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Informative title: **Thermal Osteonecrosis and Bone Drilling Parameters Revisited**

Concise title: **Thermal Osteonecrosis and Bone Drilling**

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Abstract

Introduction During the drilling of the bone, the temperature could increase above 47^{o}C and cause irreversible osteonecrosis. The result is weakened contact of implants with bone and possible loss of rigid fixation. The aim of this study was to find an optimal conditions where the increase in bone temperature during bone drilling process would be minimal.

Materials and methods Influence of different drill parameters was evaluated on the increase of bone temperature. Drill diameters were 2.5, 3.2 and 4.5 mm; drill speed 188, 462, 1140 and 1820 rpm; feed-rate 24, 56, 84, 196 mm/min; drill point angle 80, 100 and 120^{o} and externall irrigation with water of 26^{o}C.

Results Combinations of drill speed and drill diameter with the use of external irrigation produced temperatures far below critical. Without external irrigation, temperature values for the same combination of parameters ranged 31.4-55.5^{o}C. Temperatures above critical were recorded using 4.5 mm drill with higher drill speeds (1140 and 1820 rpm). There was no statistical significance of different drill point angles on the increase or decrease of bone temperature. The higher the feed-rate the lower the increase of bone temperature.

Conclusions The external irrigation is the most important cooling factor. With all combinations of parameters used, external irrigation maintained the bone temperature below 47^{o}C. The increase in drill diameter and drill speed caused increase in bone temperature. The changes in drill point angle did not show significant influence in the increase of the bone temperature. With the increase in feed-rate, increase in bone temperature is lower.

Keywords Thermal osteonecrosis, Bone drilling.

Introduction

Many orthopaedic procedures depend on the screw fixation of implanted devices to the bone. The compression fixation demands a high degree of stability of the fixating screws. Consequently, the loss of bone at the drilling site could negate any beneficial effects of this type of device. The implant failure rate for lower leg osteosynthesis is 2.1-7.1% [1-4]. One of the causes, not most important but present is the increase in bone resorption around the implanted screws from thermal osteonecrosis caused by preparative drilling [5,6]. This phenomenon is observed as ring sequestra on x-rays. The threshold for thermal osteonecrosis is 47^{o}C lasting for 1 minute [7]. In this experiment, the maximum temperature elevations were measured *in vitro*, on porcine femoral cortices while changing the drill speed, feed-rate, drill diameter, drill point angles and the use of external irrigation. These parameters were used in previous studies where all these parameters were not analyzed within same experiment [8-10]. The leading idea was that the analysis of all parameters together should diminish inter-observer errors and thus, provide the real impact of every parameter used on increase of bone temperature. Another reason was that, even in the single study, broad range of temperature values developed by specific parameter were presented. The goal of this experiment is to obtain optimal method, *in vitro*, that would maximally decrease the increase of bone temperature during drilling with all mentioned parameters.

Materials and methods

Cortical femoral specimens demonstrate large interspecies variations. The porcine and canine bones best resemble human samples [11]. For this experiment porcine femura were obtained immediately after the slaughter and used within few hours after the slaughter. In order to retain the mechanical and thermophysical properties, specimens not used within few hours were prepared according to the guidelines established by Sedlin and Hirsch; i.e., the specimens were kept moist in saline solution and stored in plastic bags at -10 ^{o}C [12]. If not used immediately, specimens prepared according to the Sedlin and Hirsch were used within 2 days after the slaughter. All specimens were collected from the same distributor and all animals were males 8-10 months old and 80-90 kg. The central part of the porcine femoral diaphyses of posterior legs in the length of 75 mm were used (Fig. 1). The cortical thickness was 4-5 mm. ASIF (Association for the Study of Internal Fixation, Davos Switzerland) 2.5 mm, 3.2 mm and 4.5 mm drills were used. The drill point angle was 100^{o}. For the purpose of this experiment, the drill point angle of 4.5 mm drill was further honed to 80^{o} and 120^{o}. Drill point angle is the angle included between the cutting lips projected upon a plane parallel to the drill axis and parallel to the two cutting lips. Smaller the angle more pointed (peaked) the drill point. The thermocouple was *Unitest Therm 100* with the range of -40 to 1200^{o}C with the reaction time under 0.1 second (Fig. 1). The maximum bone temperatures during the drilling were recorded. The standard distance between the drilling site and thermocouple site was 0.5 mm, and the depth in which thermocouple was placed in the cortical bone was 3 mm, as described in other studies [9,13,14]. All measurements were made on machine drill press ALG-100 (Prvomajska, Zagreb) with options of regulation of drill speed and feed-rate. Drill guide was hand-made with 4.5 mm holes for drills and distance between holes was 0.5 mm (Fig. 1). While drilling through one hole in the drill guide, the thermocouple was introduced into the adjacent hole. The complete process is shown in Figure 1. All measurements were made at room and bone temperature of 26 ^{o}C. The starting bone and drill temperatures are not significant factors and increase in bone and screw temperatures from room (26^{o}C) to body temperature (37^{o}C) do not change the properties of bone and do not influence the maximum temperature elevation during drilling [12]. The subsequent drilling was performed when bone and drill temperatures returned to room temperature (26^{o}C). All drills were used for 40 times before replaced with the new drills as recommended by Matthews and Hirsch [13]. The periosteum was reflected away from the point where the drill will enter the bone. This prevents the chips (being ejected from the hole) being forced under this tissue and clogging the flutes of the drill [15].

