Chapter

Orthopedic Bone Drilling Robot ODRO: Basic Characteristics and Areas of Applications

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Abstract

The orthopedic manipulation "bone drilling" is the most executed one in the orthopedic surgery concerning the operative treatment of bone fractures. The drilling process is characterized by a number of input and output parameters. The most important input parameters are the feed rate [mm/s] and the drill speed [rpm]. They play significant role for the final result (the output parameters): thermal and mechanical damages of the bone tissue as well as hole quality. During the manual drilling these parameters are controlled by the surgeon on the base of his practical skills. But the optimal results of the manipulations can be assured only when the input parameters are under control during an automatic execution of the drilling process. This work presents the functional characteristics of the handheld robotized system ODRO (Orthopedic Drilling Robot) for automatic bone drilling. Some experimental results are also shown. A comparison is made between the similar systems which are known in the literature, some of which are available on the market. The application areas of ODRO in the orthopedic surgery practice are underlined.

Keywords: automatic bone drilling, handheld robotized surgical drill, speed control, orthopedic surgery

1. Introduction

The bone drilling process is a basic manipulation in the osteosynthesis of the bone fractures. Osteosynthesis is a surgical procedure, which stabilizes and joins the ends of fractured (broken) bones by mechanical devices such as metal plates, screws, pins, rods, wires. Nowadays by statistics every year about one million people in Europe need such an operation where implants into bones are inserted.

The process of bone drilling is characterized by a number of input and output parameters. The input parameters define the conditions under which the process occurs, while the output parameters determine the outcome of the process.

The input parameters as feed rate [mm/s] and drill speed [rpm] are of the greatest importance for the final result of the drilling process: thermal and mechanical damages of the bone tissue, hole quality, second cortex breakthrough detection and penetration depth in the case of bicortical bone drilling.

A large amount of researches have been published related to the influence of these parameters on the bone drilling process. Only publications, indexed in

SCOPUS, related to the bone drilling process, are above 3000 since 2000 [1], which proves the importance and relevance of researches in this area.

Most of the drilling operations in orthopedic surgery are done manually (non-automatically) by hand drills and drilling performance depends on the surgeon's manual skills and 'drilling by feeling' [2]. That means recognizing the breakthrough detection (identification of the moment of time when the drill bit exits the second cortex), working with drilling rate good enough not to cause any damages to the bone or soft tissues closed to it [3].

The influence of the subjective factor is a prerequisite for the emergence of a number of problems in manual drilling. The most significant ones are:

- Wrong recognition the breakthrough detection in bicortical bone drilling. That means risks of damage of the bone, muscles, nerves and venous tissues when the drill bit does not stop immediately after coming out of the second wall of the bone

- Thermal osteonecrosis of bone cells as a result of bone drilling process. That means reduction the implant-bone pull-out strength.

Osteonecrosis is a kind of the health status depending on various conditions which lead to bone death [4]. The result is loss of blood supply or death of bone cells. It can be classified as vascular, infective, drugs or toxins, inflammatory, congenital, autoimmune, traumatic and endocrine or metabolic. One specific kind of traumatic osteonecrosis is thermal necrosis of bone.

The question of subjective factor reduction has its answer – automatic bone drilling. The use of robots would have a significant role for eliminating or minimizing the human error.

Robot applications possibility increase in the orthopedic surgery since 2000 [5, 6] but still they are rare in usage for the sake of their high cost. For example, ROBODOC (Curexo Technology Corp.) is applied for hip joint arthroplasty and costs 600 000 $ while RIO (MAKO Surgical Corp.) - 1 000 000 $ [7]. Nevertheless, the operation costs in social aspect decrease: patient recovery period is less than conventional one; complexity of the surgeon's manipulations and the risk of his potential errors become smaller [8]. On the other hand, the robot application in surgery requires specific maintenance and training of the medical staff aiming to guarantee the patient safety.

The first efforts for robot application in the orthopedic surgery are based on the industrial manipulating systems. The advanced tendency is oriented to a design of manipulative systems according to the specifics of concrete orthopedic manipulations aiming maximally simplification of robot mechanics [9, 10].

Thus so called Handheld Robotized Systems appear [11]. The handheld robotized systems answer entirely or partially to the definitions of robot [12] and robotic surgery nowadays has accepted the definition [13] of the Society of American Gastrointestinal and Endoscopic Surgeons and Minimally Invasive Robotic Association (SAGES–MIRA) Robotic Consensus Group.

The purpose of handheld robotized systems development is to reach the accuracy and precise working of the stationary multifunctional robots. Currently the following devices are available on the market and in the orthopedic surgery practice:

- handheld robotic device **SMARTdrillR**

It is developed by US Company SMD Inc. (Smart Medical Devices) and first time is presented in 2017. It measures the hole depth in real time and eliminates the plunge after the far cortex [14, 15]. SMARTdrillR has two motors: for rotation and for linear translation of the drill bit along the drilling direction. The data transfer between the SMARTdrillR and its control system is wireless. The drill bit and bone position are shown by LED indicator. The thrust force is not under control but it is only limited by the harp motion. The speed is set preliminary. The decision to stop drilling is taken by the surgeon. The experimental data are obtained for specimen simulating the bi-cortical bone features. They are reported when made under ideal conditions - simulated specimen with constant density (not bone) and flat surface of walls. The stop decision for drilling is manual (not automatic). The surgeon's decision is taken according to the data on the display which may cause a subjective error. The overheating problem prevention is not commented.

