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**Title: Temperature changes during drilling cortical bone with newly designed step drill and internally cooled drill**

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## **Abstract**

*Purpose* Bone drilling causes increase in bone temperature and the level above 47°C is critical and causes thermal bone necrosis. Thermal osteonecrosis is common with the drill diameter of  $\geq 4.5$  mm without cooling. The aim of this study is to determine the increase of bone temperature during drilling with the use of newly constructed two-step and internally cooled drills.

*Methods* Experiment was made according to central composite design. Internally cooled drill (3.4 mm and 4.5 mm) and two-step drill (2.5/3.4 and 3.4/4.5 mm) were used in combination with feed (0.02, 0.04, 0.10, 0.16 and 0.18 mm/rev) and cutting speed (1.18, 10.68, 33.61, 56.55 and 66.05 m/min) with and without cooling with water of 24°C. Bone temperatures were measured with thermocouple. Drillings were performed on pig diaphyses with 3-axis mini milling machine.

*Results* Bone temperatures of all combinations of parameters with internal cooling were below critical 47°C ( $p=0.05$ ). Highest temperatures were detected using 4.5 mm drill (40.5°C). Statistically significant effect other than cooling was found with the drill diameter and feed. Drill diameter of 3.4 mm with internal cooling developed maximum temperature of 38.5°C and without cooling 46.3°C. For the same conditions drill with diameter of 4.5 mm obtained temperatures 40.5°C and 55.7°C respectively. Effect of feed is inversely proportional to the increase in bone temperature. With the feed rate 0.16 mm/rev temperature was below critical even using the 4.5 mm drill (46.4°C,  $p=0.05$ ). Using the 3.4 mm drill all temperatures were below critical (46.2°C,  $p=0.05$ ). Two-step drill compared to standard drill with the same diameter did not show statistical differences in maximum bone temperatures with all combinations of parameters ( $p=0.05$ ).

*Conclusions* Two-step drill does not have any advantages over standard twist drill of the same diameter. Internally cooled drill causes significantly smaller increase of bone temperatures

during drilling with water of 24°C. Internally cooled drill is currently 'ideal' drill in traumatology/orthopedics because it produces the smallest increase in bone drilling temperature. If internal cooling is used the regulation of other drilling parameters is of no importance.

**Keywords:** Internally cooled drill, Step drill, Bone temperature, Thermal Osteonecrosis,

Bone drilling

## **Introduction**

Drills are used as a common step in operative fracture treatment and reconstructive orthopaedic surgery. The heat generated from the metal – bone interface during drilling due to the friction could cause thermal osteonecrosis. The lowest temperature threshold for thermal osteonecrosis is 47°C for 1 min [1].

The most important drill and drilling parameters on bone temperature rise are: drilling depth, drill flute geometry and design [2], sharpness of the cutting tool [3, 4], variations in cortical thickness [5], bone density [6], drilling speed, axial force – pressure applied to the drill [3], use of graduated versus onestep drilling [7, 8], irrigation [9, 10], equipment [11], torque and thrust forces [12]. Most could be varied, but some, such as drill diameter, depend on the biomechanics of specific bone. The drill diameter of 4.5 mm causes the highest increase in bone temperature commonly over critical of 47°C [9].

The aim of this study was to investigate the bone temperature increase using newly designed spiral drills: (two) step drill and open type of internally cooled drill with the aim to lower the bone temperature below critical even with 4.5 mm drill.

## **Methods**

### *Experimental setup*

Porcine femura best resemble human samples [13] and were used immediately or within few hours after the slaughter. To retain the mechanical and thermo-physical properties, specimens not used within few hours were prepared according to Sedlin and Hirsch [14], i.e., the

