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A comparative study between open reduction by distal femur locked plate and internal fixation by retrograde nail in distal femur fractures.

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Abstract

Typically, fractures of the distal femur occur in high-energy trauma in a young patient or a fall at home in an older individual. The retrograde intramedullary nail and locking compression plate are two treatment options for distal femur fractures. Stabilizing mechanisms based on biological osteosynthesis may be found in each of these systems. It was the goal of this research to compare the outcomes of distal femur fracture stabilisation using RN and LP methods. We set out to see how each fixation technique performs in terms of operational time, recovery time, knee range of motion (ROM), and complications. Methods: What we used and how we did it The functional and radiological outcomes of 32 patients with distal femoral fractures were evaluated in a prospective randomised clinical trial. Retrograde Intramedullary Nail was used to fix Group 1. a distal femur-locked plate fixed Group 2. As a consequence, while the retrograde nail took less time to operate and caused less blood loss, there was no significant difference between the two groups in terms of LEFS, knee range of motion, or overall outcomes and complications. This research found that, when compared to other studies, an acceptable result could be obtained using both approaches. The nail, however, demonstrated a higher union rate and a lower surgical morbidity in our sample of patients.

Key words: Distal femur fracture, retrograde nail, locked plate.

1. Introduction

Fractures of the distal femur occur for 3 to 6 percent of all femoral fractures, however they constitute less than 1% of all fractures. A bimodal distribution of fractures may be seen. Patients under the age of 50, mostly men, who have suffered high-energy trauma, such as in a car accident or a fall from great heights, make up one such group. In the second category, women over 50 with osteoporosis and low-energy trauma comprise the majority.[1–2].

As a common therapy for supracondylar fractures, open reduction and internal fixation with extra-medullary implants has been used for decades with substantial complication rates such as implant failure and infection. Infection and delayed union may be caused by iatrogenic soft tissue damage and devascularization of the periostium required to install the standard extra medullary fixation. This means that more bone grafting is typically required[3].

Peri-articular fracture fixation has undergone a sea change thanks to the invention of locking implant constructions. An improvement in mechanical stability may be achieved by using a fixed-angle construction. Dynamic condylar screws and blade plates have been replaced by locking plate devices because of the simplicity of usage and the superior distal fixation. Consequently, the most frequent treatment for intra-articular distal femur fractures is lateral plate fixation[4].

A biomechanical benefit of intramedullary nails over side plates and screws is that they provide less stress on the implant and distribute that stress more evenly than eccentric side plates and screws do. They are also capable of shearing loads [5]. Patients may be mobilised earlier, with less damage to soft tissues, less time spent operating, and less blood lost in the process [6].

The study's goals were to examine the benefits and risks of each technique for fixing AO type A, C1, and C2 distal femur fractures, as well as to compare and contrast the outcomes of each fixation method in terms of operative time, early mobilisation, knee range of motion, healing time, and problems.

2. Patients and Methods

A prospective study for comparison between fixation of distal femoral fractures using femoral retrograde intramedullary nails (RN) and distal femoral locked compression plates (LP). The study was done in Cairo University Hospital from May 2019 to February 2020 (date of last follow up).

2.1. Inclusion criteria:

- Skeletally mature patients .
- Fracture of the distal femur with or without intra-articular extension (AO/OTA Types A1-2-3 and C1-2).
- Fracture requiring operative treatment amenable to either Retrograde Nail or distal femur locked plate.
- Informed consent obtained.

2.2. Exclusion Criteria:

- Skeletally immature patients
- Open fractures.
- Associated vascular injury.
- Pathological fractures.
- Peri-prosthetic fractures.
- Associated ligamentous injuries of the knee.
- Medically unfit.

Patients who met the criteria above were divided into two groups:

- Group A: were treated by retrograde nail (RN)
- Group B: were treated by distal femur locked plate (LP)

2.3. Sample size:

The study included 32 patients who met the inclusion criteria they were operated upon using DHS with distal femur locked plate (16 cases) and retrograde nail (16 cases). All patients were followed prospectively for 6 months.

Randomization method:

The sealed envelope system was used for randomization. Patients who weremanaged by retrograde

nail were named group A, while patients who were managed by distal femur locked plate were named group B.

The aim of this study is to compare the result of surgical management of distal femoral fractures with two different methods of fixation, the femoral retrograde intramedullary nails (RN) or distal femoral locked compression plates (LP) regarding primary and secondary outcomes.

