# TOTAL HIP ARTHROPLASTY WITH NEW FEMORAL COMPONENT AND MONITORING OF INTRAOSSEOUS PRESSURE

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Abstract: Aim. To study whether use of newly designed rasps and femoral stem change intraosseous pressure (IOP) in distal femur during femur machining and stem implantation. Methods. The authors measured distal femur IOP in 44 patients, 19 men and 25 women with a mean age of 49.7±7.3, at six time points during Kaz NIITO hip stem (K-implant Germany) implantation using RAUMEDIC® (Germany) IOP monitor. Results. IOP averaged 62.6 ± 14.8 mm Hg (95% CI 58.2-67.0) before surgery, 61.3± 6.5 mm Hg (95% CI 59.3-63.3) after femoral neck resection, 64.5±7.6 mm Hg (95% CI 62.1-66.9) while opening the medullary canal with box chisel, 56.3± 12.6 mm Hg (95% CI 52.3-60.3) during IM canal reaming, 76.2 ± 13.1 mm Hg (95% CI 72.2-80.2) during canal rasping, 69.3 ±14.1 mm Hg (95% CI 72.2-80.2) at femoral stem impaction. Conclusions. Implantation of newly designed femoral stem does not lead to serious intraosseous pressure change, and thereby, can potentially reduce risk of fat embolism during THR.

Keywords: Hip, Arthroplasty, Intraosseous Pressure, Reaming, Rasping, Osteotomy, Embolism, Femoral, Stem, Fat Embolism, Implantation, Arthritis.

## 1 Introduction

Currently, total hip arthroplasty (THA) is the most reliable method of surgical treatment that stops the pain syndrome and restores function for patients with hip joint diseases. (1)

In the US over the past 10 years the number of surgeries of primary THA increased by 50% and according to various estimates, it will increase by 174% over the next 20 years. (2,3) It was calculated that 100000 surgeries for revision hip arthroplasty will perform by 2030 in United States. The reasons for unsuccessful outcomes that lead to the need for revision surgery are infection of the implant, joint instability, components instability (loosening), periprosthetic fracture (3), and the most dangerous complication that can occur are thrombosis and fat embolism. (4) The main risk factor for thrombosis and embolism is intraosseous pressure which dramatically increases in the processing of the intramedullary canal with instruments and the setting prosthesis stem.

Since that time till the middle of 20th century it was investigated in several studies. (5-14) The first time IOP was mentioned in 1882 by Schultze EOP and measured by Behau B.J in 1912 (15). It was found that long bones nailing could be associated with serious increase of IOP. (16-19) This IOP growth is a risk factor of pulmonary vascular complications. (20-23) According to the literature, the rate of fat embolism syndrome in surgery thin tramedullary canal intervention is 0.25% - 1.25%. (23) Deep vein thrombosis of the lower limbs without specific prevention is detected in45-70% of cases. (24)

Total hip replacement (THR) is an effective procedure for patients with degenerative and posttraumatic hip joint pathology. It gives patients release from pain, improves quality of life, and restores limb function. (25-32) In several studies, it was shown that IOP in distal femur increases during IM canal opening (33), reaming (34,35), cementing and stem insertion. (36, 37)

Clinical and experimental studies have shown that the fat emboli could be found in pulmonary capillaries few seconds after fracture or manipulation in IM canal. Fat from bone marrow (or subcutaneous) directly enters blood circulatory system due to increased IOP. This is considered one of the key pathogenic factor for pulmonary complications development or so called implantation syndrome. (32,38,39)

In most of the studies, change of IOP during THR had been measured only at some certain steps of femoral stem implantation but not monitored during all the procedure. (33-37)

The purpose of this study was to measure IOP during different steps of newly designed fluted femoral stem implantation in order to find out if use of new fluted rasps and stem can help to keep IOP on level close to base line during THR.

## 2 Materials and Methods

The authors measured distal femur IOP in 44 patients during implantation of new femoral component (KazNIITO - Patent of RK №29059. publ.10.2014, Bul. №10). There were 19 men and 25 women. The average age of the patients at the time of the surgery was 49.7±7.3. Reasons for THR were: post-traumatic coxarthrosis in 11 patients, degenerative implantation in 12, dysplastic arthritis in 9, femoral head AVN in 10, subcapital fracture neck of femur in 1, pseudarthrosis of femoral neck in 1.