specimens were kept moist in saline solution and stored in plastic bags at  $-10^{\circ}\text{C}$  and used within 2 days after the slaughter. All specimens were males 8 – 10 months old and 80 – 90 kg of weight. Femoral diaphyses of posterior legs in the length of 75 mm were used with the cortical thickness of 4 – 5 mm. The periosteum was reflected away preventing the chips being forced under this tissue and clogging the flutes of the drill [12]. Measurements were made on 3-axis mini milling machine *Flexmatic FA 530 S* enclosed in thermally isolated chamber with air and bone temperature maintained at  $37^{\circ}\text{C}$  with the heater *Budget FH 2000* and temperature regulator *Omron E5CS-X*. Temperature was measured with the thermocouples *Unitest Therm 100* (range  $-40$  to  $1,200^{\circ}\text{C}$ , reaction time under 0.1 s and accuracy of  $0.1^{\circ}\text{C}$ ). The distance between the drilling and thermocouple site was 0.5 mm, and the depth of thermocouple of 3 mm [3, 9, 15, 16]. Other two thermocouples were near the drilling site and 50 cm from the drilling site and connected to data acquisition modular station *National Instruments NI SCXI-1000 DC*. The software programmed in *LabView* had instructions that subsequent drilling could not start until bone temperature is between  $36.5 - 38^{\circ}\text{C}$  and air temperature between  $35 - 39^{\circ}\text{C}$  in both thermocouples. The cortical temperature was recorded during complete process of every drilling. Therefore initial bone temperature, maximum bone temperature and time that the temperature was greater than  $47^{\circ}\text{C}$ , were recorded. Cooling system consisted of cooling fluid reservoir with water of  $24^{\circ}\text{C}$ , motor pump, laboratory voltage source *Labornetzgerät DF-1730B* and a tube connected to a rotor of a main spindle with possibility of cooling through the tool. Cooling fluid flow was low and constant ( $0.1 \text{ dcl/min} = 0.16 \text{ cm}^3/\text{s}$ ). The complete process is shown on Fig. 1 and developed software on Fig. 2.

Drills tip wear (cutting lips wear) was analyzed using macro photography after every 45 drillings of each drill (*Olympus E-330*, *Zuiko Digital 35mm 1:3.5 Macro*, *Olympus Macro Flash FS-RF11*).

### *Determination of the drill and drilling parameters*

According to the 3-level central composite design there were 5 values of feed (0.02, 0.04, 0.10, 0.16, and 0.18 mm/rev) and cutting speed (1.18, 10.68, 33.61, 56.55 and 66.05 m/min). Drill diameter of 4.5 mm was used causing highest bone temperatures in previous studies [9]. Other drill diameter was 3.4 mm. Two spiral two-step drills have larger diameters the same as the standard spiral drills (2.5/3.4 mm and 3.4/4.5 mm). Drills were made of hard metal – Tungsten Cobalt Carbide (*TM, Čakovec*) with two spiral channels through the drill with openings on the drill tip (Fig. 3). Drillings were made with and without internal cooling of open type with water of 24°C.

### *Statistical analysis*

Due to cut-off temperature of 47°C maximum temperature values were analyzed ( $p = 0.05$ ) using licenced *Statistica 6.1 (StatSoft)*. Duncan's multiple range test was used for comparison of different combinations of parameters. Regression analysis was used to delineate the strength of relationship between specific parameters and the increase of bone temperature. Partial correlation was used for determination of the correlation of two variables (drill parameters) while influencing of the third (bone temperature). Regression analysis was used for correlation between the maximum temperature during single drilling and time period of bone temperature above 47°C.

## Results

At  $p = 0.05$  internal cooling is the most influential parameter ( $F = 1626.3$ ), followed by significantly smaller influence of the drill diameter ( $F = 15.30$ ) and feed ( $F = 8.87$ ). Influence of other parameters was not significant ( $p > 0.10$ ) (Table 1).

Using internal cooling, maximum temperatures for all combinations of parameters using all drills were well below  $47^{\circ}\text{C}$  ( $39.5^{\circ}\text{C}$ ;  $p = 0.05$ ) (Table 2). Developed temperatures were equable and near starting bone temperature ( $38.1 - 40.5^{\circ}\text{C}$ ) despite the influence of other parameters (Table 3).

Drill diameter is the second most influential parameter (Table 1). Drills with smaller diameter (3.4 and 2.5/3.4 mm) developed lower bone temperatures ( $46.9$  and  $47.8^{\circ}\text{C}$ ) in comparison to larger diameter (4.5 and 3.4/4.5 mm) drills ( $54.0$  and  $53.3^{\circ}\text{C}$ ) (Table 2). The only combinations of drilling parameters for larger diameter drills generating temperatures below critical included feed  $0.16$  mm/rev (Table 3). Duncan test confirmed significant difference on bone temperature between drills with smaller and larger diameters, while there was no difference between different drill bit geometries of the same drill diameter.

