



Compare of Anterior Approaches in Acetabular Fractures Treated by the Standard Ilioinguinal Versus the Stoppa/Iliac Approaches

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Abstract

Background. The gold standard for the displaced acetabular fractures treatment is open reduction with internal fixation of the fragments. The following anterior approaches to the acetabulum are known: ilioinguinal (Letournel) approach, anterior intrapelvic (Stoppa) approach in combination with Letournel's supplemental lateral window, anterior intrapelvic (Stoppa) approach and pararectal approach. The first two approaches are the most popular in the world practice of pelvic surgery.

The aim of this study was to compare the Letournel approach and the Stoppa approach in combination with supplemental lateral window (with and without anterior superior iliac spine osteotomy) in the treatment of acetabular fractures according to the following indicators: quality of fragments reduction, time of surgery, intraoperative blood loss volume, nerve structures injury, angle of view and convenience of using pelvic reduction forceps. **Materials and Methods.** A comparative analysis of 53 cases of treatment of patients who underwent osteosynthesis of acetabulum was performed. Patients were divided into two groups. The first group was treated through the Letournelle approach (n = 27), the second group – the Stoppa approach + supplemental lateral window (n = 26). The second group was divided into two subgroups: subgroup 2A with anterior superior iliac spine osteotomy (n=13) and subgroup 2B without osteotomy (n = 13). The following parameters were compared: quality of the fragment reduction, time of the surgery, intraoperative blood loss volume, damage to nerve structures, angle of view and convenience of using pelvic reduction forceps. **Results.** The comparison of the two approaches showed that the indicators of fragments reduction, operative time, and intraoperative blood loss did not differ statistically significant (p>0.05). There were more neurological complications in group 1, but they did not affect the treatment outcome. The angle of view during anterior superior iliac spine osteotomy was about 90°, which contributed to a more effective use of pelvic reduction forceps. The functional results of the treatment in 12 months after the surgery in both groups were the same. **Conclusion.** The Letournel approach and the Stoppa approach with supplemental lateral window were equivalent in terms of the quality of reduction, operative time and intraoperative blood loss. The Stoppa approach with supplemental lateral window in contrast to the Letournel approach made it possible to avoid iatrogenic paresthetic meralgia. The Stoppa's approach with supplemental lateral window and anterior superior iliac spine osteotomy provided a better anterior acetabular column visualization and a greater angle of view for the surgeon during reduction in comparison with the classical lateral window.

Keywords: acetabular fracture, the Stoppa approach, the Letournel ilioinguinal approach.

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Introduction

The gold standard for the treatment of displaced acetabular fractures is open reduction and internal fixation of the fragments [1, 2]. The correct choice of the surgical approach is the determining factor of the accurate fragments reduction [3]. Depending on the localization of the greatest displacement of the fragments, the nature of the acetabular fracture and the state of soft tissues in the area of the planned operation, the choice of the surgical approach is one of the factors affected the decrease in the number of post-operative complications and the functional result in general [4, 5, 6, 7].

The access to the anterior acetabular column is traditionally performed through the ilioinguinal approach developed by E. Letournel in 1965 [8]. The anterior intra-pelvic approach by R. Stoppa (AIP) began to be used in the pelvic surgery in the early 1990s as an alternative due to its less invasiveness [9]. During the surgery, this approach makes it possible to operate without an intermediate middle window, as in the classical ilioinguinal approach, and to work with fragments of the medial acetabular wall from the pelvic side. The AIP approach is very often combined with a supplemental lateral window in the iliac wing area, as in the ilioinguinal approach [10]. In order to increase the working space of the supplemental lateral window, an osteotomy of the anterior superior iliac spine is performed, followed by its refixation with a screw. The classical ilioinguinal approach was the first technique that was introduced for the surgical treatment of acetabulum fractures at the Sklifosovsky Scientific Research Institute for Emergency Care, Moscow, Russia (the Sklifosovsky). Over the past 4 years, we have begun to actively use the AIP approach combined with an supplemental lateral window as an alternative approach.