- surgical drill device **IntelliSense**

It is developed by "McGinley Orthopedic Innovations", US [16] and has two working regimes: conventional (Free Hand Mode) and bi-cortical. In bi-cortical regime the surgeon receives the signals from the device when the drill bit is close to the end of far cortex. This helps to him to stop drilling on time avoiding undesirable penetration in the soft tissues. The surgeon controls the thrust force himself all the time. No information is given for the criterion to stop rotation after the breakthrough and for penetration of the drill bit after the far cortex end. This system is not a robot according to the accepted definitions but allows receiving information for already drilled depth and far cortex end in real time. Among its disadvantages are no thrust force control, no prevention of overheating, and no automatic detection of breakthrough.

- handheld robotized system **DRIBON** [17].

It is still under development. This system is oriented to bi-cortical drilling only and especially for precise breakthrough detection and automatic stop of drilling. The stop decision is based on control algorithm where error of the feed-back position is analyzed during the motion. Constant speed is set in linear motion law and the maximal thrust force which can be applied is restricted. But the drilling time is over 400 s for cow bone bi-cortical drilling as it is reported standing on the experimental results which is very large time in comparison with the surgical practice. That reflects to high temperature in drilling zone (data for the temperature deviation are not reported) which causes negative results.

2. Orthopedic bone drilling robot ODRO

Many papers and books are written which are devoted to various aspects of robots. Lots of authors of different nationalities have given many arguments trying to confirm their arguments concerning the robot understanding, characteristics and definitions [18]. Nevertheless some variations appear about the attempts to formulate a unified definition - the general point of view includes several main features needed to describe a device or machine as a robot. So, these general common characteristics which an object must have to be really called a robot are as follows:

- Mechanical system
- Driving system
- Sensor system
- Computer control system

They are necessary but not sufficient conditions. For example the control system must be considered together with software and corresponding interface which looks after the connection and communication with environment. Moreover, the software must have possibilities for reprogramming the motion of the mechanical system concerning its positioning or trajectory tracking. And the most important thing – the system has to be autonomous one, i.e. it must be able to take decisions of its own. The last characteristic is not fulfilled for the objects operating under human being control. For instance, some people used to call them also as “robots” but that is an error – the true is that they are telemanipulators.

2.1 Basic subsystems of the ODRO

ODRO - Orthopedic Drilling Robot [11, 19] consists of control/power block and handheld surgical drill (**Figure 1**).

2.1.1 Mechanical system

Mechanical structure (surgical drill) with two degrees of freedom is proposed (**Figure 2**). It has one translation and one revolute joint with co-linear axes, where q_1 and q_2 are corresponding generalized coordinates. The new assembly drawing which corresponds to the new construction is shown in **Figure 3**.

Both actuators are mounted inside the drilling module. All parts of the mechanical module are made by stainless steel material for assuring the sterility requirements. The machine allows gas chemical sterilization before every manipulation.

2.1.2 Driving system

The drill bit rotation (0–1000 rpm) is realized by BLDC (Brushless Direct Current) motor “MAXON EC-4-pole 30” assuring 1.66 Nm torque (Maxon Motor AG, Shwaiz). These motor types have many advantages. Among them are better speed versus torque characteristics; high dynamic response; high efficiency; long operating life; noiseless operation; higher speed ranges; rugged construction etc. These features make the chosen motor useful for applications especially in cases where the space of work and the motor weight are critical factors.

Figure 1.
ODRO – Control block and handheld surgical drill.

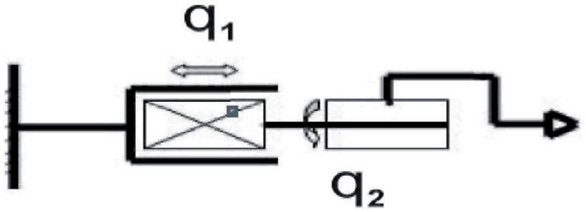

Figure 2.
Kinematic scheme of the mechanical structure.

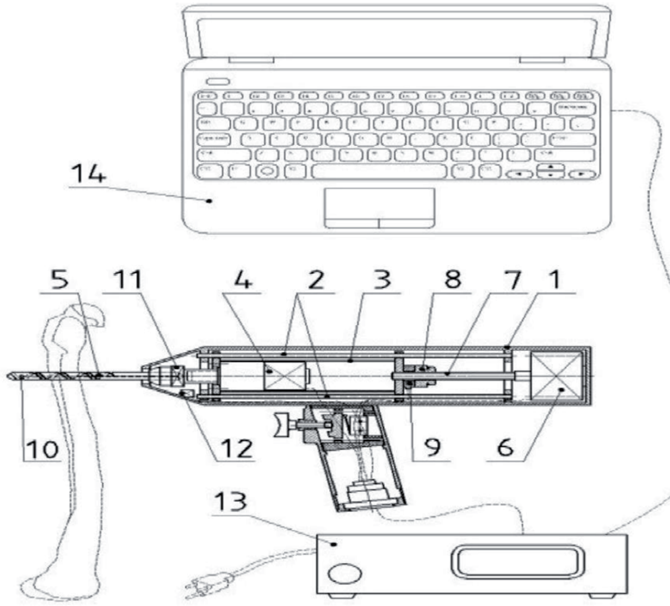

Figure 3.
The new assembly drawing and the numbers related to the main components: BLDC motor MAXON EC-4-pole 30 (number 3); step motor type 43000–17 (number 6) and force sensor LMB-A-200 N (number 8).

The linear motion (0–100 mm) is driven by step motor type "43000–17" (Haydon Switch & Instrument Inc.) which can apply thrust force up to 120 N in velocity range 0–9 mm/s. It is stepper motor with embedded screw for linear motion. It has high precision at low speeds, small by size and realizes translation of 1 mm for 4032 micro steps.

