A BIOMECHANICAL ANALYSIS OF CINGLEBIT DESIGNS

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A Biomechanical Analysis of Cinglebit Designs

Report

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PROJECT 00112-002 - A BIOMECHANICAL ANALYSIS OF CINGLEBIT DESIGNS

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1. INTRODUCTION

The use of drilling to remove bone prior to the placement of metal or polymeric fixation devices is a common procedure in most surgical and dental procedures. Accurate positioning of drill holes of maintain appropriate dimensions with minimal surgical insult to the bone and surrounding soft tissue is a desire for all surgeons for their patients. The concepts of minimally invassive surgery are based, in part, on decreasing local tissue trauma to assist the natural healing process and accelerate recovery. Excessive thermal insult to bone tissue may result in destruction or inactivation of the matrix bound proteins involved in bone healing (bone morphogenetic proteins, BMPs). A novel 3-fluted drill, *Cinglebit*, for use in drilling cortical and cancellous bone has been designed by Cingular Pty Ltd. The design claims for *Cinglebit* include a smoother torque laod transfer to the surgeon's hand, more accurate drilling, avoiding entry slippage and decreased thermal and mechanical insult to the bone and surrounding soft tissues. In addition, the *Cinglebit* drill claims to be more competent in drilling to achieve the equivalent results with other drill bit designs. This has implications in the biology of the bone healing as well as overall surgeon control of the instrument during the drilling process in surgery.

1.1 Purpose

This study compared the *Cinglebit* drill design to commonly used 2 fluted and 3 fluted designs. The structural properties, cutting characteristics and thermal insult to the surrounding bone was examined in vitro.

2. METHODOLOGY

The materials used are shown below in Table 1and Table 2

Table 1 Material List

Description	Part/Drawing Number	Qty	Lot Number
Cinglebit	20101007	27	
Smith & Nephew		3	4543297
Synthes		3	1171440
SurgiBit		6	

Table 2 Equipment List

Equipment	Identity Number/Serial Number
Instron 8874 – 25kN Load cell	8874
Electric Microaire drill	
FLIR thernal camera	B2 IR thermal
Minolta digital camera	33405573
MotionBLITZ Cube 4 High speed digital camera	

2.1 Mechanical testing

A calibrated servohydraulic materials testing machine, INSTRON 8874 was used in this study. Sensitivity on the lowest measuring range was not less than 1% of full-scale reading. The force (N), torque (Nm) and displacement (mm) were recorded through the Instron software (Figure 1). Statistical analysis was performed using SPSS (SPSS Inc, Chicago, IL). All drills were compared using the T-test. The p value was set at 0.05

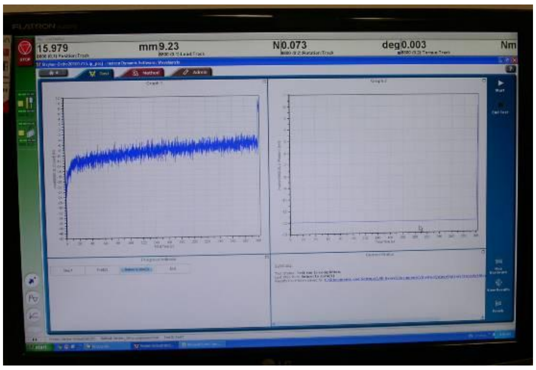


Figure 1: Instron data acquisition

2.2 Electric drill

A surgical drill handpiece (Microaire Surgical Instruments LLC, Charlottesville, VA, US) was used throughout the study. The drill handpiece (Figure 2) was mounted in a custom designed jig attached to the Instron actuator for testing. The bone specimens were mounted and fixed in position during drilling experiments. The test was performed at a displacement rate of 5mm/min to an end point of 10mm. Thermal images during the drilling process were captured.