The aim of this study was to compare the ilioinguinal approach and the AIP approach with the supplemental lateral window (with and without osteotomy of the anterior supe-

rior iliac spine) in the treatment of acetabulum fractures by the following indicators: quality of the fragment reduction, time of the surgery, intraoperative blood loss volume, damage to nerve structures, angle of view and convenience of using pelvic reduction forceps.

Materials and Methods

The study design

A retrospective cohort non-randomized study.

Patients

114 patients with acetabulum fractures were treated at the Sklifosovsky from January 01, 2014 to December 31, 2018. The majority of acetabulum fractures were the result of high-energy trauma (75% of cases) and occurred in predominantly young patients. The low-energy acetabulum fractures in the majority of cases occurred in elderly and senile patients. All the injured received first aid according to the internal protocol, primary X-rays were taken in a standard anteroposterior plane [11]. The additional oblique R. Judet planes [12] were performed after the patients stabilization. Then the acetabulum fractures were ranked by the Letournel [12] and AO/OTA classifications [13].

The *inclusion criterion* in the study was the presence of the displaced acetabulum fractures required the surgical treatment (n=68).

The exclusion criteria:

- the patient's refusal to cooperate (n = 6);
- the concomitant ipsilateral femoral head fracture (Pipkin, n = 5);
- severe cognitive impairment (n = 2);
- lethal outcome (n = 2).

Thus, a group of 53 patients was formed.

The pelvic CT with 3D reconstruction was performed with Multivox software based on Windows 7 to clarify the acetabular osteosynthesis preoperative plan. Six (11.3%) patients with transtectal and juxtatectal acetabulum fractures and femoral head subluxation were

mounted the skeletal traction with a wire in a bracket for the tibia at the level of its tuberosity, placing the lower limb on the Bohler splint and axial traction using a weight of 1 kg load per 10 kg of patient's weight. This prevented the further destruction of the femoral head articular surface against the sharp edges of the acetabular fragments.

Twelve (22.6%) patients with acetabulum fractures and femoral head protrusion into the pelvic cavity underwent the closed hip dislocation reduction with fixation the achieved position in the external fixation rod apparatus "pelvis-femur".

The complete diagnosis was formed, including injury of other skeleton anatomical areas. The injury severity was determined by the points on the ISS scale [14, 15].

The patients were divided into 2 groups. Group 1 included 27 patients with displaced acetabulum fractures reduced through the ilioinguinal approach. Group 2 consisted of 26 patients with acetabulum fractures reduced through the AIP approach with the supplemental lateral window (Fig. 1).

The following indicators were compared: quality of the fragment reduction, time of the surgery, intraoperative blood loss volume, damage to nerve structures, angle of view and convenience of using pelvic reduction forceps.

Group 2 was divided into two subgroups: subgroup 2A consisted of 13 patients underwent surgery with the supplemental lateral window with the anterior superior iliac spine, subgroup 2B comprised 13 patients without osteotomy (Fig. 2).

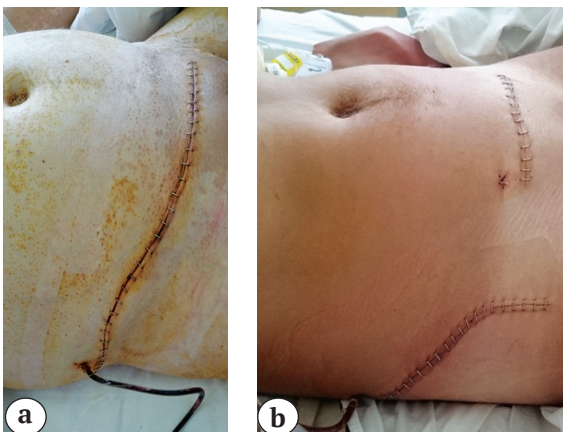


Figure 1. The approaches:
a – the ilioinguinal approach;
b – the AIP approach with the supplemental lateral window in the iliac crest