Decline of increase in bone temperature is found with the increase in feed. The lowest bone temperatures were with feed of  $0.16$  mm/rev ( $46.4^{\circ}\text{C}$ ), and the highest ( $58.7^{\circ}\text{C}$ ) with the lowest feed of  $0.02$  mm/rev,  $p = 0.05$  (Table 2). Duncan test confirmed that bone temperature is significantly different between feed of  $0.02$  mm/rev and all higher values and feed of  $0.04$  mm/rev and other higher values. There was no significant difference between feed of  $0.10$ ,  $0.16$  and  $0.18$  mm/rev.

Cutting speed ( $1.18 - 66.05$  m/min) has no significant influence on bone temperature in combination of drill and drilling parameters used ( $p > 0.05$ ) (Table 1) generating bone

temperatures in narrow interval (49.5 - 52.8°C;  $p = 0.05$ ) (Table 2). Duncan test shows that there is no significant difference between any pair of cutting speed values.

Drill geometry (standard spiral and two-step spiral drills) has no significant influence on increase in bone temperature using the same drill diameters (Table 1 and 2), and also separately with and without cooling. In the cooling group bone temperatures were well below critical for both standard spiral and two-step spiral drills (39.8 and 39.1°C;  $p = 0.05$ ) (Table 3). Without cooling, bone temperatures including both drill geometries and diameters were above critical (52.9 and 52.5°C;  $p = 0.05$ ) (Table 3).

Regression analysis showed significant correlation between maximum bone temperature (over 47°C) and duration of bone temperature above 47°C ( $p < 0.05$ ). According to 95% prediction interval bone temperature of 47°C will last (mean value) for 11 seconds (39 seconds with 95% of upper confidence interval). Bone temperature of 50°C will persist above 47°C for mean of 21 seconds (50 seconds with 95% of upper confidence interval) (Fig.4)

Drills tip wear (cutting lips wear) analyzed using macro photography did not reveal even the slightest wear after 180 drillings (Fig. 5).

## **Discussion**

The drill bit is a complex tool whose various elements allow efficient penetration through bone but still with unavoidable side-effect of generating heat. Heat causes increase in bone temperature and values over 47°C for 1 minute cause thermal osteonecrosis [1]. This leads to loosening of screws and implants further causing implant failure and/or refractures. Therefore, optimization of cutting parameters is necessary for minimizing the increase in bone temperature [17].

Newly constructed carbide spiral drills with channels through the drill and two-step drills with channels were analyzed. Despite different geometry influence of drill and drilling parameters confirm the results from previous studies. Drill diameter of 4.5 mm is critical causing temperatures over 47°C [9]. Only combinations with feed of 0.16 mm/rev caused temperatures below critical. Therefore if this feed cannot be obtained, irrigation of 4.5 mm drill is mandatory. Also if such feed cannot be obtained, the highest possible should be used. The same recommendation is for 3.4/4.5 mm drill. Bone temperatures using smaller diameter drills (3.4 mm and 2.5/3.4 mm) with higher feed (0.10 - 0.18 mm/rev) are below critical. Lower feed means higher total amount of bone cuttings (more layers cut). Cutting of every layer causes friction with more heat generation and higher increase in bone temperature. Carbide drill is extremely hard and bone as material has not significant resistance to cutting. Therefore a lower total number of cuttings are necessary to form a bore. For other drill materials experiments are needed to define the relationship between feed and increase in bone temperature because this is drill material dependent.

Drill bit of carbide drills, with every cutting speed, efficiently cuts the layers of bone causing the same heat generation and the same increase of bone temperature. Inefficient cutting is present when extremely low cutting speed is combined with extremely high feed. These combinations used in this study are extremes not applicable in clinical practice.

The result for discussion is that using both drill geometries and drill diameters the bone temperatures increase using feed of 0.18 mm/rev. Feed of 0.18 mm/rev is extremely high and currently not applicable in clinical practice. One of explanations is that axial drill motion is higher than effective cutting of bone layers making the drilling less efficient. Therefore the chips are not removed by cutting but by bone tearing and hole is created by cutting and by pushing the material. These processes cause increased friction with more heat generation and higher increase in bone temperature. During experimental setup with the use of very high feed

and very low cutting speed some of the bones broke or the specimen moved or was even pushed from the clamping tool confirming inefficient drilling.