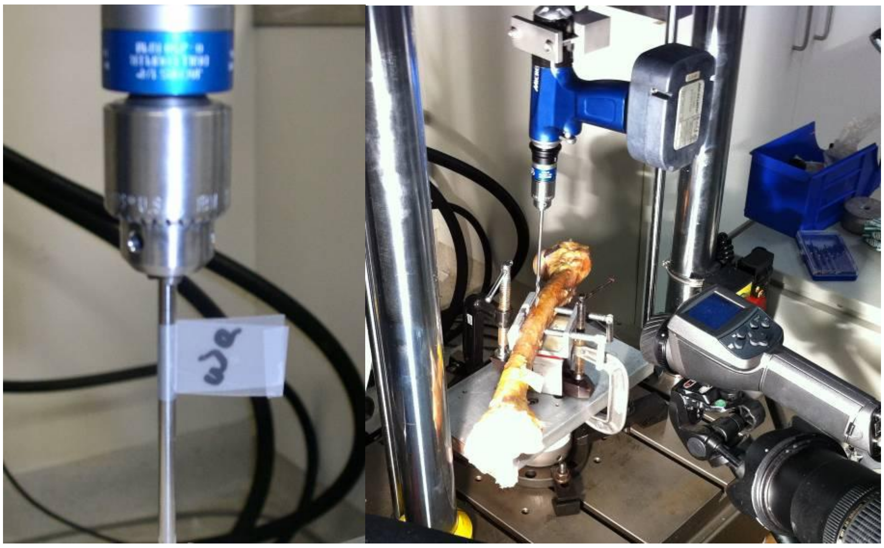


Figure 2: Drill mounted (L) and drill test setup (R)

2.3 Infrared thermal imaging (IR)

An infrared thermal imaging camera (FLIR Systems, Boston, MA) was mounted on a tripod and used to record the thermal distribution during drilling at entry (Figure 3). Themal profiles were analysed using image analysis software. A high speed camera was also used to image the initial cutting process.

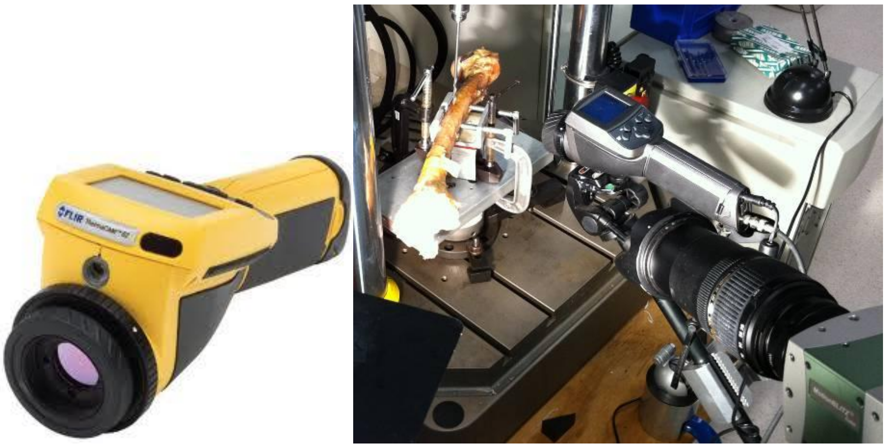


Figure 3: FLIR IR thermal camera (L) and test setup (R)

2.4 Cantilever bending

Cantilever bending tests were also performed using a custom jig shown in Figure 4. The distance between support and the applied load was set to 10mm. Samples were destructively tested at a displacement rate of 2 mm/min to a maximum of 25mm. Failure criterion of either plastic deformation or catastrophic failure and was assessed following mechanical testing. The bending stiffness, load and energy to failure were determined for each test.

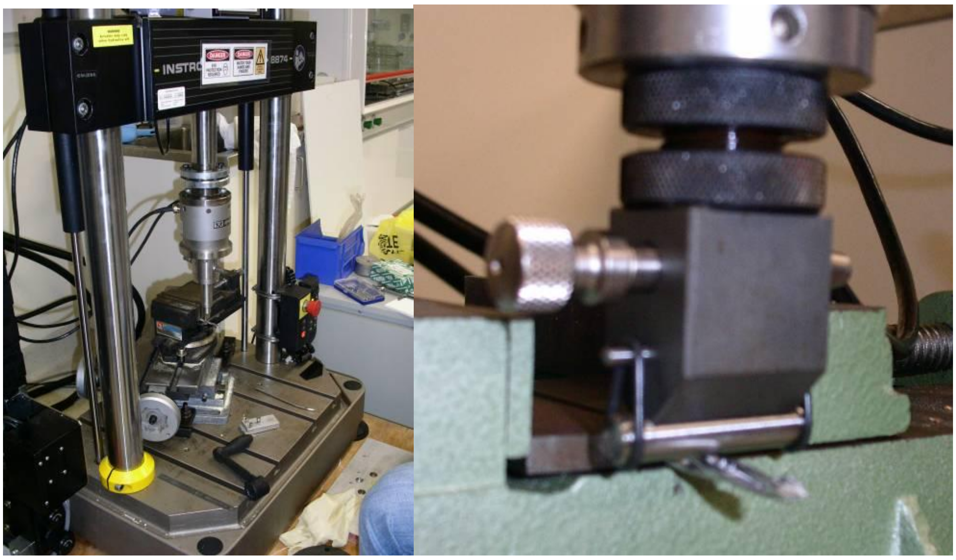


Figure 4: Cantilever bending

2.5 Soft Tissue Study

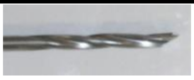
A soft tissue study was conducted on 4 different drill bit designs to determine the damage caused from the flutes during the drilling process. Each drill was weighed prior to the test and weighed after the test to determine the increase in weight. Th edrilling procedure was to place the drill into the capsule of a sheep joint and drill for a period of 10 seconds, which is a typical amount of time for a drilling process in orthopaedics. This technique measured the amount in which the drill bit engaged the tissue. It was hypothesized that the more material removed from the specimen the more damage the drilling process for a particular drill bit design is thought to cause to the soft tissue structures.

