Intraosseous temperature rise due to templateguided and freehand surgical drilling with special attention to the role of cooled irrigation fluids in its control

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PhD thesis

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Other publications

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Csonka A, Gargyan I, Borondy J, **Boa K**, Varga E.

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Advanced Trauma Life Support (ATLS) in Hungary; The First 10 Years.

Varga E, Csonka E, Kószó B, Pető Z, Ágoston Z, Gyura E, Nardai G, <u>Boa K</u>, Süveges G.

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 Fúrás által okozott intraossealis hőmérséklet-emelkedés nagyszámú csontfúrás után: in vitro vizsgálataink eredménye [Intraosseous temperature rise due to drilling after excessive number of drillings: results of our in vitro investigations]

Boa K, Pintér G, Varga E Jr., Erdohelyi B, Varga E

Biomechanica Hungarica, 2015; 8(1):28.

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• β-tricalcium phosphate granulátum alkalmazása a tibia plató törések kezelésében [Administration of β-tricalcium phosphate granulate in the treatment of tibial plateau fractures]

Gargyan I, Vagi Zs, Csonka A, Boa K, Varga E

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 Periprotetikus distalis femurtörések minimál invazív lemezes rögzítése totál térdprotézis beültetése után [Minimally invasive plate osteosynthesis of distal periprosthetic femoral fractures after total knee replacement]

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Magyar Traumatológia, Ortopédia, Kézsebészet, Plasztikai Sebészet, 2015; 58(4):209-216.

article type: *original article* [in Hungarian with English abstract]

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Complex treatment of complicated crural decollement injury in a diabetic patient

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Other works

Traumatology – concept of the first hour of management

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University of Szeged, 2015

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Abbreviations

ANOVA: analysis of variance

CBCT: cone-beam computed tomography

HU: Hounsefield units

MSCT: multi-slice computed tomography

RPM: revolts per minute

Tukey's HSD: test of honestly significant difference according

to John Tukey

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Introduction

Oral rehabilitation of total and partial edentulism can be challenging for even the experienced dental and maxillofacial professionals working in this field, however, the use of osseointegrated dental implants have become a routine procedure in the last couple of decades. [1]

Both hard tissue and soft tissue processes that follow the insertion of titanium, titanium alloy and zirconia implants into living tissue have been thoroughly investigated since the 1960's and 1970's. [1, 2]

Besides research concerning optimal design, material, and surface modification of implants, there is a growing interest among surgeons to achieve the best possible outcome by means of precise preoperative planning and intraoperative placement of the implants.

Computer-assisted planning and intraoperative guided surgery has gained more and more field in oral implantology, and its advantages concerning minimal invasivity and optimal implant placement is appreciated by the literature [3, 4], however, systematic reviews emphasize the need for further, high-quality evidence concerning long-term clinical data to justify the additional costs deriving from purchasing the software system and manufacturing the surgical guides, as well as the radiation caused by the mandatory conebeam computed tomography (CBCT) imaging . [5, 6] As the availability of 3D printing has significantly grown in the last couple of years, several guide systems have entered the market, thus, research concerning every aspect of this rapidly evolving field are of big interest.

Osseointegration of implants

Screw-shaped implants are inserted into living bone to provide stability in the following conditions:

- a) osteosynthesis with screw fixation,
- b) plate osteosynthesis,
- c) prosthetic rehabilitation using dental implants,
- d) orthodontic anchorage using mini-implants.

Overall stability at the implant-bone interface at any time is the sum of the so-called primary stability and secondary stability. After insertion, it is provided by primary stability, that is a purely mechanical phenomenon, and is affected by the following factors:

- a) macro-morphology of the implant,
- b) method of implant bed preparation (e.g. press-fit method [7] or regular diameter fitting),
- c) sink depth,
- d) the surface morphology of the implant.

As time goes on after insertion, primary stability deteriorates, however, a so-called secondary stability gradually builds up. Secondary stability is provided by the apposition of bone onto the implant surface, and this biological process is called osseointegration. [1] Osseointegration of implants has been best defined as "a direct structural and functional connection between ordered, living bone and the surface of a load-bearing implant" by Listgarten et al. [8] This phenomenon provides the possibility for a long-term load-bearing system.

Guided implant placement

Adequate oral prosthetic rehabilitation is based on the optimal placement of the dental implant in reference to the individual anatomy of the patient. The latter objective can only be achieved if:

- 1. adequately precise anatomical information is available,
- 2. this information can be used for preoperative planning,
- 3. and this preoperative plan can be transformed into reality in the operative field.

If an optimal implant position can be achieved, it can presumably lead to advantages in terms of long-term survival.

The availability of cone-beam computed tomography (CBCT) was the prerequisite for a rapid evolution in guided implant surgery, as it provided adequate imaging data with lower radiation. [6, 9] Loubele et al. have shown that dento-maxillofacial CBCT imaging results in 13 to 82 μ Sv of effective radiation, whereas multi-slice computed tomography (MSCT) of the same anatomical area results in 474 to 1160 μ Sv. [10]



Fig. 1. – User interface for preoperative planning in implantology (image courtesy of dicomLAB Kft., Szeged, Hungary).

Guided systems all have a software interface designed for the planning of the implant placement. Jung et al. have divided guided systems into two main categories [5]:

- 1. dynamic systems,
- 2. static systems.

This categorization has been used by other researchers as well. [11] Dynamic systems use optical tracking technologies to follow the position of the handpiece as well as reference points of the bones and shows the projected path of implant placement on a virtual model of the bone, based on preoperative imaging. Bouchard et al. have found a mean error of implant placement of 2.10 +/- 0.88 mm on pig mandibles [12], whereas Wittwer et al. have found a mean error of 0.9 mm in a clinical study involving 78 implants. [13] Static systems use preoperatively fabricated guides that are temporarily retained on either teeth or mucosa intraorally, thus, providing no possibility for intraoperative change in the projected implant position. Preoperative planning includes CBCT imaging, and either taking an impression or performing intraoral scanning. A meta-analysis performed by Tahmaseb et al. have found that the static method has a total mean error of 1.12 mm at the entry point and 1.39 mm at the apex of the implant when compared to the preoperative plan, they have found a failure rate of 2.7% after at least 12 months of follow-up. [6]



Fig. 2. – A 3D-printed, patient-specific surgical guide for dental implant placement (image courtesy of dicomLAB Kft., Szeged, Hungary)

Block and Emery suggest the use of either a static or a guided implant system in the following cases [11]:

- 1. the need for a flapless approach,
- 2. the need for accurate inter-implant spacing,
- 3. the need for accurate angulation:
 - a. implant placement in the aesthetic zone,
 - b. prosthetic rehabilitation using screw-retained prostheses,
- 4. the need for accurate depth control:
 - a. risk of nerve injury,
 - b. implant placement adjacent to the sinus floor,
 - c. bicortical implant placement.

Bone drilling

As application of metal implants have become a mainstay of musculoskeletal trauma surgery, orthopaedic surgery, spine surgery, maxillofacial surgery, and oral implantology, drilling of bone has become one of the most common basic surgical steps. [14]

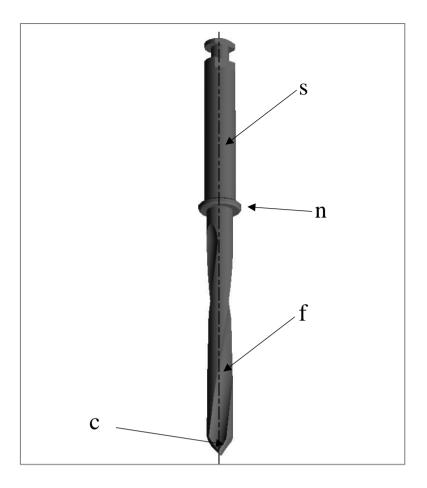


Fig. 3. – Virtual model of a 2-fluted drill bit used for implant site preparation. s - shank, n – neck, f – flute, c – cutting edge.

A typical surgical drill consists of three major parts: shank, body that contains the flutes, and a drill tip. The shank is the part that is connected into the surgical handpiece, thus, it transmits the rotatory power onto the drill bit. The flutes are either helical or straight, concave structures cut into the body of the drill, and are responsible for the removal of debris or bone chips that is created at the tip of the drill. Most surgical drills are either two-fluted or three-fluted drills. [14, 15]

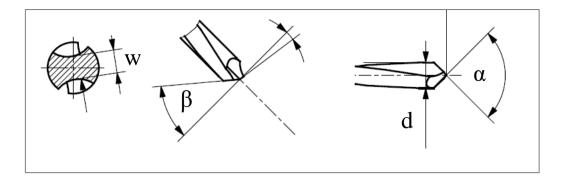


Fig. 4. – Important angles and diameters of the tip of a 2-fluted implant drill. α - drill point angle, β – clearance angle, d - drill diameter, w - web thickness

Drills are manufactured with different drill point angle. The drill point angle is the angle between two cutting edges measured in a sagittal plain, whereas clearance angle is the angle at which the flank (i.e. the non-cutting part) clears the bone debris. [15]

Thermal osteonecrosis, thermal damage

Rotatory cutting results in friction, and friction results in heat generation. Consequently, temperature rises in the bone tissue surrounding the canal that is drilled, as bone has a low thermal conductivity. [16] Eriksson and Albrektsson performed their now classic study in vivo on rabbit tibiae, using a thermal chamber. They have established that an intraosseous temperature of 47°C for 1 minute is the threshold for the histological appearance of thermal osteonecrosis. [17]

High intraosseous temperature does not only affect the viability of bone, but it can cause nerve dysfunction if the accumulation of heat presents near the bony canal of the inferior alveolar nerve, thus, care should be taken to use the optimal bone preparation method and a cooled irrigation fluid when performing osteotomies near the canal, as it has been shown by Szalma et al. [18]

Parameters affecting intraosseous temperature rise

Augustin et al. have divided bone drilling parameters into two major groups: a) parameters of the drill, b) parameters of drilling. Parameters of the drill include drill design elements, such as the number and the design of flutes, drill point design, and drill point angle, drill diameter, as well as drill material and drill wear. Parameters of bone drilling include drilling speed, feed rate, drilling energy, the method of cooling (i.e. internal, external, or the combination of the two), drilling depth, pre-drilling, and cortical bone thickness. [14]

The effect of different drill point angle on intraosseous temperature rise have been addressed by different research groups. Augustin et al. have investigated 80°, 100°, and 120°, whereas Hillery et al. have investigated 70°, 80°, and 90° drill point angles and have found no significant difference in terms of temperature rise between them. [19, 20] Increasing drill diameter results in an exponentially increasing intraosseous temperature during drilling, as it has been shown by Augustin et al. and Kalidindi. [19, 21] Drill wear is caused by the repeated use and sterilization of drills, and has been shown by Chacon et al. and Allan et al. to cause increased temperature elevation. [22, 23] Under 10000 RPM, the increase of drilling speed results in increasing intraosseous temperature, as it is confirmed by several authors. [19, 24, 25]

The effect of irrigation and intraosseous temperature on osseointegration

The real relevance of the control of intraosseous temperature rise and the avoidance of thermal osteonecrosis during implant bed preparation lies in its effect on the possible histological changes at the implant-bone interface, that might indicate the impairment of the process of osseointegration. However, most of the available literature concentrates on the elucidation of the numerous aspects and parameters that might influence the intraosseous temperature. A histological study by Isler et al. have shown that cooled irrigation fluid at a temperature of 4°C results in more active osteoblasts and a more dynamic bone marrow. [26]

Temperature rise in guided surgery

Since the introduction of surgical guides in oral implantology, there was a concern among surgeons regarding the effectivity of irrigation during drilling, as it seems reasonable to doubt that the irrigation fluid reaches the drill bit the same way as it does in case of conventional freehand implant bed preparation. This concern was further empowered by the results of Misir et al. who have found that guided drilling results in a significantly higher increment. [27] However, in another study by Jeong et al., the difference between the guided flapless and flap techniques in terms of temperature rise has not been significant [28], and two other studies have shown that the heat caused by drilling in a surgical guide stays in the safe zone. [29, 30]

7

Research questions

The presented works focused on the following main research questions:

- 1. What intraosseous temperature rises may occur during guided implant site preparation if no cooling is applied?
- 2. Does external cooling efficiently control intraosseous temperature rise during guided implant site preparation?
- 3. Does the use of cooled irrigation fluids provide better temperature control during guided implant surgery?

Investigation No. 1.

Aims

The aim of investigation No. 1. was to perform a pilot study that describes the importance of external cooling in guided surgical implant site preparation.

Materials and methods

Bone model

Drilling was performed on cortical bovine rib bones. The use of bovine bone is beneficial because of its thermophysical and anatomical properties, as well as its good availability and easy handling. Davidson et al. have shown that bovine cortical bone is thermally isotropic and the value of its conductivity is likely to be around that of the human cortical bone.[16] Yacker et al have performed CT scan of bovine bones and have concluded that bovine cortical density is about 1,400 HU, while typical human mandible cortical density is between 1,400 and 1,600 HU.[31] Cortical bone thickness of the human mandible has been investigated in 2007 by Katranji et al., finding the average edentulous cortical thickness to be between 1.0 and 2.0 mm and the dentate cortical thickness between 1.6 and 2.2 mm.[32] Value of thickness amongst our bovine rib specimens varied between 1.5 mm and 2.7 mm, suggesting that its anatomical properties are comparable to that of the human mandible. These data from the literature and our own anatomical measurements suggest that bovine rib bones provide a good model of the human mandible for scientific experiments.

The ribs were derived from the same animal and were treated as described by Sedlin and Hirsch[33]: the specimens were frozen to -10°C in saline solution when not used. Before the measurements took place, the specimens were warmed to 36±1°C. Baseline temperature of the bone was checked before every drilling. If the baseline temperature was below 35°C the specimen was placed back in the warming device.

Infrared thermographic studies performed by Augustin et al. have shown that the generated temperature rise reaches its peak in the cortical layer of the bone[34], thus we designed an experimental setting in which we can measure the bony temperature around the drilled canal right before it reaches through the cortical layer, representing the peak of intraosseous heat generation. Flat parts of the bovine ribs were divided and cut into segments as long as

attachment of the surgical guide containing 3x8 drilling holes to it was possible. After that, the edges were cut from the ribs in a longitudinal fashion, followed by cutting the specimens into two halves through its cancellous bone layer, parallel to the flat surface of the bone. This was followed by the removal of the remaining cancellous bone tissue with a chisel. Thus, we could prepare quasi flat bone specimens containing only the cortical layer (see Figure 5.).

