic surgeons to enhance and supplement bone healing[1]. Considering the importance of bone grafting and the healing potential of autogenous bone, it seems logical that leaving the bone swarf behind, within the cavity created by the drill bit, may facilitate healing as well as potential of hastened fixation. Histological evaluation of bone drill swarf has suggested the viability of the bone tissue is maintained[2].

The technology from Device Synergies presents a novel left-handed, tapered helix, open flute design incorporated into a conventional right-handed drill bit: (Fig 1).

Figure 1: Self Grafting 4.5mm Drill Bit

Aim

This in vitro study evaluated the performance of the new left-hand fluted drill (Self Grafting, Device Synergies, Sydney, Australia) compared with a standard surgical drill bit in terms of the nature of the bone tunnel created and its potential impact on surgical procedure outcomes. An analytical balance and micro computed tomography were used to assess the weight of material removed and distribution of any remaining auto-graft material left behind, for each drill type, in the bone tunnel following routine drilling procedures.

Methods

Fresh bovine cancellous femurs were obtained from a local slaughterhouse. The specimens were cleaned of soft tissue and the distal femoral condyle was exposed. Samples were drilled using a 4.5 mm Self Grafting drill bit and a standard 2 fluted 4.5 mm surgical drill bit. Three drilling episodes were repeated for each drill bit type to a depth of 40 mm. The material captured within the flutes and removed from the bone, during the drilling procedures was harvested on pre-weighed gauze and quantified using an analytical balance.

Micro computed tomography using a Siemen Inveon Micro CT system was used to evaluate the cavities created during drilling and the distribution of swarf left behind in the cavity in the axial, sagittal, and coronal planes.

Results

Drilling was performed successfully with both types of drill bit. A combination of bone marrow and cancellous bone was found within the standard drill bit flutes after each drilling episode. In contrast, the Self Grafting drill bit did not remove any cancellous bone whilst some fatty material was evident (Fig 2). The weight, in grams, of material removed for each drill type was calculated (Fig 3). The standard drill bit removed 4 times the material removed by the Self Grafting drill bit.

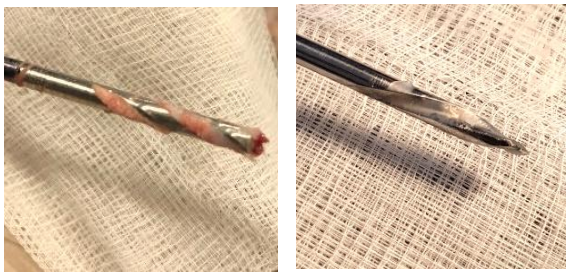


Figure 2: Example of the material removed during drilling with a standard 4.5 mm standard drill bit (left hand image). The material within the flutes was a combination of bone marrow and cancellous bone. In contrast, the Self Grafting drill bit did not remove any cancellous bone whilst some fatty material was evident (right hand Image).

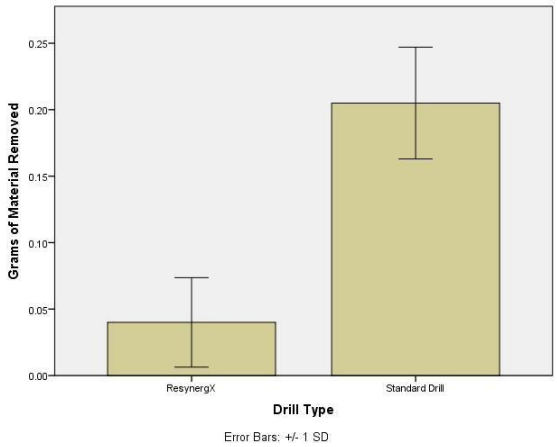


Figure 3: The standard drill bit captured, and removed from the site, more than 4 times the amount of material (combination of bone marrow and cancellous bone.) than the Self Grafting drill bit which removed less than 0.05 g from the bone tunnel created (fatty material).