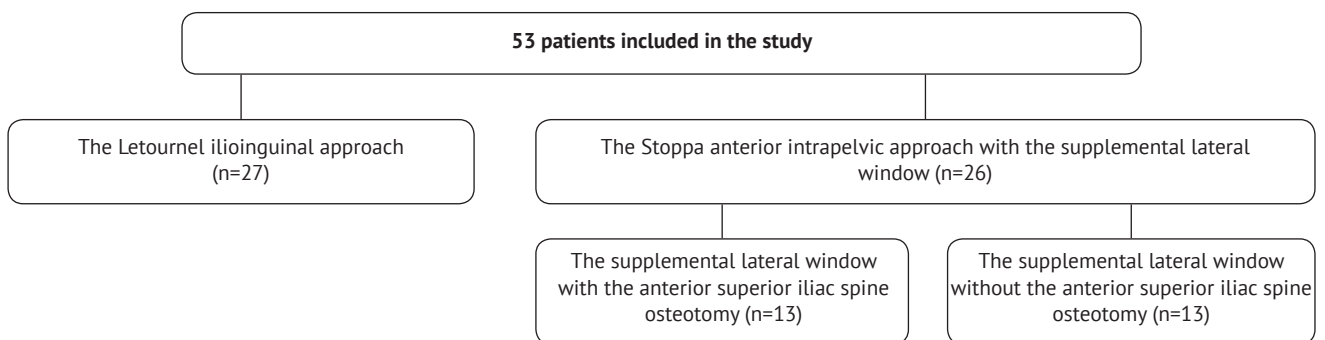


Figure 2. The study flowchart

The surgical technique. All the patients were operated on by the same surgical team. The surgeries were performed on a TruSystem 7500 U24 surgical table (Trumpf Medical, Germany). The patients were in the supine position with the lower extremities hanging over the operating table edge with a foam roller in the popliteal region and a cloth roller under the sacrum region at the injury side. If the use of the axial traction for the lower extremity was planned during the surgery, the bracket was not removed. In other cases, the skeletal traction or external fixation rod devices were dismantled immediately before the surgery. All the patients underwent elastic bandaging of the lower extremities to the thigh lower third level. To control the urine output and to exclude an intraoperative iatrogenic urinary bladder injury, all the patients were inserted the Foley catheter with a urine collection bag. The intraoperative X-ray control of surgical procedures was performed with the OEC Fluorostar 7900 COMPACT2 C-arm (GE Healthcare, UK).

Three working windows were formed for the ilioinguinal approach. They provided an access to the acetabular anterior column when the surgeon stood on the acetabulum fractures side and worked “down and into”

the pelvic cavity, starting from the top. The first or lateral, window provided the access to the iliac fossa and the anterior surface of the sacroiliac joint. This window was bounded medially by the iliopsoas muscle. This lateral window formation should be accompanied by the lateral femoral cutaneous nerve isolation. Its transverse position in the surgical wound can create technical difficulties during reduction. There also exists a risk of the nerve iatrogenic injury (Fig. 3). Clinically, the lateral femoral cutaneous nerve injury was manifested by the decrease or absence of the sensitivity along the lateral surface of the thigh from the inguinal fold to the lower third of the thigh up to the knee (paresthetic meralgia or Bernhardt-Roth syndrome).

The second or middle window gives the access to the linea terminalis and the acetabular lateral wall by dissecting the iliopectineal fascia. This window is laterally bounded by the contents of the muscle space (lateral femoral cutaneous nerve, iliopsoas and femoral nerve) and the medial vascular space, which contains the large iliac vessels and lymphatic ducts and nodes. The third or medial window is located medial to the femoral vessels and creates the access to the superior branch of the pubis and Retzius' space (prevesical space).