Currently external irrigation is single, most important parameter that minimizes the increase in bone temperature and when used all other drill and drilling parameters are of minor importance [9]. Currently there are no studies comparing external and internal irrigation in orthopedics/traumatology. Such experiments in dentistry due to significantly different drills and drilling parameters cannot be translated to orthopedics/traumatology practice. Stomatology drills have diameters less than 3 mm (such drills in orthopedics/traumatology do not cause temperatures above critical of 47°C [9] and drill speed is up to 300.000 rpm (drill speed in orthopedics/traumatology is less than 4000 rpm). Internally cooled drills of open type were introduced to dental surgery in 1975 [18]. Dental articles did not find significant difference between internal and external irrigation [19]. It is partly explained by the fact that maximal temperatures are on the most superficial part of bone due to elimination of heated bone chips exiting the drilling canal [10].

One of the aims of this study was to find out if internal irrigation of open type is technically feasible for use in orthopedics/traumatology. There are several advantages over external irrigation: a) direct lowering of bone temperature on the cutting surface; b) lubrication of the cutting surface lowering the friction and heat generation; c) higher efficacy of bone chips elimination due to backflow of the coolant through the flutes which have the highest temperature and which could also obstruct the flutes causing more heat generation and longer duration of increased bone temperature; d) lesser amount of cooling fluid delivered but more efficiently. Irrigation with water temperature of 24°C was used for comparison with previous studies. Absolute value of cooling fluid is not the most important because range of 10 - 25°C does not cause significant changes in maximum bone temperature (although lower irrigation temperatures cause lower absolute bone temperatures on superficial parts of the

bone) [10]. In our study cooling fluid flow was low ( $0.1 \text{ dcl/min} = 0.16 \text{ cm}^3/\text{s}$ ) with pressures near zero without causing damage to surrounding bone and medullar cavity and without significant spread over surrounding structures with lower probability of droplets to bounce from sterile structures back to the sterile operative field. Using external irrigation only part of the drill outside the bone is cooled directly and due to rotation and centrifugal force droplets are expelled to surrounding tissues. This results in: a) higher amount of cooling fluid consumed during the same time interval; b) part of the drill in the bone could be cooled only indirectly with lower decrease of bone temperature at the cutting lips; c) higher probability of sterility of operative field due to bouncing of droplets.

For orthopedic/traumatologic use open type of internal irrigation is the most efficient parameter for lowering the increase in bone temperature. With its use combination of other drill and drilling parameters is of no importance and any of these could be used.

Another aim was to find out does combined effect of predrilling in only one drilling has significant advantages. Predrilling caused smaller increase in bone temperature up to 50% [2]. Accordingly, two-step spiral drills made of hard metal – Tungsten Cobalt Carbide were constructed to eliminate two drillings as in the predrilling. Hard metal is chosen to eliminate drill bit wear which could influence the increase in bone temperature. Smaller diameter of the two-step drill was 2 mm long without the possibility of injury of surrounding structures when exiting trans-cortex. Hypothetical advantage of a single drilling for minimization of the increase of bone temperature was not found. Standard 2-fluted spiral drill and 2-fluted two-step drill (the same drill geometry) developed the same bone temperature when using the same combination of other drill and drilling parameters. The mechanism is manifold. During predrilling smaller diameter drill performs complete penetration through cortex. First, bone chips are eliminated throughout complete length of drilling path. Second, during replacement with larger diameter drill, the time is consumed (around 30 sec) and in this study the bone

temperature is lowered for 3°C when drilling without irrigation during that period. Third, larger diameter drill used in predrilling is at room temperature (20 - 24°C). During drilling with two-step drill transition from smaller to larger diameter is from a tenth of a second to second (depending on the drilling parameters). In such short period the bone temperature cannot be lowered as in predrilling. Also further drilling is performed with the same drill that has the same temperature as bone, not the room temperature. The result is higher bone temperature with two-step drill in comparison with incremental drilling during predrilling. Further the whole cortical channel should be drilled with both smaller and larger diameter of the drill which results in longer length of the drilling. The additional length consists of the length of smaller diameter plus transitional zone to larger diameter of the drill. Currently there is only one study published about three-step drill showing similar results with step drill and sequential drilling with increasing drill diameters [20]. We agree that step drill is a viable alternative to sequential drilling but contrary to authors' conclusion we could not recommend their three step drill in human drilling because every step of their drill is 2 cm long thus to drill trans-cortex with the largest diameter the drill should be outside the cortex about 4 cm causing surrounding tissue trauma.