2.1.3 Sensor system

The system has force feed-back which is assured by force sensor "MLP-25", "Transducer Techniques" having measurement range up to 120 N [19]. In the next version of the system this force sensor is replaced by "LMB-A-200 N (KYOWA)" [11] because it is more compact, lightweight (6 g), has low price and measurement range up to 200 N.

2.1.4 Control system

The control system is on the base of one axis stepper controller/driver TMCM-1110 (TRINAMIC, Hamburg, Germany). This module controls the linear motion and keeps the bone drilling process control program to be realized successfully.

The servo controller/driver "1-Q-CE Amplifier DEC 50-5" with build-in speed PID-regulator controls the BLDC motor.

Terminals for connection with PC are also built-in in the control block. They give a possibility to re-program the software, which is recorded in the "TMCM-1110" module, to change and update the programs and to transfer the information between the control module and PC while the drilling is executed in real time.

2.2 Technical data and functional characteristics

2.2.1 Technical data of the robotized surgical drill

- weight – 2.3 kg
- working zone – 0 – 100 mm
- precision – 0.1 mm
- working regime
- “hand”
- automatic
- drill speed (rotation speed) – 0-1000 rpm
- feed rate (translation speed) – 0 – 6 mm/s
- drill (thrust) force – up to 120 N in the feed rate range 0–6 mm/s
- drill torque – 1.66 Nm in the drill speed range 0–1000 rpm
- real time depth measurement of the hole depth
- auto-stop after the end of the far (second) cortex
- minimal drill bit penetration after the end of the far (second) cortex in the range of 0 – 1 mm
- feed rate control during drilling

The following indications can be seen on the control/power block:

- emergency indication
- digital display
- drilling mode buttons
- confirm button

Control systems give information for the drilling execution, for successful end of the task and for emergency situation.

2.2.2 Functional characteristics

Our Orthopedic Drilling Robot has two working modes: manual and automatic. In manual regime it is like a usual drilling device. The rotational speed is regulated by potentiometer in the range 0–1000 rpm.

The automatic working can be separated in three sub-modes:
Fixed depth - drilling of a hole with preliminary set depth of the hole in *mm*;
Cortex I – first cortex (unicortical) drilling;
Cortex II – both cortices (bicortical) drilling.
The latter mode (*Cortex II)* in turn supports three sub-modes:

- Cortex II Full Drill – bicortical drilling and automatic stop after second cortex end registration

- Cortex II Find – drill bit detection the far cortex wall from inside and stop automatically.

- Cortex II Drill – drilling through the near (first) cortex and partially drilling the far (second) one, making a hole with a predetermined depth in [mm].

The working modes are set by the surgeon using four buttons and a potentiometer in combination with a display (**Figures 4**–**6**). Also it gives information in real time about the duration of the drilling process and about the operation result at the end of the drilling. The drilling is realized with an accuracy of 0.1 mm.

The result is presented on the display after drilling manipulation. The second row of the display screen (**Figure 7**) shows: first number - the thickness of the near cortex (Cortex I); second number - the thickness of the far cortex (Cortex II); third number - the depth of the hole. The second row in **Figure 8** in the same manner shows the thickness of the near cortex (first number), the distance between both cortices (marrow) and the depth of the hole (third number).


↓ -- / Cortex II
Full Drill

Figure 4.
"Cortex II full drill" mode - bicortical drilling and automatic stop after second cortex end registration.


↓ -- / Cortex II
Find

Figure 5.
"Cortex II find" mode - drill bit detection the far cortex wall from inside and stop automatically.


↓ -- / Cortex II
Drill 1.5mm

Figure 6.
"Cortex II drill" mode - drilling through the near (first) cortex and partially the far (second) one, making a hole with a 1.5 depth in [mm].

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↓  OK / Cortex 37.9
[ 3.6] [ 2.4] 19.5mm
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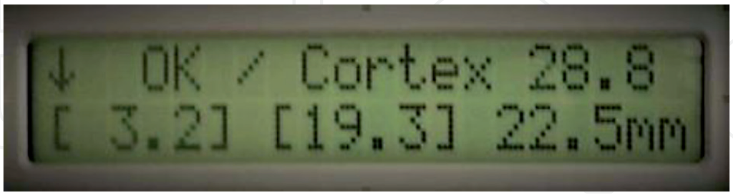
Figure 7.
Information displayed after "Cortex II Full" drill mode.



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↓  OK / Cortex 28.8
[ 3.2] [19.3] 22.5mm
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Figure 8.
Information displayed after "Cortex II Find" mode.

3. Bone drilling process execution

The successful realization of drilling manipulation depends on normal functioning of the whole system components – motors, force sensor, controllers, buttons, etc. That means the components have to be tested before the start of manipulation. A procedure 'Self Test' is developed which starts immediately after the power is switched on. The 'Self Test' procedure passes through the following testing steps:

- start button reliability (switch on and switch off)
- ability to find out the initial position (Reference position)
- ability to receive the force sensor data
- check the translation motion of the step motor (going forth and back the working zone, free motion resistance, check for missing steps)
- check the rotational motion

The force sensor test reports the ability of transferring the data for resistant force at free translation motion forth and back as well as an average value for normal motion which confirms a previously defined and known criterion.

The decision whether the component works right or wrong is taken according to criteria downloaded in the program. The 'Self Test' procedure confirms safe working the whole system. When some differences from the criteria incorporated in the software are registered then the message "Self TEST ERR" appears on the display. The robot cannot be used until the corresponding reasons are eliminated. The message confirming the positive result of the procedure is "Self TEST OK" on the display.