This study is presented in two parts.

In Part 1, influence of drill diameter, drill speed and external irrigation was analyzed. Drills of 2.5 mm, 3.2 mm and 4.5 mm with drill point angle of 100^{o} were used. Drill speed was 188, 462, 1140 and 1820 rpm. Feed-rate was set at 84 mm/min. This experiment was divided into two parts: measurements without external irrigation and with external irrigation with water of 26 ^{o}C as in other published experiments [8,13].

In Part 2, influence of drill point angle, feed-rate and drill speed were analyzed. Three different drill point angles (80, 100 and 120^{o}), four feed-rates (24, 56, 84 and 196 mm/min) and two drill speeds (1140 and 1820 rpm) were used with 4.5 mm drill. Specific combinations of feed-rates were used (84 and 24 mm/min and 196 and 56 mm/min) because in both combinations of feed-rate values, higher feed-rate value was 3.5 times higher than the lower feed-rate value for easier comparation.

Statistical analysis included several methods. First it must be stressed that the most rigorous criteria of thermal osteonecrosis (47°C) was used. Thus, not average but maximum temperature values were used as definitive results. These temperatures are expressed as upper limits of the $p = 0.05$ confidence interval (95% probability). Duncan's multiple range test was used for comparison of different combinations of parameters during drilling. Regression analysis was used to delineate the strength of relationship between specific parameters and the increase of bone temperature during drilling. Partial correlation (in the regression analysis) was used for determination of the correlation of two variables (drill parameters) while influencing of the third (bone temperature).

Results

Drill Diameter, Drill speed and External Irrigation

In this part, 2.5 mm, 3.2 mm and 4.5 mm drills were used with drill point angle of 100^{o}. Drill speed was 188, 462, 1440 and 1820 rpm. Feed-rate was set at 84 mm/min. This experiment was divided into two parts: measurements without external irrigation and with external irrigation (water at 26^{o}C). For every combination of parameters, 31 measurements were made and the results shown in the Table 1 and the box plot diagram (Fig. 2).

The most rigorous criteria was used to avoid any possibility of thermal osteonecrosis which means that the temperature threshold for thermal osteonecrosis is at 47°C. As the cut-off point for thermal osteonecrosis is defined, all the values of bone temperature, not their mean values must be below that temperature.

For every combination of drill speed and drill diameter during drilling, maximum temperature was far below critical (47^{o}C) with the use of external irrigation (range 29.9–33.9^{o}C). Without external irrigation, temperature values for the same combination of parameters ranged 31.4-55.5^{o}C.