3. RESULTS

Bending

The results of the bending drill test are shown below in Table 3. The table presents the displacement and peak load at which the failure occured.

Table 3

Drill type	Peak Failure Displ. [mm]	Peak Load [N]	Failure mode	
SurgiBit	0.80	-1577.47	*failed by fracture*	
Synthes	2.69	-1080.80	*failed by fracture*	
Cinglebit Grp 1	2.03	-1495.76	*deformed*	
Cinglebit Grp 2	1.50	-1596.30	*deformed*	
Cinglebit Grp 3	1.52	-1616.47	*deformed*	

Drilling

The results of the drill testing are shown below in Table 4. This table presents the average axial load that the drill was experiencing during the test. It should be noted here that the test was run in displacement control so the axial load is dependant on the cutting edge geometry as this will define the feedrate of the drill. The table also presents the torque that is transfered along the drill's length during the test. The column that shows the lambda (λ) values give an indication as to how the load and torque increase over time during the test. This is defined by the following equations

$$\text{Load} = Ae^{\lambda t}$$

$$\text{Torque} = Be^{\lambda t}$$

Table 4

Drill Type	Ave Load [N]	Ave Torque [Nm]	Ave Torque λ value	Ave Load λ value	Std Dev Torque λ value	Std Dev Load λ value	Std Dev Load	Std Dev Torque
Synthes	-56.92	-0.27	3.25	8.45	1.06	2.24	0.00	0.02
Surgibit	-31.97	-0.28	2.64	4.31	0.33	1.54	0.00	0.01
Cingular Grp 1	-46.91	-0.32	2.53	8.89	0.25	1.63	0.00	0.03
Cingular Grp 2	-52.66	-0.32	2.75	8.41	0.06	0.72	0.00	0.04
Cingular Grp 3	-43.77	-0.31	2.44	7.13	0.21	0.84	0.00	0.02
Cingular Mod 1	-55.46	-0.17	4.00	23.29	1.25	9.15	22.24	0.14
Cingular Mod 2	-53.19	-0.30	3.40	21.80	0.48	5.42	12.77	0.05
Cingular Mod 3	-45.15	-0.25	4.68	15.23	0.71	4.20	4.78	0.03
Cingular Mod 4	-98.18	-0.34	4.19	13.20	0.87	2.51	13.81	0.03
Cingular Mod 5	-55.60	-0.27	3.37	10.33	2.27	4.67	2.47	0.05

Thermal Imaging

Figure 5 and Figure 6 present the drilling temperatures in human cortical bone for the CingleBit and other 3 fluted designs (Synthes and SurgiBit).

