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Technical note

Experimental evaluation of cortical bone substitute materials for tool development, surgical training and drill bit wear investigations

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ABSTRACT

Surgeons, scientists and development engineers of surgical devices require phantoms and materials for testing and training purposes. Human or animal bones are the gold standard, but difficult to obtain, prepare and handle. While polyurethane foams can be used as a substitute for trabecular bone, cortical bone substitutes have not been evaluated. In this study, a standard surgical drill bit (⌀ 3.2 mm) with clinical process parameters was used to compare 5 different materials with bovine cortical bone: polyurethane with three different densities, short-fiber-filled epoxy and an artificial bone material. Drillings were repeated 100 times with 6 drill bits for each material. The results indicate that none of the substitute materials can be used without compromises. Axial drilling thrust forces in short-fiber-filled-epoxy are similar to bone. However, its hard fibers significantly deteriorate the chisel edge and flank face and increases the thrust force with each drilling (doubles within the first 10 repetitions) so that drill bits should only be used very limited times. The densest polyurethane (Renshape BM-5166) has the advantage of comparable torque values with bovine cortical bone (up to 60 repetitions). Additionally to these findings, a significant and potentially clinical relevant increase of axial drilling force (80%) and torque (56%) was found during 100 drillings in bovine cortical bone.

1. Introduction

The development of surgical tools or devices like drill bits and burs or their use for surgical training requires biological or artificial materials which resemble the intended anatomical use. While testing with human cadaveric bones is still the gold standard, they are often difficult to obtain and handle. Therefore, animal models like bovine bone, pig vertebrae or sheep skulls are often used as a substitute [1–3]. Nonetheless, scientists, development engineers and surgical trainees are looking for artificial materials which could be used as bone substitutes for their experiments and tests.

Such an artificial material would be easier to prepare and handle while having the advantage of availability, improved comparability and possible cost reduction. Some of those materials are already widely used for biomechanical testing. Especially polyurethane foams (PUR-foams), which can be purchased in different bone shapes including a cortical layer made of an epoxy resin with short fibers (e.g. Sawbones). The structural properties of such bone composites have been evaluated with good results [4,5] and PUR-foams alone have similar properties to trabecular bone [6]. Despite its importance for the testing and evaluation of surgical tools, the cortical part of such synthetic bone composites has not been adequately studied. In one publication by Cseke and Heinemann [7], an additional finding was made that drilling of cortical animal bone tissue resulted in a significantly higher thrust force and torque compared to both compact and, in particular, porous SawBones test materials. The purpose of this study, therefore, was to compare the mechanical properties of some common CORTICAL bone analogues with that of bovine cortical bone. Bone drilling was chosen as an example procedure because it is a widely used surgical procedure. Important biomechanical parameters are drilling forces and torques which can partially be used to interpret other procedures like burring, sawing or the insertion of self-tapping screw implants for the fixation of bone fractures.

Additionally, this study focuses on the issue of wear of surgical devices. Multiple reuse of drill bits in the operating room bears the risk of tool blunting and therefore deteriorating performance. Tool quality is often only controlled visually prior to surgeries. However, a blunt tool can increase temperature elevation during the surgical procedure [8–10]. Staroveski et al. [8] have previously suggested a method to monitor and classify drill wear in bone. Feldmann et al. [12,13] have suggested tool designs and process parameters to

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reduce temperature elevation during drilling [11] and have correlated the torque and force of the drilling process with the temperature elevation.

The present study aims to evaluate experimentally the suitability of cortical bone substitutes in biomechanical tool tests, and addresses questions.

2. Methods

2.1. Experimental materials

Five different materials were chosen and evaluated against bovine cortical bone: two polyurethane foams PUR-40, PUR-50 (General Plastics, USA), short fiber filled epoxy (SFFE) (Sawbone, USA), BoneSim (BoneSim Laboratories, USA) and Renshape-BM5166, a high density PUR-block (Huntsman Corporation, Switzerland). A short summary of the associated material properties can be found in Table 1. The reasoning why these materials were chosen can be found in the discussion section.