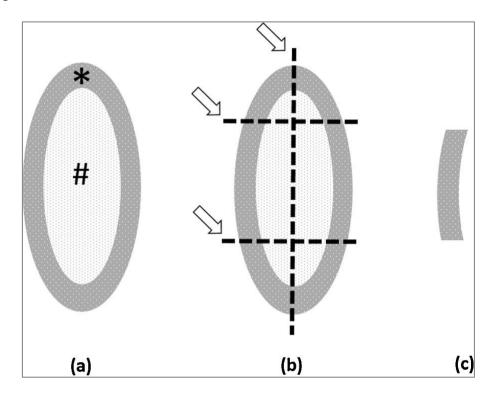


Fig. 5. – Method of preparing cortical bone layer specimens from bovine ribs. *: cortical layer. #: cancellous layer. White arrows and interrupted black lines: the represent the directions in which cutting was performed.

Setup

Heat measurement was performed with an infrared thermometric device (Voltcraft IR-380, Conrad, Germany). The device is equipped with two lasers crossing each other at the focus point of the infrared measurement, providing good ability to aim the device at the point of exit of the drill. In case of drilling through a preformed canal of lesser diameter by 0.5 mm (as it happens from the 2nd step of the drilling sequence), the thermometer was pointed immediately next to the exit of the canal (See Figure 6.)

As the specimens were flat cortical parts of the bovine ribs, a universal surgical guide was designed containing 24 guiding canals in 3 columns (See Figure 7.). The guide was

manufactured using the same standards as the guides of the Smart Guide system (Smart Dental Solutions Ltd., Szeged, Hungary), 3D printed (printer: ProJet 3510 MP), using the same material (VisiJet Stoneplast). Fixation was available by inserting the system's standard pins into pin holes placed in the four corners.

Drilling was performed by the same experienced dentoalveolar surgeon in order to achieve quasi constant applied pressure. Slight pumping drilling motion to facilitate the transfer of the heated debris from the canal was applied. The surgeon was not able to see the screen of the thermometer; thus, it was not affecting his usual drilling motion and the pressure applied by him. Drill speed was set to a constant 800 RPM as it is advised by the manual of the Smart Guide system used in this study.

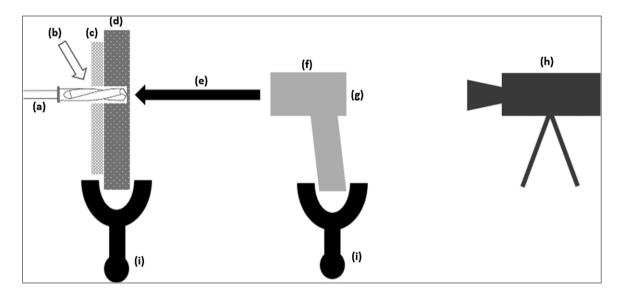


Fig. 6. – The experimental setting. (a): drilling. (b) and white arrow: external irrigation. (c): surgical guide. (d): cortical bone specimen. (e) and black arrow: direction and focus point of infrared thermometric measurement. (f): infrared thermometer. (g): display of the thermometer, visible to the video camera. (h): video camera. (i): adjustable and rotatable clamps for fixation.

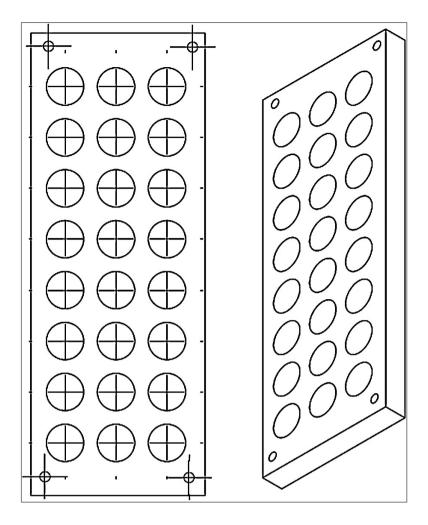


Fig. 7. – Plan of the universal surgical guide for flat bone specimens, 3D-printed according to the same guidelines as the Smart Guide system's (Smart Dental Solutions Ltd., Szeged, Hungary) oral surgical implant guide.

Every step of the drilling sequence was investigated. The applied implant preparation system includes the subsequent use of drills of the following diameters: 2.0 mm, 2.5 mm, 3.0 mm, and 3.5 mm.

External cooling was applied by the assistant with a standard 50 ml syringe at the point of the drill entering the metal sleeve of the canal in the drilling guide. Standard saline solution at a room temperature of 25°C was used as coolant liquid. The drills were washed and cooled back to room temperature after every single drilling.

Collection of data and statistical analysis

Baseline and peak temperatures were collected to one decimal point in a spreadsheet file *Microsoft Excel 2013* (v15.0) (Microsoft Corporation, Redmond, WA, USA). Temperature elevations were calculated as peak temperature minus baseline temperature to one decimal

point using the spreadsheet. After converting the dataset of temperature elevations to a comma separated values file, it was statistically analysed using *RStudio* (RStudio Inc., Boston, MA, USA) software. Two sample t-test was computed in case of similar variances of the two compared groups, and Welch's t-test was used in case of differing variances. The level of significance was set a priori at α =0.05.

Results

The first step of the implant system's drilling sequence is drilling with the 2.0 mm pilot drill. 48 drillings performed with the use of external irrigation produced a mean temperature rise of 4.77°C, while in case of 48 drillings performed without the use of external cooling it was 7.02°C (see Table 1.). The difference was statistically significant (p<0.001). Eight times out of the 48 drillings performed did the rise exceed the 10°C threshold on the latter case, while no drilling exceeded it if external cooling was applied (see Table 1.).

Drilling speed (RPM)	Diameter of the canal (mm)	Drill diameter (mm)	Cooling	Mean AT (°C)	SD	n	p-value (*<0.001)
800	0.0	2.0	+	4.77	1.90	48	7.438 x 10 ⁻⁰⁶ *
800	0.0	2.0	-	7.02	2.67	48	
800	2.0	2.5	+	5.22	1.36	48	2.068 x 10 ⁻⁰⁸ *
800	2.0	2.5	-	8.48	3.25	48	
800	2.5	3.0	+	3.32	1.23	48	9.974 x
800	2.5	3.0	-	8.48	2.95	24	10 ⁻¹⁴ *
800	3.0	3.5	+	4.75	1.28	24	5.138 x
800	3.0	3.5	-	9.40	3.73	23	10 ⁻⁰⁶ *

Table 1. – Number of drillings, mean of temperature rise, standard deviation, and level of significance comparing cooling to no cooling for every step of the drilling sequence.

Drilling speed (RPM)	Diameter of the canal (mm)	Drill diameter (mm)	Cooling	n _{≥10°C} / n	% n ≥10°C
800	-	2.0	+	0/48	0.0%
800	-	2.0	-	8/48	16.7%
800	2.0	2.5	+	1/48	2.1%
800	2.0	2.5	-	17/48	35.4%
800	2.5	3.0	+	0/48	0,0%
800	2.5	3.0	-	18/24	75.0%
800	3.0	3.5	+	0/24	0.0%
800	3.0	3.5	-	10/24	43.5%

Table 2. – Number of temperature rises exceeding $10^{\circ}C$ ($n_{\geq 10^{\circ}C}$) and proportion of these amongst measurements ($\%n_{\geq 10^{\circ}C}$) for every step of the drilling sequence.

During the second step of the drilling sequence (being 2.5 mm drilling of the 2.0 mm canal) the mean temperature rise was 5.22°C with cooling, and 8.48°C without cooling (see Table 1.). The difference was statistically significant (p<0.001). Number of measured temperature rises exceeding the threshold was 1 out of 48 with cooling and 17 out of 48 without cooling (see Table 2.).

Throughout the third step of the drilling sequence (being 3.0 mm drilling of the 2.5 mm canal) the mean temperature rise was 3.32°C with cooling, and 8.48°C without cooling (see Table 1.). The difference was statistically significant (p<0.001). No cases out 48 drillings exceeded the threshold for temperature rise with the use of external irrigation, while without the use of it 18 times out of the 24 performed drilling was the increase exceeding the limit (see Table 2.).

During the fourth step of the drilling sequence (being 3.5 mm drilling of the 3.0 mm canal) the mean temperature rise was 4.75°C if external cooling was applied, and 9.40°C if no external cooling was applied (see Table 1.). The difference was statistically significant (p<0.001). Number of measured temperature rises exceeding the threshold was 0 out of 24 with cooling and 10 out of 24 without cooling (see Table 2.).

Boxplot diagram presentation of the distribution of measured temperature rises can be seen on Figure 8.

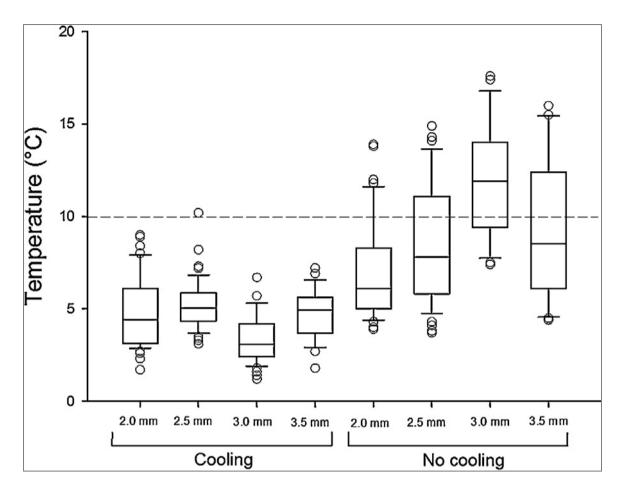


Fig. 8. – Boxplot diagram representing the distribution of the measured temperature rises. "C" means cooling, followed by the diameter of the drill, while "n" means no cooling, followed by the diameter of the drill. The dashed horizontal line represents the 10°C threshold.

Investigation No. 2.

Aims

The above presented results of investigation No. 1. suggested that the question of intraosseous temperature rise in a guided setting should be studied in an experimental setup that controls more possible factors, such as axial load and the flow of external irrigation. The results of our research group in the new setting has shown that the use of 800 RPM drilling in such a setting is safe. [35] The aim of the presented experimental investigation No. 2. was to perform a comprehensive assessment of the combination of the several factors affecting temperature rise during implant site preparation at higher drilling speeds that are widely used in implant dentistry.

The combination of the following factors was assessed in the study:

a) surgical method: guide vs. freehand drilling,

b) drilling speed: 1200 vs. 1500 vs. 2000 RPM,

c) temperature of the irrigation fluid: 10°C vs. 15°C vs. 20°C.

Another important element of this experimental design was the elimination of the human factor in terms of axial load during drilling.

Materials and methods

Bone model

The bone model used in the presented investigation was bovine rib bone, as several available data suggest that it is ideal for *in vitro* experiments in oral implantology. The proper *in vitro* bone model bears the following characteristics:

- a) ideal cortical thickness,
- b) ideal thermal conductivity,
- c) ideal cortical density.

A study by Katranji et al. have shown that the mean cortical thickness of human mandibles fall between 1.6 and 2.0 mm [32], thus, bones with a cortical thickness in the same range were chosen. In terms of thermal conductivity, Davidson and James have concluded that bovine ribs are thermally isotropic and show similar thermal conductivity when compared to human mandibles. [16, 36] An investigation by Yacker and Klein have shown that bovine

ribs have a cortical density around 1,400 HU, being similar to that of the human mandible as well. [31] The bone segments used during our experiments were deriving from the same animal. The animal was not sacrificed in order to perform our investigations. Storage of the bone segments when not used was following the protocol established by Sedlin and Hirsch: in standard saline solution, at a temperature of -10°C. [33]

Setup

The study design was designed to investigate both guided and freehand implant bed preparation techniques. In case of the guided surgical drilling group, drillings were conducted using a 3D-printed surgical guide that fit well on the quasi-flat surface of the specimens. The guide was designed using the same principles and protocols as in case of every surgical guide of a commercially available implantological guide system (SmartGuide, dicomLAB Kft., Szeged, Hungary), and contained 2x5 guiding canals with a metal insert, and was able to accommodate the metal guiding spoons that are designed to guide the drill bits of different diameters. (see Figures 9-14.) The guide was designed in a fashion that allowed a thermocouple to be placed in close proximity to the canal to be drilled (see Figures 13. and 14.). Measurement beds were placed right at the point where the guiding canal of the guide reaches the bone surface, using another 3D-printed guide for precision. In case of freehand surgical drillings, the entry points were marked on the bone surface using the same guides as in case of the guided surgical groups, but the guides were removed. Measurement beds for freehand drillings were placed using the same guides as in case of the guided subgroups. (see Figures 11. and 12.) All measurement beds were prepared with a depth control of 1.8 mm to ensure that they are still in the cortical layer of the bone, as a study investigating heat distribution during drilling confirmed that peak temperature during drilling develops in the cortical layer of the bone. [34] After placing the thermocouple inside the bed, it was tightly filled with cortical bone chips of the same animal, and the bed was insulated with plasticine to avoid any direct contact with the irrigation solution, that might influence the measurements (see Figure 14.). The measurement beds were in the following distance from the canal to be drilled: 1.0 mm when using the 3.5 mm drill bits, 1.25 mm when using the 3.0 mm drill bits, 1.50 mm when using the 2.5 mm drill bits, and 1.75 mm when using the 2.0 mm drill bits. K-type thermocouples were used for the measurements and were connected to a measurement device (Holdpeak-885A, Holdpeak, China). The bone specimens were carefully warmed to a value around body temperature (37±1°C). The temperature elevations were calculated by subtracting the

baseline temperature from the peak temperature measured. Osteotomies were performed in a regular fashion with the drill passing through the cortical layer of the bone down into cancellous bone. The drillings were terminated when the continuously measured cortical temperature reached its peak and did not show any further tendency to elevate, thus the time factor was not investigated in the experiment.

A bench drill (Bosch PBD 40, Bosch, Germany) was used for the experiments. The axial pressure was controlled at a level of 2.0 kg, as reviews suggest that it is widely used in similar studies[37, 38] and it can be considered as a light hand pressure exerted during implant site preparation.