Primary outcomes:

- Lower extremity function using LEFS
- Knee range of motion

Secondary outcomes:

- Operative time
- Intraoperative blood loss
- Post-operative hospital stay
- Time of union
- Post-operative complications

Preoperative Management Protocol

On admission:

1. **Careful history taking and clinical examination were done for all patients as follows:**
   - Personal data: name, age, sex, occupation, address, telephone number, and special habits of medical importance.
   - Co-morbidities: DM, HTN, Cardiac or Others.
   - Clinical examination carefully to detect any associated injuries, skin condition, and ecchymosis on the affected side.
   - Poly trauma patients were managed according to ATLS protocol.
2. **Radiological assessment:**
   - Plain X-ray: knee and supracondylar region AP and lateral views, pelvis AP view were obtained. to detect :
   - Fracture configuration according to AO/OTA classification.
   - Bone quality.
   - CT scans: was needed in cases with suspected intra-articular extention to detect it and for planning the surgical approach.
   - CT scan was done in 8 cases of the 32 to confirm intra-articular involvement.
   - MRI was not needed in any of the cases because no cases with ligamentous injury were included.
3. **Laboratory testing:**
   - Routine preoperative CBC, coagulation profile, liver and renal function tests.
   - Blood glucose level.
   - ECG and Echocardiography for older patients.

Pre-operative preparation:

- Long leg splintagewas applied
- Proper analgesia with caution to hepatic and renal patients
- Prophylaxis to DVT and pulmonary embolism by low molecular weight heparin (Enoxaparin 40 IU subcutaneous) was given every 24 hours in all cases and was stopped 12-24 hours pre-operative then re-administered 12 hours after surgery
- patient medical co-morbidities assessed using ASA scoring

Informed consent:

All patients were consented about surgery and possible complications and for randomization too.

Operative procedures:

Timing of surgery:

The time interval between the trauma and the surgery varied according to patient fitness, preparation, and control of comorbidities.

Anesthesia:

32 patients were operated upon by using spinal anesthesia while 2 patients using combined general anesthesia and spinal.

Antibiotics:

Prophylactic antibiotic 3rdgeneration cephalosporin (Cefotaxime 1 gm) was given to all patients 30 minutes to one hour before surgery.

Tourniquet:

Tourniquet was not used in either group.

Surgical Procedure ;(RN group):

Position: (Figure 19)

The patient was positioned supine on a radiolucent table with the knee in 30° flexion. The knee wassupported by a cushion, or rolled sheets. A small sand bag just behind the same buttock was used to prevent external rotation of the limb.

Anatomical structures:

Care should be taken with the approach for Retrograde Nail as several anatomical structures are at risk. The most important potential hazard is damage to the posterior cruciate ligament. In addition, cartilage from the weight bearing zone may be damaged if the wrong approach is selected. This can also lead to a failure to reduce the fracture properly, resulting in a varus/valgus mal-position of the distal main fragment. The anatomical landmark is the Blumensaat's line, which corresponds to the roof of the intercondylar notch.

Skin incision:

Anterior midline incision that extends from inferior pole of the patella to the superior edge of tibial tubercle Figure (1).

Fig.(1) Anterior midline incision in trans-patellar approach.

Soft-tissue handling

The patellar tendon was split centrally and retracted to gain access to the intercondylar notch

MetaphysealDiaphyseal Reduction:

For most fractures, manual traction was satisfactory. In some cases, more sophisticated reduction techniques were used such as:

- Schanz screw;One or more mono-cortical Schanz screws were helpful for providing direct control of displaced main fragments.
- Bone hook;direct reduction with a bone hook was helpful in securing anatomical alignment.
- Pointed reduction forceps.
- Blocking screws Figure (2).

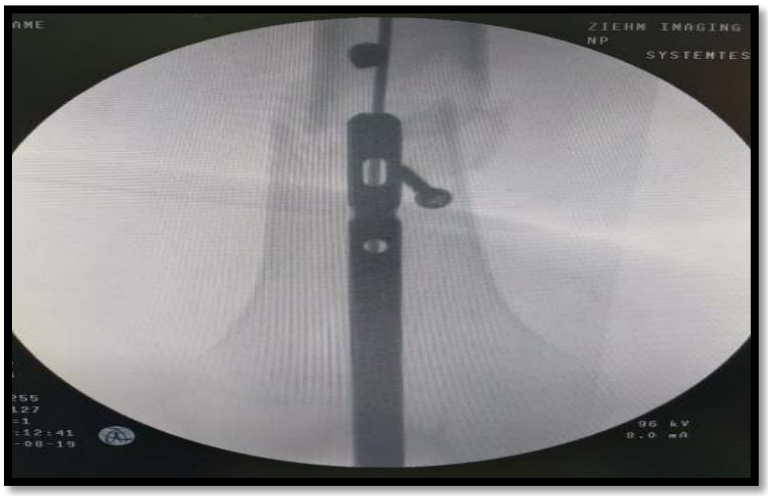

Fig.2 : Image showing reduction of fracture using blocking screws.