The next step is to set the working mode. Additionally another parameter in [mm] ($B_{\max}$) is set which is connected with the patient's safety and it is related to each specific patient. The hole depth cannot exceed $B_{\max}$. This parameter depends on the specific task, for example - it can be taken from the x-ray image of the bone before operation. During the drilling at every discretization time interval " k " the current position is compared with $B_{\max}$ and then the decision for going on or stop the process is taken.

Then the drilling process can begin.

The drilling process (**Figure 9**) is running when the button of the executive module (start button) is pressed and is held continuously by the surgeon. He can stop the manipulation aiming to set a new working regime or to prevent a drilling error. The manipulation execution goes on after the start button is pressed again and is held until the drilling ends automatically and the drill bit returns to its home (reference) position. During the operation the surgeon must keep firm contact with the bone all the time. When performing the drilling process, the selected drilling mode was indicated on the display.

The control algorithms are realized in the specialized program language (Trinamic Motion Control Language – TMCL) specific for the TMCM (Trinamic Motion Control Module) controllers in the program environment TMCL-IDE. The execution of commands start immediately after the input (direct regime) or the program can be downloaded for autonomous execution in the controller (stand-alone regime). The user is also allowed to input different axes and global parameters which enrich the control algorithms results and make its realization easier. The main control program is structured in separate states - State Search for Contact, State Contact Found, State Drilling, State Check for Missing Steps, State not Contact Found, State Ready etc. In Stand-alone regime the program recognizes the current state for every cycle and executes the corresponding algorithm, taking a decision for going to the next state in dependence on preliminary determined criteria.

The translation motion control during the drilling is based on the force feed-back. A modified PI control law (Eq. (1)) is used to calculate the new position, or the "next target position", (number of steps Δs_k where k is the time interval discretization), which the linear motor as well as the drill bit, respectively, must reach in a given interval of time Δt.

$$\Delta s_k = K_P \varepsilon_k + K_I I_k, \tag{1}$$

where:
$\varepsilon_k = F_r - F_{act}^k$; $I_k = \sum \varepsilon_i$, $\left[i=(k-4),,\ldots,,k\right]$;

K_P and K_I - feed-back coefficients of the proportional and the integral component in the control low;

F_{act}^k - actual thrust force (measured);

F_r - reference force which must be maintained following the created algorithm during the drilling process. The value of F_r is calculated for drilling of each specific (individual) bone and depends on features of the patients, for example health status, age, sex, etc.

Considering our specific task the following comments have to be done. The registration of far cortex from inside the bone and the breakthrough detection depends on the evaluation of the bone density in the current drilling zone. Because of that an integral component I_{ds} (Eq. (2)) is formed as a sliding window in the same drilling zone. By this integral component information is obtained for the change of bone density:

$$I_{ds}^k = \sum I_i, \left[i=(k-n),\ldots k\right], \tag{2}$$

In the last expression "n" is the dimension of I_{ds} in the sense of sample discretization. Its value is updated after every n sample. Decreasing of I_{ds} shows higher bone density and its increasing – drilling in lower bone density in comparison with the bone density which corresponds to Reference Force F_r.

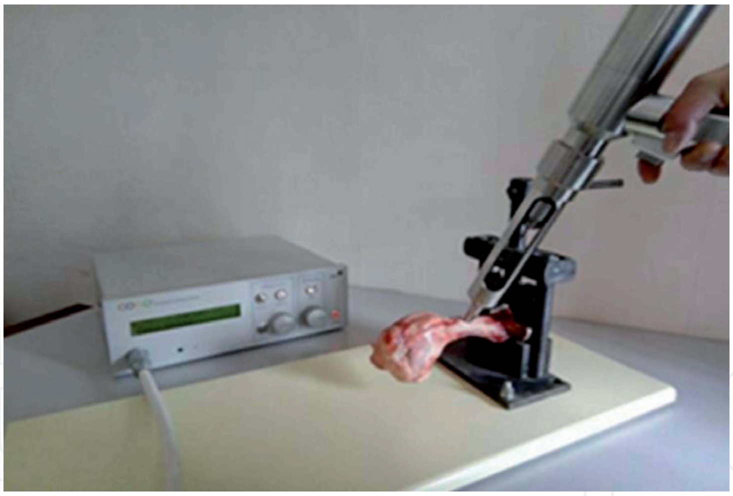

Figure 9.
Bone drilling process.

The parameter ΔI_{ds} is formed as a difference between two consecutive values. It gives information for tissue density deviation in current drilling area. The higher the ΔI_{ds} the bigger is bone density deviation in the current zone in comparison with the zone drilled just before.

Next, the comparison of the value ΔI_{ds} with some appropriately chosen reference value allows taking a decision for the breakthrough detection of second cortex as well as the far cortex registration. The dimension of I_{ds} from view point of number of subtractions ($\varepsilon_k = F_r - F_{act}^k$) assures the accurate monitoring the tendency of increasing or decreasing the bone density and in the same time minimizes the "not typical force sensor data" in the drilling area.

The dimension of I_{ds} from view point of number of samples of discretization is in connection with the extent of the drill bit penetration when it starts moving in low density area.

Once the drilling process is completed according to the selected operating mode, the result of the operation is presented on the display.

4. Areas of application and experimental results

4.1 Long bone fractures

The most common fractures are long bone fractures. In the treatment of long bone fractures by osteosynthesis, the most commonly used manipulation is bicortical drilling.

The main problem during bicortical bone drilling is the second cortex breakthrough detection and drill bit penetration value. The average soft tissue penetration in bi-cortical drilling manipulations is 6.31 mm when drilling is executed manually [20]. Furthermore, there is a significant difference in plunging (soft tissue penetration) depth when sharp or blunt drill bit was being used. Surgeons, regardless of their experience level, when used blunt drill bit, penetrate over 20 mm in normal bone and over 10 mm in osteoporotic bone [21]. This means that there is a risk of tendon or blood vessel rupture and protection of the posterior bone wall is required (leading to additional tissue excision).