External irrigation was conducted using a widely used surgical unit (W&H Implantmed SI-923, W&H, Austria) and a widely used, standard cannula (W&H, Austria). The flow was 105 mL/min. Normal saline was used as an irrigation solution. The irrigation fluids were used on three different pre-set temperatures: 10°C, 15°C, and 20°C. The measurements and drillings were only initiated if the temperature of the fluid was around the wanted pre-set value (±1°C).

In case of 2.5 mm, 3.0 mm, and 3.5 mm drillings, the canals were predrilled with 2.0 mm, 2.5 mm, 3.0 mm drills respectively.

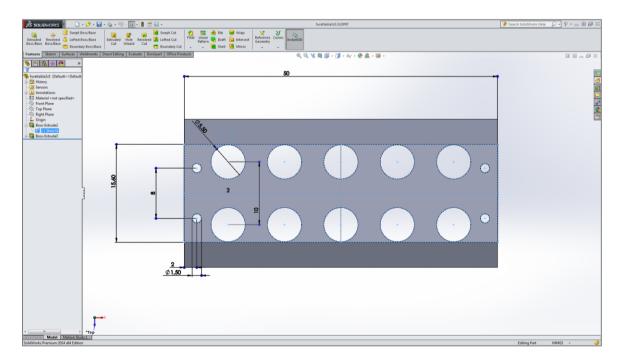


Fig. 9. – *Computer-based planning of the surgical guide for the experiments.*

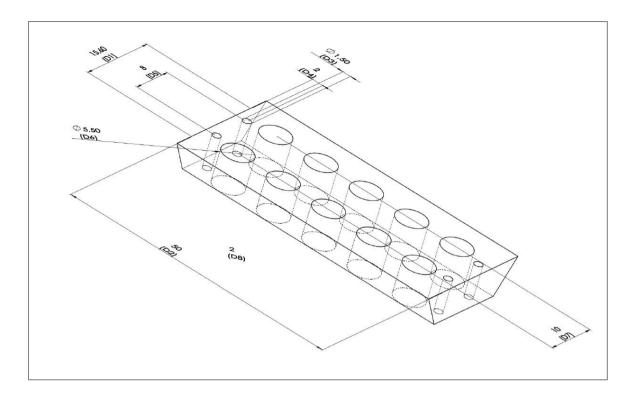


Fig. 10. – Virtual plan of the surgical guide.

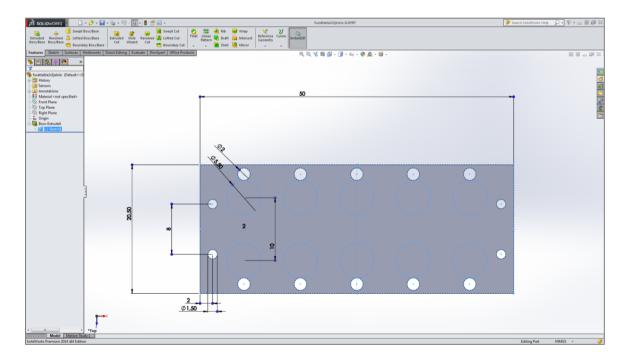


Fig.~11.-Computerised~planning~of~the~surgical~guide~for~measurement~bed~preparation.

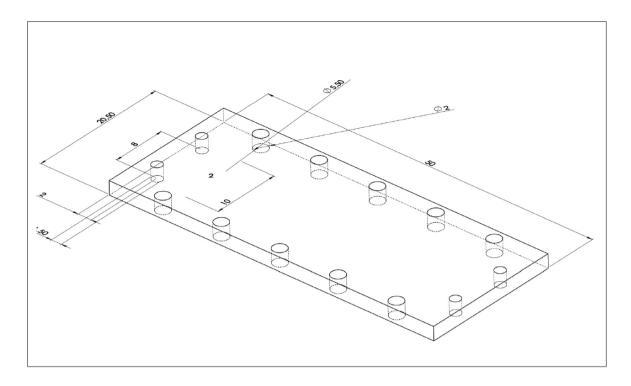
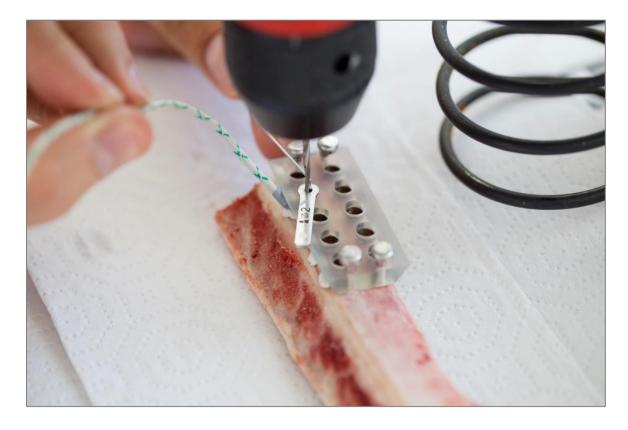


Fig. 12. – Virtual plan of the surgical guide for measurement bed preparation



 $Fig.\ 13.-Guided\ surgical\ drilling\ setup.$

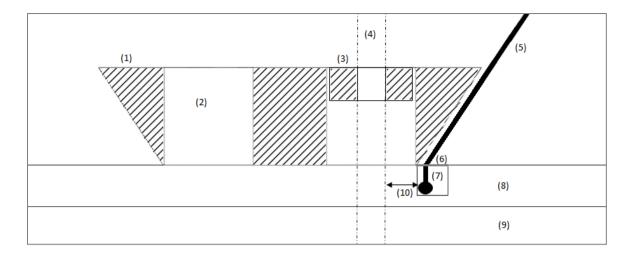


Fig. 14. – Cross-section representation of the guided surgical drilling setup. (1) surgical drilling guide, (2) guiding hole, (3) guiding sleeve, (4) projected axial path of the drill bit, (5) K-type thermocouple's wire, (6) insulation against dripping irrigation fluid, (7) measurement hole with the tip of the K-type thermocouple, tightly filled with bone chips, (8) cortical bone, (9) cancellous bone, (10) distance of the thermocouple from the drilling.

Collection of data and statistical analysis

Baseline and peak temperatures were collected to one decimal point in a spreadsheet file using *Microsoft Excel 2013 (v15.0)* (Microsoft Corporation, Redmond, WA, USA). Temperature elevations were calculated as peak temperature minus baseline temperature to one decimal point using the spreadsheet. The values were statistically analysed using *Statistica for Windows 10.0* (Statsoft, Tulsa, OK, USA). Normality of distributions was tested using Shapiro-Wilk test. One-way ANOVA with post-hoc Tukey HSD test was planned to be used in case of normal distributions, and Kruskal-Wallis ANOVA was planned to be used if non-normal distribution was detected.

Results

1200 RPM drillings

Results for the 1200 RPM drilling groups can be summarized as the following:

- 1) 1200 RPM freehand drilling with 10°C irrigation yielded a significantly lower temperature increment as compared to the 20°C guided group, regardless of the diameter of the drill.
- 2) When comparing freehand drilling with 10°C irrigation to freehand drilling with 20°C irrigation, a significant difference can be observed between groups with the same drill diameter, with the exception of 3.5 mm drill diameter groups.
- 3) When 10°C freehand irrigation was compared with 15°C freehand irrigation, the difference was significant at 2.5 and 3.0 mm, indicating the superior efficiency of lower temperature irrigation.
- 4) Guided 1200 RPM drilling with 10°C irrigation yielded a significantly lower temperature increment as compared to the 20°C guided group, regardless of the diameter of the drill.
- 5) When compared to the 20 °C freehand group, temperature reduction in the 10°C guided group was significantly more marked at all diameters, except for 3.5 mm.
- 6) When the 10 °C guided group was compared to the 15 °C groups, a significantly lower temperature rise was found at 2.5 and 3.0 mm in comparison to the guided technique, and at 3.0 mm in comparison to the freehand technique.

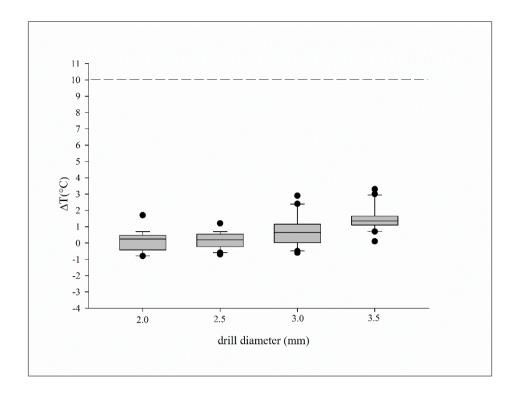


Fig. 21. – Boxplot representation of temperature rise in case of 1200 RPM freehand drilling combined with the use of irrigation fluid at 10°C

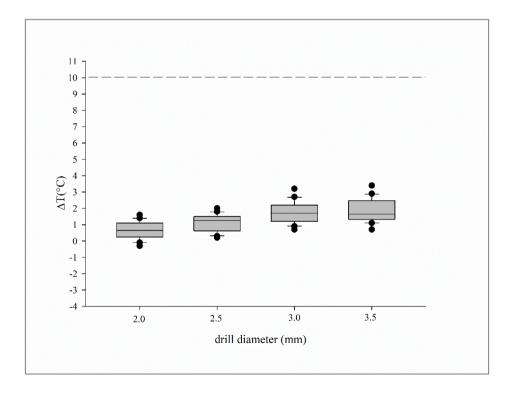


Fig. 22. – Boxplot representation of temperature rise in case of 1200 RPM freehand drilling combined with the use of irrigation fluid at $15^{\circ}C$

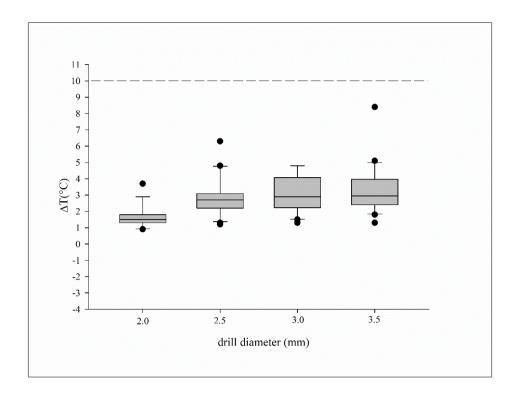


Fig. 23. – Boxplot representation of temperature rise in case of 1200 RPM freehand drilling combined with the use of irrigation fluid at 20°C

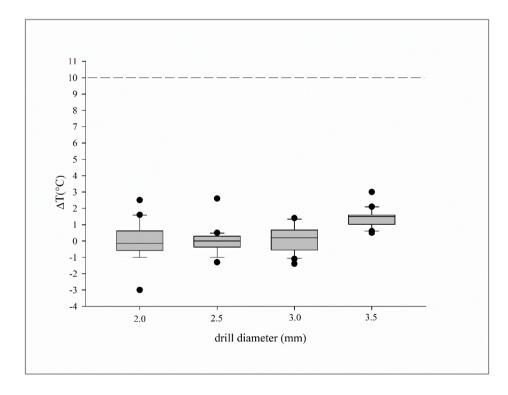


Fig. 24. – Boxplot representation of temperature rise in case of 1200 RPM guided drilling combined with the use of irrigation fluid at $10^{\circ}C$

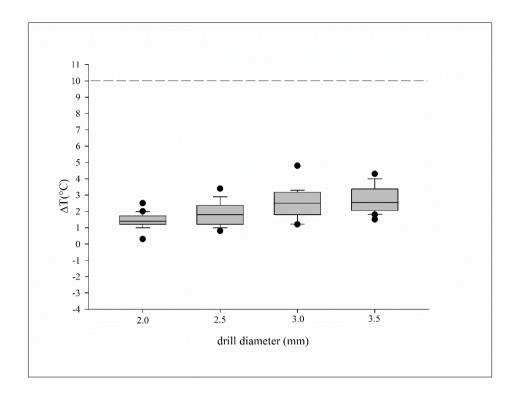


Fig. 25. – Boxplot representation of temperature rise in case of 1200 RPM guided drilling combined with the use of irrigation fluid at $15^{\circ}C$

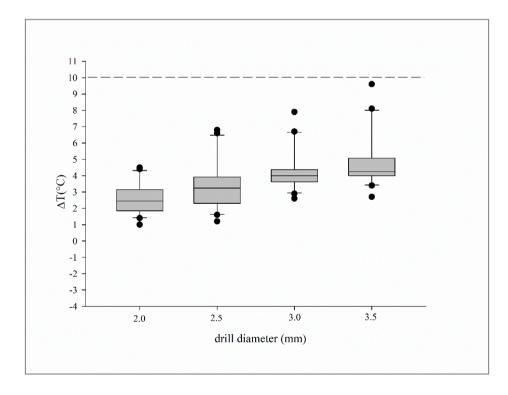


Fig. 26. – Boxplot representation of temperature rise in case of 1200 RPM guided drilling combined with the use of irrigation fluid at $20^{\circ}C$

Drilling speed (RPM)	Drill diameter (mm)	Surgical method	Pre-set temperature of the irrigation fluid (°C)	Mean ΔT (°C)	SD	Maximum ΔT (°C)
1200	2.0	freehand	20	1.7	0.7	3.7
1200	2.5	freehand	20	2.8	1.2	6.3
1200	3.0	freehand	20	3.1	1.1	4.8
1200	3.5	freehand	20	3.3	1.5	8.4
1200	2.0	freehand	15	0.7	0.5	1.6
1200	2.5	freehand	15	1.1	0.5	2.0
1200	3.0	freehand	15	1.7	0.7	3.2
1200	3.5	freehand	15	1.9	0.7	3.4
1200	2.0	freehand	10	0.1	0.6	1.7
1200	2.5	freehand	10	0.2	0.5	1.2
1200	3.0	freehand	10	0.7	1.0	2.9
1200	3.5	freehand	10	1.5	0.7	3.3

Table 3. – Mean, standard deviation and maximum of temperature elevation of 800 and 1200 RPM freehand drillings

Drilling speed (RPM)	Drill diameter (mm)	Surgical method	Pre-set temperature of the irrigation fluid (°C)	Mean ΔT (°C)	SD	Maximum ΔT (°C)
1200	2.0	guided	20	2.6	0.9	4.5
1200	2.5	guided	20	3.5	1.5	6.8
1200	3.0	guided	20	4.4	1.4	7.9
1200	3.5	guided	20	4.9	1.7	9.6
1200	2.0	guided	15	1.4	0.5	2.5
1200	2.5	guided	15	1.9	0.7	3.4
1200	3.0	guided	15	2.5	0.9	4.8
1200	3.5	guided	15	2.8	0.8	4.3
1200	2.0	guided	10	-0.0	1.2	2.5
1200	2.5	guided	10	-0.0	0.8	2.6
1200	3.0	guided	10	0.1	0.8	1.4
1200	3.5	guided	10	1.4	0.6	3.0

Table 4. – Mean, standard deviation and maximum of temperature elevation of 800 and 1200 RPM guided drillings

1500 and 2000 RPM drillings

Results of the 1500 RPM drilling group can be summarized as the following:

- 1) Guided 1500 RPM drilling with irrigation fluid at 20°C produced values exceeding the 10°C limit in case of the 3.0 and 3.5 mm drill bit diameters, with the mean exceeding 11.0°C in case of the 3.5 mm diameter.
- 2) Freehand drilling with 20°C irrigation produced no values to exceed 8.8°C, and the means to stay below 8.0°C for all diameters.
- 3) The mean freehand values were significantly lower compared to guided drilling with irrigation at 20°C at the 3.0 mm (p=0.000) and the 3.5 mm (p=0.000) diameters.
- 4) The use of 15°C irrigation managed to hold the mean temperature elevation below 8.0°C at the diameter of 3.5 mm for both guided (a mean of 7.6°C) and freehand (a mean of 7.3°C) surgery.
- 5) When using 15°C irrigation, no statistically significant difference was detectable between the two methods, with the exception of the 3.0 mm diameter, where guided surgery produced significantly higher values (p=0.032).
- 6) With the use of 10°C irrigation, every mean value was below 6.0°C and no single measured value exceeded 7.1°C.
- 7) The use of 10°C irrigation managed to completely erase every statistically significant difference between the two surgical methods.