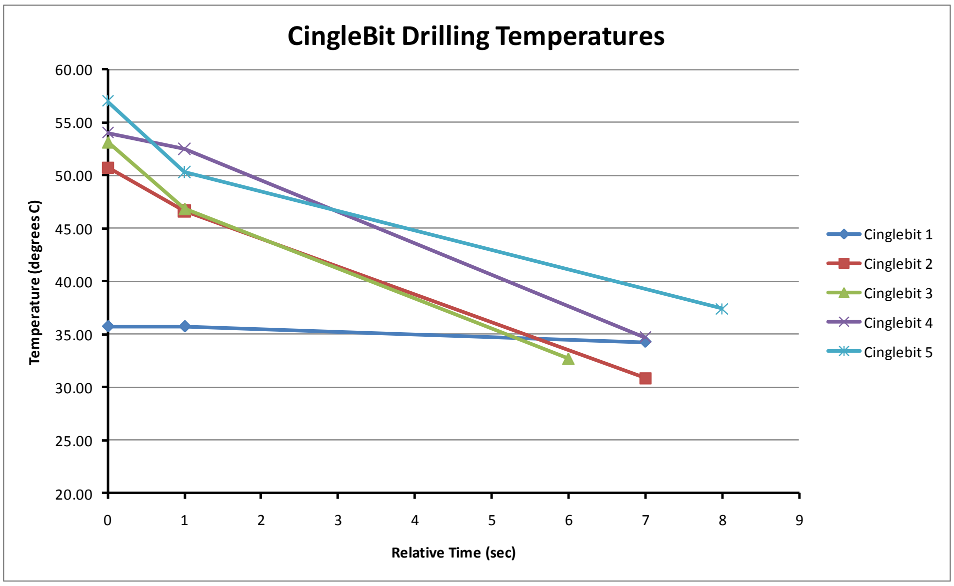


Figure 5: CingleBit drilling temperatures in human cortical bone

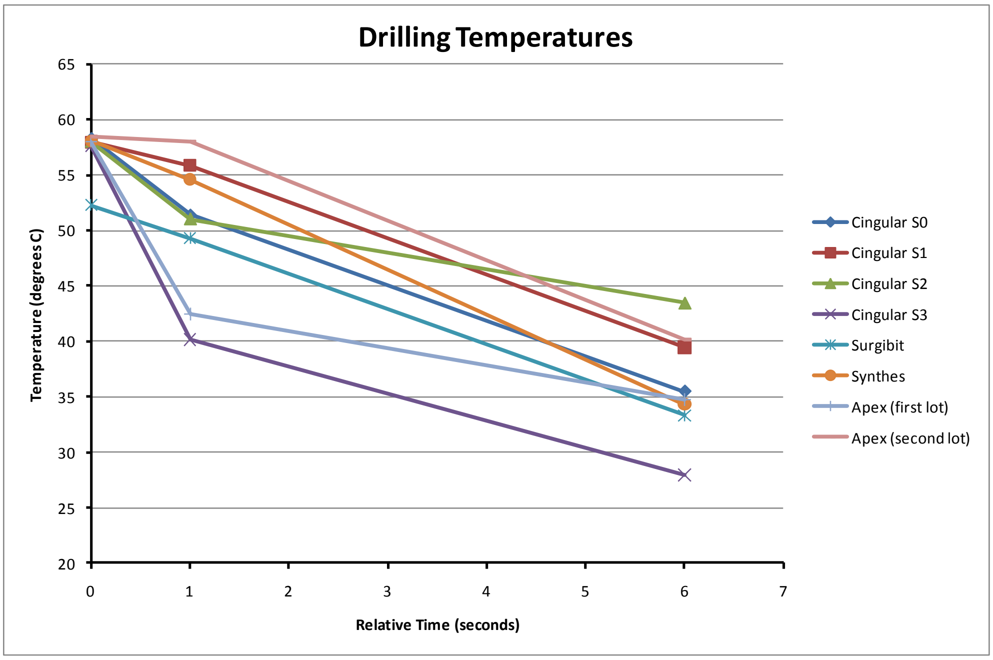


Figure 6: CingleBit (Cingular and Apex), SurgiBit and Synthes drilling temperatures in human cortical bone

Statistics

The results of the statistical analysis are shown below in Table 5.