### 2.1 IOP testing

IOP testing and THR were performed under general anesthesia with patients in lateral decubitus position. The authors tested IOP using RAUMEDIC® (Germany) pressure monitor (Figure 1). For that, they placed intraosseous needle in distal femur, through the needle, introduced into the bone catheter - microchip with sensor. In the research was monitored IOP during all steps of femoral implantation. The authors provisionally divided their IOP monitoring into 6 steps according for main steps of stem implantation.

1. Base line (Before neck resection surgery);
2. Femoral neck osteotomy;
3. IM (intramedullary) canal opening;
4. Canal Reaming;
5. Rasping;
6. Stem impaction.

Figure 1. Device RAUMEDIC® (Germany)

The plan of clinical research was approved by Ethics Comity of the Review Board of Research Institute of Traumatology and Orthopedics of the Ministry of Health of the Republic of Kazakhstan, protocol No. 213 of 13 November 2008.

**2.2 Implants and instruments features**

The authors added a groove to the lateral side of rasps of even number and groove on the medial side of odd number rasps (Figure 2). The femoral stem design based on clinically proved design of “K-implant Modell Minden V. Echtermeyer” anatomical stem. It is proximal fixation stem of tapered shape with a longitudinal “ribs” and structured surface.

Figure 2. Design features of Rasp

(Innovation patent of RK №23344, publ. 15.12.2010, Bull. №12)

The constructive feature of the stem is decompression groove on the outer surface (Figure 3).

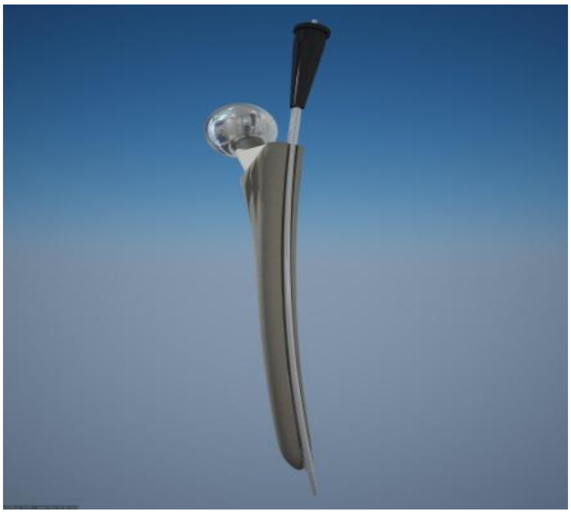


Figure 3. Design Features of the Femoral Component

On the basis of the obtained results, it was established that the sorption process intensively proceeds within 30–40 min

**2.1 Statistical analysis**

The results were exposed to statistical variation-processing and defined weighted arithmetic mean value (mean value), standard deviation (SD), confidence interval (95% CI).

**3 Literature review**

In the CIS countries the research of intraosseous pressure mainly studied the pathology of bones and joints. Intraosseous pressure response to the metal structures and prostheses wasn’t run.

A number of foreign researchers examined the effects of intramedullary reaming of the medullary canal in the intraosseous pressure in animal experiments.

On the sheep model Duwelius (40) found the significant increase of intraosseous pressure in intramedullary fixation of femur with bone canal reaming, than without reaming. This histological analysis of lung tissue testified about a lot of fat embolism and dysfunction of the lungs during surgery.

Kröpflet et al. (41) got similar results on baboon model. During the intramedullary nail fixation of not reamed medullary canal the intraosseous pressure was 11 times less than the reamed canal. Embolization fat in osteosynthesis occurs during insertion of the pin, depending on the value of intraosseous pressure, but to a lesser extent in not reamed than the reamed femoral canal. However, the increase of intraosseous pressure has seen during insertion of different diameter pins. During insertion of 7 mm pin the intraosseous pressure was 76 +/- 25 mm Hg (10.1 +/- 3.3 kPa), in insertion of 9 mm pin the intraosseous pressure was - 879 +/- 44 mm Hg (117.2 +/- 5.9 kPa).

On isolated bovine bone and sheep model Smith P, Leditschke A, McMahon D, et al (42) also confirm that during the bone canal reaming there is an increase of IOP, and histological data showed a significant higher number of fat embolism in the lung tissue of sheep.

Johnson et al. (43) studied the effect on the cadaver bone reamers of two systems Zimmer and AO for the reaction of intraosseous pressure during reaming the bone canal. They found that the IOP increases at all stages of reaming, but it has a particularly high value in the early stages of intake reamers with peak pressures ranging from 270 - 1500 mm Hg. Art. No significant differences were found in peak pressures produced by these two systems (P = 0.10) with peak pressures ranging from 270 - 1500 mm Hg. Art. No significant differences were found in peak pressures produced by these two systems (P = 0.10).