Results of the 2000 RPM drilling group can be summarized as the following:

- 1) For the 20°C irrigation guided drilling groups, the means exceeded the limit in case of the 3.0 and 3.5 mm guided, and the 3.5 mm freehand groups.
- 2) Moreover, for guided drillings with 20°C irrigation, the maximum values reached 13.0°C in case of 2.5 and 3.0 mm, and 16.0°C in case of the 3.5 mm groups.
- 3) Guided drillings with 20°C irrigation produced significantly higher values of temperature elevation compared to the freehand groups at all diameters (2.0 mm (p=0.039), 2.5 mm (p=0.001), 3.0 mm (p=0.047) and 3.5 mm (p=0.000)).

- 4) The means exceeded the limit in case of guided 3.0 and 3.5 mm drilling groups with 15°C irrigation.
- 5) Freehand drillings with 15°C irrigation remained in the safe zone for all diameters.
- 6) When using 15°C irrigation, guided drillings were shown to produce significantly higher temperature changes compared to freehand drillings at the 2.0 mm (p=0.000), 3.0 mm (p=0.000) and the 3.5 mm (p=0.000) diameters.
- 7) No means exceeded 7.0°C, and no single measurement showed an elevation exceeding 8.9°C when 10°C irrigation was used.
- 8) When using 10°C irrigation fluid, no significant difference was detectable between guided and freehand drilling.

Basic statistics, including mean values, standard deviations and maximum values are shown in Tables 5-6. for every investigated group. All statistically significant differences are noted in the text above. Boxplot presentation for all studied groups can be seen on Figures 27-38.

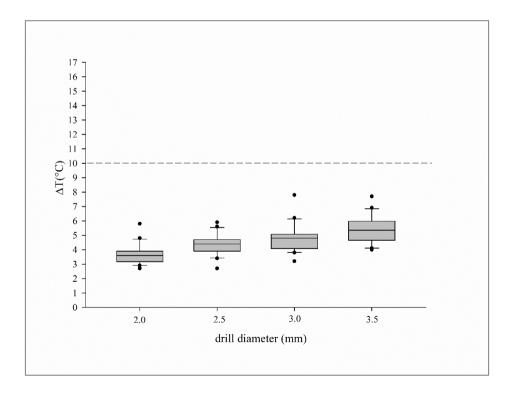


Fig. 27. – Boxplot representation of temperature rise in case of 1500 RPM freehand drilling combined with the use of irrigation fluid at 10°C

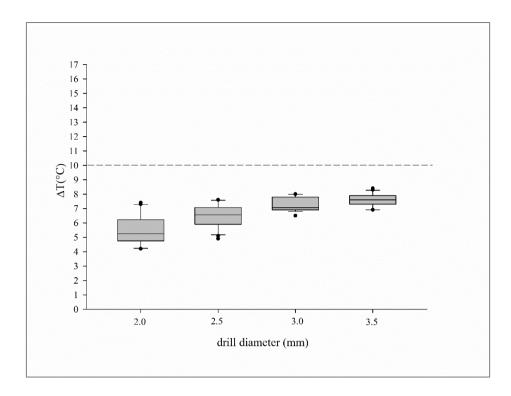


Fig. 28. – Boxplot representation of temperature rise in case of 1500 RPM freehand drilling combined with the use of irrigation fluid at 15°C

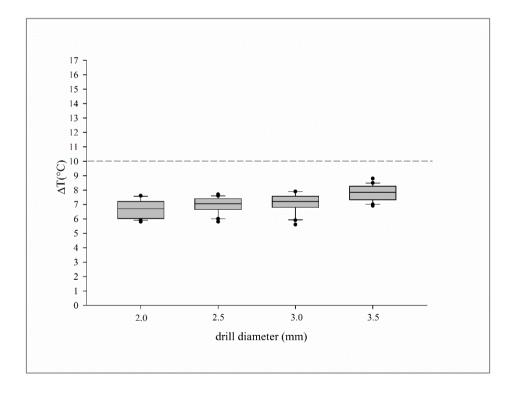


Fig. 29. – Boxplot representation of temperature rise in case of 1500 RPM freehand drilling combined with the use of irrigation fluid at $20^{\circ}C$

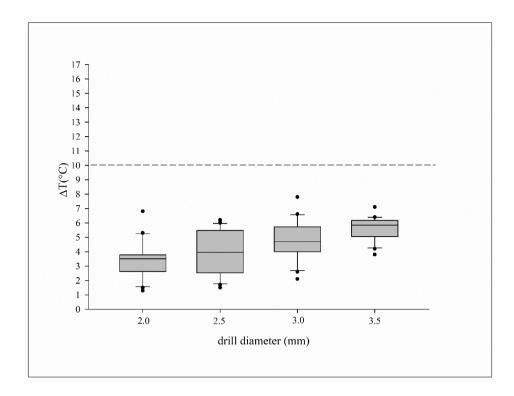


Fig. 30. – Boxplot representation of temperature rise in case of 1500 RPM guided drilling combined with the use of irrigation fluid at 10° C

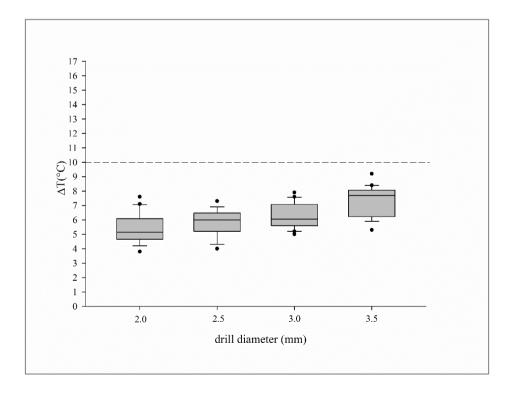


Fig. 31. – Boxplot representation of temperature rise in case of 1500 RPM guided drilling combined with the use of irrigation fluid at $15^{\circ}C$

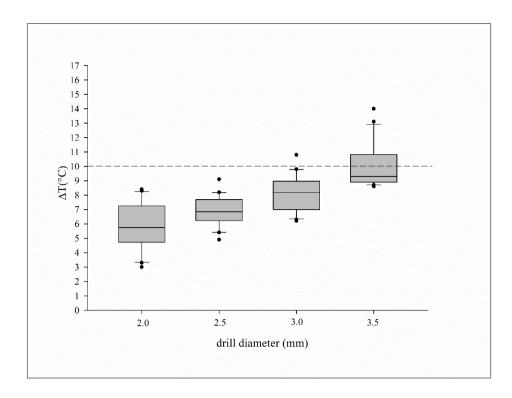


Fig. 32. – Boxplot representation of temperature rise in case of 1500 RPM guided drilling combined with the use of irrigation fluid at 20°C

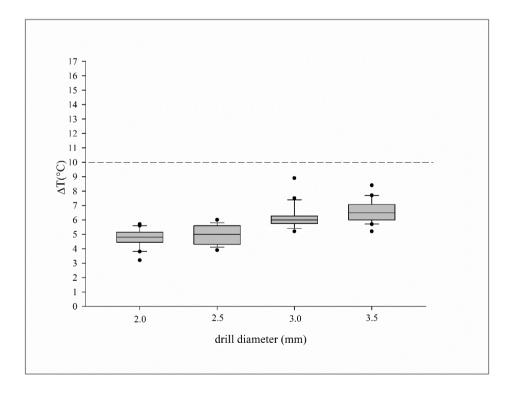


Fig. 33. – Boxplot representation of temperature rise in case of 2000 RPM freehand drilling combined with the use of irrigation fluid at 10°C

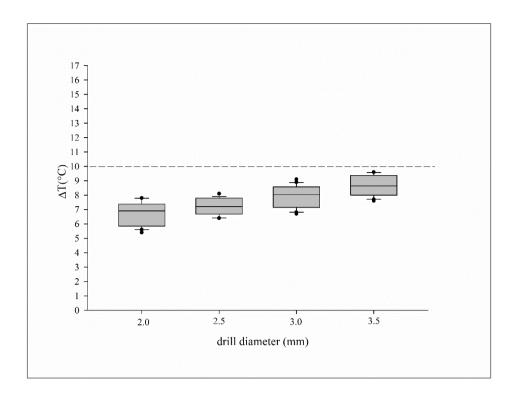


Fig. 34. – Boxplot representation of temperature rise in case of 2000 RPM freehand drilling combined with the use of irrigation fluid at 15°C

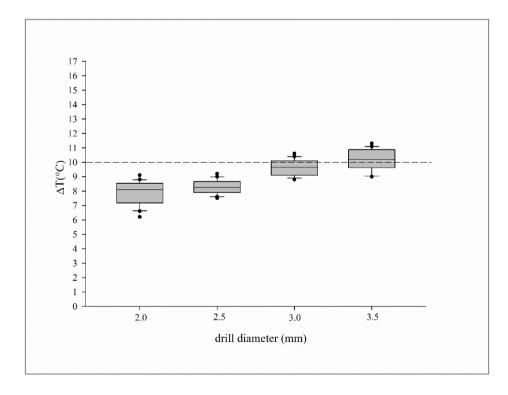


Fig. 35. – Boxplot representation of temperature rise in case of 2000 RPM freehand drilling combined with the use of irrigation fluid at 20°C

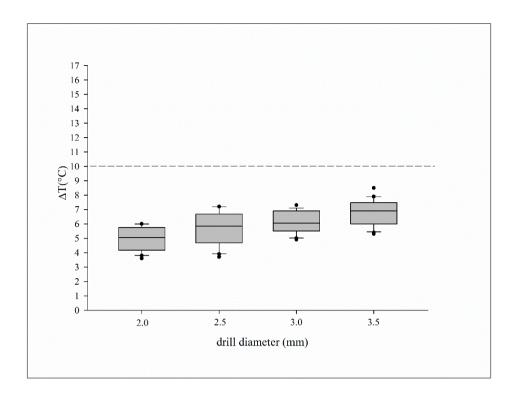


Fig. 36. – Boxplot representation of temperature rise in case of 2000 RPM guided drilling combined with the use of irrigation fluid at 10°C

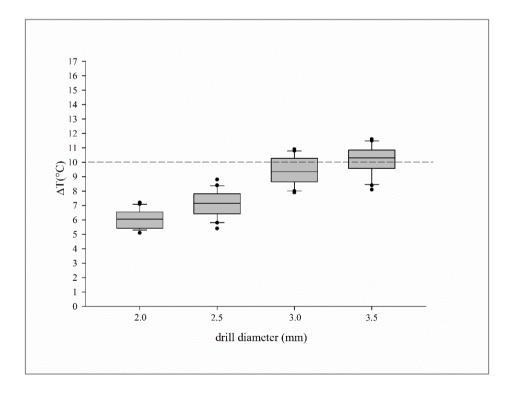


Fig. 37. – Boxplot representation of temperature rise in case of 2000 RPM guided drilling combined with the use of irrigation fluid at $15^{\circ}C$

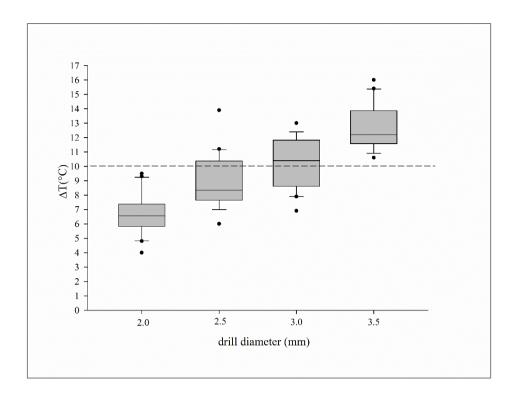


Fig. 38. – Boxplot representation of temperature rise in case of 2000 RPM guided drilling combined with the use of irrigation fluid at $20^{\circ}C$

Drilling speed (RPM)	Drill diameter (mm)	Surgical method	Pre-set temperature of the irrigation fluid (°C)	Mean ΔT (°C)	SD	Maximum ΔT (°C)
1500	2.0	freehand	20	5.8	1.6	8.4
1500	2.5	freehand	20	7.0	0.6	7.7
1500	3.0	freehand	20	7.1	0.6	7.9
1500	3.5	freehand	20	7.8	0.5	8.8
2000	2.0	freehand	20	6.6	1.5	9.5
2000	2.5	freehand	20	8.3	0.5	9.2
2000	3.0	freehand	20	9.7	0.5	10.6
2000	3.5	freehand	20	10.2	0.7	11.3
1500	2.0	freehand	15	5.4	1.0	7.6
1500	2.5	freehand	15	5.8	0.9	7.3
1500	3.0	freehand	15	6.3	0.9	7.9
1500	3.5	freehand	15	7.3	1.1	9.2
2000	2.0	freehand	15	6.2	1.0	7.8
2000	2.5	freehand	15	7.3	0.6	8.1
2000	3.0	freehand	15	8.0	0.8	9.1
2000	3.5	freehand	15	8.6	0.7	9.6
1500	2.0	freehand	10	3.7	0.7	5.8
1500	2.5	freehand	10	4.3	0.7	5.9
1500	3.0	freehand	10	4.7	0.7	6.2
1500	3.5	freehand	10	5.3	0.8	6.4
2000	2.0	freehand	10	4.7	0.6	5.7
2000	2.5	freehand	10	5.0	0.7	6.0
2000	3.0	freehand	10	6.2	0.8	8.9
2000	3.5	freehand	10	6.6	0.8	8.4

