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On the development of a New Flexible Drill for Orthopedic Surgery and the forces experience on drilling bovine bone

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Abstract

Background: This paper presents the construction of a flexible drill which is designed to cut a curved canal in the bone or remove bone materials, to improve the outcome of orthopedic surgery and to facilitate minimally invasive.
Methods: This paper reports the design of the flexible drill and uses it in an experimental rig to evaluate the drilling force generated when cutting bovine bone. The experiments facilitate the measurement of action forces between the mill bits when moving the tip towards or across a bone sample in various configurations caused by bending the flexible drill sheath to enable cutting of a curved path of variable radius in the bone. The reaction force represents the force trying to deflect the mill bit tip away from the bone sample surface and must be resisted in order to continue cutting without deflection or buckling of the tip during the drilling of curved pathways.
Results: The experiment shows the flexible drill can cut bones in both configurations an experienced a maximal force of 3.4 N in the vertical configuration and 0.54 N in lateral configuration.
Conclusion: The experimental results show that the flexible drill designed is able to produce sufficient force at variable bending angles to perform the required tasks for bone cutting.

Keywords: *flexible drill, force evaluation, Orhtopedic Surgery*

Introduction

The need for a flexible drill is driven by the clinical requirement for improving the surgical outcomes and decreasing the complications of orthopedic procedures. For instance, one of the most troublesome problems for revision hip arthroplasty is the difficulty to interrupt the bone-implant interface to extract the primary stem due to the curved shape of proximal femur. In order to remove a well fixed stem a Wagner femoral osteotomy[1] has to be performed. Such a large osteotomy requires a very invasive procedure with blood loos and comorbidity. In this case, a flexible drill is needed to remove a thin layer of bone around the stem until the stem become loose without compromise the integrity of femoral cortex. However, femoral drilling is not widely practiced or developed due to the space-constraints in minimally invasive surgery. It is our hypothesis that a minimally invasive reinvision hip arthroplasty procedure would benefit from a flexible manipulator. Conventional drills can only make a straight pilot tunnel from the entrance point of the femur. Since the femoral stem is slightly curved to follow the anatomical shape of femur, current surgical tools are not sufficient to remove femoral cortex during minimally invasive revision hip arthroplasty.

The concept of a flexible drill system using a three-bar kinematic chain as a seath to guide a 1-2mm drill /osteotome was conceived to solve this problem. The tools need to fit within the small incision. It needs to be able to bend to enable drilling the femoral stem to remove a thin layer of bone around the stem. However, a worry in using it would be the flexible drill can be deflected in the bone by stronger sclerotic bone to weaker areas of the bone. The cutting force is the key to an effective cutting tool for orthopedic

surgery. Currently surgical bone cutting tools consists of drilling, milling, and sawing devices. Flexible manipulators for surgery have been developed for ACL reconstruction surgery and arthroscopy [2][3], fetal surgery [4] and vascular catheterization [5]. However, there have yet to be described any flexible drills for femoral canal milling in hip arthroplasty. Each has different cutting methods, and requires a different cutting force. Milling is an orthogonal cutting type that cuts in a parallel direction to the uncut surface with the tool approaching at a right angle to the uncut surface. Studies on this orthogonal cutting have been published since the 1970s. The focus of study was on the influence of feed and rake angle on cutting force and chip morphology [6][7]. In these studies it was stated that cutting force and specific cutting energy decreases with the increase of cutting speed. Yeager et. al [8] conducted a study of orthogonal machining of cortical bone and the influence of osteon orientation and cutting condition. They measured the cutting and thrusting forces, and the machined surface quality when using different osteon orientation and different cutting conditions. However no studies were found of milling down a femoral canal.