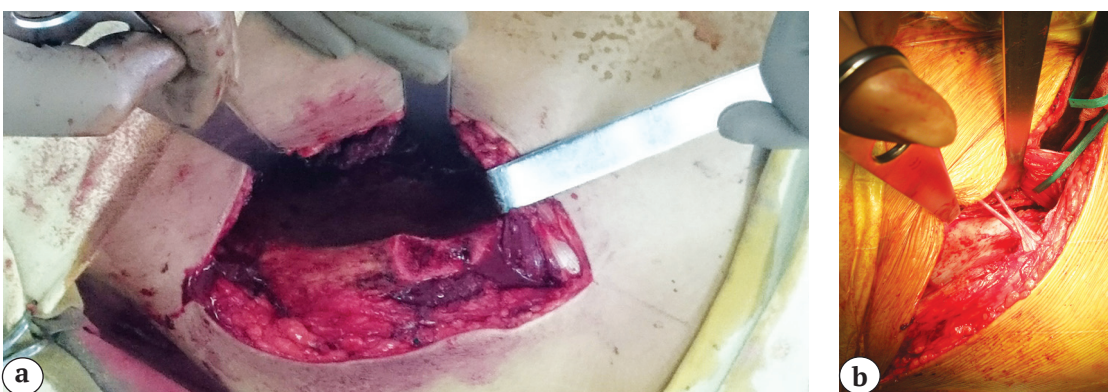


Figure 3. The comparison of the working area of the lateral window during the surgery: a – the supplemental lateral window with anterior superior iliac spine osteotomy; b – the Letournel approach

For the AIP approach the line alba was vertically dissected through the cutaneus Pfannenstiel approach as for fixation of the pubic symphysis. The surgeon, located opposite the fracture site, performed extraperitoneal access along the pubic posterior surface and the acetabular lateral surface, mainly working "from the above and from the inside", pushing back the rectus abdominis, neurovascular structures, urinary bladder and surrounding soft tissues. In this case, the iliopectineal fascia was dissected directly from the edge of the linea terminalis along with the Cooper's ligament. This technique provided the good view of the pelvis along the entire linea terminalis, the entire pubis and the anterior part of the acetabular lateral wall.

To provide the access to the iliac fossa of the iliac crest, the supplemental lateral window was formed by osteotomy of the anterior superior wing spine with its refixation at the end of the surgery (Fig. 4).

The connection of the osteotomized bone area with the oblique muscles of the abdomen was preserved proximally, and with the

sartorius and tensor fasciae latae – distally. This double belly osteotomy maintained the blood supply to the fragment and prevented its secondary displacement by balancing the traction forces. Besides, there was no need to target the lateral femoral cutaneous nerve. The entire muscle flap with its iliac vessels, femoral nerve, and a portion of the anterior superior spine was pushed medially.

If a vascular anastomosis between the iliac and obturator vessels (corona mortis) was detected, it was ligated, sutured, or clipped, regardless the surgical approach. The anastomosis was found above and behind the pubis superior branch, on average, at 5 or 6 cm from the symphysis.

The reduction and fixation of the acetabular anterior column fractures did not technically differ in both approaches. The bone fragments were fixed with the pelvic wide-angle plates, positioning them above the linea terminalis from the pubis to the anterior edge of the sacroiliac joint. The acetabular side wall fixation in some patients with a comminuted fractures was carried out by a

