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A comparison of the thermal properties of 2- and 3-fluted drills and the effects on bone cell viability and screw pull-out strength in an ovine model

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ABSTRACT

Background: Drilling of bone is associated with an increase in temperature of the surrounding bone which may result in osteonecrosis.
Methods: In this study, cutting efficiency and thermal properties of one 2-fluted drill and two 3-fluted drills were determined *in vitro* using a porcine model. Drills were then used to create pilot holes in an *in vivo* ovine model to facilitate implantation of pedicle screws. The effect of the characteristic thermal profiles of each drill on cortical bone cell viability and screw pull-out strength was then assessed.
Findings: Cutting efficiencies of both 3-fluted designs were found to be greater than that of the 2-fluted drill, but this did not translate into a decrease in the maximum temperatures during drilling for both drills. Histologically, no empty osteocyte lacunae were seen at 2 or 4 weeks, suggesting that temperatures were not sufficiently high enough to induce thermonecrosis in the ovine tibia. No differences were found in the pull-out strength of the screws.
Interpretation: Both 2- and 3-fluted drills are currently in clinical use. Despite the theoretical advantage that 3-fluted drills possess over their 2-fluted counterparts, there is a lack of evidence in the literature in support of their use. In this study the observed increases in cutting efficiency of the 3-fluted drills tested did not translate into a reduction in heat generation or improvement in bone healing or screw fixation.

1. Introduction

Drilling of bone is commonplace in surgery and is typically performed to facilitate the implantation and subsequent fixation of screws. Rigidity of the final construct is contingent upon adequate purchase of the screws' threads into the drilled defect and cells in the cortical bone hosting the threaded cylindrical defect remaining viable. Both may be compromised by the drilling procedure itself. The drill-tip can skive along the far cortex, causing the drill to bend and resulting in mal-alignment and misshapen holes. This can be problematic as excess removal of bone stock can have a negative effect on screw fixation through reduced pullout strength (Steeves et al., 2005).

Bending stiffness properties and tip geometry of the drill governs the extent of skiving (Bertollo et al., 2008). Sufficiently large bending moments induced by skiving can cause drill-bit breakage, and this mode of failure rates highly amongst the most commonly reported incidences of clinical complications pertaining to drilling (Ashford et al., 2001; Benirschke et al., 1993; Fothi et al., 1992; Hirt et al., 1992; Price et al., 2002).

Drilling is also associated with the conversion of mechanical work energy from the friction of cutting into thermal energy which is dissipated by — and causes an increase in the temperature of — the surrounding cancellous and cortical bone (Abouzgia and Symington, 1996; Augustin et al., 2008; Bachus et al., 2000; Davidson and James, 2003; Eriksson and Albrektsson, 1984; Franssen et al., 2008; Lavelle and Wedgwood, 1980; Matthews and Hirsch, 1972; Natali et al., 1996; Toews et al., 1999). Whilst there is no definitive evidence regarding critical values or their durations, an increase in temperature of the cortical bone to above 50 °C has been implicated with a reduced regenerative capacity (Eriksson et al., 1984) and above 56 °C with osteonecrosis (Matthews and Hirsch, 1972). The phenomenon of thermonecrosis is a multifactorial process in which the dwell-time (Belkoff and Molloy, 2003), defined as the period of time for which a temperature of above 50° is sustained, also plays a critical role.

Whilst irrigation has been advocated by many authors to reduce the effects and extent of the thermal insult and potential for thermonecrosis (Augustin et al., 2008; Lavelle and Wedgwood, 1980; Matthews and Hirsch, 1972), this is not practicable at the isolated far cortex in the case of bi-cortical drilling. Importantly, in the case of the lag screw, the far cortex is indeed where thread purchase is realised.

Both 2- and 3-fluted drills are currently in clinical use. The flutes of a drill-bit, or drill, are that portion which channels debris away from the cutting-face during operation whilst drilling torque and force are

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applied to the shank (Fig. 1). Despite the theoretical advantage that 3-fluted drills possess over their 2-fluted counterparts, there is a lack of evidence in the literature in support of their use. Firstly, drill theory suggests that the inclusion of the additional cutting face in the 3-fluted drill design removes additional bone during each rotation, reducing drilling time which in turn reduces heat generation and the potential for thermonecrosis; reduced drilling time has been shown to reduce thermal loading during drilling (Franssen et al., 2008). Secondly, the additional webbing dramatically changes bending stiffness properties (Flexural rigidity, EI_X) of the drill which can decrease the likelihood of drill-bit failure and further improve targeting capability for the surgeon (Bertollo et al., 2008).