The main purpose of the paper is to report the design of a new flexible drill for orthopedic surgery and the forces it experienced while cutting the bone. The flexible drill manipulator combines a three-segment planar linkage as a sheath and a motor drive mechanism to allow an accurate control of bending angles for a flexible shaft mill bit. The flexible drill is designed to tunnel a curved channel for orthopedics. To achieve this it is essential that the drill produce sufficient force to cut bone at different configurations and bending angles. To demonstrate the capabilities of this flexible drill, a test rig was designed to simulate typical operation activity and measure the forces generated for the required tasks. In this way we were able to prove that the flexible drill is able to generate sufficient forces to perform the required tasks for femur drilling and also to report the size of these forces in different configurations.

Materials and Methods

Design of a Novel Flexible Drill Mechanism

The flexible drill manipulator comprises three multiple rigid segments that act as a sheath to a flexible shaft with a drill/burr attached to the end, as illustrated in Figure 1. The outer diameter of the sheath is 14.4mm; the length of the sheath to the burr tip is 158.5mm. The proximal end segment is connected to the motor box as shown in Figure 1. The motor box controls the action of the flexible drill. It contains a servo motor and a microcontroller board. The microcontroller controls the servo and streams data from rotary encoders. The rotary encoders are located at the revolution joint that connects each two segments and linked by two rivets that allow free rotation of the joint. Inside the sheath, two ball bearings are installed to link each segment of the sheath to the flexible shaft that drives the drilling. This mechanism allows a maximal speed of 3000 rpm, with free rotation and strong force transmission. The flexible shaft runs through a 5 mm hole at the base. The hole is made wider than the shaft's diameter to enable some clearance when the shaft is rotating at high speed.

The flexible drill has a wire-driven steering capability for rotating the joints. The benefits of wire driven manipulators include the fact that there is no large space requirement for actuation and an ability to actuate the tools into a curved configuration. There are two 2 mm holes on the wall of the sheath segments running above and beneath the flexible shaft hole. These two channels are designed for wires that connect the drill end part to the servo motor with the torque value of 11.3 kg/cm at 6.0 V, enabling bending of the joints in both clockwise and counter-clockwise directions.
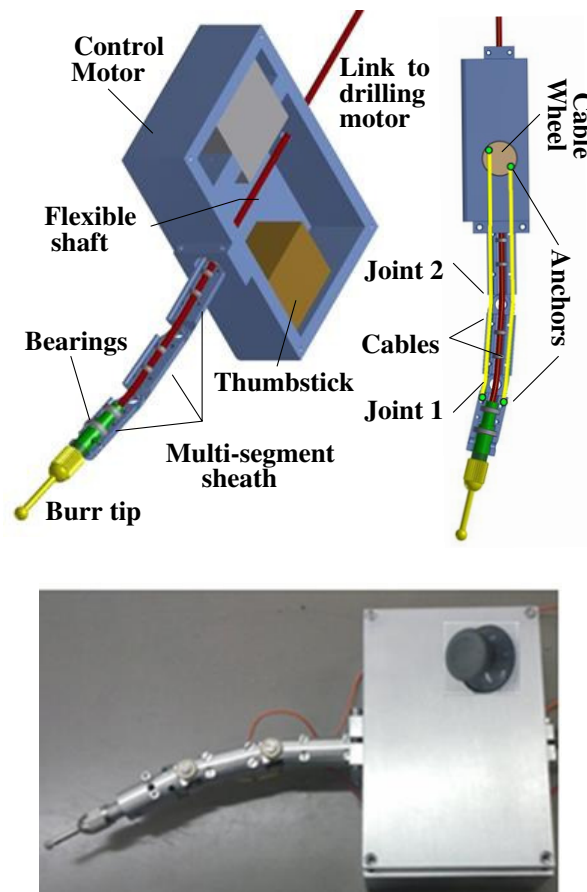
Fig. 1.Concept design of the flexible drill

The bending of the flexible drill sheath is controlled by the wires running inside the flexible drill sheath. The wires are braided steel wires that have a tensile limit of 50 pounds of force (222 N). The wires act like tendons, providing opposing tension when bending the flexible drill sheath. The wires are anchored at the drill's end to provide active bending at joint 1, while joint 2 bends passively in response to the bending of joint 1. The wire is tied to the servo arm of a high torque servo motor. The high torque servo motor is used so that the bending can be sustained during the milling of the femoral canal. The bending will provide one more degree of freedom to the flexible drill sheath. This enables it to navigate through the small incision and inside the femoral canal and cut a curved path. The twist or rotational motion of the flexible drill can be performed manually.