Bovine bone was chosen as a reference material. This bone is widely used as a substitute for human cortical bone especially for drilling experiments [17]. The advantages are the availability, size, homogeneity and similar characteristics, notably for aged osteonal bovine bone [1]. The femora of six four-year-old milk cows were acquired from a local slaughterhouse. Samples were harvested from the diaphysis in axial direction and cut to appropriate dimensions, using a diamond band saw, for the sample holder of the experimental setup (thickness > drilling depth). Samples were then frozen at −20 °C and thawed to room temperature in saline solutions just prior to the experiments to prevent water loss.

2.2. Experimental setup

Two different experimental setups were used: Both comprised a standard CNC setup with a motor spindle and drill chuck as well as a clamping device for the specimens. One setup was used to drill efficiently most of the holes into the samples (will be referred to as “CNC-1”) while the other included an additional load cell (F310-400N-2Nm, Novatech, UK) for measuring drilling forces and torques in certain intervals (“CNC-2”, described in a previous publication [11], see 2.3. experimental procedure).

Standard surgical two flute drill bits (DePuy Synthes, Johnson&Johnson, USA) with a diameter of 3.2 mm and a rake angle of 16° (defined at outer diameter of drill bit) and a point angle of 80° were used (see Fig. 1 for nomenclature). These drill bits do not have special tip shapes (e.g. tip sharpening, split point, S-shape) and cutting edges were ground to maximum sharpness (no defined cutting edge radius).

2.3. Experimental procedure

To evaluate the different materials and to investigate the influence of tool wear, 100 holes were drilled with 6 different drill bits for each of the 5 materials (in total, 30 drill bits were used to drill 3000 holes). The drilling depth was 14 mm with a material thickness of 12 mm. Axial thrust forces and torques were only compared from the 2nd to the 6th mm of the drilling process. This ensured a fully penetrated drill bit with a homogeneous amplitude similar to the average thickness of the cortical layer in human bone.

Drilling forces and torques were measured for each of the first 10 holes except bovine bone (only first drilling recorded) using “CNC-2”. For the remaining holes, forces and torques were measured in an interval of 20 drillings starting with hole number 20 (#20, #40, #60, #80, #100) for all materials (also CNC-2). All other holes were drilled with “CNC-1”. Force were measured more frequently at the beginning because a faster drill degradation was expected for a new drill bit. Additionally, microscopic pictures (CT-12000, M-Service, Germany) were taken of the cutting and chisel edge for each interval and, for drilling in bovine

Table 1
Material properties of tested materials. These values have been taken from the data sheets of the manufacturer.

Material	PUR-40 [14]	PUR-50 [14]	SFFE [14]	BoneSim [15]	Renshape-BM5166 [16]	Bovine cortical bone [1]
Density [kg/m^3]	640	800	1640	1800	1700	ca. 2000
Hardness [Shore-D]	60	70	90	90	85	ca. 95
Compressive Strength [MPa]	31	48	157	110	95	ca. 200
Compressive modulus [MPa]	759	1148	17,000	N/A	7500	ca. 15000