This study examined the cutting efficiency and heat generation associated with commonly-used 2- and 3-fluted surgical drills (in addition to a new 3-fluted drill) in an *in vitro* porcine model. An *in vivo* ovine model was then used to determine whether these characteristic thermal profiles of the drills, when used to create the pilot holes, would affect fixation parameters (pull-out strength and histological appearance) of pedicle screws implanted into the proximal tibia after 2 and 4 weeks *in situ*.

2. Methods

Parameters of the drill designs tested in this study (Manufacturer, city & country, number of flutes and point-angle) are listed in Table 1. All drills were surgical-grade stainless steel, standard-point, parabolic, slow spiral (36° helix angle) twist-drills. The point-angle of a drill is defined as the angle formed by a projection of the cutting faces onto a plane passing through the long-axis of the drill, as is shown in Fig. 1. The 2-fluted Smith and Nephew (S&N) and 3-fluted Synthes (SYN) drills were specifically chosen for inclusion in this study as they are amongst the most commonly used drills in theatres for orthopaedic applications in the authors' home country (Australia).

The *in vitro* component of this study consisted of an examination of cutting efficiency and temperature elevation encountered when drilling uni-cortical 3.2 mm diameter holes in fresh porcine cortical bone at a constant feed-rate. In the *in vivo* component, an ovine model was used to assess the effects which the different drills (and their characteristic thermal profiles) have on healing and bone-screw pullout strength.

2.1. In vitro component

Fresh porcine femora were obtained from a slaughterhouse and fixed into vice-grips attached to the load-cell of a servohydraulic testing machine (MTS 858 Mini Bionix, MTS Systems Corporation, Eden Prarie, MN, USA). A pneumatic surgical handpiece (7100 Drill, MicroAire Surgical Instruments LLC, Charlottesville, VA, USA) was attached to the linear actuator of the MTS machine using a specialised jig, constraining motion of the drill-bit to 2 degrees-of-freedom (DOF) only; 1 rotational and 1 translational DOF (Fig. 2). The operating air pressure was kept constant for all experiments (680 kPa) using a calibrated regulator, which purportedly translated into an approximate chuck speed of 750 rpm (MicroAire Surgical Instruments LLC, Charlottesville, VA, USA); unloaded chuck speed nor speed of the chuck during drilling were measured during the experiment.

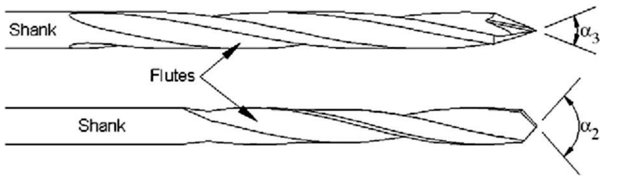

Fig. 1. Properties of the OI 3-fluted (top) and Smith and Nephew 2-fluted (bottom) drills. α denotes the point angle.

Table 1
Drill designs tested in the current study. Both 3.2 mm and 4.5 mm diameter versions were utilised.

Drill	Flutes	Point-angle, α
Smith & Nephew (Memphis, TN, USA)	2	94°
Orthopaedic Innovation (Sydney, Australia)	3	44°
Synthes (Paoli, PA, USA)	3	83°

Prior to conducting the thermal analyses, an estimation of the axial load (thrust force) typically imparted by the surgeon on the surgical handpiece (and ultimately the drill-bit) during routine clinical drilling of 3.2 mm diameter holes in bone was undertaken. This involved four of our orthopaedic surgeons, each of whom were instructed to drill 4 uni-cortical 3.2 mm diameter holes each in a single porcine femur fixed in the vice-grips attached to the load-cell of the MTS machine. The S&N 2-fluted drill was used in this experiment. Each surgeon performed the drilling procedure 4 times, giving a total of 16 data points from which the 95% confidence interval (CI) values for axial thrust force were obtained. So that cutting efficiency of the drills was not compromised by excessive wear of the cutting surface, a single drill was limited to performing 8 drilling episodes only and promptly discarded.