Assembly of the test rig

In order to evaluate the drilling force required, a test rig has been designed to perform a comprehensive measurement at variable configurations and bending angles for the flexible drill. The test rig comprised of five components which were a linear stage, flexible drill, bone holder platform, load cell, and bone sample holder. These five components, when assemble allowed the measurement and acquisition of feedback force of the bone sample when it is milled by the flexible drill. The flexible drill's motor box was attached to the linear stage and that was fixed to the test rig platform. The bone holder platform was attached to three pylons which fixed it to the test rig platform. The flexible drill could be attached to the linear stage in two configurations. One in which the bottom of the motor box was attached to the linear stage for vertical

configuration and a second in which the side of the motor box was attached to the linear stage for lateral configuration. The load cell was attached to the bone holder platform by tightening the load cell connector through a horizontal slit and a nut. The load cell was a 450 N Dry Load Cell linked to a BOSE Electroforce 3200 machine and utilize its software for data acquisition.The horizontal slit enabled adjustment of the connector's position horizontally. The bone sample holder held a 1 cm^3 bone sample that is cut from fresh bovine femur. The bone sample holder was attached to the load cell via a second load cell connector. The linear stage motion was powered by a stepper motor with a stepper motor controller that had a micro-stepping facility. Micro-stepping is required since the motion occurs in the millimeter range and the feed rate is only 1 mm/s. The control of the linear stage was operated via computer terminal control. The load cell was connected to a BOSE Electroforce DAX and computer unit to read and obtain the force produced. The flexible drill was powered by a high speed hand drill that was fixed to a table vice by attaching the end of the flexible shaft of the flexible device to the drill. The total bending angle to be measure was set and the center of bone sample was aligned to the center of mill bit tip.

Vertical configuration setup

The aim of this test is to measure the force required to mill the bone, in which the axis of the flexible drill is perpendicular to the surface plane of the bone and in the direction of axis perpendicular of the surface plane of the bone. The milling will be done in various total bending angle of the flexible drill. The bending direction of the flexible drill is parallel to the surface plane of the bone. This test simulates the pushing action of the flexible drill (straight to bend) in milling the bone of the flexible or femoral stem implantation. The result of this test is to evaluate the response force generated from the milling, which is the force required by the flexible drill tip towards the bone surface in order for the milling blade to mill the bone.
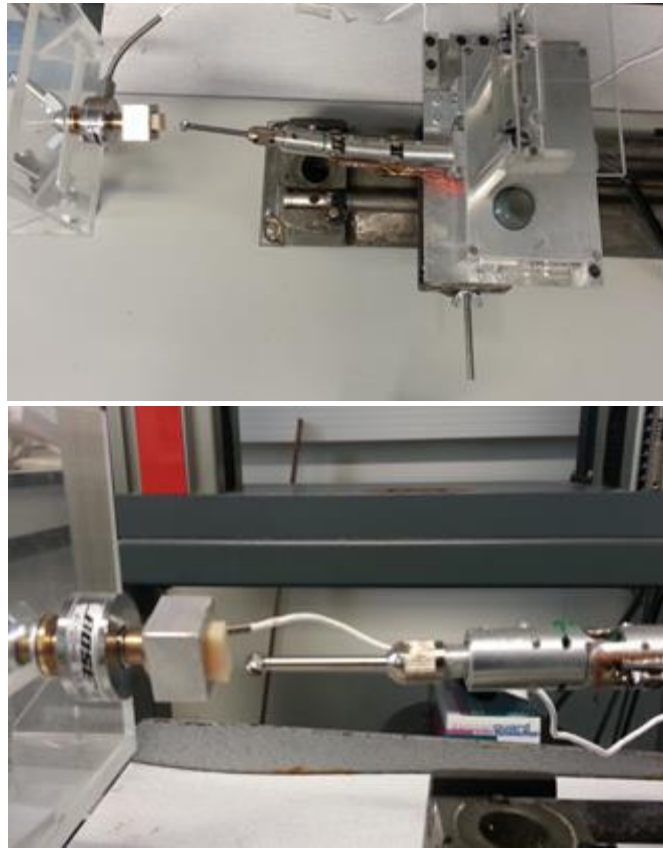
Fig.2. Test rig setup in vertical configuration

