The Influence of Drill Sterilization and Drill Guide Modifications on the Quality of Bone Drilling Process

Miho Klaic, Tomislav Staroveski, Toma Udiljak, Zlatko Catlak and Tin Ehrenfreund

Abstract—This paper investigates influence of dry sterilization process on the dynamics of the medical drill wear rate, as well as the effects of slotted drill guide on bone drilling temperature. Experiments were characterized with the machining parameters commonly used in everyday surgical practice. Both experiments were performed using standard commercial surgical drills. Dry sterilization is selected due to the higher temperatures and cycle durations compared to the steam sterilization, in order to expose the drill to greater thermal stress. Surgical drill guides were perforated with two symmetrical helical slots near the drilling zone in order to ensure faster bone chip removal and to prevent chip obstruction inside the guide channel.

Index Terms—drill guides, sterilization, surgical drill, thermal osteonecrosis, wear

I. INTRODUCTION

Bone drilling interventions have become usual and everyday practice in bone and joint surgery as well as dental surgery. Thermal impact on a bone tissue during drilling is known for centuries. However, first comprehensive research studies on that matter have been conducted some 30-40 years ago, and they have confirmed that bone exposure to the temperature of 47°C in the period of 1 minute and higher [1] or more than 30 seconds exposure to the temperature of 50 °C [2] / 55 °C [3] causes thermal necrosis of cortical bone tissue.

Primary source of heat generation is related to the energy released during bone tissue intramolecular bonds breaking [4]. Other (secondary) sources are connected to the friction between removed bone particles or chips and drill rake face, worn drill flanks and machined surface, and between drill body (flute edges) and hole surface. In the case of bone drilling, negligible part of generated heat is carried away by blood due to low blood flow (2-3ml/100mg), fast blood coagulation and occlusion of blood vessels [2]. Bone has low thermal conductivity coefficient [5], which also substantially contributes to the temperature rise in the drilling zone.

Unlike its mechanical characteristics, biochemical processes which occur in bone tissue during heat exposure are not completely described and are still in the research focus. There are several major factors which influence on heat generation in bone drilling process, such as drill design [6, 7], machining parameters [8-10], drilling depth or cortical thickness [1, 11], cooling technique [12-14] and drill wear rate [15, 16]. In this research, two additional factors were analyzed: drill sterilization influence on the intensity of its cutting edge wear dynamic, and the influence of modified (perforated) forms of drill guides on bone drilling temperature reduction.

Sterilization of surgical drills is nowadays usually performed using a steam sterilization procedure under a higher pressure and temperatures between 120 °C – 135 °C. This type of sterilization is often used because of relatively short cycles which last up to 30 minutes. However, in this research, a dry sterilization process is used because it is characterized with higher temperatures and cycles duration than steam sterilization. The idea was to analyze the worstcase scenario since it is expected that dry sterilization will have more negative impact on drill cutting edge stability than steam sterilization process, and that it will increase drill wear intensity. Consequently, this would result in a higher bone drilling temperatures.

On the other hand, the utilization of drill guides is very common in a nowadays bone and joint surgery practice. Since a majority of generated heat during drilling is expected to be accumulated in bone chips, their faster removal from the cutting zone could have positive impact on temperature reduction. Therefore, standard commercial drill guide was modified with two perforations located at the top of the drill guide body near the drilling zone. Their function would be to ensure faster chip removal and to prevent potential chip obstruction in the drill guide channel since majority of them will pass thru those perforations and leave the drill guide immediately after getting out from the hole.

Influence of sterilization on drill wear rate and drill guide modifications on bone temperature reduction has been analyzed in two case studies. The results are presented in two following sections.
II. INFLUENCE OF DRY HEAT STERILIZATION ON DRILL WEAR

A. Experimental Setup and Parameters

The experiment was performed on the 3-axis bench-top mini laboratory milling machine (Fig. 1), which has been retrofitted with the 0.4 kW (1.27 Nm) permanent magnet synchronous motors with integrated incremental encoders (type Mecapion SB04A), corresponding motor controllers (DPCANIE-030A400 and DPCANIE-060A400), ball screw assemblies, LinuxCNC open architecture control (OAC) system and National Instruments data acquisition hardware and software.

Two surgical drills type 310.450 manufactured by DePuy Synthes Co. was used in this experiment. The drill has two cutting edges and a diameter of 4.5 mm. One drill was never sterilized and the other was sterilized after every 10 drilled holes. Drill was sterilized in a dry environment at the 180 °C within 60 minutes of exposure. It was cooled down gradually at the room temperature, and then used to drill another 10 holes before new sterilization process occurred. After drilling one hole, a 30 second break was introduced before drilling the next hole. During this period, drill and the drilling sample were cooled down by using compressed air at the room temperature. That way, a potential influence of excessed drilling temperature on drill wear intensity was avoided.

Also, in order to avoid the influence of bone structure heterogeneity on drill wear dynamic, fresh pig bone samples were substituted with the artificial biomechanical test material, the so-called “Short Fiber Filled Epoxy”, produced by the Sawbones Co. This fourth-generation cortical bone model produced as a mixture of short glass fibers and epoxy resin injected around a solid rigid polyurethane foam core was shaped in the form of 130 x 180 x 6 mm block sample (Fig. 2).