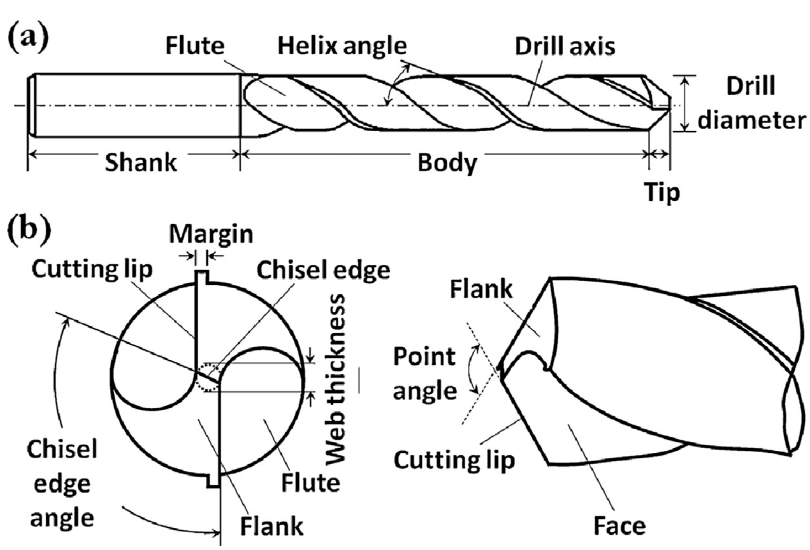

Fig. 1. Drill bit nomenclature for a standard two flute surgical drill bit. The drill bit used in this study has a diameter of 3.2 mm.

cortical bone, the cutting edge radius was measured (KH-8700, Hirox, Japan).

Process parameters were chosen to replicate clinical conditions as closely as possible. Rotation speed was therefore set to 1250 RPM (according to Depuy Synthes drilling devices) and constant feed rate to 1 mm/s representing an average constant applied pressure of the surgeon in a homogeneous bone part [18,19].

3. Results

3.1. Evaluation of artificial materials

The average axial thrust force and torque values for the first 6 mm of the first drilled hole (six measurements for every drilling depth) are shown in Fig. 2 top row. The axial thrust forces when drilling in SFFE are closest to those measured in bovine bone even though there is still a 9.77 N difference. For the torque amplitude, the values measured for the dense PUR-block (BM-5166) are closest to bovine bone with an average difference of 8.01 N mm. A further observation is that after full penetration of the drill bit tip (from 2 mm depth), the axial thrust force stays constant while the torque values still rise.

The artificial materials were chosen because they have been used as bone substitutes for mechanical testing before. Both low density PUR foams (PUR-40, PUR-50; density in pounds per cubic foot) and the SFFE are used as an artificial substitute material for trabecular bone for the “Sawbone” products (Sawbone, USA). While the cortical bone is mimicked by a layer of glass fibers reinforced with epoxy resin. However, it was found that even the low density PU-foams were sometimes used as a cortical bone substitutes. The Renshape-BM5166 high density PUR-block was selected because it is a standard material and a more affordable alternative to the aforementioned specialized testing materials with similar density and compressive strength values than bovine cortical bone.

If the whole drilling depth of the first drilled hole is analyzed (Fig. 2 bottom row), the most notable is the force and torque increase for bovine bone starting at 6 mm. This increase up to 75 N or 225 N mm is due to bone chips clogging the flutes of the drill bit at a deeper drilling depths. Irrigation and interval drilling have been shown to reduce the incidence of clogging of flutes [11]. This increase in axial thrust force and torque was not found for the other materials except for BoneSim, but with a much lower amplitude.

3.2. Drill Bit wear investigation

Fig. 3 shows the axial thrust force of the drilling process for each of the different materials over the one hundred repetitions