Peter et al. (44) studied the effects of 2 types of reamers on IOP during reaming the intraosseous canal in 9 patients. It is universal reamers AO / ASIF and Grey is a flexible system reamer (Howmedic). The maximum pressure was 450 mm Hg. Art. in the process of expansion with 9.0-and 9.5-mm reamers.

Mousaviet et al. (45) determined that the pressure changes during the expansion with different parameters and scanning projects. They studied the reaction of IOP using different diameter reamers (9,14,18 mm) silicon cylinder models, the rate was 15,30,50 mm per second, the number of revolutions was 150,250,500. Using a stepwise linear regression analysis, leading the speed was the most important parameter. Lowest pressure increase occurred at the lowest speed and driving the highest level at high speed and the speed of all. In their subsequent studies, the authors found that the change and improvement of intraosseous pressure depends not only on the diameter of the reamer, but from the manufacturers (JSC, Gray, Howmedica) minimum 80 mm Hg, a maximum of 2700. (46)

In Green (47) works, reported that the problem of IOP during intramedullary fixation was taken out for the first time by the founder of intramedullary fixation Gerhard Kuncher in 1940, and with the use of tools for reaming bone canal issue was still relevant. The first researchers who have proposed in the late 1960s, various systems to reduce IOP were Lorenzi, Olerud, Dankwardt-Lilliestrom. They proposed method of active bone aspirate the contents of the canal before reaming to create a negative pressure and subsequent irrigation fluid during reaming. K.M. Sturmer has proven the effectiveness of this technique in his research on sheep, made in the 1980s.

Endoprosthesis replacement is an effective treatment of diseases and injuries of the hip joint, which saves patients from the pain and lameness, improve quality of life, allows restore limb function and the ability to work. However, despite improvements in surgical technique, the treatment of pain there is a risk of complications. (54-60)

Hofmann et al (61) measured pressure after the opening of the canal, and it increased, and proposes to develop a technique of insertion to reduce.

Song et al. (62) in their studies found that during the cement prosthesis has been a significant increase of intraosseous pressure and the value ranges from 2385 mm Hg to 3710 mm Hg with the cement insertion.

Mueller et al. (63) provide evidence that the insertion of reamer is not only an increase of intraosseous pressure, but also the temperature rises inside the medullary canal. Studies of foreign scientists devoted mainly to the study of intraosseous pressure on the individual stages of arthroplasty. Although it can be assumed theoretically, that any interference in the medullary canal leads to the risk of intraoperative complications.

Beck et al. (64) studied the intraosseous pressure in the implantation of Mueller's endoprosthesis stem. IOP range varied from 590-2570 mm Hg. Art. (median = 1,293, SD = 627 mm Hg. Art.). During modified stem prosthesis the IOP - 59-574 mm Hg. Art. (median = 289, SD = 219 mm Hg. Art.). The differences were statistically significant (p = 0.0008).

Barden et al (65) conducted a randomized clinical trial using a standard endoprosthesis stem and a hollow stem with vertical and longitudinal. During installation, the standard prosthetic stem mean pressure was 82 mm Hg. Art. (minimum high, 12-259 mm Hg. Art.) and with a hollow stem - 27 mmHg (minimum high, 0-48 mm Hg. Art.). This difference was statistically significant (t-test, p = 0.00076). Opening the inside of the medullary canal the IOP averaged 35 mm Hg. Art. (Minimum maximum 4-72 mm Hg. Art.). Both groups were higher pressure at the opening of the canal and processing tools.

Significant increase in the value of intraosseous pressureis observed during hip arthroplasty especially in the implantation of the femoral componentand thus the risk of intraoperative complications increases. Thereby modern technology implants and implants to prevent excessive intraosseous pressure in the medullary cavity should be improved.

**3 Results and Discussion**

The main objective of the research is to determine the IOP during hip arthroplasty with new stem prosthesis. Results of research quantities of intraosseous pressure (IOP) are shown in Table I.

The average value of IOP in the distal femur, before surgery was 62.6 ± 14.8 (95% CI 58.2 -67.0) mmHg. Art. The lowest IOP observed in 1 (2.2%) patients and found 47 mm Hg. Art. High IOP was also in 1 (2.2%) patients and was 156 mm Hg. Art. In other cases, IOP in 17 (38.6%) patients ranged from 52 to 62 mm Hg, in 25 (57%) patients - from 64 to 67 mm Hg. Art.