Localization of entry point:

The entry point was located under image intensifier guidance. On the AP view, guide wire was centeralized exactly in the middle of the inter-condylar notch. The entry point for the nail is in line with the axis of the medullary canal, just below the crest of the intercondylar notch. The correct position is located anterior and lateral to the proximal attachment of the posterior cruciate ligament.

3. Results

Demographic analysis:

Age:

The mean age Group A was 35.7 while mean age Group B was 36.1. There was not statistically difference between 2 groups regarding mean age (**P value = 0.84)**

Table (1) age distribution between 2 groups.

	Mean	SD	Range	P value
Group A	35.7	10.2	10-40	0.84
Group B	36.1	14.3	13-42	

Gender

In Group A there was 12 male 5 females while LP Group there was 10 males 7 females.There was no statistically significant difference between both groups **(P value =0.44**).

Table (2) gender distribution among study groups.

	Males		Females		P value
	N	%	N	%	
Group A	12	70.6%	5	29.4%	0.44
Group B	10	58.8%	7	41.2%	

Smoking:

No statistically significant difference regarding smoking between both groups.

Table (3) smoking status among study groups.

	Smoker		Non-smoker		P value
	N	%	N	%	
Group A	8	47.1%	9	52.9%	0.83
Group B	9	52.9%	8	47.1%	

Mode trauma:

12 patients both groups had low energy trauma while 22 patients had high energy trauma, difference didn't reach statistical significance (**P value = 0.54**).

Table (4) mode of trauma among study groups.

	Low energy		High energy		P value
	N	%	N	%	
Group A	7	41.2%	10	58.8%	0.54
Group B	5	29.4%	12	70.6%	

Operative time minutes:

There is Statistically significant difference regarding operative time between both groups favor group B (P value 0.017).

Table (5) comparison of operative time between study groups.

	Mean ± SD	P value
Group A	95.36 ± 16.3	
Group B	107.5 ± 12.6	0.017

Intraoperative blood loss cc:

There is statistically significant difference regarding intraoperative blood loss between both groups (P value 0.003).

Table (6) intraoperative blood loss between study groups.

	Mean ± SD	P value
Group A	258.1 ± 147.23	
Group B	424.3 ± 177.41	0.003

Postoperative hospital stay days:

Group A had a mean hospital stay was 2.5 days. While group B showed a mean hospital stay was 2.81 days. No statistically significant difference regarding postoperative hospital stays between both groups (P value 0.42).

Table (7) postoperative hospital stays among the study groups.

	Mean ± SD	P value
Group A	2.58 ± 1	
Group B	2.91 ± 1.01	0.42

Time union weeks:

Mean time till union group A was 11.7 weeks while group B was 18.5 weeks. There is statistically significant difference time union, shorter nail.There is statistically significant difference regarding time union between both groups (P value 0.001).

Table (8) time to union in weeks among the study groups.

	Mean ± SD	Range	P value
Group A (Range 9 12 weeks)	11.7 ± 2.1	9-12	0.001
Group B (Range 9 20 weeks)	18.5 ± 3.7	9-20	

Lower extremity function

Measured by Lower Extremity Function Scale (LEFS).

In group A; there was 9 cases had No difficulty, 4 cases had Little bit difficulty, 2 cases had Moderate difficulty, 1 cases had Quite bit difficulty 1 case had Extreme difficulty or unable perform activity, while in group B there is 7 cases had No difficulty, 5 cases had Little bit difficulty, 2 cases had Moderate difficulty, 2 cases had Quite bit difficulty 1 case had Extreme difficulty or unable perform activity. No statistically significant difference regarding Lower extremity function between both groups (P value 0.89).

Table (9) lower extremity function Measured by Lower Extremity Function Scale among study groups.

	Group A	Group B	P value
Extreme difficulty or unable perform activity	1 (5.9%)	1 (5.9%)	0.89
Quite bit difficulty	1 (5.9%)	2 (11.8%)	
Moderate difficulty	2 (11.8%)	2 (11.8%)	
Little bit difficulty	4 (23.5%)	5 (29.4%)	
No difficulty	9 (52.9%)	7 (41.2%)	

Knee range motion:

In group A; there was 15 cases more than 100 ^{o} knee flexion, 1 case 90^{o}-100^{o} flexion, while group B; there was 14 cases more than 100 ^{o} knee flexion, 1 case 90^{o}-100^{o} flexion 1 case 70^{o}-89^{o} flexion. There was no extension deficit any cases both groups. There is No statistically significant difference regarding knee range motion between both groups

Table (10) Range of motion among the included patients.

