The OsteoAccess System – Low-Force, Controlled Angled Bone Access for Bone Biopsy and Bone Marrow Aspiration a NIH/NCI SBIR Funded Platform


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ABSTRACT

For diagnostics procedures following bone lesion identification as well as other medical causes, bone marrow biopsies are often required. Current methods to perform bone biopsies require significant forces to penetrate cortical bone, are unable to perform insertions at low inclination angles (<50°), and often require additional samples (and bone insertions) due to inadequate initial sampling. These combined factors can lead to extended procedure time, which in turn can increase radiographic exposure and in pediatric cases, time under anesthesia to patients. The OsteoAccess System is a patented novel medical advancement that allows clinicians greater flexibility in planning the path to the lesion by enabling oblique angle penetration, providing easier anchoring into bone surfaces with high curvature, and allowing greater control by reducing penetration force. These system attributes will significantly benefit bone lesion biopsy outcomes, improving overall safety and sample quality. Actuated Medical, Inc. (Bellefonte, PA) is developing the OsteoAccess System using a National Institutes of Health / National Cancer Institute (NIH/NCI) Small Business Innovation Research (SBIR) Phase II grant.

Keywords: bone biopsy, cancer, hematology, intraosseous infusion, bone marrow

BACKGROUND

Various medical and diagnostic procedures require penetrating hard cortical bone to perform percutaneous bone marrow biopsies. Bone lesions identified through imaging or clinical evaluation are biopsied to obtain the required tissue to diagnose a wide range of potential cancers and blood diseases. Sampling locations can include the iliac crest (hips), legs, arms, spine, or ribs. It is estimated that >50,000 bone lesion biopsies are performed on patients, and >25,000 patients are diagnosed with a malignant bone tumor annually in the USA [1]. The OsteoAccess System (see Figure 1) is an innovative bone access device that reduces insertion force, improves clinician control, and provides more favorable paths for entry into the target.

Currently, the most common method of performing bone marrow biopsies is using a Jamshidi® needle consisting of an 11 gauge cannula surrounding a 15 gauge trocar-tipped stylet attached to a “T” shaped handle. To penetrate through cortical bone, the trocar tip is twisted and ground against the bone until the outer cannula is worked completely through the cortical layer. The stylet is then removed, and bone marrow is aspirated through a syringe attached to the cannula via a Luer-lock connection. Additionally, a core sample is obtained by twisting the cannula into the cancellous bone.

The design of Jamshidi-style needles falls short of addressing many challenging aspects of biopsy procedures. It cannot obtain samples at low inclination angles (<50°), and the significant forces (see Figure 2) required to penetrate the cortical bone limits the operator’s fine control. Under such excessive forces, the risk to surrounding tissue when attempting to penetrate obliquely or on irregular or highly curved cortical surfaces severely limits the ability to safely sample from ribs, vertebrae and other bones adjacent to delicate or vital structures. For adult patients, bone lesion biopsies are often performed under CT-image guidance to ensure accurate sampling [2, 3]. However, the gantry prohibits the clinician from generating enough leverage on the biopsy system. This often requires pulling the patient out of the imaging gantry to improve leverage, and advancing the device “blindly”. The patient is then pushed back in to re-check positioning, and the process is iterated, adding to procedure time [4].

Figure 1: The OsteoAccess System enables angled bone access.
Because high forces pose challenges for precise, controlled insertions, core sample quality ultimately suffers. Samples of inadequate length, too much cortical tissue, or artifacts due to rotation, rocking and compression-decompression must be repeated [5] (see Figure 3). This leads to clinician fatigue and increased patient discomfort, anxiety, and healing time [6, 7]. The recommended biopsy core length for the most accurate diagnoses is 1.5 - 2 cm [9, 10]; however, a study focusing on pediatrics concluded that 17% of the submitted 822 bone marrow specimens examined were inadequate [11]. Additionally, of the 13 centers submitting at least 20 core samples, failure rates ranged from 2.6 to 50% [11]. A similar study considered 25% of 605 pediatric bone marrow biopsies examined inadequate [12].