After osteotomy of the femoral neck and head was 61.3 ± 6.5 (95% CI 59.3-63.3) mmHg. Art. Thus lowest IOP was 44 mm Hg, high - 101 mm Hg. Art. IOP from 46 to 58 mm Hg. Art. was present in 18 (40.9%) patients, from 60 to 73 mm Hg. Art. - 24 (54.5%) patients.

While opening the medullary canal with fenestrated tool was 64.5 ± 7.6 (95% CI 62.1-66.9) mm Hg. Art. Low IOP was 48 mm Hg. Art, the value of high IOP - 104 mm Hg. Art. IOP from 53 to 62 mm Hg. Art. occurred in 11 (25%) patients, from 63 to 69 - in 31 (70.4%) patients.

Analysis of the data obtained (Table 1) shows that with an increase in the concentration of oil from 100 to 1000 mg/l, the degree of water treatment with KM-1a is 98.21% and 68.21%. It has been established that a further increase in the oil content does not contribute to an increase in the degree of water treatment. For example, when the concentration of oil in water is 3000 mg/l, the degree of water treatment from oil is 43.03%. The obtained results made it possible to determine the optimal ratio of the initial components of the oil from the "Zhylankabak" field and composite materials.

Table 1. Value of Intraosseous Pressure

| Stages of surgery | Number | Mean | SD | 95% CI |
|---|---|---|---|---|
| Before surgery | 44 | 62,6 | 14,8 | 58,2 – 67,0 |
| After osteotomy | 44 | 61,3 | 6,5 | 59,3 – 63,3 |
| Prosection of canal | 44 | 64,5 | 7,6 | 62,1 – 66,6 |
| Intervention of rimmer | 44 | 56,3 | 12,6 | 52,3 – 60,3 |
| Intervention of rasp | 44 | 76,2 | 13,1 | 72 ,2 – 80,2 |
| Insertion of endoprosthesis Stem | 44 | 69,3 | 14,1 | 65,1– 73,5 |

SD = standard deviation, 95% CI = confidence interval

The while introducing and processing with Rimmer – 56.3 ± 12.6 (95% CI 52.3-60.3) mm Hg. The value of the low IOP was 45 mm Hg. Art., IOP high - 122 mm Hg. Art. IOP from 46 to 61 mm Hg. Art. occurred in 13 (29.6%) patients, from 62 to 68 mm Hg. Art. - In 29 (65%) patients.

When using new rasp in medullary canal– 76.2 ± 13.1 (95% CI 72.2-80.2) mm Hg. This low IOP was 56 mm Hg. Art., IOP high - 152 mm Hg. Art. IOP of 57 to 74 mm Hg. Art was observed in 12 (27.2%) patients from 76 to 81 mm Hg. Article - 30 (68.2%) patients.

When fixing a new stem of prosthesis – 69.3 ± 14.1 (95% CI 72.2-80.2) mm Hg. Art. The value of the low IOP was 54 mm Hg. Art., IOP high - 155 mm Hg IOP of 55 to 65 mm Hg. Art had in 10 (22.7%) patients, 66 to 74 mm Hg. Art. - 32 (72.7%) patients.

High IOP was patient T., 33 years old (male) with aseptic osteonecrosis head of the left femur and chronic osteomyelitis in remission. Low IOP was observed in patient A., 60 years old (male) with aseptic necrosis of the head of the right femur.

The authors found no significant differences in value of IOP at the time of neck osteotomy and IM canal opening ($p > 0.05$), IOP decreased during canal reaming ($p < 0.05$) and slightly increased during rasping and stem impaction (The difference was not significant ($p > 0.05$).

The authors have studied the anatomical and functional condition of the hip joint before and after surgery at term of 6, 12, 24, 36 months in 44 patients. The results were evaluated by Harris score. In the study group under the age of 20 years was 1 (2.3%) patients, 21 to 30 years - 5 (11.4%), from 31 to 40 years old - 7 (15.9%), from 41 to 50 years - 11 (25%), over 51 years - 20 (45.4%). There were 34 Asians (18male, 16 female) patients, 10 Europeans – 10 (3 male, 7 female).