When performing the drilling by the orthopedic bone drilling robot ODRO, the manipulation can be conditionally described by several stages: searching the contact with the first cortex; its drilling; automatic stop; searching the contact with the second cortex; its drilling; automatic stop; going to reference position after the drilling end.

In **Figures 10** and **11** experimental results are presented for the current position and the feed rate consequently during a bicortical mid-diaphyseal pork femur bone drilling procedure.

Figures 12 and **13** present experimental data for thrust force variation during bicortical pig femur bone drilling when using a new drill bit (**Figure 12**) and a drill bit after 35 drillings (**Figure 13**).

The time is expressed in arbitrary units (AU) of measurement where 1 unit is defined as the scoring time, i.e. the interval of time between two measurements.

During bicortical bone drilling process the feed rate takes various values in any stage in the range 0.5-6 mm/s. These values depend on drill bit position and real time force sensor data.

The first drilling stage is illustrated in **Figure 11** (search of contact with first cortex). Its parameters are feed rate 6 mm/s and drill speed 0 rpm. When the contact is realized, the feed rate stops (at 145 AU in **Figure 11**) and the drill speed is switched on. As the tubular bones generally have not flat shape the drill bit may slip from the needed point of drilling start. That can be notices and corrected by the surgeon

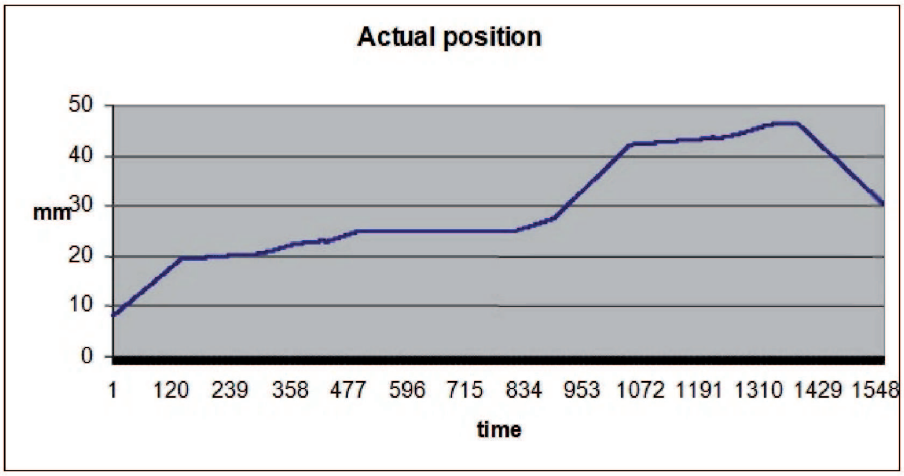

Figure 10.
Actual position [mm] versus time during drilling. Maximal drilling feed rate 2 mm/s; drill bit 2.8 mm; total time 21.016 s, 1561 AU.

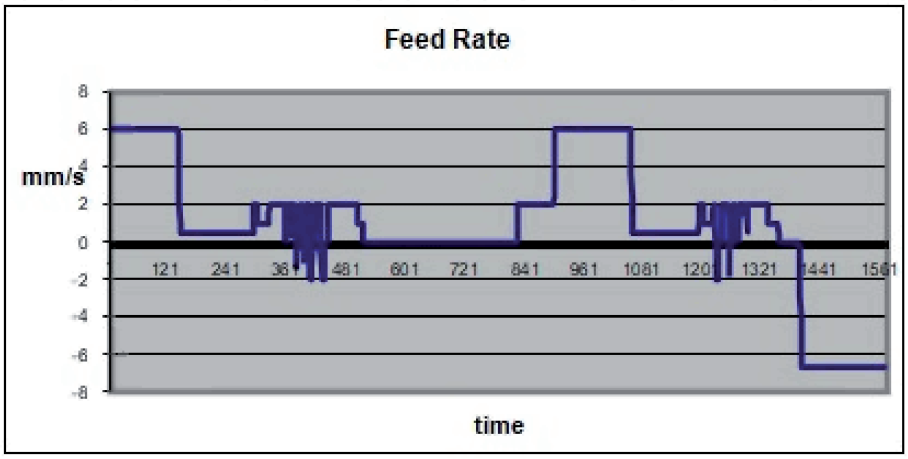

Figure 11.
Feed rate [mm/s] versus time during drilling. Maximal drilling feed rate 2 mm/s; drill bit 2.8 mm; total time 21.016 s, 1561 AU.

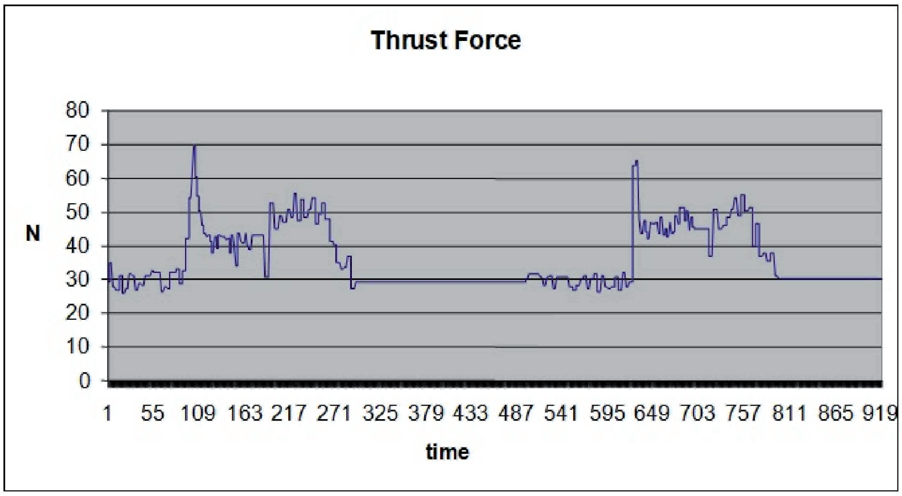

Figure 12.
Thrust force [N] versus time during drilling maximal drilling feed rate 2 mm/s; new drill bit 2.8 mm; total time 18.297 s, 919 AU. Drilling time (101–796 AU) – 13.85 s.