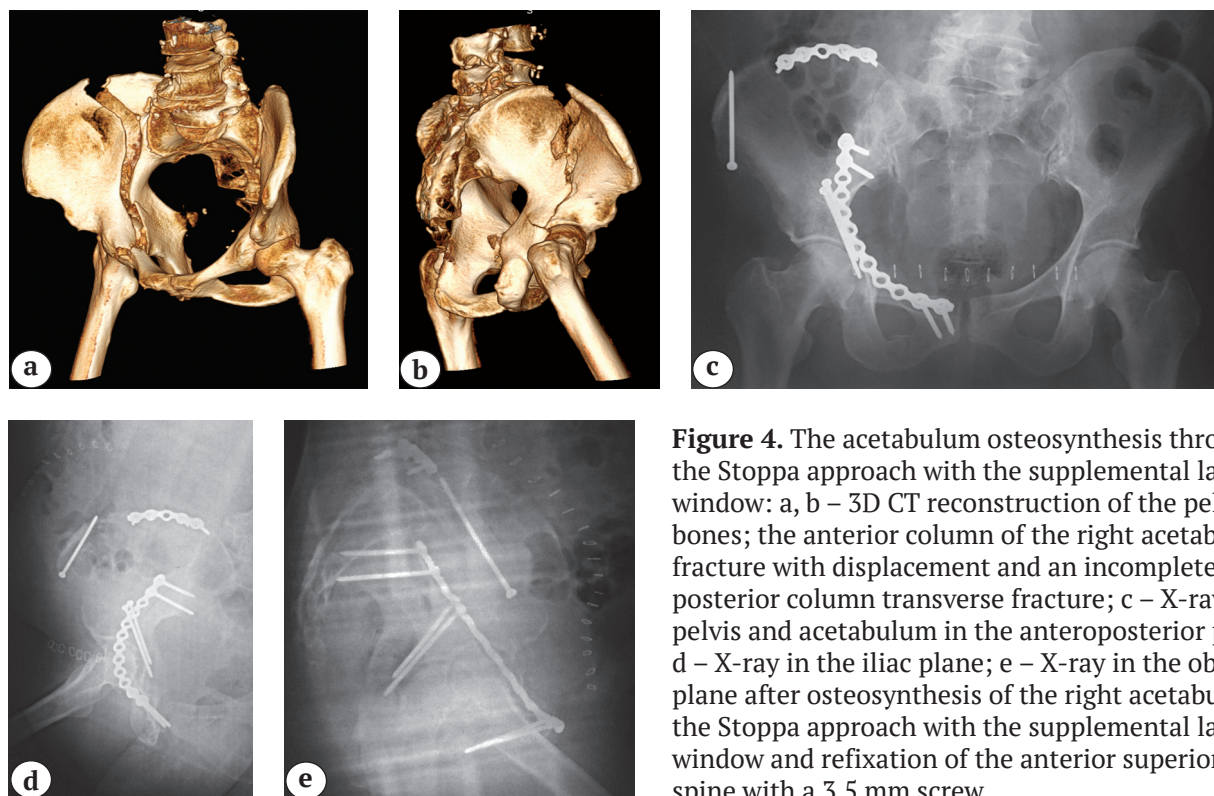


Figure 4. The acetabulum osteosynthesis through the Stoppa approach with the supplemental lateral window: a, b – 3D CT reconstruction of the pelvic bones; the anterior column of the right acetabulum fracture with displacement and an incomplete posterior column transverse fracture; c – X-ray of the pelvis and acetabulum in the anteroposterior plane; d – X-ray in the iliac plane; e – X-ray in the obturator plane after osteosynthesis of the right acetabulum by the Stoppa approach with the supplemental lateral window and refixation of the anterior superior iliac spine with a 3.5 mm screw

spring-plate technique. These two approaches practically did not differ in the method of reduction of the acetabular posterior columns in two-column fractures. The posterior column displacement was corrected by the insertion of the large asymmetrical pelvic forceps through the lateral window. We additionally used the coaxial repositioning forceps through the lateral or middle window in case of ilioinguinal approach employment. As a rule, the posterior column fractures were fixed with 3.5 mm screws antegrade from the anterior surgical approach or with 6.5 mm cannulated screws retrograde through a 0.5 cm skin puncture in the area of the ischial tuberosity. The additional posterior approach on the same operating day was used if the displaced posterior column fracture could not be repaired through the anterior approach.

The methods of the results evaluation

We compared quality of the fragment reduction, time of the surgery, intraoperative blood loss volume, damage to nerve structures, angle of view and convenience of using pelvic reduction forceps in two groups. The assessment of the quality of the fragment reduction in the postoperative period was carried out by pelvic X-ray in the anteroposterior plane, oblique plane by R. Judet and CT. The patients follow-up X-ray was done within 6 weeks, 3, 6 and 12 months. The final functional outcome was assessed within 1 year after the surgery using the Majeed scale [16].

The publication ethics

The patients gave their voluntary informed consent for participation in this study and publication their clinical observations.

The statistical analysis

The calculations were performed using the STATISTICA 12 program. The descriptive statistics was used with presentation of absolute values and proportional ratios. The Shapiro–Wilk test was used to assess

the correspondence of the obtained data to the normal distribution. Most of the data did not correspond to the normal distribution. In that case, we used the nonparametric statistics. The quantitative traits between groups were compared using the Mann-Whitney test presenting the data by medians and 1st and 3rd quartiles as Me (25%; 75%).

Results

The parameters of the studied groups were similar, in particular, in terms of patients characteristics, the nature of the injury, and the acetabulum fractures morphology. This made it possible to obtain the statistically significant results. The existing differences between the groups did not contradict the logic of the study (Table 1). The associated acetabulum fractures (by the AO/OTA classification) in both groups accounted for more than 80% of all cases. The other bones fractures were diagnosed in 11 (20.8%) patients.