Characteristic feed-rates (speeds of the MTS actuator) corresponding to the specified upper and lower bounds of the 95% CI for axial thrust force were determined by refinement on a trial-and-error basis (Table 2). As above, and in this experimental determination of the characteristic feed-rates, fresh drill samples were strictly limited to creating 8 drill holes ($n = 8$) only.

A sample size of $n = 24$ 3.2 mm diameter uni-cortical holes per drill type were then drilled into porcine femurs held in vice-grips attached to the load-cell at the characteristic feed-rates (Table 2) in a semi-automated experiment. New drills were used for this experiment and discarded once used to create a maximum of 4 holes. A factory-calibrated Infrared Thermal Imaging Camera (Digicam-IR, Ircon, Niles, IL, USA) was rigidly fixed to a tripod and used to record two still-shots for each drilling episode. The first image was taken of the site immediately prior to the commencement of drilling. A second image was then taken at the point where the drill breached the cortex. Thermal images (Fig. 3) were then analysed using Inspect-IR thermal imaging software (Ircon, Niles, IL, USA). The mean maximum elevation in temperature of the surrounding cortical bone across 24

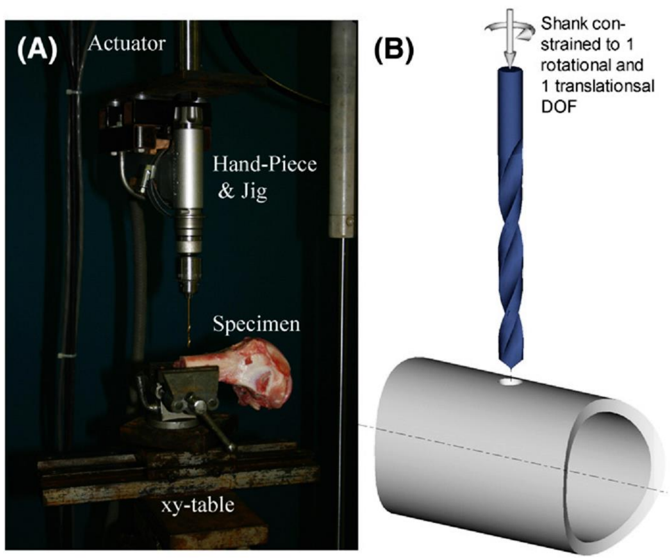

Fig. 2. *In vitro* experimental design. (A) Actual setup for the experiment conducted in air. (B) Jig securing the handpiece ensured motion of the drill-bit was limited to 2 DOF only.

Table 2
Characteristic feed rates of the 3.2 mm drill used in the *in vitro* testing of cutting efficiency and heat generation.

Drill	Feed rate (mm/s)	
	Lower (79 N)	Upper (142 N)
Orthopaedic Innovation 3-fluted (Sydney, Australia)	5.0	9.0
Smith & Nephew 2-fluted (Memphis, TN, USA)	2.0	3.2
Synthes 3-fluted (Paoli, PA, USA)	2.5	4.7

drilling episodes for each drill design was the dependent variable used in the statistical analysis. To account for a range of clinical circumstances the drilling procedures were conducted in both (1) air at ambient temperature (26 °C) and (2) a phosphate-buffered saline waterbath maintained at 37 °C.

2.2. In vivo component

Sixteen ($n=16$) skeletally mature adult wethers (1.5 yrs) were used following the granting of ethical approval by the University of New South Wales' Animal Care and Ethics Committee. Principles of laboratory animal care (NIH publication No. 86-23, revised 1985) were followed in this study.