The test was performed within the flexible drill's maximum bending angle and specifically at 0° 10°, 20° and 30°. To achieve the desired bending angles, each joint angle was adjusted to half of the total bending angle and locked by the stall torque of the servo motor. The depth of milling was designed to be 1 mm thickness. The milling was tested at a constant feed rate of 1 mm/s and maximum drill motor speed of 3000 rpm.

Lateral Configuration setup

The lateral configuration is shown in figure 4, with the axis of the flexible drill parallel to the surface plane of the bone and in the direction of an axis perpendicular to the surface plane of the bone. The milling was performed in various total bending angles of the flexible drill. The bending direction of the flexible drill was perpendicular to the surface plane of the bone. These setups simulate the side-pulling action of the flexible drill (bend to straight) when milling the bone for femoral stem implantation. The result of this test demonstrate the forces generated from the milling, which is the force required by the flexible drill tip towards the bone surface in order for the milling blade to mill the bone. The test was performed at bending angles at 0°, 10°, 20°, and 30°.
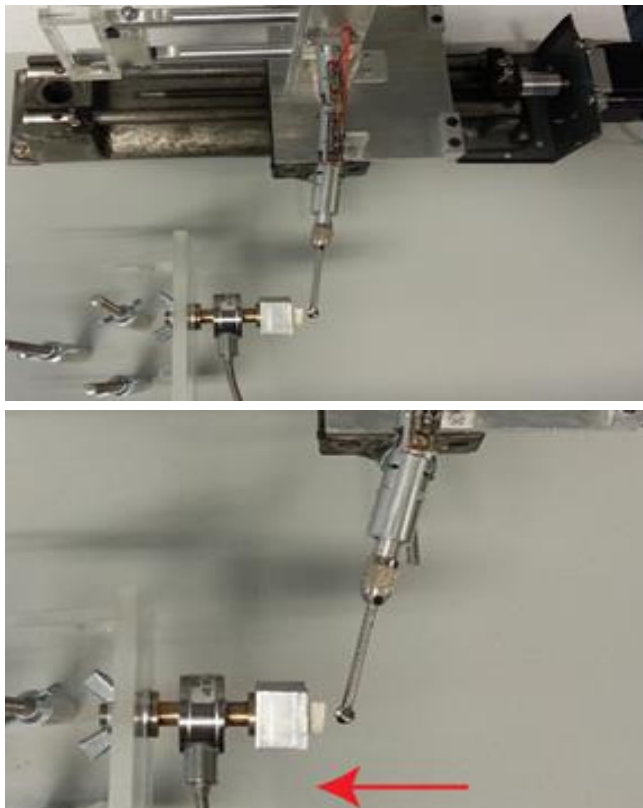
Fig.3. Test rig setup in lateral configuration

In this configuration, the bone holder platform is placed at the side of linear stage, holding the bone sample parallel to linear stage axis.

Results

Data Analysis

Data was collected by the BOSE Electroforce 3200 Data Acquisition Card and Software. It could measure force up to ±450 N and had a sensitivity of less than a Newton. The test was set at hand drill speed of 3000 rpm, feed rate of 1 mm/s, and milling depth of 1 mm. The linear stage was set up so that the tip of mill bit is about 2 mm from the surface of bone sample and was able to move 3 mm back and forth. The force starts to record when the linear stage and the flexible drill start to run. Once one cycle of linear stage motion was complete, the recorded force readings were saved as a CSV file format. The tests were repeated with the maximum bending angle at 30 degree in both vertical and lateral configurations.