The third important conclusion of this study is relation of maximum bone temperature and the period of that increase temperature over critical. Thermal damage to bone is the combined result of the temperature and the duration of elevated temperature. The bone temperature of 47°C last for mean of 11 seconds before decreasing to lower temperatures. The more important is that the bone temperature of 50°C will persist above 47°C for mean of 21 seconds but 95% of results will be around 50 seconds. From the definition of thermal osteonecrosis (47°C lasting for one minute) the temperature of 50°C should never be accomplished as a safe margin for avoiding thermal osteonecrosis during drilling.

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## **Conflict of interest**

None.

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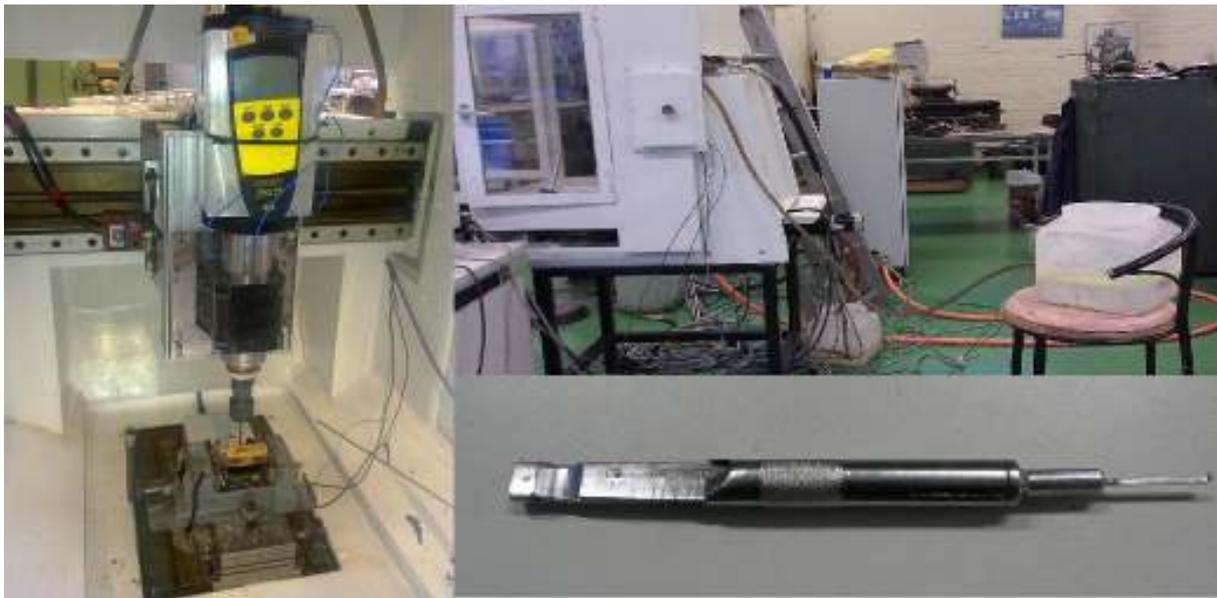
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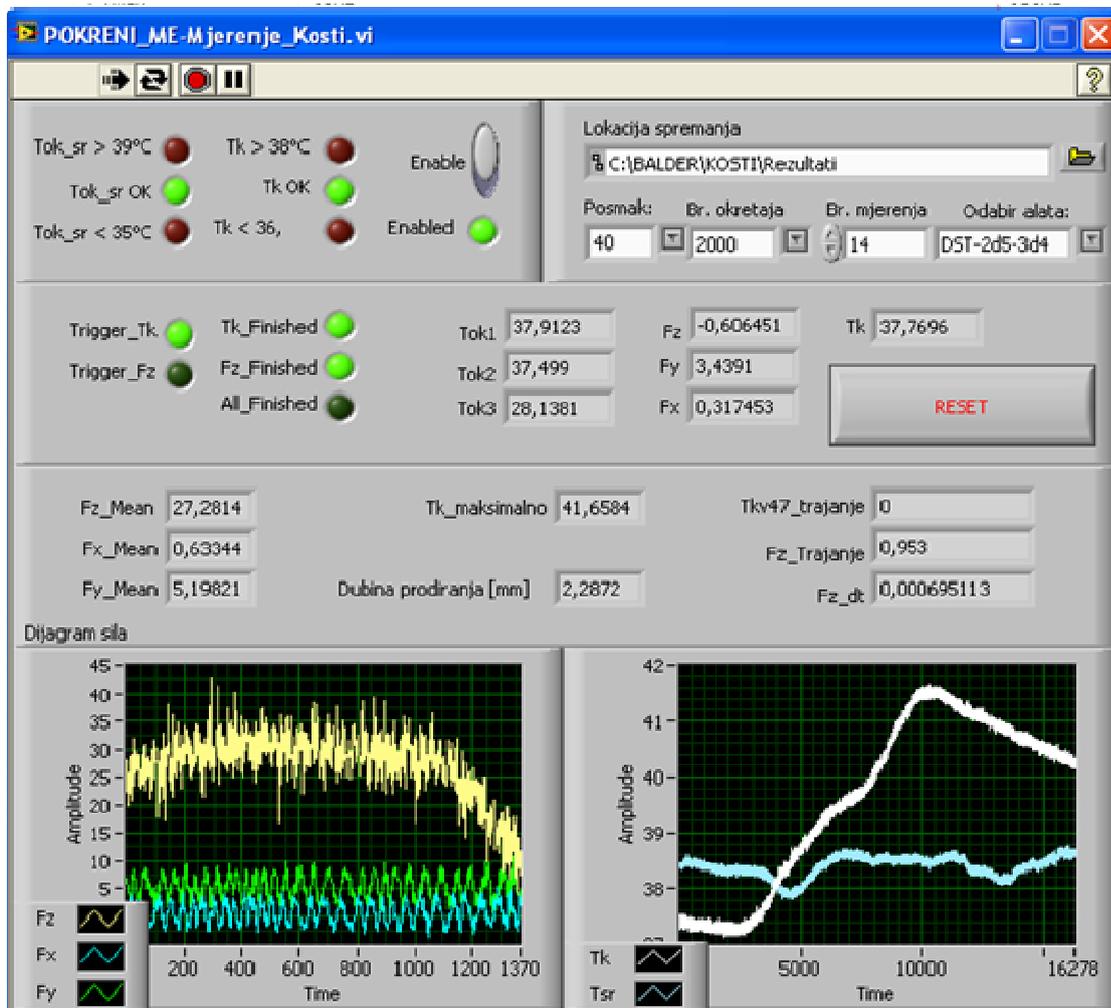
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## FIGURE LEGENDS