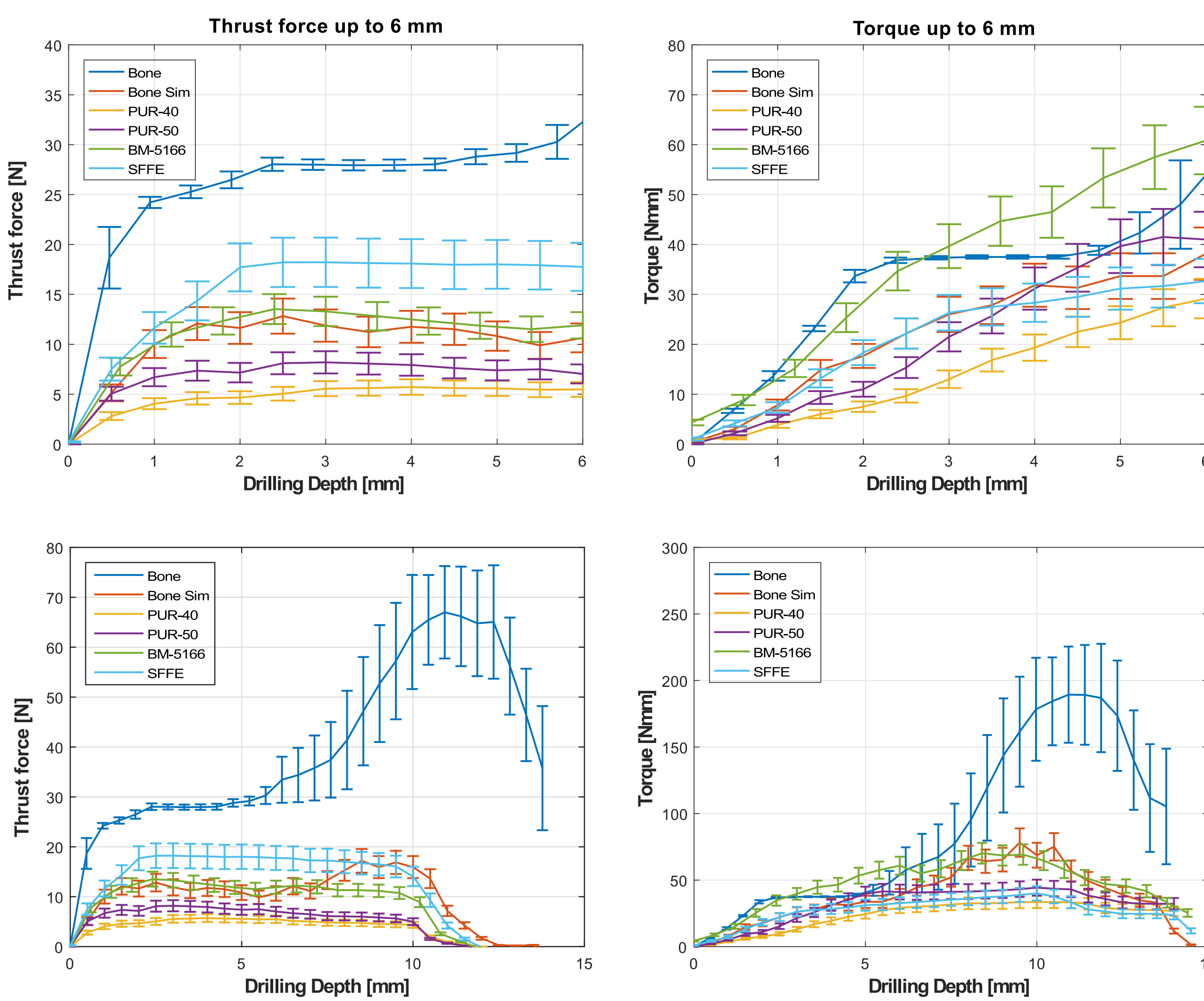

Fig. 2. *Top row diagrams:* Forces and torque up to 6 mm of the first drill hole. Thrust forces in SFFE and torque values of BM-5166 are closest to cortical bone. *Bottom row diagrams:* Axial thrust forces and torques over total drilling depth of first hole show significant increase at 6 mm when drilling in bovine cortical bone. Error bars denote standard deviation and statistical analysis was only done between the 2nd and the 6th mm to ensure full drill penetration.