The data was then analyzed in a force vs time graph; and the minimum peak value and the graph pattern were identified Figure 4. The individual bending angle graph shows the graph pattern and minimum peak value while showing the changes of minimum peak values according to bending angles. The peak value is obtained when there is plateau phase and the highest value in the plateau phase is the peak.

The force-time curves show the response forces generated in the vertical configuration at 0, 10, 20, and 30 degree bending in figure 4. The negative force values represent compression towards the load cell. The feedback force increases as the depth of milling increases until the peak minimum value that is within plateau phase and later decreases as the mill tip moves backwards from the bone sample. From the force-

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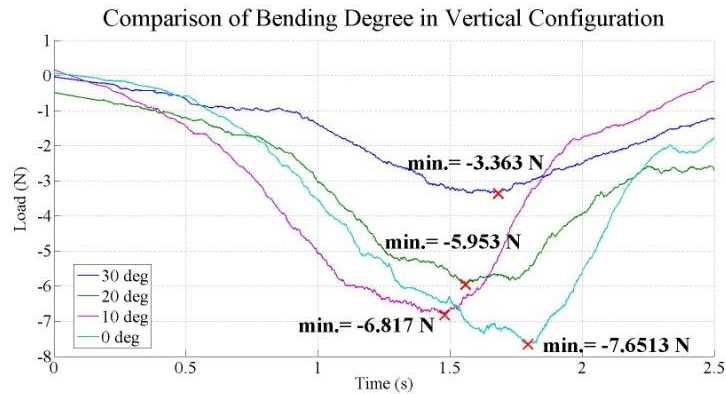time curves shown in Figure 4, the peak minimum value at maximum bending angle at 30 degree is -3.363 N.

Fig. 4. Force-Time Curve of Comparison of Bending Degree in Vertical Configuration.

From the force-time curves shown in Figure 4, the magnitude of the peak minimum value increases as the bending angle increases from 0 degree to 30 degree. The results show that it is harder to mill at 30 degree bending when compared with less bending angles in the forward milling configuration. This was as expected since the mill bit cutting blade has the highest depth at the sides and the sides of mill bit has better cutting power compared to the front.

The force-time curves in figure 5 show the feedback force generated from the lateral configuration at 0, 10, 20, and 30 degree bending. From the force-time curves shown in Figure 5, the peak minimum value is -0.56 N at zero degree. The force-time curves show the feedback force generated rises to -1.647 N at 30 degree bending in the lateral configuration as the mill tip moves backwards from the bone sample.
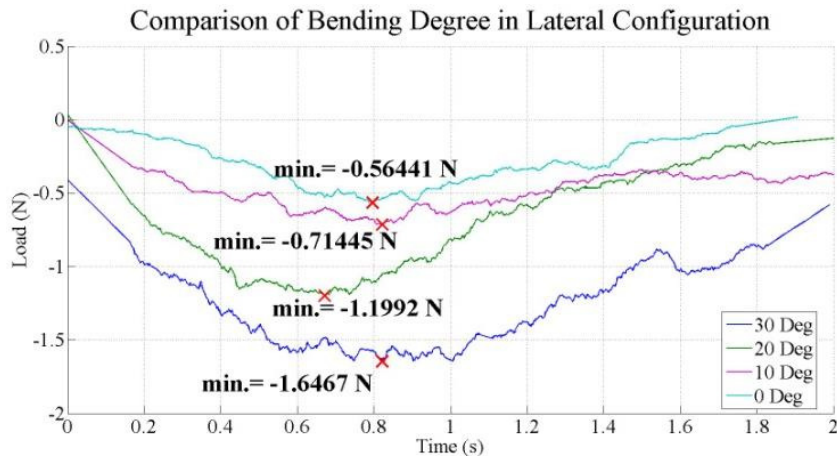

Fig. 5. Force-Time Curve of Comparison of Bending Degree in Lateral Configuration.