From 44 patients there were 25 (56,8%) patients with comorbidities in remission-14 patients with cardiovascular system chronic diseases (coronary heart disease, hypertension, varicose veins), 2 patients with respiratory system diseases (chronic bronchitis, chronic obstructive pulmonary disease), 3 patients with chronic gastrointestinal disease (chronic cholecystitis, gastric ulcer), 3 patients with endocrine system disease (diabetes, chronic pancreatitis), 3 patients with urinary system diseases (chronic pyelonephritis, chronic prostatitis).

All patients had persistent pain, severe activity limitations (Table 2) in estimating the anatomical and functional condition of the hip joint. The average Harris score was 14. In joint function association the moderate and severe lameness was observed, patients used the additional support to walk, there were difficulties in climbing stairs, there were problems with using public transport and restrictions on the self-service. The average score was 18.7. So, the overall average score was 36.7 (95% CI 26-48).

Hip joint function assessment after 6 and 12 months indicates that there are significant positive developments in the anatomical and functional hip joint state (Figure 4). In this way the quality of patients' life improved. The decline and lack of constant pain improved in the patient's condition a lot. At home patients move around without additional support. Most of patients start using the public transport with no problems. There is an improvement of the anatomical and functional hip joint condition compared with the initial state before joint replacement surgery. In this way, the average Harris score was 91 after 6 months, 93 after 12 months. This was because of absence of pain, improving function and movement amplitude of hip joint.

Analysis of the data presented in Figure 5 shows that the degree of wastewater treatment from oil by the GKM preparation depends on the duration of the sorption process. For example, after 5 minutes of contact, the degree of water treatment from oil is 61.20%, and with a sorption duration of 10, 20, 30, 40 and 60 minutes, respectively, 73.0; 86.2; 93.6; 94.1 and 94.6%.

Table 2. Hip Joint Function by Harris Before Surgery

| Patient no. | Pain | Function | Absense of deformity | Range of motion | Total score |
|---|---|---|---|---|---|
| 1 | 10 | 20 | 4 | 3.7 | 37.7 |
| 2 | 20 | 13 | 4 | 1.3 | 38.3 |
| 3 | 10 | 20 | 4 | 3.7 | 37.7 |
| 4 | 10 | 20 | 4 | 3.7 | 37.7 |
| 5 | 10 | 28 | 4 | 3.7 | 45.7 |
| 6 | 10 | 19 | 4 | 4.2 | 37.2 |
| 7 | 0 | 2 | 4 | 3.9 | 19.9 |
| 8 | 10 | 24 | 4 | 4.6 | 42.6 |
| 9 | 10 | 29 | 4 | 4.6 | 47.6 |
| 10 | 10 | 15 | 4 | 3.3 | 32.3 |
| 11 | 10 | 29 | 3 | 3 | 46 |
| 12 | 10 | 13 | 4 | 4.3 | 31.3 |
| 13 | 10 | 22 | 4 | 4.4 | 40.4 |
| 14 | 10 | 17 | 4 | 1.6 | 32.6 |
| 15 | 10 | 25 | 4 | 4.9 | 43.9 |
| 16 | 10 | 16 | 4 | 3.1 | 33.1 |
| 17 | 10 | 17 | 4 | 2.5 | 33.5 |
| 18 | 10 | 17 | 4 | 2.5 | 33.5 |
| 19 | 10 | 17 | 4 | 4.6 | 35.6 |
| 20 | 10 | 7 | 4 | 3.3 | 24.3 |
| 21 | 10 | 24 | 3 | 2.5 | 39.5 |
| 22 | 20 | 25 | 4 | 4.8 | 53.8 |
| 23 | 20 | 29 | 4 | 4.8 | 57.8 |
| 24 | 10 | 5 | 4 | 4.3 | 23.3 |
| 25 | 10 | 15 | 4 | 0.1 | 29.1 |
| 26 | 0 | 5 | 4 | 0.1 | 9.1 |
| 27 | 10 | 26 | 4 | 4 | 44.9 |
| 28 | 10 | 24 | 4 | 2.1 | 40.1 |