All animals underwent a bilateral procedure in which three 3.2 mm diameter uni-cortical pilot holes were made in the anteromedial aspect of the proximal tibia at locations 2, 3 and 4 cm distal to the tibial plateau. In order to promote consistency in the drilling procedure, holes were created using the said surgical handpiece mounted in a sterilisable mobile drill-press placed over the operating table. Air pressure was maintained at 680 kPa using the calibrated regulator as in the *in vitro* experiment. Weights corresponding to the mean of the peak axial loads, determined in the *in vitro* phase of this project (Table 2) were attached to the drill press. Irrigation was not applied during drilling to simulate the worst-case scenario .i.e. the isolated far-cortex in bicortical drilling.

The 4.5 mm diameter, 20 mm length pedicle screws (Smith & Nephew, Memphis, TN, USA) used were not self-tapping and threads were created using a hand-held tap. These screws had a thread depth of 0.75 mm, giving a minor diameter of 3.0 mm. As a result of this there was approximately 100 μm of radial clearance between the body of the screw and bone. The cross-sectional profile of the implanted pedicle screw is shown in Fig. 4.

Empty, non critically-sized (Viateau et al., 2007) 4.5 mm diameter uni-cortical 'control' defects were also created in four animals ($n=4$) using 4.5 mm diameter version of each drill to assess intrinsic healing. The fixation parameters of the screws and healing of the empty defects was then assessed following 2 and 4 weeks *in situ*.

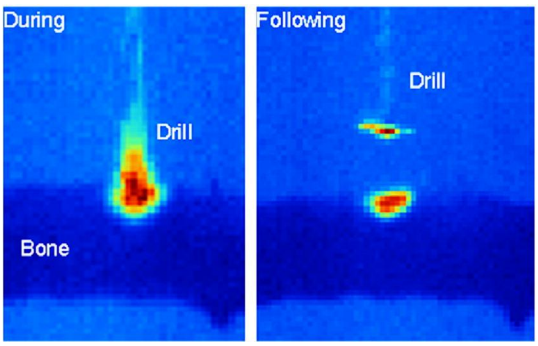

Fig. 3. Thermal profile during drilling (left) and immediately following (right) with the drill retracted. The maximum temperature rise in the cortical bone following the cessation of drilling was computed.

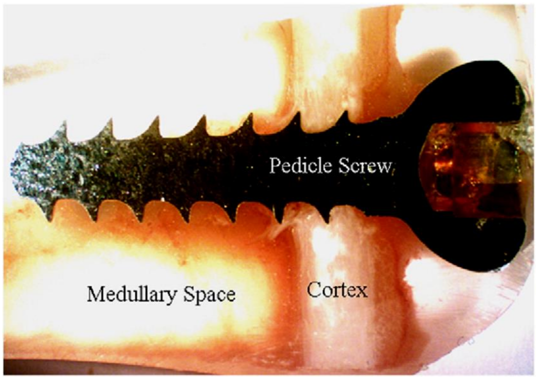

Fig. 4. Unstained cross-section of a pedicle screw in the proximal tibia following 2 weeks in situ embedded in PMMA. Thread depth and pitch were 0.75 mm and 1.8 mm, respectively.

Following sacrifice, the proximal tibiae were harvested and placed in phosphate-buffered saline. A sample size of eight ($n=8$) and four ($n=4$) screws for each drill design were randomly assigned for mechanical pull-out testing or PMMA histology, respectively. Specimens designated for mechanical testing were then secured to the load-cell of the MTS machine and the screw-head engaged using a customised jig attached to the machines' actuator. The maximum pull-out strength (N) of the screw-bone interface was then tested by displacing the screw at a rate of 5 mm/min. Additional tibiae were also obtained from other adult sheep sacrificed in our laboratory for other experiments and were used to evaluate the time-zero fixation properties of the cortical bone screws following the drilling of the pilot hole using each of the drill-bits ($n=8$ per design).

Specimens designated for histological analysis were fixed in phosphate-buffered formalin, dehydrated in increasing concentrations of ethanol and embedded in polymethylmethacrylate (PMMA). The polymerized samples were sectioned using a diamond wire saw (DDK 1000, Delaware Diamond Knives, Newark, DE) and viewed under a light microscope to assess the bony integration at the screw-bone interface. Empty 'control' defects were isolated and decalcified using 10% formic acid-formalin solution. The decalcified sections were embedded in paraffin wax and sectioned in the coronal plain using a Leica Microtome (Leica, Germany). Haematoxylin and eosin (H&E) and tetrachrome stains were used to evaluate tissue damage and regeneration. Sections were examined by light microscopy using an Olympus microscope (Olympus, Tokyo, Japan).