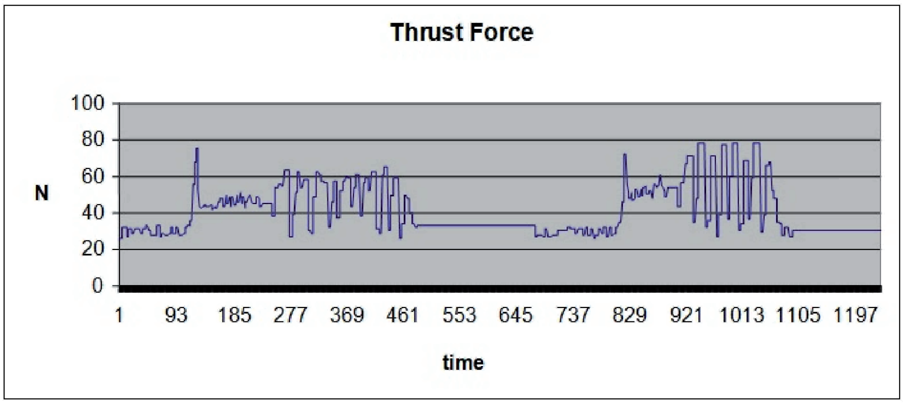

Figure 13.
Thrust force [N] versus time during drilling. Maximal drilling feed rate 2 mm/s; hole-used 35 times drill bit 2.8 mm; total time 24.828 s, 1,239 AU. Drilling time (128–1,097 AU) – 19.42 s.

in the case of first cortex but for drilling the second cortex such a slippage (which starts from inside the bone) cannot be avoided. It results to drill bit bending which reflects to hole inaccuracy, bigger friction and heat generation [1].

The second drilling stage (drilling start) begins after the contact is established. In order to eliminate the case of drill bit bending at the first cortex entrance site the drilling is executed with a feed rate 0.5 mm/s (from 148 to 288 AU in **Figure 11**). During this time interval the thrust force is identified for the first cortex (thrust force = 40 N, **Figure 12**). So that a thrust forces reference value is set to 50 N (**Figure 12**) for the first cortex wall for further drilling.

At the third drilling stage the feed rate has maximal value 2 mm/s. The fourth drilling stage indicates the end of the first cortex drilling at 509 AU in **Figure 11** and the drilling automatically stops; drill speed and feed rate become equal to 0 (the fifth drilling stage) according to the auto-stop criterion [22].

The registration of the inner (or outer) wall of the near (or far) cortex and the decision to stop the drilling process depends on the bone density evaluation in the current drilling zone (thrust force = 40 N, **Figure 12**) [22]. After pressing the start button again the drilling process starts at 817 AU in **Figure 11**. The drill speed is 1000 rpm and the drill bit movement is executed with feed rate of 2 mm/s (along 2 mm distance - from 818 to 892 AU in **Figure 11**).

The drill bit does not penetrate through the bone wall entirely when the first cortex wall drilling is finished from the "robot viewpoint" (the penetration is less than 1 mm but the stop decision works out successfully). This way, delamination of bone layers at the exit of the drill bit at the second wall of the first cortex is eliminated. Then the process continues with feed rate 6 mm/s until the second cortex contact is reached (in the same style like the first drilling stage but now for the second cortex) – feed rate 6 mm/s (893–1046 AU in **Figure 11**). When the second cortex contact is registered (1047 AU in **Figure 11**) the drilling process continues according to the algorithm steps already described up to now for the first cortex drilling until an automatic stop is realized when the second cortex drilling is finished. Then the drill bit was extracted back to the reference position (after 1400 AU in **Figure 11**) with negative value (6 mm/s) of the feed rate (the fifth drilling stage for the second cortex).

The drilling of the first or second cortex, which is in the interval of 299–509 AU in **Figure 11**, is executed with feed rate not greater than 2 mm/s. This value changes during the drilling process in dependence on the force sensor data.

When the resistant force values become less than the reference force, drilling is executed with feed rate 2 mm/s, for example in the intervals 320–351 AU and 438–497 AU in **Figure 11**. Feed rate values less than 2 mm/s correspond to slower translation motion (the resistant force values are higher than the reference value) and also correspond to application of a smaller thrust force (352–399 AU in **Figure 11**).

Thus, the negative feed rate values correspond to drill bit back-motion while a recurring overshoot of the reference value occurs (for example 400–431 AU in **Figure 11**). That is in agreement with the scientific reports of ultrasonically-assisted drilling method (UAD) [23–27]. This is a concept of minimizing the thrust force during drilling. The original idea of this approach is a module coupled with the drill bit, realizing the micro back translation motions with 5-25 μm amplitude and 10–30 kHz frequency. The advantages of UAD in comparison with conventional drilling reflect in a decrease of force from 60–65 N to 35–38 N (for UAD) [23, 25].