| | | | | | |
|---|---|---|---|---|---|
| 29 | 10 | 14 | 4 | 3.5 | 31.5 |
| 30 | 10 | 27 | 4 | 3.8 | 44.8 |
| 31 | 10 | 28 | 4 | 4 | 46.0 |
| 32 | 10 | 25 | 4 | 4.2 | 43.2 |
| 33 | 10 | 28 | 4 | 1.9 | 43.9 |
| 34 | 44 | 13 | 4 | 0.1 | 61.1 |
| 35 | 10 | 8 | 4 | 3.4 | 25.4 |
| 36 | 10 | 28 | 4 | 5 | 47.0 |
| 37 | 10 | 2 | 4 | 3.4 | 19.4 |
| 38 | 10 | 16 | 4 | 3.9 | 33.9 |
| 39 | 10 | 14 | 4 | 4.9 | 32.9 |
| 40 | 10 | 9 | 4 | 1.9 | 24.9 |
| 41 | 10 | 22 | 4 | 3.1 | 39.1 |
| 42 | 10 | 13 | 4 | 3.2 | 30.2 |
| 43 | 10 | 25 | 4 | 4 | 43.0 |
| 44 | 10 | 29 | 4 | 1.6 | 44.6 |
| | 11.2 (10-13) | 18.7(18-20) | 3.9(3.8-4.0) | 3.3(3.1-3.7) | 36.7(26-40) |

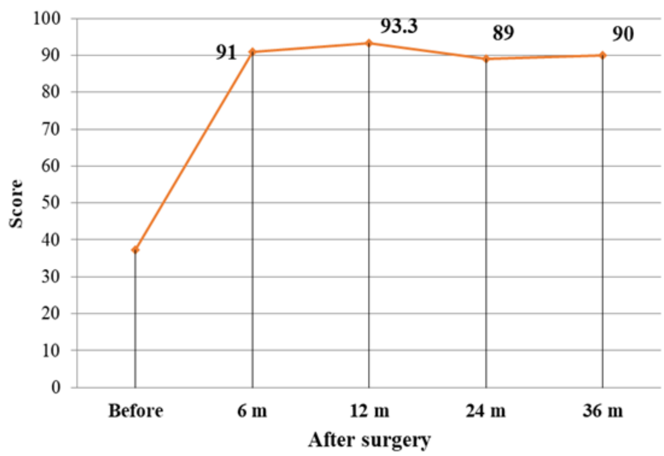
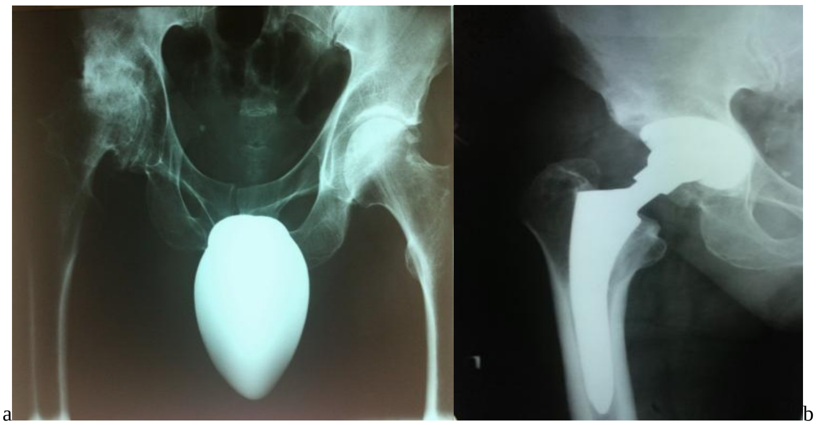



Figure 4. Average Score by Harris in Dynamics in Patients Before and After Arthroplasty Surgery

Long-term results after the new hip prosthesis components implantation were studied in 41 patients after 2 and 3 years.

The dynamics of the joint anatomical and functional condition does not deteriorate and remains at the same level. So, in the study group, after 2 years the mean Harris score was 89 ± 1.2 (95% CI 87-91), after 3 years 90 ± 1.1 (95% CI 88 - 92) points. However, it should be noted that in the dynamics anatomical and functional state of hip joint after 2 and 3 years after surgery deteriorated slightly, but remained stable. Compared with the immediate period. It should be noted that in the test group after 6 and 12 months the results were better (91 ± 1.1; 93 ± 1.3), after 2 years, and 3 (89 ± 1.2; 90 ± 1.1).

As a result, good results were seen in 85.9% of patients, satisfactory in 2 and 3 years - 11.7%, unsatisfactory - in 2.4%. Reasons for the unsatisfactory result were the instability of the acetabular implant component in 1 patient. The result of the new femoral component is shown in Figure 5.

a  b

c d

Figure 5. Pre-operative radiographs of 49 – year-old men with coxarthrosis (a). Post-operative radiographs after total hip arthroplasty with new femoral component (b) and after 2 years result (c, d)

In this way, according to the literature above there is a significant increase of the intraosseous pressure and risk of peri-operative complications in hip joint arthroplasty in particular the implantation of the femoral component. During the femoral component Kaz. NIITO implantation, the value of intraosseous pressure decrease and thereby the risk of fat embolism reduces during surgery.