**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 with the distance between drilling site and thermocouple site of 0.5 mm. All measurements were made on 3-axis mini milling machine *Flexmatic FA 530 S* enclosed in thermally isolated chamber where the air and bone temperature was maintained at 37°C. Cooling fluid of water of 24°C went through the tool. Cortical thickness was measured with depth gauge for screws (*Synthes, Switzerland*)



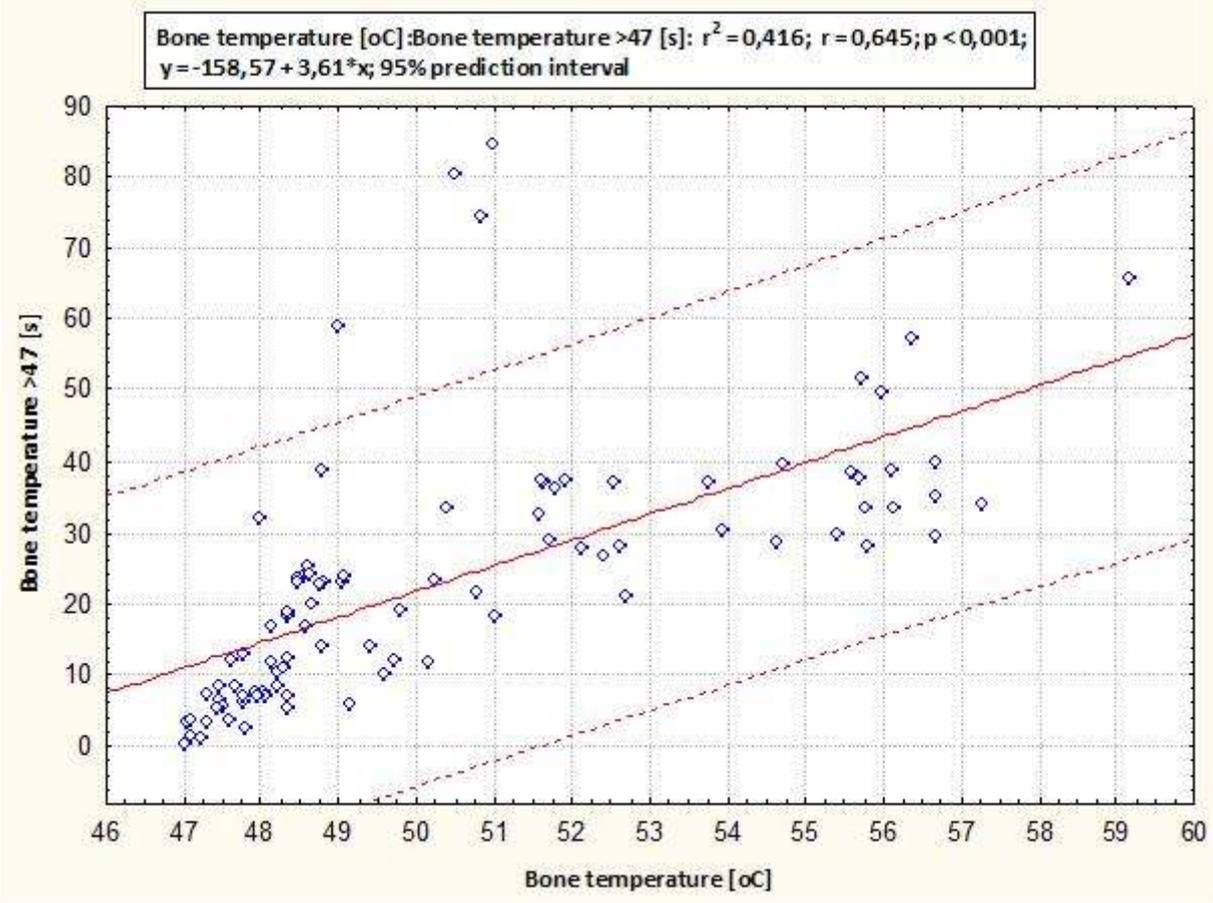
**Fig. 2** Specific software developed and programmed in *LabView* providing equal and standardized conditions for every drilling (see text for details)



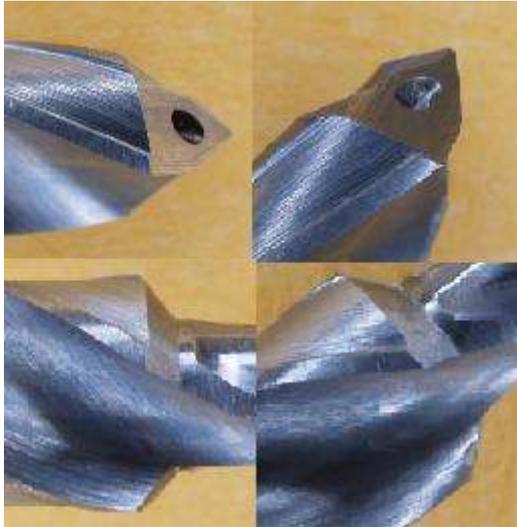
**Fig. 3** Two-step drill with diameter of 4.5 mm and channels through the drill with openings on the tip where cooling fluid exits



**Fig. 4** According to regression line and prediction interval bone temperature of 47°C will last (mean value) on that temperature for 11 seconds (39 seconds with 95% of upper confidence interval). Bone temperature of 50°C will be above 47°C for mean of 21 seconds (50 seconds with 95% of upper confidence interval)



**Fig. 5** Cutting lips before and after 180 drillings of 2.5/3.4 mm carbide drill with channels for internal irrigation showing no wear on both smaller diameter drill tip and transitional cutting lips to larger diameter part of the two-step drill



**Table 1** Influence of specific parameters on increase in bone temperature

Bone temperature (°C)					
Parameter	SS	Degrees of freedom	MS	F	p
Cooling	11606	1	11606	<b>1626.3</b>	<b>&lt;0.001</b>
Drill diameter	1008	3	336	<b>15.30</b>	<b>&lt;0.001</b>
Feed	791	4	198	<b>8.87</b>	<b>&lt;0.001</b>
Cutting speed	57	4	14	0.61	0.655
Drill geometry	0	1	0	0.01	0.930