Table 5

Paired Samples Test

		Paired Differences								Significant Difference Detected
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of Lower	Upper	t	df	Sig. (2-tailed)	
Pair 10	SurgiBit Axial Loading - Cinglebit Axial Loading Grp 1	15.4258916	9.6711569	4.8355785	0.0369228	30.8148604	3.190	3	0.050	*
Pair 11	SurgiBit Axial Loading - Cinglebit Axial Loading Grp 2	20.1805669	5.3317207	2.6658604	11.6966094	28.6645244	7.570	3	0.005	*
Pair 12	SurgiBit Axial Loading - Cinglebit Axial Loading Grp 3	9.6880482	4.0541769	2.0270885	3.2369479	16.1391484	4.779	3	0.017	*
Pair 13	SurgiBit Axial Loading - Cinglebit Axial Loading Mod 1	22.4776542	22.7137505	11.3568752	-13.6649914	58.6202999	1.979	3	0.142	
Pair 14	SurgiBit Axial Loading - Cinglebit Axial Loading Mod 2	20.2075438	9.9988739	4.9994369	4.2971042	36.1179835	4.042	3	0.027	*
Pair 15	SurgiBit Axial Loading - Cinglebit Axial Loading Mod 3	12.1654466	6.8598482	3.4299241	1.2498973	23.0809960	3.547	3	0.038	*
Pair 16	SurgiBit Axial Loading - Cinglebit Axial Loading Mod 4	65.1951844	17.0119210	8.5059605	38.1254218	92.2649469	7.665	3	0.005	*
Pair 17	SurgiBit Axial Loading - Cinglebit Axial Loading Mod 5	22.6112341	1.7044354	0.8522177	19.8990971	25.3233712	26.532	3	0.000	*
Pair 26	Synthes Torque Loading - Cinglebit Torque Loading Mod 5	-0.0041540	0.0371286	0.0185643	-0.0632339	0.0549260	-0.224	3	0.837	
Pair 27	SurgiBit Torque Loading - Cinglebit Torque Loading Grp 1	0.0433451	0.0360846	0.0180423	-0.0140735	0.1007637	2.402	3	0.096	
Pair 28	SurgiBit Torque Loading - Cinglebit Torque Loading Grp 2	0.0486313	0.0374888	0.0187444	-0.0110218	0.1082844	2.594	3	0.081	
Pair 29	SurgiBit Torque Loading - Cinglebit Torque Loading Grp 3	0.0189561	0.0383053	0.0191527	-0.0419962	0.0799085	0.990	3	0.395	
Pair 30	SurgiBit Torque Loading - Cinglebit Torque Loading Mod 1	-0.1167345	0.1323687	0.0661844	-0.3273626	0.0938937	-1.764	3	0.176	
Pair 31	SurgiBit Torque Loading - Cinglebit Torque Loading Mod 2	0.0145450	0.0541453	0.0270726	-0.0716122	0.1007023	0.537	3	0.628	
Pair 32	SurgiBit Torque Loading - Cinglebit Torque Loading Mod 3	-0.0430125	0.0379048	0.0189524	-0.1033275	0.0173025	-2.270	3	0.108	
Pair 33	SurgiBit Torque Loading - Cinglebit Torque Loading Mod 4	0.0504363	0.0339553	0.0169777	-0.0035942	0.1044668	2.971	3	0.059	
Pair 34	SurgiBit Torque Loading - Cinglebit Torque Loading Mod 5	-0.0165552	0.0515172	0.0257586	-0.0985305	0.0654201	-0.643	3	0.566	
Pair 44	SurgiBit Torque Gradient Loading - Cinglebit Torque Gradient Loading Grp 1	-0.0075250	0.1887272	0.0943636	-0.3078321	0.2927821	-0.080	3	0.941	
Pair 45	SurgiBit Torque Gradient Loading - Cinglebit Torque Gradient Loading Grp 2	-0.2904250	0.2299092	0.1149546	-0.6562618	0.0754118	-2.526	3	0.086	
Pair 46	SurgiBit Torque Gradient Loading - Cinglebit Torque Gradient Loading Grp 3	0.0918250	0.3886842	0.1943421	-0.5266582	0.7103082	0.472	3	0.669	
Pair 47	SurgiBit Torque Gradient Loading - Cinglebit Torque Gradient Loading Mod 1	-1.4977750	1.3329149	0.6664574	-3.6187400	0.6231900	-2.247	3	0.110	
Pair 48	SurgiBit Torque Gradient Loading - Cinglebit Torque Gradient Loading Mod 2	-0.9034500	0.3397487	0.1698743	-1.4440659	-0.3628341	-5.318	3	0.013	*
Pair 49	SurgiBit Torque Gradient Loading - Cinglebit Torque Gradient Loading Mod 3	-2.1771250	0.7257127	0.3628564	-3.3318959	-1.0223541	-6.000	3	0.009	*
Pair 50	SurgiBit Torque Gradient Loading - Cinglebit Torque Gradient Loading Mod 4	-1.6873750	1.0765426	0.5382713	-3.4003945	0.0256445	-3.135	3	0.052	
Pair 51	SurgiBit Torque Gradient Loading - Cinglebit Torque Gradient Loading Mod 5	-0.8728750	2.4122303	1.2061151	-4.7112716	2.9655216	-0.724	3	0.522	
Pair 61	SurgiBit Loading Gradient Loading - Cinglebit Loading Gradient Loading Grp 1	-3.0836500	1.3824543	0.6912272	-5.2834434	-0.8838566	-4.461	3	0.021	*
Pair 62	SurgiBit Loading Gradient Loading - Cinglebit Loading Gradient Loading Grp 2	-3.4629250	0.7192320	0.3596160	-4.6073837	-2.3184663	-9.630	3	0.002	*
Pair 63	SurgiBit Loading Gradient Loading - Cinglebit Loading Gradient Loading Grp 3	-1.9887250	0.8408742	0.4204371	-3.3267435	-0.6507065	-4.730	3	0.018	*
Pair 64	SurgiBit Loading Gradient Loading - Cinglebit Loading Gradient Loading Mod 1	-18.2577250	9.9513198	4.9756599	-34.0924954	-2.4229546	-3.669	3	0.035	*
Pair 65	SurgiBit Loading Gradient Loading - Cinglebit Loading Gradient Loading Mod 2	-16.7624750	6.3235896	3.1617948	-26.8247172	-6.7002328	-5.302	3	0.013	*
Pair 66	SurgiBit Loading Gradient Loading - Cinglebit Loading Gradient Loading Mod 3	-10.1939750	2.9490091	1.4745046	-14.8865066	-5.5014434	-6.913	3	0.006	*
Pair 67	SurgiBit Loading Gradient Loading - Cinglebit Loading Gradient Loading Mod 4	-8.1674750	1.9474483	0.9737242	-11.2662999	-5.0686501	-8.388	3	0.004	*
Pair 68	SurgiBit Loading Gradient Loading - Cinglebit Loading Gradient Loading Mod 5	-5.2955250	4.5829125	2.2914563	-12.5879615	1.9969115	-2.311	3	0.104	