Analysis of the given data revealed that in total and in unicompartmental hip replacement with regard to fat intravasation, the greatest danger is the stages of the medullary canal of the femur processing, placing the femoral component of the endoprosthesis. It is necessary to perform method preventing a sharp rise in pressure in the treated cavity. The simplest of these are: placing the spongy substance cork premises of the spongy substance of removed femoral head below the tip of implemented endoprosthesisstems; placing the drainage tube to the distal cavity.

In terms of the massive fat droplets intravasation the most dangerous is period of time until the completion of the osteotomy implant prosthesis components. Severe blows to the osteotomy with no broken bones integrity can cause fat intake in the bone marrow veins. Opening of the medullary cavity of the femur causing its outflow to the outside, and the subsequent reaming exposes vascular lumen as bones and bone marrow, allowing access to their liquid fat. Each implementation of the rasp, the test prosthesis causes intake of fat tissue detritus, the air into the bloodstream.

For surgical measures preventing fat embolism operating equipment without severe impacts intact femur technic include, including the gradual opening of the medullary cavity, the removal of fatty degeneration of the bone marrow, draining its distal, as well as getting rid of coarse reintroduction of the drill, the femoral component of the endoprosthesis.

As can be seen many scholars from the evidence-based perspective medicine have seen that there is a danger of complications in hip replacement during the operation. Foreign researchers, on the basis of experimental and clinical studies, have identified key indicators of intraosseous pressure during femoral component implantation and the peak value of using different tools during joint replacement surgery.

To reduce the risk of complications in performing hip replacement, foreign scientists in conjunction with the manufacturer's studied the modernization of tools and offered a variety of aspiration-irrigation system scans, and systematic literature review has shown the effectiveness of these tools that can reduce peak intraosseous pressure.

The advantage and importance of the designs is the fact that authors have developed not only tools, but also the hip joint prosthesis. This makes it possible to minimize the intraosseous pressure in all phases of operation of the hip arthroplasty.

This replacement technology is new and promising direction compared to other implants, designed for hip replacement. The authors can see this technology in the future replacement, as this direction will improve the results of treatment and quality of patients' life.

**4 Conclusion**

According to the results of the clinical studies it is observed that implantation of new femoral prosthesis decreases the intraosseous pressure during implantation, and thereby reduces the risk of fatty embolism during surgery.

In scientific studies of many authors it was found that intraosseous pressure increases since the moment of opening the medullary canal. (33) Increase of intraosseous pressure while using the rimmer depends on its diameter and ranges from 45 to 2800 mm Hg. (34,35)

The studies have shown that while processing the medullary canal with rimmer the intraosseous pressure was56.3 ± 12.6 [95% CI 52.3-60.3] mm Hg. Art. when inserting new rasp – 76.2 ± 13.1 [95% CI 72.2-80.2] mm Hg. Art. While applying the cement and inserting the stem, the intraosseous pressure reaches 3710 mm Hg and holds for 8-10 minutes (36-39).

Beck et al. (64) in his prospective study of 8 patients defined intramedullary pressure in the distal femur during implantation of the femoral stem using Mueller's prosthesis. The range of the intraosseous pressure was 590-2,570 mm Hg (Mean value is 1293, SD = 627 mm Hg).

Barden et al. (65) developed a femoral endoprosthesis with vertical and long itudinal hole at the surface of an implant for reducing the intramedullary pressure and fat embolism during implantation. Randomized clinical research works have shown the intraosseous pressure ranged from27 to82 mm Hg. Art. when using a femoral component with long itudinal grooves. These authors claim that the intraosseous pressure was lower while inserting the cored femoral component than while opening the canal and working with drills. When installing new stem, the intraosseous pressure was 69.3 ± 14.1 mm Hg. Art., and it was slightly higher than during osteotomy of femoral head and neck (61.3 ± 6.5 mm Hg. cent.), and opening the medullary canal with fenestrated tool (64.5 ± 7.6 mm Hg. cent.). There are no significant differences in the values of intraosseous pressure (p>0.05).

According to Mueller et al. (35), during the intervention of reamer not only the intraosseous pressure increases, but also the temperature in the medullary canal reaches 39.7 degrees C.

The studies have shown that the greatest value of IOP occurs when administering the rasp and fixing the stem, but there were no complications during and after surgery.