All data was analysed using an ANOVA followed by a post-hoc multiple comparison (Games-Howell) using SPSS for Windows (SPSS Inc., Chicago, IL). Differences were considered significant where $P<0.05$.

3. Results

The upper and lower bounds of the 95% CI for axial thrust force applied by the surgeons whilst drilling 3.2 mm diameter holes in cortical bone were found to be 79 N and 142 N (mean 110.5 N). The characteristic feed-rates associated with these axial loads (Table 2) were determined by trial-and-error and used in the *in vitro* testing. (To reduce the number of surgical sites (and animals) required for the *in vivo* component only the mean value of the thrust force was used in the surgical creation of holes).

Characteristic feed rates were considerably higher for both 3-fluted drills in this study, which did translate into decreased drilling time. In order to produce reaction forces equal in magnitude to the 95% CI of the thrust force values, the 3-fluted SYN and 3-fluted OI drills required feed rates approximately double and 1.5 times that of the 2-fluted drill, respectively. In other words, on average the 3-fluted drills were, on average, 75% quicker than the 2-fluted drill used in this study (drilling in identical conditions).

Results from the *in vitro* infrared temperature analysis are shown in Fig. 5. Mean temperatures of the bone prior to drilling were 21.7 ± 2.8 °C for the dry environment and 32.4 ± 1.4 °C for the wet saline environment (Mean ± SD). Irrigation (wet environment) decreased the magnitude of the mean temperature increase in the cortical bone for all drills at both feed rate levels, only being a significant reduction in the case of the Synthes 3-fluted drill at the 142 N axial thrust force level ($P<0.001$). Conversely, thrust force (through increased feed rate) had no significant effect on the temperature elevation in the cortical bone during drilling for either the S&N 2-fluted or OI 3-fluted drills ($P>0.05$), whereas increasing thrust consistently reduced mean temperature for the Synthes 3-fluted drill, and was a significant reduction for the wet environment only ($P=0.001$).

Histologically, no empty osteocyte lacunae were observed in the cortical bone surrounding the screws or the empty defects. Woven bone occupied between 70 and 85% of the empty 4.5 mm defects at 4 weeks. Little to no appreciable differences in histological appearance was noted between groups which could have been attributable to the drill design used to create the pilot holes or empty defect.

Results from the mechanical testing of the pull-out strength of the bone screws are shown in Fig. 6. No significant differences were observed at each time-point in the maximum pull-out strength based on the drill used to create the pilot hole ($P>0.05$). Mean pullout strength (N) increased as a function of time for all groups, except for the OI drill, which showed a decrease from 2 to 4 weeks post-operatively. No correlation between pull-out strength and drills was observed.

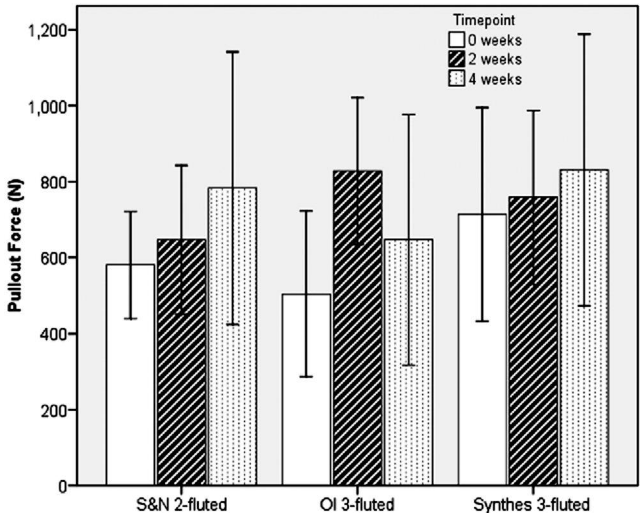

Fig. 6. Pullout force of the bone-screws at 0, 2 and 4 weeks (Mean±SD).