From the force-time curves shown in Figure 5, the peak minimum value increases as the bending angle increases from 0 degree to 30 degree. It shows that it is harder to mill in 30 degree bending when compare with less bending angles in lateral configuration.

Discussion

Although there are lots of studies on milling force evaluation and related modelling studies for traditional rigid drilling for arthroplasty [9-11], there is no such research for a new flexible drill. In the study, we simulated two configurations by moving the mill tip in a forward direction and a lateral direction. In the test rig, the step motor was controlled by a slow and constant speed and this pushed the flexible drill device, thus, the system was in equilibrium. From the basic static law, we suppose forward configuration generate larger force than lateral configuration, as a larger torque is required for lateral pushing control, and the presence of cutting blade at lateral side of the tip. The results of this experiment support the hypothesis that the drill is sufficient to cut bone in orthopedic surgery. From the Force-time curve at vertical configuration test in figure 4 and lateral configuration test at figure 5, the vertical configuration shows approximately 6 times larger forces than the lateral configuration at the different bending angles. However even in the harder lateral condition we found that the flexible drill have sufficient stiffness to cut a bone sample by a depth of 1 mm. and hence meets the key requirement for the surgical task.

We suppose, at vertical configuration, larger bending angles would generate less force as in equilibrium, large bending angles mean more lateral component force to generate torque is in contact with the bone resulting in better bone cutting. The opposite outcome would be obtained in lateral configuration data. The measurement proved that at vertical configuration, the maximum force decreased from 7.65 N at 0 degree to 3.363 N at 30 degree. At lateral configuration, the maximum force increased from 0.564 N at 0 degree to 1.464 N at 30 degree. These results imply that at vertical configuration the capability of the flexible drill to cut the bone is the weakest. It also implies, more than 30 degree bending at both configurations is not properly allowed by the design.

We showed that the capability of the flexible drill to cut the bone is dependent on the bending angle and configuration. High bending angle in the vertical configuration and low bending angle in the lateral configuration have the best ability to cut the bone. The vertical configuration signifies the bone cutting ability of a push down the shaft action when tunneling, while the lateral configuration signifies the cutting ability of a pull or scraping action when tunneling. This effect would be the opposite if we change the mill bit to standard drill bit.

The significance of our findings is that the milling behavior of the flexible drill in static conditions is the same as when milling with a rigid mill tool. The cutting force and the ability of the flexible drill to cut bone followed the orthogonal bone cutting modelling done by Moghaddam et. al [12]. These authors did a study on voxel-based force modelling of orthogonal bone cutting by using spherical rotating tool such as burr which cuts the bone by orthogonal cutting when each cutting element comes in contact with the bone piece. Their results showed that the force along the X axis is around 1 N. They concluded that the cutting force decreases as the number of teeth or spindle speed increases. Our findings have similar result to their force modelling result. At 0 degree bending of the lateral configuration, we found that the flexible burr cuts as an orthogonal cutting device with the highest number of teeth, and highest area of teeth that come in contact with the bone. Hence, our findings at zero degree bending angle of lateral configuration have similar force measured. However, this is limited to depth cut of 1 mm at a rate of 1 mm/second. Further research on the variation of cut depth and cut rate is recommended.

Another significance of our finding is the force measured in all configurations is less than the servo motor's stall torque in the flexible drill. Therefore, the flexible drill is proved to have the ability to sustain its bending configuration when milling a bone. Should the servo motor's stall torque at less than the force measured, the flexible drill would not be able to maintain the bending angle and buckling would be more likely to happen. The buckling effect is minimized in the flexible drill via placement of bearings inside the sheath, limitation of the bending angle, and the high torque of the servo motor.

The test rig is only a set up at an ideal static model to avoid some more complexed parameters such as vibration and impaction. Future studies should include more complex laboratory based measurement and biomechanical modelling in a complexed surgical environment but if these proves satisfactory then the flexible burr should be tried in cadaveric specimens.

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