Micro computed tomography of the standard right-handed drill bit cavities revealed clear voids, as the bone was almost completely removed by the flutes. In contrast, the Self Grafting drill bit, with its tapered left-hand helix design did not remove the bone swarf, instead leaving it distributed within the cavity as autograft (Fig 4).

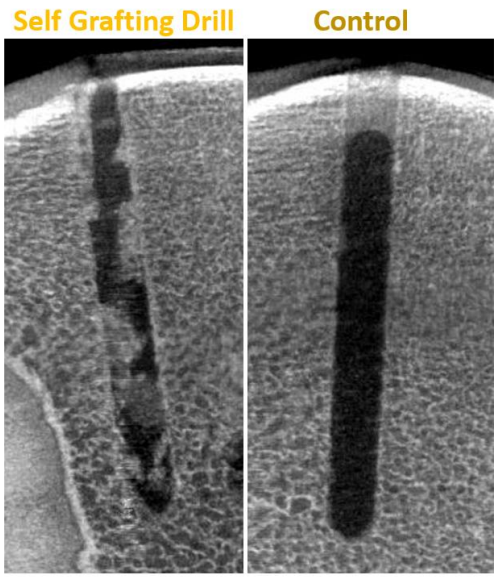
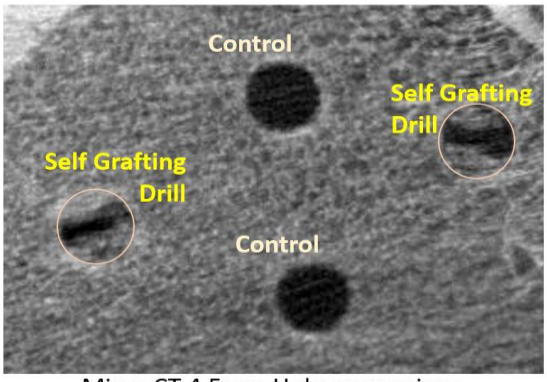


Figure 4: Sagittal view of the bone cavities after drilling using the Self Grafting drill bit and Control (standard drill bit). Autograft is left behind inside the cavity created during drilling

by the Self Grafting drill bit.

An axial Micro Computed Tomography view through the middle of the cavity is shown in Figure 5. Here also it can be observed how material is cleanly removed with the standard drill bit while the Self Grafting drill leaves behind the bone fragments collected within the left-handed flutes, as the drill exists the hole.



Micro CT 4.5mm Hole comparison

Figure 5: Axial views through the cavities created by the two drills. Bone is left behind with the Self Grafting drill with what appears to correlate with the flute geometry while the control (standard drill) removes the material resulting in an empty cavity.

Observations and Conclusions

Failure of orthopaedic procedures is often the result of failures in biological healing.

The biology of healing is complex and minimising removal of healthy autologous tissue from the body may enhance the biological healing response. The left-hand tapered helix open flute design of the Self Grafting drill bit did not remove bone during drilling and did provide local autogenous bone graft within the drill site hole. Creating bone tunnels using drill bits is a common procedure in many surgical subspecialties - and autograft helps to prepare a bone to respond to injury[1].

Considering these points; the presence of healthy local autogenous graft within the drill site hole may play an important role in healing and/or osteointegration at the implant-bone interface. Therefore; the future potential impact on surgical procedure outcomes utilising the Self Grafting drill bit definitely warrants thorough clinical evaluation.

The Device Synergies Self-Grafting Drill Bits may have positive implications in healing and orthopaedic surgery in general.

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1. De Long, W.G., Jr., et al., *Bone grafts and bone graft substitutes in orthopaedic trauma surgery. A critical analysis.* J Bone Joint Surg Am, 2007. **89**(3): p. 649-58.

2. Santagata, M., et al., *Autologous bone graft harvested during implant site preparation: histological study.* Plastic and Aesthetic Research, 2014. **1**(3).