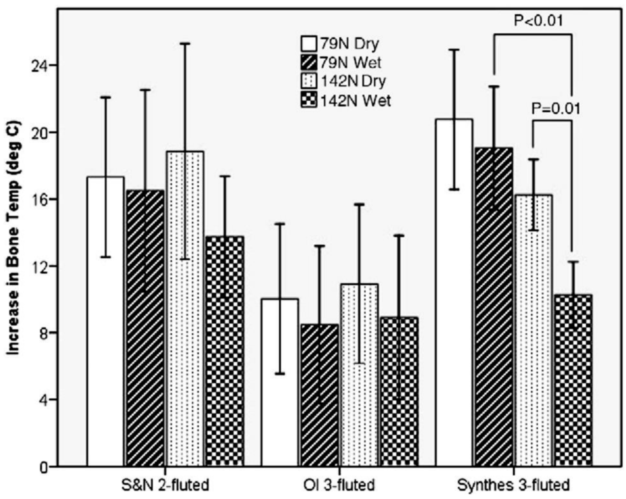

Fig. 5. Maximum temperature increase at the bone cortex due to drilling (Mean±SD).

4. Discussion

In this study the feed rates for both 3-fluted drills were found to be higher than that of the 2-fluted drill (Table 2). Furthermore, the feed-rate of the OI drill was approximately double that of the Synthes drill at both 79 N and 149 N. Since feed-rate is a direct measure of cutting efficiency, it is possible to conclude that the 3-fluted drills had a higher cutting efficiency than the 2-fluted drill used in this study. Cutting efficiency of surgical drills has been shown to be an important characteristic in the reduction of heat generation during drilling and the prevention of bone loss through thermonecrosis (Bachus et al., 2000; Toews et al., 1999). Theoretically, cutting efficiency of 3-fluted drills should exceed that of diameter-matched 2-fluted drills due to the 50% increase in the cutting surface by inclusion of the additional webbing.

Despite the finding of improved cutting efficiency for the 3-fluted drills, only for the OI 3-fluted drill did this translate into a significant and parallel reduction in maximum cortical temperatures encountered whilst drilling through porcine bone when compared to the 2-fluted drill. Conversely, mean cortical temperatures encountered using the 3-fluted Synthes drill where higher than the 2-fluted drill for both simulated environments at the 79 N but not at the 149 N level. The OI drill also out-performed the Synthes drill in this regard.

In devising the method for the quantification of the maximum temperature rise in the bone, we utilised the findings of Abouzgia and Symington (1996) who demonstrated that the peak, or maximum temperature associated with the drilling of bone occurs at the instant in time where the drill-tip breaches the underside of the cortex. That is, no further increase in the maximum temperature of the bone immediately adjacent to the hole was recorded following the cessation of cutting, which was shown by plotting thrust force (N) and temperature profiles.

It has previously been reported that increasing thrust force leads to a reduction in the elevation of temperature in bone during drilling (Bachus et al., 2000). Despite using the experimentally-determined upper and lower bounds of the 95% CI for axial thrust force typically exerted by a surgeon on the handpiece, we did not see a concomitant reduction in temperatures at the outer cortex with increasing thrust for either the 2-fluted S&N or 3-fluted OI drills (Fig. 5). Only the Synthes 3-fluted drill performed consistently in this regard — the S&N 2-fluted drill behaving in this manner in the wet 142 N environment only. Conversely, the introduction of irrigation (wet environment) consistently reduced the mean temperature elevation in the cortical bone at both thrust force levels, the change being significant only for the Synthes 3-fluted drill at the 142 N thrust force level.

The suggestion that maximum cortical temperatures can be reduced by increasing thrust force applied to the surgical handpiece by the surgeon can have serious and undesirable ramifications. Applying too much axial load can lead to either excessive breakthrough, which alters hole geometry and decreases bone stock, or uncontrolled plunging of the drill-tip, resulting in subsequent soft tissue damage which could contribute to non-primary post-operative morbidity. The extent of this damage would indeed be exacerbated by the generally more acute tip-geometry which 3-fluted drills — and, in-particular, the OI drill (44° point angle) — exhibit compared to their 2-fluted rivals (S&N — 94°). High speeds (20,000–100,000 rpm) have also been shown to produce a decrease in the maximum cortical temperature during drilling and burring (Abouzgia and Symington, 1996; Iyer et al., 1997; Toews et al., 1999).