Table 5. – Mean, standard deviation and maximum of temperature elevation of 1500 and 2000 RPM freehand drillings

Drilling speed (RPM)	Drill diameter (mm)	Surgical method	Pre-set temperature of the irrigation fluid (°C)	Mean ΔT (°C)	SD	Maximum ΔT (°C)
1500	2.0	guided	20	5.8	0.6	7.6
1500	2.5	guided	20	7.5	1.0	9.1
1500	3.0	guided	20	9.4	0.9	10.8
1500	3.5	guided	20	11.2	1.7	14.0
2000	2.0	guided	20	7.9	0.8	9.1
2000	2.5	guided	20	9.9	1.8	13.9
2000	3.0	guided	20	10.9	1.6	13.0
2000	3.5	guided	20	13.8	1.5	16.0
1500	2.0	guided	15	5.5	1.0	7.4
1500	2.5	guided	15	6.4	0.8	7.6
1500	3.0	guided	15	7.3	0.5	8.0
1500	3.5	guided	15	7.6	0.4	8.4
2000	2.0	guided	15	7.7	0.8	8.6
2000	2.5	guided	15	7.9	0.8	8.9
2000	3.0	guided	15	10.1	0.9	11.1
2000	3.5	guided	15	11.1	1.1	12.7
1500	2.0	guided	10	3.2	0.9	5.3
1500	2.5	guided	10	4.0	1.0	5.6
1500	3.0	guided	10	4.9	0.9	6.9
1500	3.5	guided	10	5.6	0.8	7.1
2000	2.0	guided	10	5.0	0.8	6.0
2000	2.5	guided	10	5.7	1.1	7.2
2000	3.0	guided	10	6.1	0.8	7.3
2000	3.5	guided	10	6.8	0.9	8.5

Table 6. – Mean, standard deviation and maximum of temperature elevation of 1500 and 2000 RPM guided drillings

Discussion

There is a limited amount of publications available about intraosseous temperature change during guided surgery. Misir et al. have shown, that significantly higher temperature changes can develop while using the guided method. [27] On the other hand, others have found guided surgery to be safe from a heat generation point of view. Jeong et al. have shown no relevant difference between the guided flapless and the open-flap approach [28]. Result of Migliorati et al. and dos Santos et al do also suggest that guided surgery is a safe approach. [29, 30]

The use of pre-cooled irrigation fluid in controlling intraosseous temperature during bone drilling might seem a straightforward approach, however, data concerning the use of cooled irrigation fluids in bone drilling is very limited as well. Results of Isler et al. have shown that the use of 4°C saline can have a positive effect on bone healing in an in vivo setting. They have observed a more prominent osteoblastic ring when using irrigation fluid at 4°C compared to irrigation at 25°C, however, there was no statistically significant difference concerning new bone formation. They have also found a prevalence of bone necrosis over 90% when using no cooling, emphasizing the importance of proper irrigation. [26] Sener et al. have concluded that 10°C saline can be more effective in an implant preparation setting [39], while Kondo et al. have shown cold irrigation fluid to minimize temperature elevation in a neurosurgical setting, where temperature change is relevant in terms of the vitality of neurons as well. [40]

The previous results of our research group suggest that the use of a low drilling speed of 800 rpm combined with the external irrigation fluid being cooled to 10°C can result in a mean cortical intraosseous temperature change being below 1.0°C, regardless of drill diameter or drilling method (freehand surgery or guided surgery). The use of irrigation fluid being pre-cooled to 15°C provides no significant reduction of temperature change though. [35]

Our presented results confirm that the use of prefabricated drilling guides during implant site preparation results in a higher temperature rise when compared to that of the freehand method, however, the use of 1200 RPM is still a safe choice. Higher drilling speeds of 1500 and 2000 RPM have also been investigated in our study. The above presented results show that the use of these higher drilling speeds results in critical temperature elevations in a

Kristóf Boa, 2018 Discussion

guided setting, and only the use of irrigation fluid pre-cooled to 10°C can hold the increment in the safe zone. Moreover, the use of 2000 RPM produces critical elevations in a freehand setting as well, while in case of 1500 RPM freehand drillings, the elevations stay somewhat below the threshold.

Considering the fact that axial pressure was controlled in the presented setup, and other local factors can influence the temperature elevation as well, we can suggest that the use of 1500 and 2000 RPM drilling should be avoided if possible.

The limitation of our study lies in its *in vitro* nature, in the axial pressure being controlled at a constant light hand pressure value, whereas in reality it can change in a wide range, and in the fact that axial pumping motion was not investigated. The strength of our study is that it investigated the combination of several factors in a well-controlled setup.

Kristóf Boa, 2018 Conclusions

Conclusions

New findings of the above presented work can be summarized as the following:

1) According to the presented data, guided surgery using a drilling speed of 1200 RPM can be safe in terms of intraosseous temperature rise.

- 2) Our results suggest that 1500 and 2000 RPM drilling combined with the use of irrigation fluid at a temperature of 20°C might result in critical temperature elevations, thus, the use of these higher drilling speeds in implant site preparation should be avoided. If the clinical situation requires the use of these higher drilling speeds, irrigation with an irrigation fluid cooled to 10°C is advisable.
- 3) We can conclude that according to our data, the safe choice for guided implant placement is the combination of a lower drilling speed of 800 or 1200 RPM drilling and the use of a cooled irrigation fluid.

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Appendix

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External cooling efficiently controls intraosseous temperature rise caused by drilling in a drilling guide system: an in vitro study

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Abstract

The purpose of this study was to measure the rise in intraosseous temperature caused by drilling through a drilling guide system. We compared the rise in temperature generated, and the number of increases of more than 10°C, between drills that had been cooled with saline at room temperature (25°C) and those that had not been cooled, for every step of the drilling sequence. Cortical layers of bovine ribs were used as specimens, and they were drilled through 3-dimensional printed surgical guides. Heat was measured with an infrared thermometer. The significance of differences was assessed with either a two-sample *t* test or Welch's test, depending on the variances. The mean rises (number of times that the temperature rose above10°C) for each group of measurements were: for the 2 mm drill, 4.8°C (0/48) when cooled and 7.0°C (8/48) when not cooled; with the 2.5 mm drill, 5.2°C (1/4/8) when cooled and 8.5°C (17/48) when not cooled (2 mm canal); with the 3 mm drill, 3.3°C when cooled (0/48) and 8.5°C (18/24) when not cooled (2.5 mm canal); and with the 3.5 mm drill, 4.8°C when cooled (0/24) and 9.4°C when not cooled (10/23) (3 mm canal). The temperature rose significantly less with cooling at every step of the drilling sequence (p<0.001). We conclude that external cooling can maintain the intraosseous temperature within the safe range while drilling through an implant guide system, whereas drilling without irrigation can lead to temperatures that exceed the acceptable limit.

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Keywords: Implants; Implant site preparation; Patient-specific guide; Drilling guide; Intraosseous temperature rise; Cooling; Drilling.

Introduction

Drilling of bone is commonly required in orthopaedic, craniomaxillofacial, and neurosurgery as well as dentistry, and the frictional heat that is generated leads to a rise in the intraosseous temperature. It is widely accepted that

this should be kept below 47 °C, as was established by Eriksson and Adell¹ and Eriksson et al.² When the temperature exceeds this figure thermal osteonecrosis can develop, which leads to the bone in the affected area being replaced by fatty tissue and compromises osseointegration of the implant.³

More and more evidence, including a recent prospective randomised clinical study,⁴ supports the premise that the use of patient-specific drilling guides can provide improved accuracy in implant dentistry. As more soft tissue and the guide itself surround the area of drilling, concerns may arise about the conduction of heat during drilling. Misir et al. concluded that drilling with the use of a guide generates more heat than

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it is generated during conventional preparation of the site of an implant.⁵ Jeong et al. investigated the use of a wood and silicone model, and concluded that there was no difference between the guided flapless and flap techniques.⁶ Migliorati et al. compared standard open-flap surgery, flapless standard surgery, open-flap guided surgery, and guided flapless surgery, and concluded that while guided surgery produced higher rises in the temperature of the bone, the temperature stayed in the safe zone in the latter cases as well.⁷ When they compared guided surgery with the conventional technique, dos Santos et al. found that the rise in temperature also stayed within the safe zone.⁸

As this technique develops, we think that further elucidation of the topic is of importance.

Material and Methods

We used cortical bovine rib bones for drilling as they are easily available and easy to handle, as well as having ideal thermophysical and anatomical properties. Davidson and James showed that bovine cortical bone is thermally isotropic and the value of its conductivity is likely to be similar to that of human cortical bone.9 Yacker and Klein made computed tomographic scans of bovine bones and concluded that the cortical density is about 1400 Hounsfield units (HU), while the cortical density of typical human mandible is between 1400 and 1600 HU. ¹⁰ The thickness of the cortical bone of the human mandible was studied by Katranji et al, who found that the mean edentulous cortical thickness was between 1 and 2 mm and the dentate cortical thickness between 1.6 and 2.2 mm.11 The thickness of our specimens of bovine rib varied between 1.5 mm and 2.7 mm, which suggests that its anatomical properties are comparable with those of human mandible. This - together with our own anatomical measurements - confirm that bovine ribs are a good experimental model.

The ribs were derived from the same animal and were treated as described by Sedlin and Hirsch. ¹² The specimens were frozen to -10 °C in saline solution when not in use. Before the measurements were made the specimens were warmed to 36(1)°C, and the baseline temperature of the bone was checked before every episode of drilling. If it was less than 35 °C the specimen was returned to the warming device.

Infrared thermographic studies by Augustin et al. showed that the rise in temperature that is generated reaches its peak in the cortical layer of the bone, ¹³ so we designed an experiment in which we could measure the temperature of the bone around the drilled canal just before it reaches through the cortical layer, which indicates the peak intraosseous heat.

Flat parts of the ribs were divided and cut into segments that were long enough for attachment of the surgical guide that contained 3×8 drilling holes. The edges were then cut from the ribs longitudinally, and the specimens cut into halves through the cancellous bony layer and parallel to the flat surface of the bone. The remaining cancellous bone was then

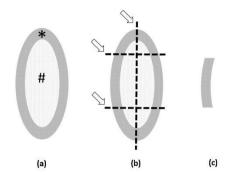


Fig. 1. Method of preparing specimens of cortical bone from bovine ribs. *=cortical layer, #=cancellous layer. White arrows and interrupted black lines indicate the directions of cutting.

removed with a chisel. We could therefore prepare quasiflat specimens of bone that contained only the cortical layer (Fig. 1)

Heat was measured with an infrared thermometric device (Voltcraft IR-380, Conrad, Germany). The device is equipped with 2 lasers that cross each other at the focus point of the infrared measurement, which means that it is well able to be aimed at the point of exit of the drill. In the case of drilling through a preformed canal of less than 0.5 mm in diameter (as happens during the second step of the drilling sequence), the thermometer was pointed immediately next to the exit of the canal (Fig. 2).

As the specimens were flat cortical parts of bovine ribs, a universal surgical guide was designed that contained 24 guiding canals in 3 columns (Fig. 3). The guide was manufactured using the same standards as the guides of the Smart Guide system (DicomLab Kft., Szeged, Hungary), and printed 3-dimensionally (printer: ProJet 3510 MP), using the same material (VisiJet Stoneplast). The guides were anchored by placing standard pins into pinholes in each of the 4 corners.

The same experienced dentoalveolar surgeon drilled every hole to achieve as constant applied pressure as possible. Heated debris was removed from the canal with a light pumping motion. The surgeon was not able to see the screen of the thermometer (Fig. 2), so it did not affect either his usual drilling movement or the amount of pressure applied. Drill speed was set to a constant 800 rpm as advised by the manual of the Smart Guide system.

Every step of the drilling sequence was investigated, and drills of 2 mm, 2.5 mm, 3 mm, and 3.5 mm were studied.

External cooling was applied by the assistant (with a standard 50 ml syringe that contained saline solution at a room temperature of $25\,^{\circ}$ C) at the point where the drill entered the metal sleeve of the canal in the drilling guide (Fig. 2). The drills were washed and cooled to room temperature after each drilling.

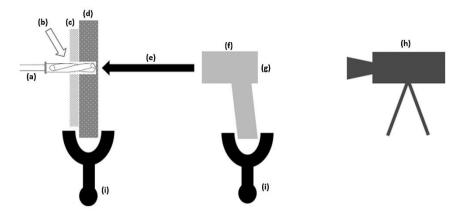


Fig. 2. The experimental setting: (a) drilling., (b) white arrow=external irrigation. (c)= surgical guide (d)= specimen of cortical bone, (e) black arrow=direction and focus point of infrared thermometric measurement, (f)=infrared thermometer, (g)=display of the thermometer visible to the video camera, (h)=video camera, and (i)=adjustable and rotating clamps for fixation.

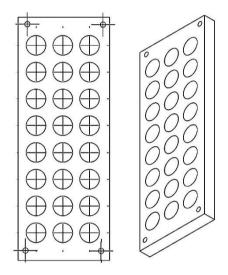


Fig. 3. Plan of the universal surgical guide for flat specimens of bone, printed in 3 dimensions according to the same guidelines as the Smart Guide's Oral Surgical Implant Guide (DicomLab Kft., Szeged, Hungary).

Baseline temperature, and peak temperature at the exit point, were recorded by reviewing the videos. The rise in temperature was calculated by subtracting the baseline temperature from the peak temperature, the latter being read just before the appearance of the drill bit so that the temperature recorded was the temperature of the bone and not that of the

drill material. The rises in temperature were collected in files using Microsoft Excel. The significance of differences was assessed with the aid of the open-source RStudio software. In case of similar variances we used the two-sample t test, while in case of differing variances we used Welch's test. Probabilities of less than 0.05 were accepted as significant.