Use of drill diameter (2.5 mm, 3.2 mm and 4.5 mm) was analyzed with constant drill speed set at 188, 462, 1140 and 1820 rpm. Without external irrigation, temperature ranges were: 31.4-41.5^{o}C for 2.5 mm drill; 33.4-44.8^{o}C for 3.2 mm drill and 36.9-55.5^{o}C for 4.5 mm drill. Temperature ranges with external irrigation were: 29.9-31.1^{o}C for 2.5 mm drill; 30.9-31.4^{o}C for 3.2 mm drill and 30.2-33.9^{o}C for 4.5 mm drill (Table 1). The measured temperatures were far below critical for all combinations of parameters with external irrigation. The temperature values without external irrigation are higher and values using 4.5 mm drill with higher drill speed (1140, 1820 rpm) were above critical level (50.9^{o}C and 55.5^{o}C respectively).

Drill speeds analyzed were 188, 462, 1140 and 1820 rpm with constant drill diameter (2.5 mm, 3.2 mm and 4.5 mm). The temperature range without external irrigation at 188 rpm was 31.4-36.9°C; at 462 rpm was 35.2-43.0°C; at 1140 rpm was 41.2-50.9°C and at 1820 rpm was 41.5-55.5°C. Higher drill speeds (1140 and 1820 rpm) with 4.5 mm drill developed temperatures above critical. Using external irrigation at 188 rpm, temperature range was 29.9-30.2°C; at 462 rpm was 30.1-31.9°C; at 1140 was 30.4-32.7°C and at 1820 was 31.1-33.9°C. All measured temperatures for all drill speeds used, using external irrigation, were below critical level.

The regression analysis showed a high degree of correlation (R = 0.91) between increase in drill speed and drill diameter and increase in bone temperature during drilling without external irrigation. The partial correlation showed also high influence of both parameters. Drill speed had a higher influence $R(s)_{part} = 0.87$, than drill diameter $R(d)_{part} = 0.77$. Using external irrigation the degrees of correlation were lower. Correlation was R = 0.71, and partial correlation for both parameters were the same: $R(s)_{part} = R(d)_{part} = 0.57$ (Table 2).

Drill Point Angle and Feed-Rate

In this section, the influence of drill point angle and feed-rate on the increase in bone temperature during drilling with 4.5 mm drill was studied. Three different drill point angles (80, 100 and 120°), four feed-rates (24, 56, 84 and 196 mm/min) and two drill speeds (1140 and 1820 rpm) were used. The biggest drill diameter at higher drill speeds were used because these combinations of parameters caused increase of bone temperature above critical in the first part. These measurements were made without external irrigation. For every combination of parameters, 9 measurements were conducted (Table 3).

For combination of drill speed set at 1140 rpm and different drill point angles (80, 100 and 120°), feed-rates at 24 and 84 mm/min (Table 3), the measured temperatures were: 56.2°C and 49.8°C (drill point angle 80°); 58.4°C and 53.8°C (drill point angle 100°); 54.4°C and 50.3°C (drill point angle 120°). Another combination of parameters included drill speed set at 1820 rpm and feed-rates at 56 and 196 mm/min. The obtained values were: 59.0°C and 55.2°C (drill point angle 80°); 58.4°C and 56.9°C (drill point angle 100°); 60.9°C and 52.0°C (drill point angle 120°).

The influence of drill point angle on the increase in bone temperature was analyzed in four measurement groups (Table 3). The obtained temperature range was 49.8-60.9°C. Statistical analysis ($p < 0.05$) did not show statistical significance of different drill point angles on the increase or decrease of bone temperature (Fig. 3). All measured temperatures obtained were above critical for all combinations of parameters.

The absolute values of bone temperatures were 1.5-9°C lower for higher feed-rates used. The influence of feed-rate on the level of increase in bone temperature exists and is significant ($p < 0.05$) for given combination of parameters, but still all temperatures were above critical (49.8-60.9°C).

Discussion

During drilling, the resistance of compact cortical bone causes increase of bone temperature. The main cause for increase in bone temperature is frictional heat [10,16,17] which can result in thermal bone necrosis. Determining the specific thermal damage threshold for living bone tissue is a rather complex problem. The cellular death caused by heat is immediately evident with temperatures above 70°C [7,18]. Others found that 50°C caused irreversible cortical bone necrosis. Lundskog conducted one of the few thorough studies on thermal damage to living bone tissue. He performed biomechanical, histochemic and morphologic studies on rabbit tissue. He demonstrated that the threshold for irreversible enzymatic disturbance to cortical bone is 50 ^{o}C during 30 seconds [20]. Bonfield and Li reported irreversible bond weakening of the bone-collagen hydroxyapatite complex at 50°C [19]. On the other hand, Eriksson and Albrektsson found that the minimum critical temperature for delayed death of osteocytes, not seen until three weeks or more after the injury, is much less and around 47°C. The exposure to temperature of 47°C for one minute causes bone resorption and subsequent replacement also disturbs the middle- and long-term anchorage of implants [21]. They constructed optical thermal chambers for *in situ* microscopy. The thermal chamber method makes it possible to follow the 'true' tissue reactions after a defined heat trauma by repeated light microscopic observations of the same bone specimen for an indefinite follow-up period.