A reduction in the heat generated during drilling by the 3-fluted OI compared to the 3-fluted Synthes drill (and, to a lesser extent, the S&N

2-fluted) did not translate into increased pullout force of the pedicle screws in the *in vivo* model. Histologically, no empty osteocyte lacunae were seen in any of the cortical bone surrounding the screws or empty defects at either 2 or 4 weeks post-operatively, signifying that the temperature increases themselves (or, their durations) were not sufficiently high enough to induce necrosis — with such features being the hallmark of thermonecrosis (Eriksson et al., 1984, Franssen et al., 2008).

Whilst a porcine *in vivo* model was not used for logistical reasons, it has been suggested that bone composition, density and quality between the ovine and porcine species are comparable (Aerssens et al., 1998). Based on the results of our *in vitro* study we estimated (using linear regression) the range of temperatures at the cortical bone surface during non-irrigated drilling during surgery whilst using the 3-fluted Synthes and 2-fluted S&N drills to be 46.3 °C–63.9 °C and 51.7 °C–68.9 °C, respectively. Despite these predicted temperatures, necrosed tissue was not a histological finding, which may suggest that the dwell-time (time above 50 °C) was insufficient for such a consequence. Although less likely, our limited results may also suggest that, despite their similarities, the thermoconductive properties of porcine and ovine bone may be dissimilar.

It is also conceivable that some necrosed tissue was removed whilst using the hand-held tap. Admittedly, however, the minor (core) diameter of the tap and screw were purposely identical (at 3 mm each). This fact, combined with a considerably large thread pitch (Fig. 4) mean that only a small amount of bone — corresponding to volume of thread itself — was removed. In other words, the margins of the 3.2 mm pilot hole would not have been altered in the creation of the threads.

It should also be noted that we have assumed that the characteristic feed-rates determined in the porcine bone translated into the same axial thrust force in the ovine bone. This may not have been the case.

In 1982, Saha et al. (1982) reported the optimal surgical drill-bit design as being a 2-fluted, split point, parabolic twist-drill with helix and point angles of 36° and 118°, respectively. These parameters were subsequently supported by Natali et al. (1996). Results from this study clearly demonstrate that the 3-fluted OI drill results in a decrease in temperature of the cortical bone when compared to the 2-fluted S&N drill, suggesting that this design may be of clinical benefit. Whether this advantage is maintained at different drill diameters is another consideration as drill flutes are known to clog with debris as the depth of the hole becomes appreciable compared to its diameter (Mellinger et al., 2003). The same advantage does not exist for the 3-fluted Synthes drill.

Although the OI design demonstrated a potential for reducing thermal insult, this study did not verify a clinical advantage with respect to defect healing or screw fixation. Based on the findings of the present study we are unable to make categorical claims about any *in vivo* benefits to using either 2-fluted or 3-fluted drills in orthopaedic applications. That is, apart from increased cutting efficiency and reduced drilling time associated with the use of either of the 3-fluted drills. One can only speculate how improved cutting efficiency will affect the surgeon; whether or not a lesser thrust force will or should be applied to compensate for an increase in cutting speed.

The current study did have some limitations. We are limited to drawing conclusions about the drill designs that were tested within it. Statements regarding the ideal number of flutes cannot be made as there were a number of other variables in the drill designs which may also have influenced the results, such as point-angle, relief-angle, rake angle, manufacturing process, etc. A further study would need to be undertaken for a valid determination of the ideal number of flutes in which these parameters — and, in particular, the point-angles — are tightly controlled.

Although the bone used in this study was specifically sourced from species whose bone properties closely resemble that of humans, verification is still needed to demonstrate that the results are transferable to the human model. The study utilised only 3.2 mm and 4.5 mm diameter drill-bits as they are the standard sizes produced commercially and used in theatres. Further studies need to be conducted to confirm the effects of drill diameter on the measured parameters. Finally, the chuck speed was not measured which prevented us from measuring the work of cutting. This parameter may have elucidated a difference between the drill designs.

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