Results

The first step of the implant system's drilling sequence is drilling with the 2 mm pilot drill. Forty-eight episodes of drilling with the use of external irrigation produced a mean (SD) rise in temperature of 4.77 (1.9°C, while 48 episodes of drilling without external cooling resulted in a rise of 7.02 (2.7)°C (Table 1), which was significant (p<0.001). Eight of the 48 episodes without cooling caused a rise that exceeded the 10°C threshold, while no episode exceeded it if external cooling was applied (Table 2).

The results of the second (2.5 mm drilling of a 2.0 mm canal), third (3.0 mm drilling of the 2.5 mm canal), and fourth (3.5 mm drilling of the 3.0 mm canal) steps of the drilling sequence were also significant (p<0.001) and are also shown in Table 1. The numbers of measured rises in temperature that exceeded the threshold with and without cooling are shown in Table 2.

Fig. 4 shows a boxplot of the distribution of measured rises in temperature.

Discussion

The rise in temperature caused by drilling was significantly less at every step of the drilling sequence when external

Table I
Number of episodes of drilling, mean (SD) rise in temperature, and p value when cooling is compared with no cooling for each step of the drilling sequence.
The speed of the drill was 800 rpm in each case.

No of episodes of drilling	Diameter of canal (mm)	Diameter of drill (mm)	Cooling	Mean (SD) difference in temperature (°C)	P value
48	0	2	Yes	4.77 (1.9)	< 0.001
48	0	2	No	7.02 (2.67)	
48	2	2.5	Yes	5.22 (1.36)	< 0.001
48	2	2.5	No	8.48 (3.25)	
48	2.5	3	Yes	3.32 (1.23)	< 0.001
24	2.5	3	No	8.48 (2.95)	
24	3	3.5	Yes	4.75 (1.28)	< 0.001
23	3	3.5	No	9.4 (3.73)	

Table 2 Number of rises in temperature of more than $10\,^{\circ}\text{C}$ ($n_{\geq 10\,^{\circ}\text{C}}$) and percentage of these among measurements for every step of the drilling sequence. The speed of the drill was 800 rpm in each case.

Diameter of the canal (mm)	Diameter of the drill (mm)	Cooling	No of episodes of drilling	No (%) during which temperature exceeded 10°C
-	2	Yes	48	0
2	2	No	48	8 (17)
2	2.5	Yes	48	1(2)
2	2.5	No	48	17 (35)
2.5	3	Yes	48	0
2.5	3	No	24	18 (75)
3	3.5	Yes	24	0
3	3.5	No	23	10 (42)

irrigation was used, being between $3.32\,^{\circ}\mathrm{C}$ and $5.22\,^{\circ}\mathrm{C}$, whereas when the drill was not cooled it varied between between $7.02\,^{\circ}\mathrm{C}$ and $9.40\,^{\circ}\mathrm{C}$. While the mean rise stayed below $10\,^{\circ}\mathrm{C}$ despite the lack of cooling, several individual measurements rose above the established limit of $10\,^{\circ}\mathrm{C}$. External cooling efficiently held the temperature of the bone in the safe zone with only one outlier that rose slightly above $10\,^{\circ}\mathrm{C}$. However, the latter phenomenon may require further elucidation and consideration.

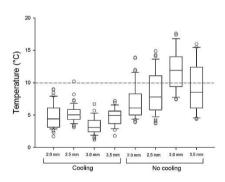


Fig. 4. Boxplot showing the distribution of the measured temperature rises. The red horizontal line indicates the $10\,^{\circ}\mathrm{C}$ threshold.

As it is the last step of the preparation sequence and the affected tissue is not removed by subsequent drillings, it should be emphasised that 3.5 mm drilling with external irrigation did generated a mean rise in temperature of only 4.75 °C and no measurement exceeded the limit. As on 10/24 occasions episodes of drilling with the 3.5 mm drill without cooling resulted in the temperature exceeding the limit, the lack of cooling is potentially harmful.

Misir et al. investigated the generation of heat on bovine femoral specimens, and found that the mean maximum temperature of the bone was 37.9 °C with surgical guides and 30.2 °C without surgical guides, but they published only the mean baseline temperature of 30.1 °C. ⁵ Bovine femoral cortical anatomy differs from bovine rib anatomy, so we cannot compare their data with ours. Jeong et al. compared a guided flapless technique with a flap technique on a wood-and-silicone model in which the wood had the same density as human bone.6 They found no significant difference between the two approaches and concluded that external irrigation with up-and-down pumping motions is a safe technique for preparation of the site of an implant. This confirms our results and shows that external irrigation can hold the temperature of bone within the safe zone with the guided flapless technique. Migliorati et al. measured heat in pig rib bones, and compared an open-flap technique with a guided flapless technique.7 They found significantly higher peak temperatures in bone with the guided technique, but these remained within the safe zone. 7 Dos Santos et al. investigated

heat generation during guided surgery on rabbit tibias, sand found that guided surgery generated higher temperatures than classic techniques, but no temperature rose more than 5.8 °C. They concluded that the guided technique was safe in that it did not cause osteonecrosis.

Our study is limited by being in vitro, but measurement of bony temperature in vivo might be difficult. However, the strength of our study is that in the experimental setting it is possible to measure heat just before the drill bit reaches through the cortical layer of the bone, so we suggest that it provides a good estimation of the highest bony temperature compared with studies that used thermocouples placed at a distance from the drilled canal. A further strength is that we investigated the thermal consequences of drilling in a guided surgical setting.

We conclude that despite the fact that there is more soft tissue together with the surgical guide itself around the area being prepared for the implant, external irrigation can efficiently control and hold the temperature of bone in the safe zone as part of the flapless guided surgery technique. Guided flapless surgery using 3-dimensional printed surgical guides can therefore be used safely with external irrigation as a coolant.

Conflict of Interest

We have no conflict of interest.

Ethics statement/confirmation of patient permission

Not required.

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Intraosseous generation of heat during guided surgical drilling: an ex vivo study of the effect of the temperature of the irrigating fluid

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Abstract

We measured the rise in the intraosseous temperature caused by freehand drilling or drilling through a surgical guide, by comparing different temperatures of irrigation fluid (10 °C, 15 °C, and 20 °C), for every step of the drilling sequence (diameters 2.0, 2.5, 3.0, and 3.5 mm) and using a constant drilling speed of 1200 rpm. The axial load was controlled at 2.0 kg. Bovine ribs were used as test models. In the guided group we used 3-dimensional printed surgical guides and temperature was measured with a thermocouple. The significance of differences was assessed with the Kruskal-Wallis analysis of variance. Guided drilling with 10 °C irrigation yielded a significantly lower increment in temperature than the 20 °C-guided group. When compared with the 20 °C freehand group, the reduction in temperature in the 10 °C guided group was significantly more pronounced at all diameters except 3.5 mm. Finally, when the 10 °C-guided group was compared with the 15 °C groups, the temperature rise was significantly less at 2.5 and 3.0 mm than with the guided technique, and at 3.0 mm compared with the freehand technique. We suggest that the use of 10 °C pre-cooled irrigation fluid is superior to warmer fluid for keeping temperature down, and this reduces the difference between guided and freehand drilling.

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Keywords: Irrigation fluid; Implants; Guided surgery; Drilling guide; Temperature; Bone drilling

Introduction

Keeping bony trauma to a minimum during preparation of the bed of an implant permits optimal conditions for osseointegration, which plays a key part in primary healing and so contributes to the long term success of dental implants.

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Drilling of bone is a common technique used in various types of surgery, and the generation of heat and associated mechanical damage during rotary cutting can influence the process of osseointegration. Previous studies have shown that necrosis can develop when the temperature during osteotomy exceeds

In recent years progress in the field of guided surgery has accelerated, and static surgical guides are now common devices.4,5 Misir et al. found that when a guide is used during drilling the increase in temperature is greater than when the implant site is prepared conventionally. 6 In another study, the

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difference between the guided flapless and flap techniques in terms of increase in temperature did not differ significantly. Two other studies have shown that the heat caused by drilling in a surgical guide stays within the safe zone. 3,9

To overcome thermal damage irrigation is essential ^{10,11} and, in particular, cold irrigation fluid has been found to be superior to fluid warmed to room temperature in minimising rises. ^{12,13}

However, to the best of our knowledge there has been no research into the use of irrigation solutions at different temperatures together with a surgical guide. We have previously found that with a higher drilling speed (1200 rpm) the rise in temperature could be near the necrotic threshold, so we wished to know if the use of saline solutions at various temperatures during guided surgical drilling at a speed of 1200 rpm would result in smaller rises.

Material and methods

Bovine ribs were used, because of their favourable thermophysical and anatomical characteristics. Davidson and James had already shown that bovine ribs are thermally isotropic, whilst their conductivity is identical to that of human mandible. ¹⁴

The densities of the cortical and cancellous bone of bovine ribs have been shown to be analogous to those of human bone as measured by computed tomography, ¹⁵ and the study by Katranji et al. concluded that the mean edentulous and dentate cortical thickness falls between 1 and 2 mm, and 1.6 and 2.0 mm, respectively. ¹⁶ The thicknesses of our segments of bovine rib were within the same range. Sener et al. concluded that the increase in temperature was greater in cortical bone than in the deeper parts of the drilling cavity, ¹² which has been confirmed by other studies. ^{17,18} Specimens of bovine rib bone with a cortical thickness similar to that of the human mandible were therefore used, and the measurements (which were made in the cortical layer of the bone) described the peak temperature during drilling.

Every specimen was taken from the same animal, and they were all stored at -10 °C in normal saline solution between the experiments, as described by Sedlin and Hirsch. 19 The animal was not killed for the experiment.

Our measurements were designed to replicate the rise in temperature during preparation of an implant site throughout a full drilling sequence (2.0, 2.5, 3.0, and 3.5 mm drilling), using a standard drilling speed (1200 rpm) and a standard quantity of external irrigation solution. The factors that were varied were whether the drilling was freehand or guided, and the temperature of the irrigating saline: $20\,^{\circ}\text{C}$, $15\,^{\circ}\text{C}$, or $10\,^{\circ}\text{C}$. Each group was defined by the depth of drilling, the technique, and the temperature of the irrigant. Twenty-four groups were studied, and 20 measurements made in each group. In the groups in which guided surgery was evaluated we used a model surgical guide that had 2×5 guiding holes with metal sleeves (Fig. 1) and four holes for the fixing pins.

Entry points for the freehand groups were marked on the surface of the specimens with the help of the surgical guide.

K-type thermocouples were used to measure temperature with a connecting measurement device (Holdpeak-885A, Holdpeak, China). The thermocouples were consistently placed into a well that had been prepared with a start drill 2.0 mm in diameter and a depth of 1.8 mm (so that we could make sure that the depth of the cavity never exceeded the cortical layer). The thermocouple was placed so that it touched the lateral bony wall of the cavity that was closest to the implant bed to be drilled and then tightly filled with bone chips derived from specimens of rib from the same animal, and the hole was thoroughly sealed with plasticine to maintain adequate insulation (Fig. 2).

Measurement cavities were positioned directly underneath the metal sleeve of the surgical guide, 1.75 mm horizontally from the 2.0 mm drilling canal, 1.5 mm from the 2.5 mm drilling canal, 1.25 mm from the 3.0 mm drilling canal, and 1.0 mm from the 3.5 mm (final) drilling canal (Fig. 2). To ensure comparable results, the measurement cavities were prepared in the same positions for the freehand groups. The precise position of the measurement cavities was calculated from a 3-dimensionally printed guide, which could be anchored with pins in the same position as the model surgical guide (Fig. 1).

A constant axial pressure was maintained throughout the procedure, and the axial load was controlled at 2.0 kg. Tehemar et al. had concluded that 2.0 kg can be considered as low hand pressure, ²⁰ and this correlated with the observations of a recently-published systematic review by M hlhenrich et al. which confirmed that 2.0 kg is the most extensively used axial load. ²¹ A bench drill (Bosch PBD 40, Bosch, Germany) with adjustable speed was used for drilling.

Before the measurements were made the specimens of bone were warmed to 37 °C in saline tanks, and we drilled only when the baseline temperature had fallen between 35 °C and 37 °C. Standard, constant, external irrigation generated by a commercially-available physiodispenser surgical unit (W&H Implantmed SI-923, W&H, Austria) was applied through a standard cannula (W&H, Austria) attached to the drilling machine and directed to the drill bit at a flow rate of 105 ml/minute. The temperature of the irrigation fluid was either 20 (1) °C (room temperature), or 15 (1) °C, or 10 (1) °C. Before each measurement the temperature of the saline solutions was checked with an infrared thermometric device (Holdpeak-320, Holdpeak, China).

The full experiment is shown in Fig. 3. Each one was made (and the full apparatus stored) in the same air-conditioned room at a temperature of 20 (1) °C. Temperature rises (peak temperature minus baseline temperature) were analysed statistically with the help of Statistica for Windows 10.0 (StatSoft, Tulsa, OK, now Dell Software Group, CA, USA). As the Shapiro-Wilk test indicated that the distributions were skewed, we used the Kruskal-Wallis analysis of variance for comparisons between groups.

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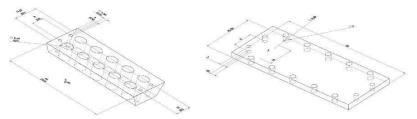


Fig. 1. The 3-dimensional printed surgical drilling guide (left) and the 3-dimensional printed guide to help measure the position of the cavity (right).

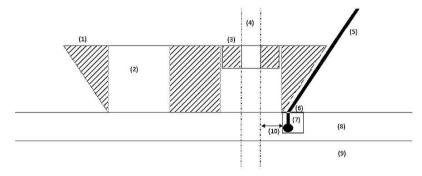


Fig. 2. Cross-section of the drill (1) = surgical drilling guide, (2) = drilling canal, (3) = drill sleeve for the actual diameter of the drill, (4) = projected drilling path, (5) = thermocouple, (6) = insulation, (7) = bone chips, (8) = layer of cortical bone, (9) = layer of cancellous bone, and (10) = distance from the canal to be drilled (1.75 mm for the 2.0 mm drill, 1.50 mm for the 2.5 mm for the 3.5 mm drill, and 1.0 mm for the 3.5 mm drill).