Therefore, Hofmann et al. (33) proposes to develop the technique on how to effectively fix the prosthesis to reduce the value of pressure. During the clinical study, intraosseous pressure after osteotomy of femoral head and neckshowed61.3 ± 6.5 (95% CI 59.3-63.3) mm Hg, while opening medullary canal with fenestrated tool- 64.5 ±7.6 (95% CI 62.1-66.9). mm Hg. Art. There was no significant difference in the value of the average values of intraosseous pressure in comparison with the intraosseous pressure before surgery(p>0.05).

Especially it is interesting to work on improving the design of the femoral component of hip endoprosthesis (64-65), which enables to reduce the IOP during implantation. Other authors propose to reduce the IOM to form the bone hole in the distal femur. (75,77)

Research and literature data of many authors suggest that all stages of joint replacement surgery have changes in intraosseous pressure, which reaches significant numbers, especially when inserting rasp and stem of prosthesis (33-39). However, while using new implant and rasp, there was no higher value of intraosseous pressure and complications in the study group (44 patients) at post-operative period.

And so, many researchers have noted that the implantation of the femoral component of the endoprosthesis is an increased intraosseous pressure during the opening of the channel (66), the processing of the medullary canal with reamer (155,165), the insertion of the cement and the implant stem. (67) Clinical and experimental studies have shown that fat emboli in the pulmonary capillaries appear after a few seconds after a fracture or manipulation in the medullary cavity. (68-70) The fat from the bone marrow (and subcutaneous tissue) falls directly into the systemic circulation due to increased pressure in the medullary cavity (intravasation tissue of bone marrow, fat and "debris". (71-73) It is considered the main pathogenic factor for the development of pulmonary complications and is called implantation syndrome. (74-76)

In order to reduce IOP, the authors (48-51) have proposed and investigated new aspiration-irrigation system scans (RSR, RIA), that have been tested on models of sheep, pigs, and in the clinical practice. During the study was an assessment of the following parameters: the pressure inside the medullary, hemodynamics, blood tests, lung histology and hip X-rays. At all stages of reaming IOP using the new scan (RSR) It was significantly lower compared with the AO reamer, as well as marked reduction in the number of intravenous blood fat, and Husebye et al. (52) reported that while reaming the bone channel using conventional scan IOP was 188 +/- 38 mmHg, and when using a new scanning (RIA) - 33 +/-8 mmHg.

Coxet al. (53) conducted a systematic review of the literature on the effectiveness of aspiration-irrigation system scans and the results of clinical trials. This study included a systematic review through Pubmed® and Google Scholar®, English language sources (nine non-clinical studies, seven clinical studies and seven case histories) using keywords: 'reamer' 'irrigator', 'suction'. Position is established with evidence that aspiration-irrigation system scans lead to lower IOP and simultaneously allows the sampling of bone material, reduce fat embolism (FE) and thermal necrosis (TN).

In the most research the reaction of intraosseous pressure in hip arthroplasty was studied only at certain stages of arthroplasty. The research of intraosseous pressure reaction wasn’t performed since the start of surgery until completion of the femoral component endoprosthesis installation up to the present day.

In this way, the results comparison of clinical contact intraosseous pressure value shows that the hip joint endoprosthesis technology proposed by us with new femoral component has significant advantages compared to current prostheses. The intraosseous pressure during installation and during implantation of the femoral component does not increase substantially and thereby reduce the risk of fat emboli.

The advantages of this technology are shown in clinical studies conducted by us after 6, 12, 24, 36 months after surgery. Comparative analysis of the immediate and medium-term results with the data of several authors has shown a steady improvement in the dynamics of hip function.

Mironovet al. (87) obtained the results of primary total hip arthroplasty before surgery were 37.6 points by Harris score and after surgery 89.3, 92.2, 89.1 points in term of 12, 24, 36 months. In applying the new femoral component following results were obtained: preoperative Harris score was 36.7, after 12 months were 93 ± 1.3 points, after 24 months -89 ± 1.2 score, 36 months - 90 ± 1, 1 score. Similar results were also observed by other authors. (78-86) There were no significant differences in clinical outcomes (p> 0.05). However, it should be noted that there was no thromboembolic complications or fat embolism during surgery with the new femoral component.

In this way, short-term (6 and 12 months) and long-term (2 and 3 years) clinical outcomes after using new femoral component were not worse than those of other authors (88-90) and were presented by us on International combined meeting British Hip Society. (91)

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**Primary Paper Section:** F

**Secondary Paper Section:** FH, FJ, FS