The statistical tests show that there are differences detected between the drill designs in some cases. These are marked with an ***.**

However, the main point from this table is that there is no statistical differnce between SurgiBit and Cinglebit Mod 5 for either the torque, axial load gradient or torque gradient. There was difference detected for the axial load, but as mentioned previously this is dependant on the drill's feedrate.

The following graphs (Figure 7 &) present the axial load characterisitcs. The images placed beside the curves are to give an idea of how the cutting edge geometry plays a key role in the drill's performance during entry and exit of the bone.

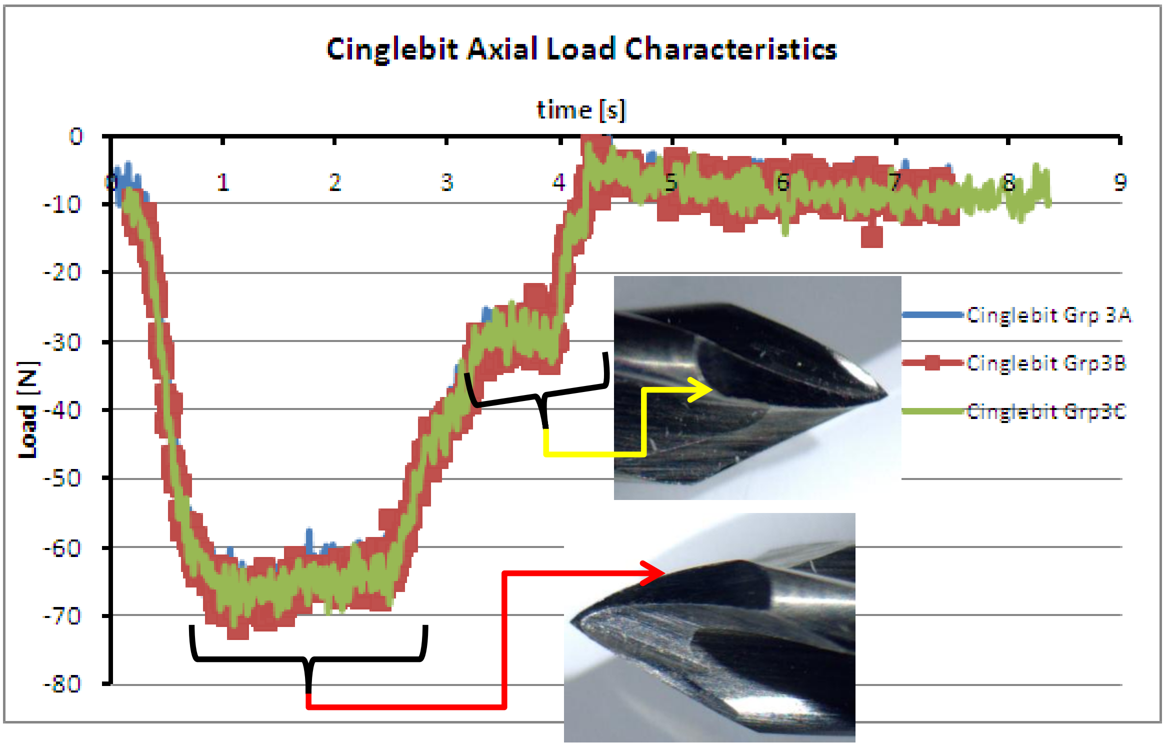


Figure 7: These example axial load curves for the Cinglebit show how the curve gently slopes away once the peak load has been reached; this is a characteristic of the curved cutting edge (red arrow). As the cutting edge approaches the full diameter the "brake" in the curve is due to the cutting edge "run off" to the flute (yellow arrow)