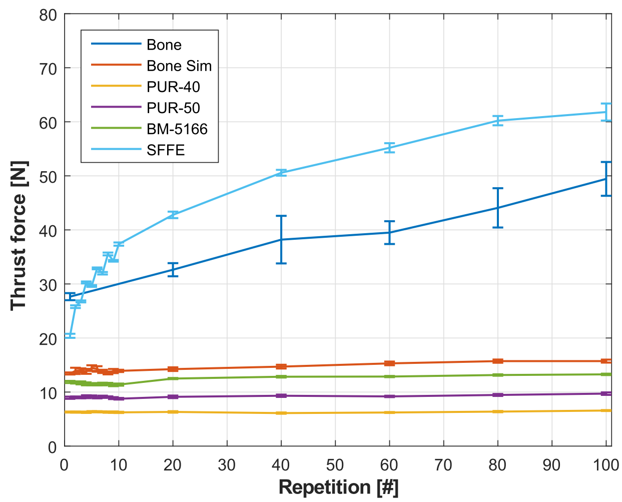

Fig. 3. Comparison of axial thrust force of tested materials over one hundred repetitions (averaged from the 2nd to the 6th mm of drilling depth). Bovine cortical bone was used as a reference material. A high increase in thrust force was found for the drilling in SFFE. A linear increase can be seen for bovine cortical bone.

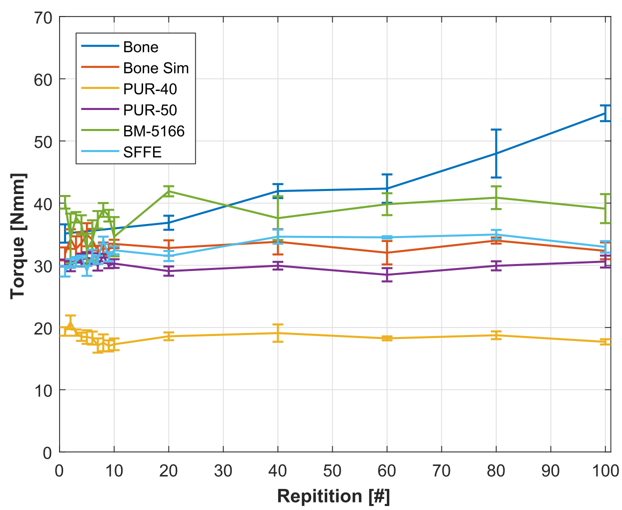

Fig. 4. Comparison of axial drilling torque of tested materials over one hundred repetitions (averaged from the 2nd to the 6th mm of drilling depth). An increase in torque was found for cortical bone while all other torques remained nearly constant.

Table 2
Drilling force and torque increase in bovine cortical bone with increasing cutting edge radius due to blunting of the drill bit. These values are mean values measured at different points along the cutting edges. While the torque increase is mainly due to the detoriation of the cutting edge, the thrust force increase is most likely due to the blunting of the chisel edge.

Hole [#]	10	20	40	60	80	100
Cutting edge radius [μm]	1	12	20	22	27	30
Thrust force increase [%]	0	18	38	44	60	80
Torque increase [%]	0	6	20	21	37	56

(averaged from the 2nd to the 6th mm of drilling depth). A significant increase in thrust force was found for the drillings in bovine bone and SFFE. The increase of force in bone is approximately linear over the repetitions and raises from 30 N to 50 N. The force increase in SFFE shows a more logarithmic shape and nearly doubles within the first 10 drillings and triples from the first (20 N) to the hundredth drilled hole (60 N). No significant change in the thrust force amplitude within the repetitions was found for the other materials. In general, the force when drilling in SFFE is closest to bovine bone with a mean difference of about 6 N.

Fig. 4 shows the axial torque of the drilling process for each repetition. Torque values vary less significantly as compared to axial forces, but the change in torque amplitude over all repetitions is similar to the force amplitude change except for the SFFE material. While the linear change for bovine bone is still visible (from 0.35 to 0.55 N m), no significant change was found for the rest of the tested materials. The torque amplitude when drilling in the dense PUR-block (BM-5166 material) is closest to the torque amplitude in bone up to about 60 repetitions.