[19,20].

The most rigorous criteria to avoid any possibility of thermal osteonecrosis with temperature threshold for thermal osteonecrosis of 47°C was used in this study. Newer surgical instruments have integrated sensors to sense actual temperature. Thus, the MicroAire console automatically shuts off its power as the temperature increases to 43°C [22]. Apart from the thermal damage, additional problems arise in bone drilling. The difficulties in maintaining a freehand control of the drill even when using a drill guide in attaining geometrical accuracy in the hole size and location were observed. When the drill bit begins to enter the bone surface, it tends to „walk“ or slip on the bone surface [23,24]. The goal of this study and that of every orthopaedic surgeon is to build a robotic system that will control these parameters. The procedure would then minimize the technical errors despite the clinical condition of a patient and the type of the fracture [25].

In this experimental study, the influences of drill diameter, drill speed, external irrigation, drill point angle and feed-rate on the increase of bone temperature were analyzed.

The goal was to find optimal combination of these parameters in order to minimize the increase of bone temperature during drilling with standard *Synthes* (AO/ASIF) drills.

Since the critical temperature for thermal osteonecrosis is the most rigorously defined to be 47^{o}C, all the values of bone temperature, not their mean values, must be below that critical level. That is the reason why all the temperature values are expressed as upper limits of the $p = 0.05$ confidence interval (95% probability).

Influence of Drill Diameter, Drill Speed and External Irrigation

From the data obtained, external irrigation (water at 26^{o}C) is the single, most important factor in decreasing the increase in bone temperature during drilling. For every combination of drill speed and drill diameter during drilling, maximum temperature was far below critical. There are three mechanisms that contribute to the lowering of bone temperature during drilling: 1) irrigant (water) directly lowers bone temperature by conduction; 2) irrigant eliminates bone chips which contribute to increased friction and 3) it lubricates drills and thus lowers friction [13,15,26,27]. Influence of internal irrigation was also investigated [28], but recent experiments in dentistry show no difference between internal and external irrigation [29].

The influence of drill diameter was analyzed at a constant drill speed. The results show that the increase in bone temperature increases with the increase in drill speed with and without external irrigation. The bone temperatures obtained during drilling with 2.5 and 3.2 mm drills, using all drill speeds, were found to be below critical level. Therefore, these smaller drills could be used without external irrigation. Higher drill speeds (1140 and 1820 rpm), using 4.5 mm drill without external irrigation developed temperatures above critical level. And therefore, external irrigation using 4.5 mm drill is mandatory. With external irrigation, the increase in drill diameter also causes the increase in bone temperature, but temperature levels were much lower. Absolute values are 10^{o}C to 22^{o}C lower than without external irrigation (Fig. 2). All measured temperatures for all drill diameters were far below critical. The problem in this setting is that drill diameter cannot be changed because the use of drill diameter depends upon the magnitude of forces that act upon a specific bone. To eliminate this problem the process of pre-drilling with smaller drills can be introduced [30]. Clinical observation is that this process significantly increases the operative time and that sometimes it is impossible to make larger holes with subsequent drilling in the same direction. This can also result in subsequent loosening of the fixating screws.

With the increase in drill speed (with constant drill diameter), there is a statistically significant difference in the increase of bone temperature during drilling as in other studies [13,30]. Comparatively, drill speed has higher influence on increase of bone temperature than drill diameter. At lower drill speeds (188, 462 rpm), bone temperature did not attain critical temperature even without external irrigation. Use of higher drill speeds (1140 and 1820 rpm) with 4.5 mm drill, without external irrigation, caused increase in bone temperature above critical level. Therefore, as previously stated, it is mandatory to use external irrigation when higher drill speeds are used with larger drills.