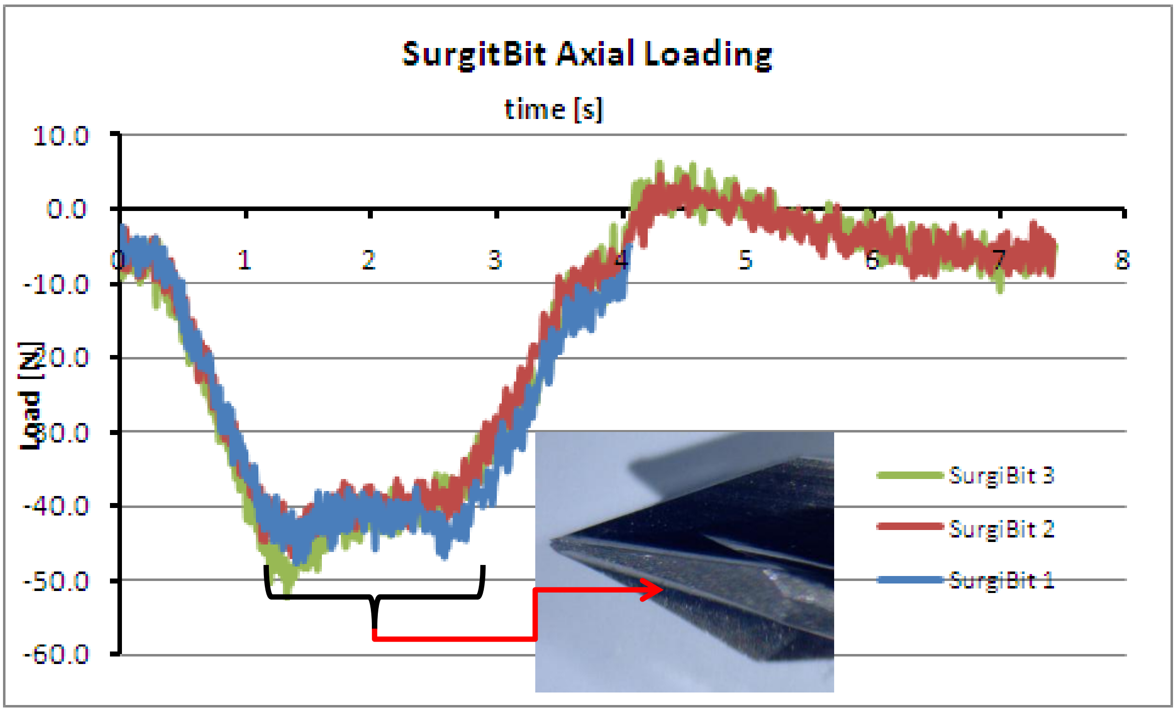


Figure 8: These example axial load curves for the SurgiBit show how the curve does not slope away as the Cinglebit does, but flattens out once the peak load has been reached; this is a characteristic of the straight cutting edge (red arrow). There is no "brake" prior to the cutting edge reaching the flute.

Table 1 presents the results of the soft tissue damage procedure. It can be seen that the CingleBit has damage the least amount of tissue followed by the Smith & Nephew, SurgiBit and Synthes designs respectively. Figure 9 presents an image of the drills following testing.

Table 6

Drill Design	Initial Drill Mass [g]	Drill Mass Post Drilling Procedure [g]	Damaged Tissue Mass [g]
SurgiBit	16.15	17.31	1.16
Smith & Nephew	14.58	15.01	0.44
Synthes	15.16	18.23	3.07
CingleBit	17.52	17.64	0.12

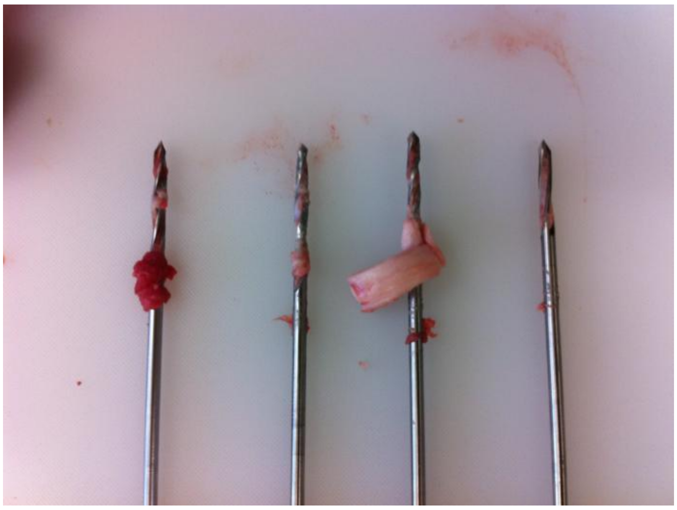


Figure 9: Drills following soft tissue damage testing.