The operative time

The time of surgery in group 2 with the AIP approach with the supplemental lateral window was less than in group 1 with the ilioinguinal approach, 182.2±42.0 min vs 199.6±24.0 min. The difference was statistically insignificant (Table 2).

The additional posterior approach was required in 20% of cases with the ilioinguinal approach and in 10% with the AIP approach. The use of the spring-plate technique to fix the acetabular lateral wall took place in 2 cases with the ilioinguinal approach and in 1 case with the AIP approach with the supplemental lateral window. The technique 6.5 mm cannulated screw closed insertion into the posterior column through the ischial tuberosity was used in 2 patients in the group with the ilioinguinal approach and in 1 patient in the group with the AIP approach.

Intraoperative and drainage blood loss. The intraoperative blood loss volume and the drainage blood loss did not differ significantly between the compared groups (see table 2).

Table 1

The characteristics of the patients included in the study

Indicators		Group 1	Group 2
Gender, n	M	20	15
	F	7	11
Age, years		43.25±10.69	44.00±9.14
The cause of injury, n	Fall	8	4
	Road traffic accident	18	16
	Other	1	6
Fracture type according to the AO/OTA classification, n	62A3.3	2	1
	62B1.2	4	2
	62B1.3	5	4
	62B2.2	4	7
	62B3.2	7	3
	62C2	3	6
	62C3	2	3
Fractures of other bones, n		3	8

Table 2

The intraoperative indicators assessment

Indicator	Group 1, n=27	Group 2, n=26	p
Operative time, min	160 (100; 300) min 100, max 500	150 (100; 250) min 100, max 400	0.088
Additional posterior approach by Kocher-Langenbeck, n (%)	4 (14.8%)	1 (3.8%)	–
Operative blood loss, ml	500 (450; 600) min 200, max 650	300 (200; 350) min 150, max 550	0.078
Drainage blood loss, ml	100 (80; 130) min 30, max 200	100 (80; 150) min 40, max 180	0.069

The surgical wound field of view

The angle of view of the "classic" lateral window in subgroup 2B averaged 60°. It was significantly less than the angle of view in subgroup 2A (about 90°). The surgery in this subgroup employed the lateral window and the anterior superior iliac spine osteotomy. This provided the visualization of the almost entire acetabular anterior column up to the pubis base (Fig. 5).

Employment of reposition instruments. No differences were subjectively found in the bone fragments reduction with pelvic forceps in both groups. However, in group 1, the transverse position of the lateral femoral cutaneous nerve interfered with the correct placement of the reducing instruments, or the desired position of the pelvic forceps caused the excessive nerve overstretching with subsequent complications development.

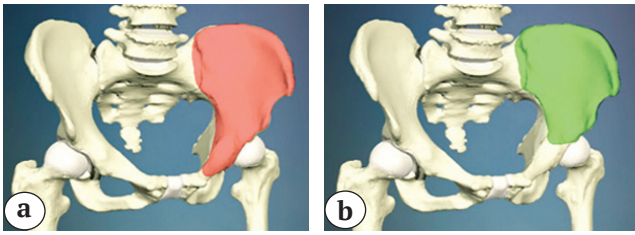


Figure 5. The degree of visualization in the surgical wound of the lateral window: a – the lateral window with anterior superior iliac spine osteotomy; b – the lateral window without anterior superior iliac spine osteotomy

The intraoperative iatrogenic rupture of the lateral femoral cutaneous nerve was noted due to the insertion of the pelvic reduction forceps in 1 patient. The injured nerve suturing was not performed. The patient noted a persistent absence of temperature and tactile sensitivity along the anterior lateral surface of the thigh from the level of the greater trochanter to the middle third of the thigh during the entire follow-up.

Reposition quality assessment

The quality of the fragment reduction was higher in group 2 with the AIP approach with the supplemental lateral window. However, the difference in the mean values of groups 1 and 2 as well between the subgroups was not statistically significant, $p > 0.05$ (Table 3).