Analyzing the microscope images, no alteration of the cutting or chisel edge in PUR-foams or BoneSim material was found. Fig. 5 shows the tip (side and top view) of a new drill bit in comparison with a drill bit after 100 drillings for bovine cortical bone, Renshape BM-5166 and SFFE. When drilling in bovine cortical bone (b), the cutting edge (1*) and chisel edge (4*) are worn down. The abraded cutting edge has an increased radius which were measured and shown in Table 2. The increasing cutting edge radius leads to an increase of both thrust force and torque. Only minor visible damage was found on the cutting and chisel edge of the drill bits used for BM-5166 (c). The found damage mostly accumulated on the lateral margin of the drill bits (2*).

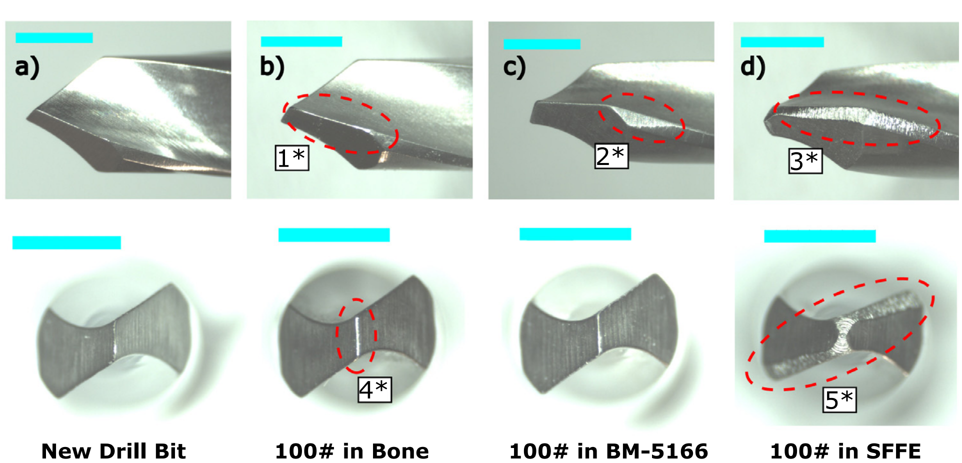

Fig. 5. Microscope images of cutting edge and flute *(top row)* as well as chisel edge and flank *(bottom row)*. The length of the blue line in the images resembles 2 mm. (a) Initial drill bit (b) Drill bit after 100 repetitions in bovine cortical bone (c) After 100 holes in Renshape BM-5166 and (d) After 100 holes in Short fiber filled epoxy. Visible damage to the cutting **(1*)** and chisel edge **(4*)** was found for drillings into cortical bone. **(2*)** and **(3*)** shows ground side face (margin) for drillings in BM-5166 and SFFE. Additionally, major damage to chisel edge and flank face **(5*)** was found after 100 repetitions in SFFE.

Major damage was found after 100 repetitions in SFFE (d). The side face (3*) as well as the the chisel edge and a chamfer (5*) was ground by the abrasive material. A chamfer with the width of 0.35 mm was measured at the flank face close to the cutting edge which leads to an increase of thrust force (not torque).

4. Discussion

This study investigates potential materials which could be used to substitute cortical bone for testing, development and teaching purposes of surgical tools or devices. A drilling process similar to clinical practice is used as a reference method and results can potentially be used for other surgical interventions (e.g. sawing, milling, chiseling or self-tapping screw insertion). However, this study did not investigate if these materials are suitable for general biomechanical tests.

Bovine bone was used as a reference material which has the advantage of homogeneity but which is less porous than human bone and measured forces might therefore be slightly higher than in human cortical bone.

The results show that none of the tested materials can be used as cortical bone substitutes without certain compromises. To recommend a material, the user of such products needs to define the aim of their tests or experiments. If, for example, in a training session, surgeons would like to practice the drilling process, from the tested materials, SFFE would be the best option. Even tough still statistically different, thrust forces are closest to cortical bone, so that a more clinically relevant force feedback is given to the user during drilling. However, the torque amplitude is different to bovine bone which makes it less ideal for the development of new surgical devices, such as drill bits or power tools. Additionally, drill bits become dull very quickly (forces double within 10 uses) due to the abrasive glass fibers in the material and drill bits should only used once if tested with this material.