Results and Discussion

The results of our measurements are shown in Table 1. Data from the drilling procedures were divided into groups by the following aspects: temperature of the irrigation fluid, method of drilling, and diameter of the drill. The values of the thermal changes in each group are shown in Figure 4 (supplementary data).



Fig. 3. The experiment.

There was a significantly smaller rise in temperature with freehand drilling with $10\,^{\circ}$ C irrigation compared with the $20\,^{\circ}$ C guided group ($\mathbf{p}=0.000$ for all diameters), regardless of the diameter of the drill. If freehand drilling with $10\,^{\circ}$ C irrigation was compared with freehand drilling with $20\,^{\circ}$ C irrigation, the difference between groups with the same drill diameter was significant ($\mathbf{p}=0.026$ for 2.0 mm, ($\mathbf{p}=0.000$ for 2.5 and 3.0 mm), with the exception of 3.5 mm drill diameter groups. When $10\,^{\circ}$ C freehand irrigation was compared with $15\,^{\circ}$ C guided irrigation, the difference was significant at 2.5 ($\mathbf{p}=0.005$) and 3.0 ($\mathbf{p}=0.004$) mm, indicating the superior efficiency of lower temperature irrigation

rior efficiency of lower temperature irrigation. Guided drilling with $10\,^{\circ}\text{C}$ irrigation also yielded a significantly lower temperature than the $20\,^{\circ}\text{C}$ guided group (p = 0.000 for all diameters), regardless of the diameter of the drill. When the $10\,^{\circ}\text{C}$ guided group was compared with the $20\,^{\circ}\text{C}$ freehand group, the reduction in temperature was significantly more pronounced at all diameters except for $3.5\,\text{mm}$ (p = 0.431 for $2.0\,\text{mm}$, p = 0.000 for $2.5\,\text{and}\,3.0\,\text{mm}$, whereas p = 0.055 for $3.5\,\text{mm}$ and p = 0.2?). Finally, when the $10\,^{\circ}\text{C}$ guided group was compared with the $15\,^{\circ}\text{C}$ group, there were significantly lower rises in temperature at $2.5\,^{\circ}$ (p = 0.003) and $3.0\,^{\circ}$ (p = 0.000) mm compared with the guided technique, and at $3.0\,^{\circ}$ mm compared with the freehand technique (p = 0.025).

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Table I

Mean rises in temperature for the examined groups showing the significant differences between groups with the same diameter of drill.

Group	Diameter of the drill	Guided/ free-hand	Temperature of irrigation fluid (°C)	Mean (SD) rise in temperature (°C)	Significant differences compared with groups with the same drill diameter (group number, * p<0.05, ** p<0.01, *** p<0.001)
1	2.0	Free-hand	10	0.11 (0.61)	17*, 21***
2	2.5	Free-hand	10	0.15 (0.49)	14**, 18***, 22***
3	3.0	Free-hand	10	0.71 (0.96)	15**, 19***, 23***
4	3.5	Free-hand	10	1.48 (0.74)	24***
5	2.0	Guided	10	-0.04 (1.15)	17*, 21***
6	2.5	Guided	10	-0.02 (0.80)	14**, 18***, 22***
7	3.0	Guided	10	0.10(0.76)	11*, 15***, 19***, 23***
8	3.5	Guided	10	1.40 (0.58)	24***
9	2.0	Free-hand	15	0.66 (0.52)	21***
10	2.5	Free-hand	15	1.13 (0.51)	18*, 22**
11	3.0	Free-hand	15	1.75 (0.65)	7*, 23**
12	3.5	Free-hand	15	1.89 (0.70)	24**
13	2.0	Guided	15	1.44 (0.46)	*
14	2.5	Guided	15	1.85 (0.71)	2**, 6**
15	3.0	Guided	15	2.48 (0.91)	3**, 7***
16	3.5	Guided	15	2.75 (0.82)	2
17	2.0	Free-hand	20	1.74 (0.73)	1*,5*
18	2.5	Free-hand	20	2.84 (1.19)	2***, 6***, 10*
19	3.0	Free-hand	20	3.11 (1.14)	3***, 7***
20	3.5	Free-hand	20	3.30 (1.52)	
21	2.0	Guided	20	2.56 (0.92)	1***, 5***, 9***
22	2.5	Guided	20	3.45 (1.49)	2***, 6***, 10**
23	3.0	Guided	20	4.35 (1.36)	3***, 7***, 11**
24	3.5	Guided	20	4.86 (1.67)	4***, 8***, 12**

In all cases the drilling speed was 1200 rpm and the number of episodes of drilling was 20. For the grouping numbers marked with one *, the exact p-values rounded to three decimal digits are the following: Group 1: 17* (p=0.026); Group 5: 17* (p=0.043); Group 7: 11* (p=0.025); Group 10: 18* (p=0.031); Group 11: 7* (p=0.025); Group 17: 1* (p=0.026) and 5* (p=0.043); Group 18: 10* (p=0.031).

Kondo et al. concluded that cold irrigation might lessen the rise in temperature caused by drilling, 13 and the use of $10\,^{\circ}\mathrm{C}$ irrigation could be better at keeping the temperature under the necrotic threshold. 12 Isler et al. concluded that the use of a 4 $^{\circ}\mathrm{C}$ saline irrigation might result in better, quicker healing. 22

Publications about the production of heat during guided surgery have so far studied only the use of normal saline at room temperature, and their findings may be summarised as follows. Misr et al. showed that a significantly higher peak in temperature could be measured during guided preparation of the implant site. In a study in which they used resin models there was no comparable difference when they used a flapless or a flap approach during guided surgery. An in vitro study by Migliorati et al. concluded that with proper irrigation, guided surgery can be as safe as the conventional method. Dos Santos et al. also showed that the rise in temperature stayed within the safe zone when a surgical guide was used. Finally, we have also shown that external irrigation can efficiently control the rise in temperature with the guided technique.

A limitation of our study is that it was ex vivo. However, its strengths include the comparison of guided and freehand techniques, the use of saline solutions at different temperatures (10 °C, 15 °C, and 20 °C), drilling throughout a whole sequence of four different drill diameters with the same axial

load, and the quantity of external irrigation being well controlled.

Conclusion

The use of saline as irrigating fluid at $10\,^{\circ}\text{C}$ meant that a significant reduction in peak temperature was achieved regardless of both the preparation technique of the site or the diameter of the drill. Considering our results that with irrigation at room temperature $(20\,^{\circ}\text{C})$ at a drilling speed of $1200\,\text{rpm}$, and a drill diameter of $3.5\,\text{mm}$, near-necrotic temperatures may be reached, we suggest that the use of $10\,^{\circ}\text{C}$ precooled irrigation fluid is a better way to control temperature.

Conflict of Interest

EV Jr. is the CEO, and EV is a consultant for and part-owner, of Dicom LAB Kft, Szeged, Hungary.

Ethics statement/confirmation of patient permission

No ethics approval was required as the research was done using samples of dead bone.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/ j.bjoms.2016.06.004.

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Publication No. III.

Heat generation during guided and freehand implant site preparation at drilling speeds of 1500 and 2000 RPM: an in vitro study

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Contribution: hypothesis, study design, experiments and measurements, statistical analysis, preparation of the manuscript

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Contribution: hypothesis, study design, supervision of the experiments, preparation of the manuscript

Abstract

Purpose The purpose of our study was to evaluate the impact of different irrigation fluid temperatures on intraosseous temperature increment during guided and freehand implant site preparation.

Materials and methods Bovine rib bones were used. Temperature was detected using K-type thermocouples. Studied groups were established as combination of the following: drilling speed (1500, 2000 RPM), drill diameter (2.0, 2.5, 3.0, 3.5 mm), surgical method (guided, freehand), and irrigation fluid temperature (10°C, 15°C, 20°C). Statistical analysis using Kruskal-Wallis ANOVA and ANOVA was performed.

Results At 1500 RPM, guided drilling with irrigation fluid at 20°C produced values exceeding the limit in case of 3.0 and 3.5 mm diameters. The use of 15°C irrigation managed to hold the mean increment below 8.0°C at the diameter of 3.5 mm for both guided and freehand surgery. Irrigation at 10°C cancelled every statistically significant difference between guided and freehand groups. At 2000 RPM, 20°C irrigation produced significantly higher changes when comparing guided to freehand groups at all diameters, with means exceeding the limit in case of 3.0-3.5 mm guided and 3.5 mm freehand groups. No significant difference was detected with 10°C irrigation between guided and freehand drillings, and every measurement remained in the safe zone.

Conclusion 1500 and 2000 RPM drillings produce temperature elevations exceeding the limit in a guided setting. 2000 RPM drilling produces potentially harmful temperatures in a freehand setting. At 2000 RPM, 10°C irrigation fluid is successful in controlling temperature. At 1500 RPM, 15°C irrigation lowers values into the safe zone.

Key words: Implant, Temperature, Oral surgery

Introduction

Bone drilling is a method used in various fields of surgery (orthopedics and traumatology, spine surgery, oral and maxillofacial surgery, and ear-nose-throat surgery). Rotary cutting induces heat generation around the drilled canal. The classic study by Eriksson and Albrektsson have concluded that an intraosseous temperature of 47°C for 1 minute of time is the threshold for the histological appearance of bone tissue damage. ¹² The developing temperature change can be controlled by means of irrigation. Other studies have since confirmed, that insufficient heat control can result in osteonecrosis and impaired new bone formation ¹⁴ and might cause massive peri-implant bone resorbtion. ²⁷

Methods enhancing the accuracy of implant placement are of great interest, and computer-aided techniques in dentistry and oral surgery are emerging. Static surgical guides are the most widely used devices in the field of guided implant placement.²⁸ Questions might arise amongst professionals concerning the safety of guided drilling in terms of the sufficiency of irrigation, as drilling is performed through a guiding hole and the bone surface is not directly exposed to the irrigation fluid. One study has shown that the guided technique induces a significantly higher increment compared to freehand drilling²⁰, however, other studies have concluded that the guided technique produces intraosseous temperatures staying in the safe zone.^{11, 15, 18, 7}

Irrigation fluid is most widely used externally and at room temperature. The use of cooled irrigation fluid might be a straightforward approach, however, only a few studies have investigated its use, some suggesting a better temperature control^{24, 17, 6}, and one study suggesting that it might enhance bone healing on a histological level.¹⁴The use of internal cooling systems has been shown to produce significantly lower heat generation compared to external irrigation in case of stainless steel drills. 13 The same study have found no difference between three different drill materials (stainless steel, stainless steel coated with zirconium nitride, and zirconium oxide). 13 In terms of different drill designs, Augustin et al. have shown no significant difference between different drill point angles (80°, 100°, and 120°),3 whereas Oh et al. have shown that two fluted drills show significantly lower temperature increas compared to that of three fluted and four fluted drills.²² Drilling speed is a known factor of heat generation as well.^{5, 19, 21} Most manufacturers recommend low-speed drilling for implant site preparation with speeds usually ranging from 800 to 2500 RPM. An early study by Thompson have suggested that the increase of drilling speed in this range results in an increase of intraosseous temperature. 26 A study by Brisman has shown that the combination of 1800 RPM and 1.2 kg of axial load has produced the same temperature increment as the combination of 2400 RPM and 2.4 kg, whereas independent increase of any of these two factors results in an increase of temperature.8 A significant positive correlation between drilling speed and temperature change has been proved by Augustin et al.3 Repeated use of drills in the clinical setting results in drill wear, and it is well known that heavily used drills produce significantly higher temeperature change¹, however, a longevity study by Allsobrook et al. have concluded that implant drill bits can be used safely for up to 50 osteotomies.² As it is already mentioned above, Eriksson and Albrektsson have stated that the threshold is 47°C for 1 minute¹², however, to the best of our knowledge, there is no data available about the time factor in case of bony temperatures exceeding 47°C.

An earlier study has investigated the effect of cooled irrigation *ex vivo* in both guided and freehand settings at a drilling speed of 1200 RPM.⁶ The aim of this present study is to evaluate heat control in guided and freehand implant site preparation at higher implantologically relevant drilling speeds of 1500 and 2000 RPM, in case of both room temperature and cooled irrigation, in the same experimental setting.

Materials and methods

The study was aimed at investigating the temperature elevating effect of new implant drills, comparing the following aspects: different drill diameters (2.0, 2.5, 3.0, and 3.5 mm drill bits), different surgical techniques (freehand technique and guided drilling), two different drilling speeds of the higher end of the low-speed range accepted in the implantological practice (1500 RPM and 2000 RPM), and irrigation fluids preset at different temperatures (20°C, 15°C, 10°C). The combination of these factors meant the evaluation of 48 different subgroups. Twenty measurements were conducted in every subgroup. Drill bits were stainless steel, two fluted drill bits with drill point angles of 90°in case of the 2.0 mm diameter and 120° in case of 2.5, 3.0, and 3.5 mm diameters, from a commercially available guided implantology system (SMART Guide, dicomLab Kft., Szeged, Hungary). No drill bit was used for more than 20 drillings to avoid any effect on its temperature elevating effect due to drill wear.

Bovine ribs were chosen as a bone model for the investigations, as several studies show it to be ideal for *ex vivo* drilling studies mimicking oral implantology. Katranji et al. have shown that the mean dentate human mandibular cortical thickness is between 1.6 and 2.0 mm. ¹⁴ Bovine ribs have segments with similar values, thus, specimens can be chosen to fit this requirement. Davidson and James have shown bovine ribs to be thermally isotropic and to have a thermal conductivity that is similar to that of the human mandible. ^{9, 10} In terms of cortical density, Yacker and Klein have shown them to have similar values to human mandible (with values being around 1400 Hounsfield units). ²⁹ The specimens used in the study were derived from the same animal that was not sacrificed for the sake of our investigations. The ribs were stored at a temperature of -10°C, and in standard saline solution, as Sedlin and Hirsch suggest this protocol to best preserve the physical properties of bone specimens. ²³ The specimens were chosen to have a quasi-flat surface and a cortical thickness of about 2.0 mm.