High degree of correlation ($R = 0.91$) between increase in drill speed and drill diameter and increase in bone temperature during drilling was documented with high partial correlations: $R(s)_{part} = 0.87$, than drill diameter $R(d)_{part} = 0.77$. Results obtained with external irrigation showed lower degrees of correlation and partial correlation ($R = 0.71$, $R(s)_{part} = R(d)_{part} = 0.57$). Correlations indicate high influence of drill diameter and drill speed on increase in bone temperature, higher without external irrigation.

Some relevant studies came up with different conclusions with optimum drill speed of 750-1250 rpm when the bone temperature was below threshold level of tissue damage [15,31]. Another problem that has not been stressed sufficiently is the difference between free-running speed and drill speed during drilling (operating speed). At very high-speed rates of 20,000-100,000 rpm operating speed may be as much as 50% below the free-running speed

[8]. This 50% reduction is comparable to the 40% reduction reported by Sorenson et al. for an air-turbine hand-piece [32]. Machine drill press ALG-100 that we used, maintains operating speed at the same level as the free-running speed. This topic was not addressed in previous experiments and could be one of the explanations for the reporting of different results.

Influence of Drill Point Angle and Feed-Rate

The ideal point angle depends on the material being drilled and the ideal point angle for bone is yet to be determined. The drill used was 4.5 mm because the results of the first part showed that 4.5 mm drill at higher drill speeds (1140 and 1820 rpm) without external irrigation caused increase in bone temperature above critical.

Results using drill point angle of 80, 100 and 120^o did not show significant difference on the increase in bone temperature during drilling. The more important observation other than statistical significance was that all measured temperatures were far above critical. Drill point angle as isolated parameter could not lower the increase of bone temperature below critical using 4.5 mm drill. (Fig. 3, Table 3). The same conclusion was recently published [33]. In contrast, Wiggins and Malkin found the ideal drill point angle to be 118^o [34].

In our preliminary experiment, the drill point angle of 60^o was also used. The problem was 'walking' on the bone surface of the 60^o drill and it was found that the drill hole was ellipsoidal and not circular. After drilling ellipsoidal hole, the screw could not be inserted in the bone and the drill point angle of 60^o was excluded from the experiment. Wiggins and Malkin analyzed the influence of drill point angle on bone temperature. They did not notice this phenomenon of drill walking during the experiment with 60^o point angle [34].

Influence of feed-rate on the increase in bone temperature was also studied. The absolute temperature values point out that the increase in feed-rate causes a significantly lesser increase in the bone temperature (1.5-9°C), the results also obtained by Toews [35]. The second important observation is that for 4.5 mm drill, all feed-rates used caused increase in bone temperature above critical. From the data obtained, higher feed-rate causes lower increase in the bone temperature but for the defined combination of parameters it is not clinically applicable as an isolated parameter. Feed-rate must be used with other factors that lower bone temperature such as external irrigation or lower drill speed. Also, it must be pointed out that the higher feed-rate causes shorter drilling time and subsequently shorter period of increased bone temperature [34].

The present analysis has several limitations. None of the animal models is similar to the human situation for all examined parameters. Some animals, however, more closely resemble humans than others. In particular, with regard to bone density and quality parameters of the lumbar spine, humans appear to be very different from the other species examined. Based on a combination of all the parameters the characteristics of human bone are best approximated by the properties of dog and pig bone [11].

It should also be kept in mind that these experimental results were obtained *in vitro,* under conditions that differ from clinical situations: the bone specimens were porcine and there was no blood flow and therefore, no heat transfer by convection to cool and hydrate the specimens [36]. These results could be somewhat different with the same combinations of parameters during drilling in human traumatology and orthopaedics.

In summary, many parameters have influence on the increase in bone temperature during drilling. External irrigation is the single, most important factor in decreasing the increase in bone temperature during drilling and must be used for bone drilling. Simply put, the optimal method for decreasing the increase in bone temperature during drilling is: use smaller drill diameters (if possible) with lower drill speed and higher feed-rates. External irrigation is MANDATORY!