4. DISCUSSION

Destructive mechanical testing (cantilever bending) and performance based experiments (drilling) were determined for two 3 fluted designs (Synthes & SurgiBit) and the new Cinglebit 3-fluted design. The Synthes 3-fluted design differs from the SurgiBit 3-fluted design by having shorter cutting faces as well as a more rounded tip. CingleBit differs from both the Synthes and SurgiBit 3-fluted design by utilising longer and curved cutting edges that sweep into the outer flute diameters. Controlled drilling experiments were performed using human cadaveric femurs under a displacement control at 5mm/s. Infrared thermal distributions were recorded during the standard surgical drilling procedure in human cadaveric femur cortical bone to assess the thermal insult to the bone.

Cantilever bending

All samples underwent plastic deformation during cantilever bending tests. The drill samples then either failed catastrophically or yielded (Table 3). The lower failure load reflects the larger 2nd moment of area (moment of inertia) of the Cinglebit 3-fluted designs. The larger displacement to failure is a reflection of the different manufacturing materials utilised (Table 3). All catastrophic and yielding failures occured at the fixed base of the samples. This is becuase the largest moment will occur at that location (Figure 10).

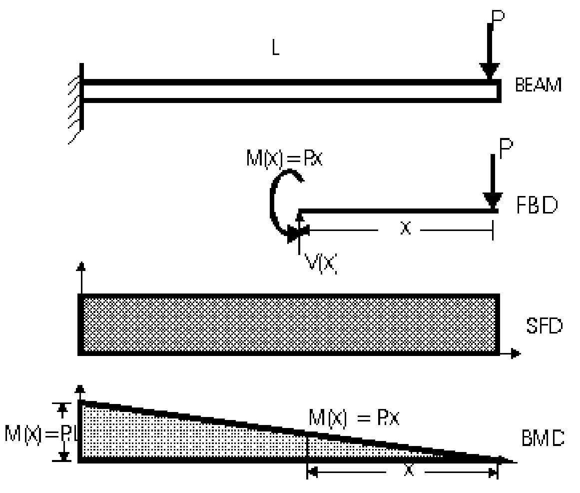


Figure 10: Schematic showing a bending moment diagram (BMC). In the bending test, L=10mm and P was applied at 2mm/s. And $M_{Max}=P_{Peak}L$

Drill Performance

Drill performance was investigated by drilling using a constant feed-rate for each drill design; this was indicative of the median axial force applied by the surgeons during the drilling procedure in surgery[1]. The axial load and torque data was analysed statistically. The statistics table (Table 5) shows that there is no statistical difference between SurgiBit and Cinglebit Mod 5 for either the torque, axial load gradient or torque gradient. There was difference detected for the axial load, but as mentioned previously this is dependent on the drill's feedrate. .

Infrared Thermal Distributions

All drill temparatures presented were measured during the first drilling cycle. The temperature measurements show that the CingleBit, generally, has an initial temperature similar to all drill designs. However, CingleBit 2 has the lowest initial and final temperatures after 7 seconds of drilling.

Soft Tissue Damage

The conventional designs appeared to engage to soft tissue far greater than the new CingleBit design. In some cases once the drill bit sufficiently wrapped enough tissue around the flute the flute continued to engage the tissues in an increasing manner. The CingleBit design did not engage the soft tissue specimen and caused the least amount of material being removed from the specimen which represents the least if any damage caused to the soft tissue specimen.

Study Limitations

This initial investigation only considered drilling into cortical bone. The performance of these drills in cancellous bone should be considered in the future since many procedures are performed where cortical as well as cancellous bone is drilled. A single drill diameter (4.5 mm) was examined and other diameters commonly used are worthy of such an investigation.

Biological Implications and Future Directions

The current use of 'minimal-access-surgery' is based, in part, on a decrease in tissue damage and local trauma, which has been shown to hasten postoperative recovery and reduce morbidity[2, 3]. The biology of healing is complex and minimising tissue damage and thermal insult to the tissues may play an important role in enabling the maximal biological healing response to be realised. The CingleBit design results in less damage due to its novel cutting edge design and less trauma to the tissues due to its relief built into its flutes. This can be hypothesised to result in an overall improvement in healing at the drilling site. This may have important implications in the fixation of screws, both metal and polymer types, in the case trauma as well as the biology of healing between tendon grafts and bone tunnels in sports medicine.

Complex and design specific instruments are used in surgery to properly deploy and accurately implant prostheses. The drilling procedure is fundamental in virtually all aspects of surgery where a device or tissues are placed into bone and healing is a required endpoint. Failure of healing is well known and can lead to implant failure, clinical failure of the procedure and an expensive revision surgery is then required. Drill designs have evolved very little in surgery and single use is virtually unheard of for drills, but is a true requirement. Cross contamination due to drilling devices has been reproted in the literature[4, 5]. There is a need for improvement in drilling stability and performance and for single use; this may, in part, provide a reduction in infection risks and a clinical advantage as well as a biological benefit.

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