SS – sum of squares; MS – mean square; F – F-value as indicator of influence; p – p value

**Table 2** Descriptive statistics for the variable *Temperature (with and without cooling)* for each combination of parameters (in °C)

Parameter	N	MV ± SD	p = 0.05*
<b>Cooling</b>			
Without cooling	360	45.5 ± 3.6	<b>52.7</b>
With cooling	360	37.5 ± 1.0	39.5
<b>Drill geometry</b>			
Standard	360	41.5 ± 4.9	<b>51.1</b>
Two-step	360	41.5 ± 4.8	<b>50.9</b>
<b>Drill diameter (mm)</b>			
3.4	180	40.2 ± 3.4	46.9
4.5	180	42.9 ± 5.7	<b>54.0</b>
2.5/3.4	180	40.5 ± 3.7	<b>47.8</b>
3.4/4.5	180	42.5 ± 5.5	<b>53.3</b>
<b>Feed (mm/rev)</b>			
0.02	80	43.8 ± 7.6	<b>58.7</b>
0.04	160	42.3 ± 5.2	<b>52.4</b>
0.10	240	41.4 ± 4.3	<b>49.8</b>
0.16	160	40.3 ± 3.1	46.4
0.18	80	40.7 ± 3.7	<b>47.9</b>
<b>Cutting speed (m/min)</b>			
1.18	80	41.5 ± 4.7	<b>50.8</b>
10.68	160	41.2 ± 4.4	<b>49.9</b>
33.61	240	41.9 ± 5.6	<b>52.8</b>
56.55	160	41.4 ± 4.3	<b>49.9</b>
66.05	80	41.4 ± 4.2	<b>49.5</b>

N – number of measurements; MV – mean value; SD – standard deviation; \* - 95% upper level of confidence

**Table 3** Descriptive statistics for the variable *Temperature (with and without cooling)* with all combinations of parameters (in °C)

Parameter	Cooling			No cooling	
	N	MV ± SD	p = 0.05	MV ± SD	p=0.05
<b>Drill geometry</b>					
Standard	180/180	37.5 ± 1.2	39.8	45.5 ± 3.7	<b>52.9</b>
Two-step	180/180	37.5 ± 0.9	39.1	45.5 ± 3.6	<b>52.5</b>
<b>Drill diameter (mm)</b>					
3.4	90/90	37.0 ± 0.8	38.5	43.4 ± 1.5	46.2
4.5	90/90	38.1 ± 1.2	40.5	<b>47.7 ± 4.1</b>	<b>55.7</b>
2.5/3.4	90/90	37.3 ± 1.0	39.3	43.8 ± 2.4	<b>48.5</b>
3.4/4.5	90/90	37.7 ± 0.6	38.9	<b>47.3 ± 3.6</b>	<b>54.4</b>
<b>Feed (mm/rev)</b>					
0.02	40/40	37.4 ± 0.8	39.0	<b>50.1 ± 5.9</b>	<b>61.6</b>
0.04	80/80	37.5 ± 0.9	39.3	<b>47.0 ± 2.8</b>	<b>52.4</b>
0.10	120/120	37.4 ± 1.0	39.4	45.3 ± 2.3	<b>49.8</b>
0.16	80/80	37.5 ± 1.1	39.8	43.1 ± 1.7	46.4
0.18	40/40	37.7 ± 1.2	40.0	43.7 ± 2.9	<b>49.3</b>
<b>Cutting speed (m/min)</b>					
1.18	40/40	37.0 ± 0.6	38.1	46.0 ± 1.9	<b>49.6</b>
10.68	80/80	37.4 ± 0.8	39.0	45.0 ± 3.2	<b>51.2</b>
33.61	120/120	37.6 ± 1.0	39.6	46.2 ± 4.9	<b>55.7</b>
56.55	80/80	37.6 ± 1.2	40.0	45.1 ± 2.9	<b>50.7</b>
66.05	40/40	37.7 ± 1.1	40.0	45.0 ± 2.5	<b>49.9</b>

N – number of measurements (cooling / no cooling); MV – mean value; SD – standard deviation