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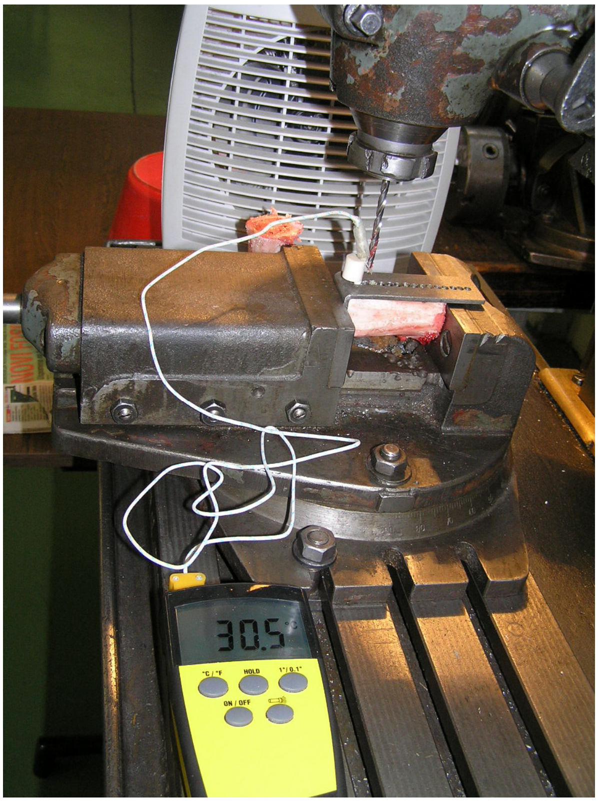

Fig. 1 Complete process of bone drilling and bone temperature measurement. Porcine femoral diaphyses of posterior legs in the length of 75 mm were used. The maximum bone temperatures during drilling were measured with the thermocouple. The standard distance between drilling site and thermocouple site was 0.5 mm, and the depth in which thermocouple was placed in the cortical bone was 3 mm. All measurements were made on machine drill press ALG-100 with options of regulation of drill speed and feed-rate. Drill guide was hand-made with 4.5 mm holes for drills and distance between holes was 0.5 mm. While drilling through one hole in the drill guide, the thermocouple was introduced into the adjacent hole

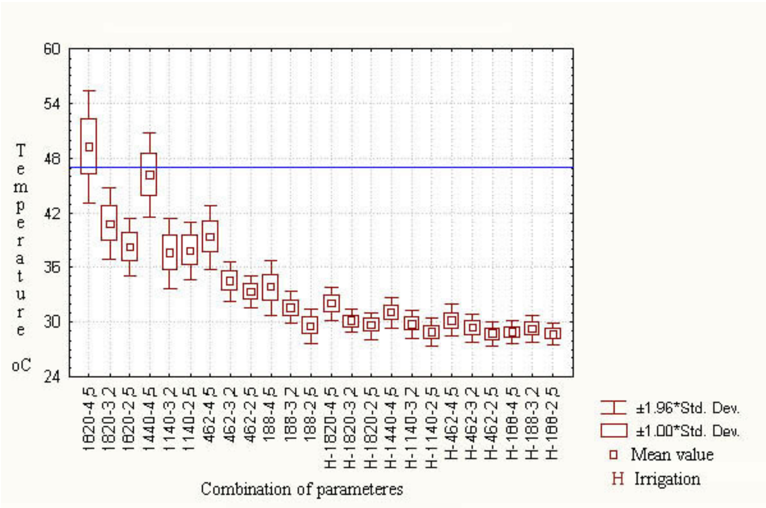

Fig. 2 Box plot of maximum bone temperatures of different combinations of bone drilling parameters with and without external irrigation, (line represents temperature of 47^{o}C that causes thermal osteonecrosis). The first number on the x-axis represents the drill speed (rpm) and the second one, drill diameter (mm)