If the emphasis is on the development, design evaluation and/or testing of surgical devices, a very dense polyurethane (block or foam) like the Renshape BM-5166 (Huntsman Corporation, Switzerland) might be the better choice. A torque feedback close to cortical bone can not only help to optimize drill bit design but might also allow the evaluation of the design and sharpness of, for example, self-tapping implants (e.g. screws). It is necessary to know the limitations of such materials, however. Fig. 2 shows that jamming of drill bit flutes with bone chips in bovine cortical bone is a serious issue (for drilling force and torque) at deep drilling depths (>6 mm) [20] which does not occur in artificial materials. In clinical practice, the clogging of the flutes can be avoided by an intermittent removal of the drill bit and sufficient irrigation to clean the flutes [11]. Also the thermal conductivity is different to bone (≈ 0.08 W/mK for the PUR 40 pcf compared to 0.6 W/mk for cortical bone [21]). Eventually, experiments using human or animal bone is still the gold standard and should be used if possible, especially if more complex topics like thermal evaluation, chip-formation, -geometry or -build-up are evaluated. Also, it is important to consider the actual anatomic situation and its common bone density when planning to do tests with artifical bone (e.g. bone density differences between mandibula and maxilla).

The other focus of this study was the investigation of wear for standard surgical drill bits in cortical bone. Drill bits are used for many surgical procedures and mostly reused until visible damage occurs. The results of this study suggest that drilling forces and torque increase linearly with successive drilling episodes up to 180% within 100 reuses in the bovine bone. The microscope images confirm the drill bit blunting of the cutting edges which is consistent with findings in the literature [8]. This is due to the hard and dense properties of cortical bone. Human bone is slightly more porous, but trends should be similar.

This rise of cutting forces does not only increase the force which needs to be applied by the surgeon, but also increases the temperature elevation of the drilling process [8,9,12] which can lead to thermal bone necrosis [22]. Therefore, a limitation of the repetitions of drill bit usage or periodic microscopic control of the tool tip condition is therefore suggested in clinical practice. Additionally, the force (and torque) signal could be used as wear indicators as suggested by Staroveski et al. [8] or temperature indicators as suggested by Feldmann et al. [12]. The blunting of tools (at least the cutting edge) could also be reduced if the sharp cutting edge would be produced with a defined radius [23,24] and the chisel edge is for example improved with a split-point or s-shape design. However, it should be noted that a defined cutting radius increases the life expectancy of a tool, but might also increase general cutting forces. More research on this important issue is need and the influence of dull tools and temperature rise on bone healing should be investigated *in vivo*.

5. Conclusions

Different substitute materials for cortical bone were evaluated which could be used for tool development or surgical training. No material has been found which satisfies all requirements. Axial thrust forces in short-fiber-filled-epoxy are close to bovine cortical bone which is useful for surgical training. However, the torque amplitude is different and the material is very abrasive to the tool tip so that drill bits should only be used once. A very dense polyurethane material (Renshape BM-5166) is able to simulate an accurate torque amplitude which can be helpful for tool development and other experimental testings (e.g. screw insertion). Moreover, drill bit flute clogging with bone chips (force/ torque raise) occurred in cortical bone at a drilling depth larger than the clinically more relevant 6 mm.

Additionally, a significant increase of drilling thrust force (80%) and torque (56%) was found when repeating the drilling process in bovine cortical bone. The drill bit blunting leads to higher forces which needs to be applied by the surgeon and therefore higher temperature elevation during the drilling process. These tool blunting should be further investigated in a clinical relevant environment.

Conflict of interest

We also like to disclaim that the drill bits have been contributed by DePuy Synthes and that part of the experiments were realized within DePuy Synthes Switzerland. No research funds have been received from DePuy Synthes.

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Ethical approval

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