The study design was designed to investigate both guided and freehand implant bed preparation techniques. In case of the guided surgical drilling group, drillings were conducted using a 3D-printed surgical guide that fit well on the quasi-flat surface of the specimens. The guide was designed using the same principles and protocols as in case of every surgical guide of a commercially available implantological guide system (SmartGuide, dicomLAB Kft., Szeged, Hungary), and contained 2x5 guiding canals with a metal insert, and was able to accommodate the metal guiding spoons that are designed to guide the drill bits of different diameters. (Figures 1 and 2.) The guide was designed in a fashion that allowed a thermocouple to be placed in close proximity to the canal to be drilled (Figures 1 and 2.). Measurement beds were placed right at the point where the guiding canal of the guide reaches the bone surface, using another 3D-printed guide for precision. In case of freehand surgical drillings, the entry points were marked on the bone surface using the same guides as in case of the guided surgical groups, but the guides were removed. Measurement beds for freehand drillings were placed using the same guides as in case of the guided subgroups. (Figure 3.) All measurement beds were prepared with a depth control of 1.8 mm to ensure that they are still in the cortical layer of the bone, as a study investigating heat distribution during drilling confirmed that peak temperature during drilling develops in the cortical layer of the bone.⁴ After placing the thermocouple inside the bed, it was tightly filled with cortical bone chips of the same animal, and the bed was insulated with plasticine to avoid any direct contact with the irrigation solution, that might influence the measurements (Figure 1.). The measurement beds were in the following distance from the canal to be drilled: 1.0 mm when using the 3.5 mm drill bits, 1.25 mm when using the 3.0 mm drill bits, 1.50 mm when using the 2.5 mm drill bits, and 1.25 mm when using the 2.0 mm drill bits. Ktype thermocouples were used for the measurements, and were connected to a measurement

device (Holdpeak-885A, Holdpeak, China). The bone specimens were carefully warmed to a value around body temperature (37±1°C). The temperature elevations were calculated by subtracting the baseline temperature from the peak temperature measured. Osteotomies were performed in a regular fashion with the drill passing through the cortical layer of the bone down into cancellous bone. The drillings were terminated when the continuously measured cortical temperature reached its peak and did not show any further tendency to elevate, thus the time factor was not investigated in the experiment.

A bench drill (Bosch PBD 40, Bosch, Germany) was used for the experiments. The axial pressure was controlled at a level of 2.0 kg, as reviews suggest that it is widely used in similar studies^{21, 25} and it can be considered as a light hand pressure exerted during implant site preparation.

External irrigation was conducted using a widely used surgical unit (W&H Implantmed SI-923, W&H, Austria) and a widely used, standard cannula (W&H, Austria). The flow was 105 mL/min. Normal saline was used as an irrigation solution. The irrigation fluids were used on three different preset temperatures: 10° C, 15° C, and 20° C. The measurements and drillings were only initiated if the temperature of the fluid was around the wanted preset value ($\pm 1^{\circ}$ C).

In case of 2.5 mm, 3.0 mm, and 3.5 mm drillings, the canals were predrilled with 2.0 mm, 2.5 mm, 3.0 mm drills respectively.

The calculated values were statistically analyzed using Statistica for Windows 10.0 (Statsoft, Tulsa, OK, USA). For statistical comparison between groups, either Kruskal-Wallis ANOVA or one-way ANOVA with post-hoc Tukey test was used, depending on the distribution of the compared subgroups. The level of significance was set at α =0.05.

Results

Results of the 1500 RPM drilling group can be summarized as the following: 1) guided 1500 RPM drilling with irrigation fluid at 20°C produced values exceeding the 10°C limit in case of the 3.0 and 3.5 mm drill bit diameters, with the mean exceeding 11.0°C in case of the 3.5 mm diameter, 2) freehand drilling with 20°C irrigation produced no values to exceed 8.8°C, and the means to stay below 8.0°C for all diameters, 3) the mean freehand values were significantly lower compared to guided drilling with irrigation at 20°C at the 3.0 mm (p=0.000) and the 3.5 mm (p=0.000) diameters, 4) the use of 15°C irrigation managed to hold the mean temperature elevation below 8.0°C at the diameter of 3.5 mm for both guided (a mean of 7.6°C) and freehand (a mean of 7.3°C) surgery, 5) when using 15°C irrigation, no statistically significant difference was detectable between the two methods, with the exception of the 3.0 mm diameter, where guided surgery produced significantly higher values (p=0.032), 6) with the use of 10°C irrigation, every mean value was below 6.0°C and no single measured value exceeded 7.1°C, 7) the use of 10°C irrigation managed to completely erase every statistically significant differences between the two surgical methods.

Results of the 2000 RPM drilling group can be summarized as the following: 1) for the 20°C irrigation guided drilling groups, the means exceeded the limit in case of the 3.0 and 3.5 mm guided, and the 3.5 mm freehand groups, 2) moreover, for guided drillings with 20°C irrigation, the maximum values reached 13.0°C in case of 2.5 and 3.0 mm, and 16.0°C in case of the 3.5 mm groups, 3) guided drillings with 20°C irrigation produced significantly higher values of temperature elevation compared to the freehand groups at all diameters (2.0 mm (p=0.039), 2.5 mm (p=0.001), 3.0 mm (p=0.047) and 3.5 mm (p=0.000)), 4) the means exceeded the limit in case of guided 3.0 and 3.5 mm drilling groups with 15°C irrigation, 5) freehand drillings with 15°C irrigation remained in the safe zone for all

diameters, 6) when using 15°C irrigation, guided drillings were shown to produce significantly higher temperature changes compared to freehand drillings at the 2.0 mm (p=0.000), 3.0 mm (p=0.000) and the 3.5 mm (p=0.000) diameters, 7) no means exceeded 7.0°C, and no single measurement showed an elevation exceeding 8.9°C when 10°C irrigation was used, 8) when using 10°C irrigation fluid, no significant difference was detectable between guided and freehand drilling.

Basic statistics, including mean values, standard deviations and maximum values are shown in Table 1. for every investigated group. All statistically significant differences are noted in the text above. Boxplot presentation for all studied groups can be seen on Figures 4-7.

Discussion

The number of publications discussing temperature change in guided surgery are limited. A study conducted by Misir et al. using bovine femora, a drilling speed of 1500 RPM, an axial load of 2 kg, and thermocouples for measurements have found that drillings with the guided technique produced peak temperatures more than 7°C higher compared to the conventional technique. 20 However, bovine femora have significantly thicker cortical layers, these results are not directly comparable to ours. Migliorati et al. have performed their experiments on pig ribs at a drilling speed of 1200 RPM, with an axial load of 2.5 kg, and thermocouples for measurement purposes. 18 They have found that mean peak temperature change with guided surgery was 4.81°C, significantly higher compared to the open-flap technique (4.21°C), however, the former value is still markedly in the safe zone. 18 These results show somewhat lower temperatures compared to the present data, which might be due to the fact that drilling have been performed at a lower speed and in a different bone model. Jeong et al. have measured heat production in a guided flapless setting and compared it to a flap procedure on resin models at a drilling speed of 1200 RPM, with manually loaded drillings and thermocouples for measurement purposes, and they have found no significant differences.¹⁵ This is contrary to the present findings at room temperature, as the guided technique produced significantly higher temperature elevation at 2000 RPM for all diameters and at 1500 RPM for the bigger diameters (3.0 and 3.5 mm). Dos Santos et al. have observed the guided technique in vivo on rabbit tibias at a drilling speed of 1600 RPM, with manual drillings and thermocouples for measurement purposes, and they have found no temperature change exceeding 5.8°C, whereas the guided technique have been found to produce significantly higher elevation compared to the control group. 11 The fact that guided surgery might produce significantly higher temperature elevation corresponds with present findings at a similar drilling speed (1500 RPM), but our results show markedly higher temperature elevations for bigger diameters, however, temperature elevations for the different diameters in the drilling sequence have not been published separately by Jeong et al., and the method of temperature registration is not clear. It has to be noted that there are marked differences between the bone models and experimental setups in the available literature, thus, comparison with the presented results is difficult.

Only a few studies dealt with the question of using cooled irrigation fluid. Kondo et al. have concluded that cold irrigation might lessen the temperature increment during rotary cutting, and the use of 8°C irrigation could be more efficient at maintaining the temperature under the necrotic threshold. In an earlier study, Boa et al. have investigated the use of cooled irrigation fluid during guided and freehand surgical procedure at a drilling speed and 1200 RPM, and have concluded that the use of pre-cooled irrigation fluid at 10°C is superior to room temperature fluid in terms of temperature control and that it diminishes the difference between the two surgical methods. These results are in line with the current data. Isler et al. have investigated the effect of 25°C irrigation, 4°C irrigation, and no irrigation on histological indicators of bone formation in vivo, in rats. No

statistically significant difference has been found between 25° C and 4° C irrigation on new bone formation and the presence of osteonecrosis, however, a more prominent osteoblastic rim has been observed in case of the 4° C group, suggesting a better osteoblastic potential. 14

As the limitation of this study, its ex vivo nature has to be remarked. Strength of the current study is the comparison of guided and freehand technique, as well as 1500 rpm and 2000 rpm drilling throughout a whole drilling sequence of four different drill diameters, with the axial load and the external irrigation being well controlled. As a further limitation the use of a 2 kg axial load correlates with low hand pressure which might vary between dental implant surgeons, and as Brisman have shown, increasing axial load at a given constant drilling speed results in an increase of temperature change. It also has to be noted that this study investigated a specific implant drill bit system with the aforementioned parameters (two fluted, stainless steel drill bits with a drill point angle of 90° for the 2.0 mm and 120° for the 2.5, 3.0, and 3.5 mm drill bits), however, as it has been discussed in the introduction section, only the number of flutes have been shown to influence heat generation in the literature. As 3,3,22 Measurements were performed in the cortical layer of the bone using bovine rib bone specimens with cortical thickness similar to that of the human mandible were used and, as it is well described that peak temperature change presents in that layer.

Conclusion

The presented results show that both 1500 and 2000 RPM drilling can produce temperature elevations exceeding the limit in a guided setting, moreover, 2000 RPM drilling can produce potentially harmful temperatures in a freehand setting as well. In case of 2000 RPM drillings, only irrigation fluid at a temperature of 10°C was completely successful in controlling the temperature and in completely abolishing the difference between guided and freehand drilling, whereas, in case of 1500 RPM drillings, the 15°C irrigation succeeded in lowering the values into the safe zone.

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Figure legends

Figure 1. – The experimental setup showing guided drilling.

Figure 2. – Schematic drawing representing the guided drilling setup. (cort): cortical bone. (canc): cancellous bone. (g): guide. (s): metal guiding sleeve. (d): drill bit. (tc): thermocouple. (mb): measurement bed.

Figure 3. – Schematic drawing representing the freehand drilling setup. cort): cortical bone. (canc): cancellous bone. (d): drill bit. (tc): thermocouple. (mb): measurement bed.

Figure 4. – Plot presentation of 1500 RPM freehand drillings.

Figure 5. – Plot presentation of 1500 RPM guided drillings.

Figure 6. - Plot presentation of 2000 RPM freehand drillings.

Figure 7. - Plot presentation of 2000 RPM guided drillings.

Tables

 $\label{thm:condition} \textbf{Table 1.} - \textbf{Mean temperature elevation, standard deviation, and maximum elevation (guided drilling groups).}$

drilling speed (rpm)	diameter (mm)	surgical method	preset temperature of the irrigation fluid (°C)	mean ΔT (°C)	SD	maximum ΔT (°C)
1500	2.0	guided	20	5.8	0.6	7.6
1500	2.5	guided	20	7.5	1.0	9.1
1500	3.0	guided	20	9.4	0.9	10.8
1500	3.5	guided	20	11.2	1.7	14.0
2000	2.0	guided	20	7.9	0.8	9.1
2000	2.5	guided	20	9.9	1.8	13.9
2000	3.0	guided	20	10.9	1.6	13.0
2000	3.5	guided	20	13.8	1.5	16.0
1500	2.0	guided	15	5.5	1.0	7.4
1500	2.5	guided	15	6.4	0.8	7.6
1500	3.0	guided	15	7.3	0.5	8.0
1500	3.5	guided	15	7.6	0.4	8.4
2000	2.0	guided	15	7.7	0.8	8.6
2000	2.5	guided	15	7.9	0.8	8.9
2000	3.0	guided	15	10.1	0.9	11.1
2000	3.5	guided	15	11.1	1.1	12.7
1500	2.0	guided	10	3.2	0.9	5.3
1500	2.5	guided	10	4.0	1.0	5.6
1500	3.0	guided	10	4.9	0.9	6.9
1500	3.5	guided	10	5.6	0.8	7.1
2000	2.0	guided	10	5.0	0.8	6.0
2000	2.5	guided	10	5.7	1.1	7.2
2000	3.0	guided	10	6.1	0.8	7.3
2000	3.5	guided	10	6.8	0.9	8.5

Table 2. – Mean temperature elevation, standard deviation, and maximum elevation (freehand drilling groups).

drilling speed (rpm)	diameter (mm)	surgical method	preset temperature of the irrigation fluid (°C)	mean ΔT (°C)	SD	maximum ΔT (°C)
1500	2.0	freehand	20	5.8	1.6	8.4
1500	2.5	freehand	20	7.0	0.6	7.7
1500	3.0	freehand	20	7.1	0.6	7.9
1500	3.5	freehand	20	7.8	0.5	8.8
2000	2.0	freehand	20	6.6	1.5	9.5
2000	2.5	freehand	20	8.3	0.5	9.2
2000	3.0	freehand	20	9.7	0.5	10.6
2000	3.5	freehand	20	10.2	0.7	11.3
1500	2.0	freehand	15	5.4	1.0	7.6
1500	2.5	freehand	15	5.8	0.9	7.3
1500	3.0	freehand	15	6.3	0.9	7.9
1500	3.5	freehand	15	7.3	1.1	9.2
2000	2.0	freehand	15	6.2	1.0	7.8
2000	2.5	freehand	15	7.3	0.6	8.1
2000	3.0	freehand	15	8.0	0.8	9.1
2000	3.5	freehand	15	8.6	0.7	9.6
1500	2.0	freehand	10	3.7	0.7	5.8
1500	2.5	freehand	10	4.3	0.7	5.9
1500	3.0	freehand	10	4.7	0.7	6.2
1500	3.5	freehand	10	5.3	0.8	6.4
2000	2.0	freehand	10	4.7	0.6	5.7
2000	2.5	freehand	10	5.0	0.7	6.0
2000	3.0	freehand	10	6.2	0.8	8.9
2000	3.5	freehand	10	6.6	0.8	8.4