Re-seeding of tumor cells along the biopsy needle track, leading to cancer recurrence, is a recognized risk with primary sarcomas [13, 14]. Recurrence of bone tumors is particularly lethal, with 5-year survival rates as low as 14% [15, 16]. If tumor resection is required, the entire biopsy needle tract must also be removed along with portions of transected tissue compartments [2]. In order to ensure the best prognosis and the option of limb-sparing resection, the clinical team must carefully plan out the approach to the lesion to ensure the needle track avoids vital structures and tissue compartments while obtaining the highest quality biopsy sample possible [2, 17]. Biopsy paths that are poorly planned or limited by anatomical location can lead to functional limb loss or even unnecessary amputation (5-8% of cases) [18]. The range of possible paths is partially limited by current technology and its inability to penetrate the cortical bone at low inclination angles and the high forces that limit control.

THE SOLUTION

A device that allows greater flexibility in planning the path to the lesion by enabling oblique angle penetration, and easier anchoring into bone surfaces with high curvature, while at the same time allowing greater control by reduced penetration force, would significantly benefit bone lesion biopsy outcomes, improving overall safety and sample quality. The OsteoAccess System’s patented technology oscillates a needle system under precise electronic control to enable low-force, angled penetration of rounded, hard surfaces where traditional needles and drill bits tend to slip dangerously off the surface. This actuation would significantly reduce the above discussed risks and repeat procedures.

BENCHTOP DATA

Benchtop testing of the OsteoAccess System demonstrated its ability to reduce the insertion force required to enter a cortical and cancellous bone. Insertions were performed to a depth of 10 mm with a solid 11 gauge needle in 37°C hydrated porcine hock bones. Insertion force was measured...
by attaching a load cell (Shimpo FGV-XY) to the hock bone. The OsteoAccess System’s actuated insertion force was 62.5% of non-actuated insertion force (see Figure 4). Additionally, insertions were performed with a 13 gauge stylet and 11 gauge cannula. Five insertions were performed with non-actuated (manual) insertions and 4 insertions were performed with actuation (OsteoAccess). Insertion force was measured during each trial. Actuation statistically reduced the average force required to penetrate bone by 52 ± 8.3% (see Figure 5; Student’s T-test, p<0.001).

**PEDIATRIC INDICATION**

Actuated Medical received a seed grant from the Philadelphia Pediatric Medical Device Consortium (PPDC) (a center funded by the FDA) - based at the Children’s Hospital of Philadelphia (CHOP) - to evaluate the OsteoAccess System for pediatric bone biopsy and bone marrow aspirations [22]. In addition to the previously mentioned biopsy challenges, pediatric patients face the added risk of requiring general anesthesia, as this is a necessary measure due to the pain caused by the procedure [23, 24]. A lack of adequate samples, requires additional insertions and results in longer procedure times, extending the time the child remains under general anesthesia. Evidence in rodent and non-human primate models suggests that anesthesia has neurotoxic effects on brain development [25].

**SUMMARY**

Actuated Medical has developed a platform technology, the OsteoAccess System, to enable reduced force bone access of greater than 52 ± 8.3%. The reduced force enables oblique angled access. The oblique access enables improved clinician control, and provides more favorable paths for entry into the target tissue to diagnose cancer and other diseases. OsteoAccess’ proprietary technology will enable low-force, angled penetration of rounded, hard surfaces where needles and drill bits tend to slip dangerously off the bone. The first commercial device will be the OsteoAccess-Biopsy for bone biopsy and bone marrow biopsy. The biopsy system will be followed by the development of devices for bone marrow harvesting, transplant, and intraosseous access. The OsteoAccess technology platform development has been funded by NIH/NCI SBIR grants.

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**REFERENCES**

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