Altogether, 200 holes were drilled with each drill using 1300 rpm drill speed and 1 mm/s feed rate (machining parameters were chosen based on similar drilling regimes used in the clinical practice). After every 10 drilled holes, both edges were inspected by industrial camera type DMK41AF02 (produced by Imaging Source Europe Gmbh) equipped with the telecentric lenses type TC2309 (produced by Opto Engineering S.r.I.).

B. Results and Discussion

Pictures of cutting edges were processed in the IC Measure software for on-screen measuring and image capture by which flank wear area values were quantified for both cutting edges (Fig 3). As it can be seen from Fig. 4,
flank wear zones related to different phases of experiment (initial phase, situation after 100 drilled holes and after 200 holes) of both drills turn out to be very similar. Detailed results of 20 flank wear areas quantified for both drills and their cutting edges are presented in Fig. 5.

These graphs reveal that both drills and their cutting edges have shown similar wear dynamic. During the first half of experiment (the first 100 holes) wear intensity of unsterilized drill was slightly higher than sterilized one, while in the second half (the remaining 100 holes) sterilized drill has shown higher wear rate. However, the differences in wear dynamics between unsterilized and sterilized drill are too small to unambiguously confirm any influence of dry heat sterilization procedure on drill wear rate.

III. INFLUENCE OF PERFORATED DRILL GUIDE ON BONE DRILLING TEMPERATURE

A. Experimental Setup and Parameters

The second experiment of this research was also performed on the same testbed shown in Fig 1. However, characteristics of modified drill guide were not analyzed by drilling artificial cortical bone but fresh pig femur samples. DePuy Synthes Co. drill guide type 312.460 was used together with the Komet Medical type S2727.098 surgical drill. Each drill guide (standard/commercial and modified) were tested using the sharp drill, 4.5 mm in diameter, at 1300 rpm and with 1 mm/s feed rate.

Modified variant of drill guide was made from the abovementioned commercial drill guide by grinding two spiral axial perforations on opposite sides of guide body (Fig. 6). Perforations were 3 mm wide and approximately 10 mm long. They were orientated opposite to the drill helix angle, with respect to the longitudinal axis, to avoid contact with the drill flute edges and to ensure fast chips removal.

Performance of compared drill guides were analyzed by measuring maximum occurred bone drilling temperatures. Temperatures were measured with the 3D printed temperature probe containing K-type thermocouple. The probe was placed in a two consecutively drilled holes of a bone sample whose centers were positioned at a distance of 5 mm. The next hole was used for temperature measurement (Fig. 7). Once positioned, the probe ensured thermocouple to be placed 3 mm in the cortical bone. Since the drill was 4.5 mm and the drill guide 6 mm in diameter, the distance between thermocouple and the hole edge was 0.75 mm (drill guide wall width).

B. Results and Discussion

For every drill guide, 10 measurements of bone drilling temperature were performed using the same bone sample. Maximum values are presented in Table I. Temperature variations, related to both drill guides, can be explained by the cortical bone non-homogeneities and thickness (drilling depths) variations.

Obtained results indicate that the spiral perforations at the tip of a drill guide have some positive effect in reducing bone temperature during drilling. Standard type of drill guide accomplished maximum temperature values higher than 40 °C in more measurements than the modified one. When comparing average maximum temperature value for both types of drills, it can be observed that the one both types of drills, it can be observed that the one associated with the standard drill guide was 1.9 °C higher than the one achieved with the modified drill guide (42.2 °C vs 40.3 °C). This small difference in temperature reduction can be

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<th>No.</th>
<th>TMAX, °C</th>
<th>Standard Drill Guide</th>
<th>Modified Drill Guide</th>
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<tr>
<td>1</td>
<td>37.6</td>
<td>35.5</td>
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<tr>
<td>2</td>
<td>44.4</td>
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<td>3</td>
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Average bone temperature before the experiment: 24.5 °C
Average surrounding air temperature during the experiment: 26.4 °C
explained by sufficient capabilities of standard drill guide to remove bone chips through drill flutes and relatively short drilling time. However, it should be stated that in the case of longer drilling process and/or possible obstruction of bone chips in the drill flutes zone higher drilling temperatures can occur rapidly. In these situations perforated drill guides can prevent sudden bone temperature rise.

At the end, it is also important to notice that temperatures were measured 0.75 mm from the hole edge, which, according to the [6], does not reflect the true maximal bone drilling temperature. Although this was the closest possible position of a temperature sensor to the hole in this experiment, authors of the abovementioned study have shown that temperature increases rapidly as moving toward the hole edge due to the low bone thermal conductivity. It is therefore logically to expect that the difference between average maximum temperatures obtained with this two type of drill guides are higher in bone layers closer to the hole.

IV. CONCLUSION

Effect of sterilization process on surgical drill wear rate dynamics together with the influence of modified (perforated) drill guide on bone drilling temperature reduction have been analyzed in two case studies.

Comparison of results achieved with unsterilized and sterilized drill has indicated that sterilization process has practically no influence on drill wear rate dynamics. Since this study was performed using dry sterilization procedure, characterized with higher temperatures and exposure periods than steam sterilization, it is logically to presume that the same conclusion can be drawn for steam sterilization. However, this claim still had to be confirmed by the ongoing research.

On the other hand, perforations made on the commercial drill guide have shown small but still positive effect, which can potentially be higher in the cortical bone layers near the hole edge. Furthermore, those perforations prevented any possibility of particles flow obstruction which would lead to the sudden bone temperature rise. The effect of drill guide perforations will also be further investigated in situations when used/worn drill is applied.

REFERENCES