Complications

The neurological complications similar to femoral nerve neuropathy were diagnosed in 2 patients with the ilioinguinal approach and none in the patients with the AIP approach. The complications were interpreted as postoperative neuropraxia of the femoral nerve

and did not require any special treatment. The spontaneous remission occurred in 4 months. In addition, in the same group, the lateral femoral cutaneous nerve neuropathy of various severity was noted in 12 (44.4%) cases, which also did not require any specific treatment. The obturator nerve neuropathy was diagnosed in only one (3.84%) patient in group 2. In group 1, one patient suffered the intraoperative injury to the iliac vein required suturing. There were 2 patients of the same group with the iatrogenic rupture of the corona mortis treated by the venous anastomoses stumps ligation with minimal blood loss.

The infectious complication in the form of postoperative wound suppuration in the iliac wing area on the 8th day was recorded in one (3.7%) patient with the ilioinguinal approach. The patient was a heavy smoker and suffered from type II diabetes with malnutrition. The patient had the stitches of the lateral window area removed under spinal anesthesia in the operating room. The iliac fossa was washed abundantly with an aqueous solution of chlorhexidine. Then the patient was

Table 3

The quality of acetabular fragments reduction assessment by the Matta criterion

Reposition quality assessment	Group 1		Subgroup 2A		Subgroup 2B	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Excellent	6	22.2	4	30.8	4	30.8
Good	15	40.0	6	46.2	5	38.5
Unsatisfactory	6	22.2	3	23.1	4	30.8

treated with negative pressure against the background of antibiotic therapy. No signs of osteosynthesis instability were revealed during the wound revision, so the implants

were not removed. The wound healed by secondary intention on the 21st day. There were no inflammatory complications in group 2 (Table 4).

Table 4

Complications in patients of both groups

Complications	Group 1		Group 2	
	n	%	n	%
Obturator nerve neuropraxia	0	–	1	3.84
Neuropraxia of the lateral femoral cutaneous nerve	12	44.40	3	11.50
Femoral nerve neuropraxia	2	7.40	0	–
Vascular injury	1	3.70	2	7.69
Loss of reduction	1	3.70	1	3.84
Infection	1	3.70	0	–
TOTAL	17	62.90	7	26.87

Discussion

Despite the abundance of the data on the results of the use of ilioinguinal approach and the AIP approach, the authors opinions remained controversial. N. Shazar et al. showed that with the AIP approach, the accuracy of the fragments reduction was higher than with the ilioinguinal approach [17].

K. Ma et al conducted a multivariate analysis of these two approaches use. They took into account the demographic characteristics of the patients; preoperative parameters by the nature of the fractures, concomitant injuries, the time to surgery, and the severity of injury; intraoperative blood loss volume and time of surgery for each approach. Postoperative parameters included wound drainage, blood transfusion, intraoperative, early and late surgical complications, quality of fragments reduction, radiological findings, and clinical outcomes. Their study did not show any significant differences in all studied variables between the two approaches, although the modified AIP approach would have been expected to significantly reduce intraoperative blood loss volume [18].

In our study, all our patients were operated on by one surgeon and one surgical team. Traditionally, we used ilioinguinal approach in all cases until July 2017. Then, without any exceptions, a complete transition was made to the AIP approach with the supplemental lateral window. Since the two approaches differ in terms of surgical technique and reposition, our experience with the ilioinguinal approach did not lead to the expected improvement in the results with the AIP approach with the supplemental lateral window. Our study has III level of evidence, which is not considered as high. Our foreign colleagues T. Pohlemann and U. Culemann also pointed out the difficulty of conducting studies of a higher level of evidence in the field of acetabulum fractures surgery [19]. The reason lies in the relative paucity and heterogeneity of such fractures.

The location of the pelvic reduction forceps in the AIP approach with the supplemental lateral window makes it difficult to fully visualize the acetabular anterior column. According to H. Sagi et al., this circumstance forced the transformation of the AIP

approach with the supplemental lateral window into the classic ilioinguinal approach in 4 cases due to the comminuted fracture of the superior pubic ramus root [20]. To solve this problem, we performed the osteotomy of the anterior superior iliac spine. This made it possible to significantly increase the angle of view and to use the repositioning instruments with good visualization of the hip.