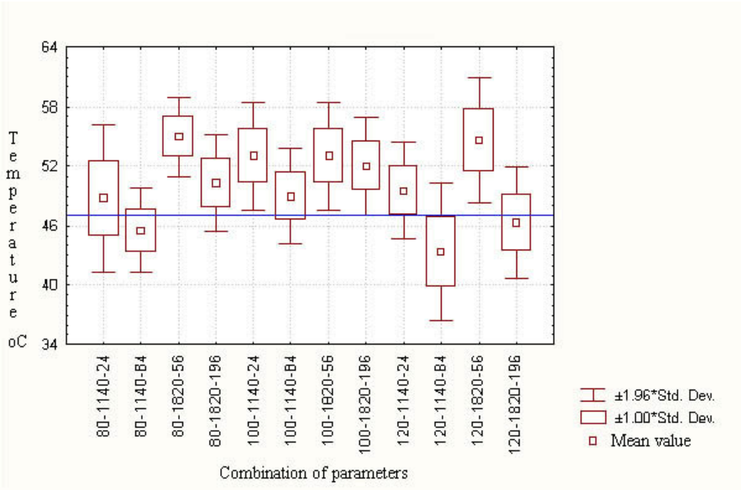

Fig. 3 Box plot presentation of results using different drill point angles and feed-rates on the increase of bone temperature (line represents temperature of 47^{o}C that causes thermal osteonecrosis). The first one on the x-axis represents drill point angle, the second one drill speed (rpm) and the third one feed-rate (mm/min)

Table 1 Descriptive statistics for variable maximum bone temperature in °C (with and without external irrigation) with different combinations of parameters

Drill diameter (mm)	Statistics	Drill speed (rpm)			
		1820	1140	462	188
4.5	M ± SD	49.2 ± 3.1	46.2 ± 2.4	39.4 ± 1.8	33.8 ± 1.5
	$p = 0.05$	**55.5**	**50.9**	**43.0**	**36.9**
3.2	M ± SD	40.8 ± 2.0	37.6 ± 1.9	34.5 ± 1.2	31.6 ± 0.9
	$p = 0.05$	**44.8**	**41.5**	**36.8**	**33.4**
2.5	M ± SD	38.3 ± 1.6	37.8 ± 1.7	33.4 ± 0.9	29.5 ± 1.0
	$P = 0.05$	**41.5**	**41.2**	**35.2**	**31.4**
4.5-H	M ± SD	32.0 ± 1.0	31.0 ± 0.8	30.2 ± 0.9	28.9 ± 0.7
	$p = 0.05$	**33.9**	**32.7**	**31.9**	**30.2**
3.2-H	M ± SD	30.1 ± 0.7	29.8 ± 0.8	29.3 ± 0.8	29.3 ± 0.8
	$p = 0.05$	**31.4**	**31.4**	**31.0**	**30.9**
2.5-H	M ± SD	29.6 ± 0.8	28.8 ± 0.8	28.7 ± 0.7	28.7 ± 0.6
	$p = 0.05$	**31.1**	**30.4**	**30.1**	**29.9**

H, External irrigation, M, Mean value, SD, Standard Deviation, rpm, rounds per minute

Table 2 Multiple variants of regression analysis of influence on bone temperature using *Statistica 6.0*

	Without external irrigation		With external irrigation	
	Partial corr.	*p* value	Partial corr.	*p* value
Drill speed	0.8721	0.0000	0.5723	0.0000
Drill diameter	0.7777	0.0000	0.5759	0.0000
Correlation	R= 0.9120		R= 0.7134	

R, correlation

Table 3 Descriptive statistics for variable bone temperature in ^{o}C (without external irrigation) with different combinations of parameters

Drill point angle - drill speed – feed-rate	**M ± SD**	***p* = 0.05***
80-1140-24	48.8 ± 3.8	56.2
80-1140-84	45.6 ± 2.2	49.8
80-1820-56	55.0 ± 2.1	59.0
80-1820-196	50.3 ± 2.5	55.2
100-1140-24	53.0 ± 2.7	58.4
100-1140-84	49.0 ± 2.5	53.8
100-1820-56	53.0 ± 2.7	58.4
100-1820-196	52.0 ± 2.5	56.9
120-1140-24	49.6 ± 2.5	54.4
120-1140-84	43.3 ± 3.5	50.3
120-1820-56	54.7 ± 3.2	60.9
120-1820-196	46.3 ± 2.9	52.0

M, Middle value, SD, Standard Deviation
*As cut-of point was 47^{o}C all measured values (p=0.05) must be below this threshold not just mean values