When the drill position becomes close to the second cortex outer surface (which can be recognized by additional criteria) then the feed rate decreases to 1 mm/s (498–508 AU in **Figure 11**). The reduction of the feed rate aims to guarantee a minimal penetration (maximum 1 mm) in the tissue outside the bone. Additionally, reduction the speed to 1 mm/s (respectively the thrust force) at the end of drilling allows forming accurately the breakthrough itself, i.e. without bone debris.

The feed rate control has important role from viewpoint of usage of spoiled drill bits which occurs very often in orthopedic practice. It is confirmed by a report where about 600 and more drillings are executed [28]. The dulled drill bits cause higher temperature in the drilling area. The maximal temperature reached by a bit taken from the operation room is 54.5^0 C [28, 29]. A proportional relationship is observed between the intensity of wear and the temperature increase and the same can be said for cutting forces [29].

After the end of every concrete drilling, the result is shown on the display. In **Figures 14** and **15** results of the drilling in both cases concerning the new and the used drill bits (see **Figures 12** and **13**) are shown on the display. The thickness of the

↓ OK / Cortex 50.1
[5.5] [4.4] 23.0mm

Figure 14.
The result of the drilling process; new drill bit 2.8 mm.

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↓  OK / Cortex 56.8
[ 6.9] [ 4.5] 26.3mm
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Figure 15.
The result of the drilling process; hole-used 35 times drill bit 2.8 mm.

near cortex (Cortex I), the thickness of the far cortex (Cortex II) and the depth of the hole are shown in the second row on the display.

At equal drilling conditions – drilling process control algorithm, drill bit diameter, bone specimen, drilling area – the following can be seen in **Figures 12** and **13**: for new drill bit max thrust force is 55 N; for used drill bit max thrust force is 80 N; for new drill bit the hole depth is 23 mm for 13.85 s duration and for used drill bit the hole depth is 26.3 mm for 19.42 s respectively.

At automatic drilling the reasons for the negative final result caused by dulled drill bits should be minimized by feed rate control [30]. Also, it successfully solves the problem of higher drill bit penetration after the end of second cortex. It is realized by feed rate reduction to 1 mm/s just before the breakthrough.

4.2 Hip fractures

Generally said a hip-fracture is a break in the upper part of the femur bone. It occurs mostly to the patients over 60 years old. Worldwide the human population growing older is a clear tendency. It is expected such changes can cause higher number of hip fractures increasing from 1.66 million in 1990 to 6.26 million in 2050 [31]. Moreover, it is proved the hip fractures are one of the main reasons for mortality of the old people. For example the mortality to the end of the first year after the trauma reaches 27.3% depending on the kind and the type of hip fracture treatment [32]. These data underline the social importance of the problem and lots of researches concern their efforts for optimization of hip fracture treatment and maximal patient's recovery.

For metal osteosynthesis of proximal femur fracture the implant is placed (inserted) through the lateral cortex and anchors into the hip head. The postoperative complications, which often occur at fracture treatment by osteosynthesis and require an implant change or arthroplasty, are the so called hip head re-fracture and implant penetration into the joint capsule.

The main reason for that is a wrong positioning of the screws into the femoral head–neck fragment. As a criterion for implant position the so called Tip-to-Apex Distance index (TAD – index) is used. The optimal positioning corresponds to TAD – index minimization. For instance, it is the best factor of prognosis to realize the cut out of the hip head and when the TAD – index is less than 24 mm, the cut outs are unfortunately not registered [33]. That means drilling through the lateral cortex along the hip neck axis, which ends when the drill bit tip is as much as possible close to the far cortex of the hip head.

The experimental results for far cortex registration during proximal pig femur drilling along the neck axis are presented in **Figure 16**. The measured proximal femur length is 65 mm. The hip head cortex registration is in a distance 61.7 mm from the contact point [34].

The hip head cortex registration occurs at 1107 AU in **Figure 16** where I_{ds} again takes values less than zero. Then the drilling automatically stops and the robot takes out the drill bit at the initial position.

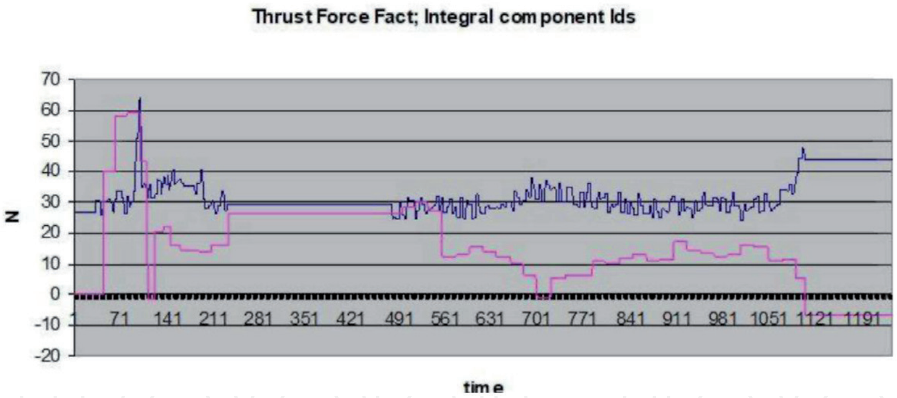

Figure 16.
Far cortex registration during proximal pig femur bone drilling along the neck axis. Maximal drilling feed rate = 4 mm/s; drill bit 2.8 mm; Total time 24.84 s, 1235 AU; hole depth 61.7 mm. The values of the integral component I_{ds} *(red line) are scaled by multiplication of* 10^{-1}.