The ilioinguinal approach was associated with slightly longer time of surgery. This may be explained by the fact that the dissection takes a long time to isolate the lateral femoral cutaneous nerve due to its variable anatomy and the difficulty of its visualization. The overall rate of postoperative complications was comparable to the literature data. Most authors reported the complications in the early postoperative period. E. Letournel, in a series of observations, reported 3 (2.1%) cases of infection, 8 (6%) cases of neuropathies of the femoral and/or sciatic nerves, one of which with irreversible damage, 2 (1.4%) cases of abdominal hernia required surgery, 3 (2.1%) cases of the external iliac vein injury, 1 case of the internal and external iliac arteries thrombosis, and 1 bladder injury [21]. J.M. Matta reported 13% of complications, which included the femoral artery rupture, femoral nerve paralysis, and 3 cases of postoperative wound infection [22]. H. Sagi et al., in a series of observations, found one (1.8%) patient with vascular injury requiring embolization, one (1.8%) patient with wound infection, 2 (3.5%) patients with direct inguinal hernia required surgery, one (1.8%) patient with the ipsilateral rectus abdominis muscle atrophy without hernia [20]. In our study, we observed the lateral femoral cutaneous nerve neuropathy in 12 (44.4%) patients. All of them underwent surgery using the ilioinguinal approach. The patients operated on with the AIP approach with the supplemental lateral window did not demonstrate any complications. Such a difference can be explained by the inevitable nerve injury by the traction during spreading the surgical wound edges.

However, this complication did not significantly affect the final functional outcome.

The wound infection after acetabulum fractures open reduction and internal fixation is one of the most serious complications. A history of an infection episode can negatively affect the outcome of a possible future hip arthroplasty. In our study, a wound infection was diagnosed in one (3.8%) patient. We were unable to establish a direct link between the infection and the type of surgical approach. As we noted above, the patient had several risk factors for the wound infection. S.A. Sems et al. reported an increased risk of infection in obese patients undergoing surgery for pelvic and acetabulum fractures [23].

From our point of view, both approaches turned out to be identical in terms of quality of fragments reduction and clinical outcomes. The AIP approach is more convenient in the case of a two-column fracture and in situations requiring direct support of forceps on the quadrangular surface of the inner plate. On the other hand, the middle window of the ilioinguinal approach is more helpful in visualizing anterior wall and transverse acetabulum fractures. The unsatisfactory reduction was noted in the fractures with significant displacement of both acetabular columns at once: transverse fractures, fractures of the anterior column with a transverse fracture of the posterior column. From our point of view, this fact is associated with the technical difficulties of the reduction simultaneously with both columns from the same approach, the bone callus development and the impossibility of the additional posterior approach employment.

All the patients with unsatisfactory functional outcomes had unsatisfactory reduction rates according to Matta criteria: 3 patients from group 1 (50% of all unsatisfactory outcomes) and 4 patients from group 2 (57% of all unsatisfactory outcomes). In our opinion, this fact confirms the importance of restoring the hip congruence.

The study limitation

The study was not randomized and prospective, so a bias in the patients selection was inevitable. The time of surgery decreased and the quality of fragments reduction increase in our study can be explained by the improvement of the surgeon's operational technique in the process of gaining experience. The number of the patients was relatively small, so it was difficult to make an unambiguous conclusion in a direct comparison of these anterior approaches to the acetabulum.

Conclusion

The ilioinguinal approach and the AIP approach with the supplemental lateral window are equivalent in terms of the quality of fragments reduction, time of surgery and intraoperative blood loss volume. The use of the AIP approach with the supplemental lateral window, in contrast to the ilioinguinal approach, allows the surgeon to avoid iatrogenic paresthetic meralgia. The AIP approach with the supplemental lateral window and the anterior superior spine of the pelvic wing osteotomy provides better visualization of the anterior acetabular column and a greater degree of freedom for the surgeon during manipulations with repositioning instruments in comparison with the classical lateral window.

Publication Ethics

The patients gave their voluntary informed consent for participation in this study and publication their clinical observations.

Source of financing: The state budget.

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