For some types of fractures, like a midshaft clavicle fractures, it is advisable to fix the implants without drilling the second cortex. Comprising uni-cortical far-cortex–abutting locking screw fixation with bi-cortical fixation, it can be seen that both types of fixation have similar mechanical properties concerning axial and torsional loads in the case when the far cortex penetration not occurs. [35]. Uni-cortical far-cortex-abutting locking screw fixation risks far cortex penetration which requires protection of near anatomical structures. [35]. Drilling modes of ODRO as Cortex I (unicortical drilling), Cortex II Find and Cortex II Drill can be used in such cases.

One more application of ODRO is related to the proximal humerus fractures. This problem is discussed in [36–38] and here we will present it briefly by citing some sentences from there aiming to show this problem clearer way.

Proximal humerus fractures may occur at the surgical neck, anatomic neck, greater tuberosity, and lesser tuberosity. They are common fractures which can often be seen in elder patients with osteoporotic bone after low level energy impacts. These patients usually have very low bone mineral density and that makes fracture fixation much complicated. Proximal humerus fractures account for 5% of all fractures and represent the third most common osteoporotic fracture [36]. The incidence of these injuries is expected to increase due to the aging population and the growing prevalence of osteoporosis [37].

Within the surgically treated fractures open reduction and internal fixation using locked plates is the most commonly applied joint-preserving treatment of proximal humerus fractures [38]. Failure rates of locked plating depend on the so-called “overdrilling”. Perforation of the joint surface during pilot hole drilling is referred to as “overdrilling” [37]. Possible reasons for the overdrilling include: the restricted tactile feedback especially in osteoporotic bone; the spherical morphology of the humeral head that, together with the angulated locking screw projections, make interpreting of intra-operative X-ray images very complicated; the surgeons’ experience level; the blunt drill bit [37].

Precision drilling to the correct depth could help prevention of overdrilling and significantly increases endurance until screw perforation failure, i.e. reduce failure rates of locked plating in an unstable proximal humerus fractures [37].

The drilling mode “Fixed depth” of ODRO (preliminary set depth of the hole in mm) can be used in such cases when ODRO is applied. When working in this mode, the set depth of the hole is realized with an accuracy of 0.1 mm.

During bicortical drilling, when the drilling is done manually, the magnitude of the drill bit penetration requires protection of the posterior bone wall. That means the obligatory cutting of the tissues immediately after it.

The drilling through the lateral cortex along the hip neck axis in fractures of the hip joint, as close as possible to the distal hip head cortex, can be performed successfully manually only under continuous X-ray control. This is of the utmost importance for stable fixation of the implant. The use of ODRO in this type of manipulations allows the use of surgical techniques associated with minimally invasive surgery.

5. Discussion and conclusion

The process of bone drilling is characterized by a set of input and output parameters. The input parameters define the conditions under which the process takes place, while the output parameters determine the outcome of the process.

Many scientific investigations are done concerning input parameters as drill speed, feed rate, different types of drill bit, its diameter, bone type and drilling methods. These parameters are responsible for heat generation, micro cracks, hole delamination, breakthrough detection and penetration. The results are reported only for the case when one of the parameters has a fixed value (drill speed) and the other one has a discrete variation (feed rate) or vise versa.

The experiments are made by Computer Numerical Control (CNC) machines or CNC milling machines [39–41]. The purpose is to find such combinations of input parameters which may guarantee optimal output parameters during the process of bone drilling.

The difference between the experimental results of various studies arise for the sake of the wide variety of test conditions used by researchers regarding drill-bit diameter, drill bit type, rotational speed, feed rate and bone type. [42]. However, the following dependencies stand out:

Increasing the feed rate leads to:

- reducing the drilling time, i.e. reducing heat generation [43, 44], i.e. reduces the risk of thermal osteonecrosis
- increase of the thrust force [42], i.e. increase the risk of bone damage (traumatic osteonecrosis)
- Increasing the drill speed leads to:
- increase in temperature [43, 45, 46], i.e. the risk of thermal osteonecrosis
- decrease of thrust force [42], i.e. reduces the risk of bone damage (traumatic osteonecrosis)

Summarizing, to minimize heat generation during drilling (avoid thermal osteonecrosis) one should work with the highest possible value of feed rate and the lowest possible value of drill speed. To avoid traumatic osteonecrosis it is necessary to work with the lowest possible value of feed rate and with the highest possible value of drill speed.

Therefore, there are conflicting requirements regarding the values of the parameters drill speed and feed rate, which should be maintained (implemented) during the bone drilling process in order to obtain an optimal result.

During the manual drilling these parameters are controlled by the surgeon on the base of his practical skills. But the optimal results of the manipulations can be assured only when the input parameters are under control during the automatic execution of the drilling process. This is the main reason for the appearance of the handheld robotized systems.

As it was said, the purpose of handheld robotized systems development is to reach the accuracy and precise working of the stationary multifunctional robots. In addition, these systems combine robotic drilling technology with the familiarity of traditional, handheld medical drills. Among the important characteristics of the handheld robotized systems must be underlined no requirements of pre-operative planning, calibration, intraoperative navigation systems. Moreover, they are cheaper, easy and convenient for working and maintenance which allows their mass application in surgery practice.

ODRO has some advantages in comparison to other considered systems: an algorithm for synthesis of the referenced feed rate during drilling, ability for far cortex detection from inside the bone, various specialized working regimes. Up to now, according to the author's knowledge, there are no reports for automatic bone drilling handheld systems that do not use a fixed feed rate during the whole drilling process. The only two systems available in the market which are used in hospitals - SMARTdrillR and IntelliSense orthopedic surgical drill device, also work in fixed feed rate mode. It is important to underline again that the other systems ability of work report only for bicortical drilling. The ODRO system has not only such ability but many additional drilling working modes which were already discussed.

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Conflict of interest

The authors declare no conflict of interest.

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