Knee Range Motion		Group A	Group B	P-value
Flexion	More than 100^{o}	16	15	**0.89**
	90^{o}-100^{o}	1	1	
	70^{o}-89^{o}	0	1	
	Lessthan70^{o}	0	0	
Extension deficit	Less than 5^{o}	17	17	**1.0**
	5^{o} -10^{o}	0	0	
	11^{o} -20^{o}	0	0	
	More than 20^{o}	0	0	

Local complications:

Infection:

One case in group B was complicated by superficial infection early postoperative period and was managed by debridement antibiotics according culture sensitivity leading complete resolution infection.

Knee stiffness:

Group A had only one case (5.9%) suffered from mild knee stiffness was managed by physiotherapy. While 2 cases were present in group B who were managed by physiotherapy.

Delayed union:

Group A showed only one case with delayed union managed by dynamization at the 14th week fracture went union after 8 weeks dynamization. While one case reported on union was reported in group B. no cases developed malunion.

Knee pain:

- In group A: one case suffered pain the medial aspect of the knee due to locking screw protrusion on the medial aspect of medial condyle, case was managed by screw removal after healing process established (4th month post-operative)
- In group B: one case complained of anterior knee pain with clicking sound with flexion and extension of the knee. Examination of the patient revealed tight lateral retinaculum and X-ray showed no patellar tilt, then underwent physiotherapy injection local anesthetic and pain improved after 2 months physiotherapy.
- No statistically significant difference regarding complications between both groups with p value 0.64.

4.Case presentation

A male patient 20 years old had closed left femoral fracture type A1 after RTA.On admission, clinical examination was done plain x rays. he was prepared for surgery next day admission fracture was fixed by retrograde nail.

Follow up showed Delayed union occurred was manifested clinically by pain at site fracture radiologically by no appearance callus at till 3rd month was most probably due heavy smoking.Dynamization was done by removal proximal static screw union occurred 2 months after dynamization, Knee range motion was 0 ° 110 °, LEFS was 47(58.75% = moderate difficulty), was improved after union 69 (86.25% = no difficulty).

Table (11) incidence of complications among study groups.

	Group A	Group B	P Value
Infection	0 (0%)	1(5.9%)	
knee stiffness	1(5.9%)	2 (11.8%)	0.64
Non-union	0 (0%)	1(5.9%)	
knee pain	1(5.9%)	1(5.9%)	
Delayed union	1 (5.9%)	0 (0%)	

Fig.(3) lateral view x-ray postoperative.

Fig. (4) Lateral view X-ray showing fracture distal femur

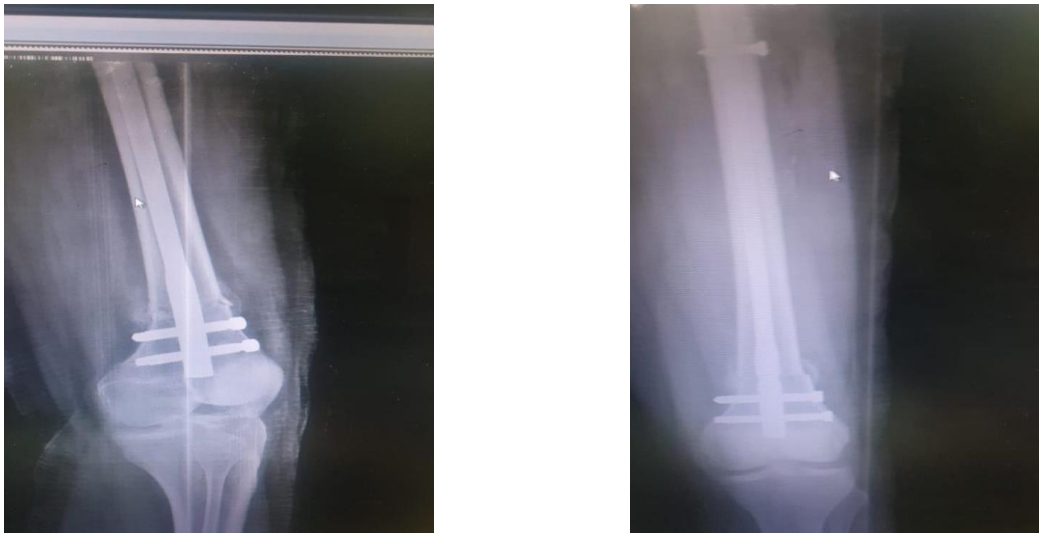

Fig. (5) AP x-ray showing distal femur after 3 months postoperatively.

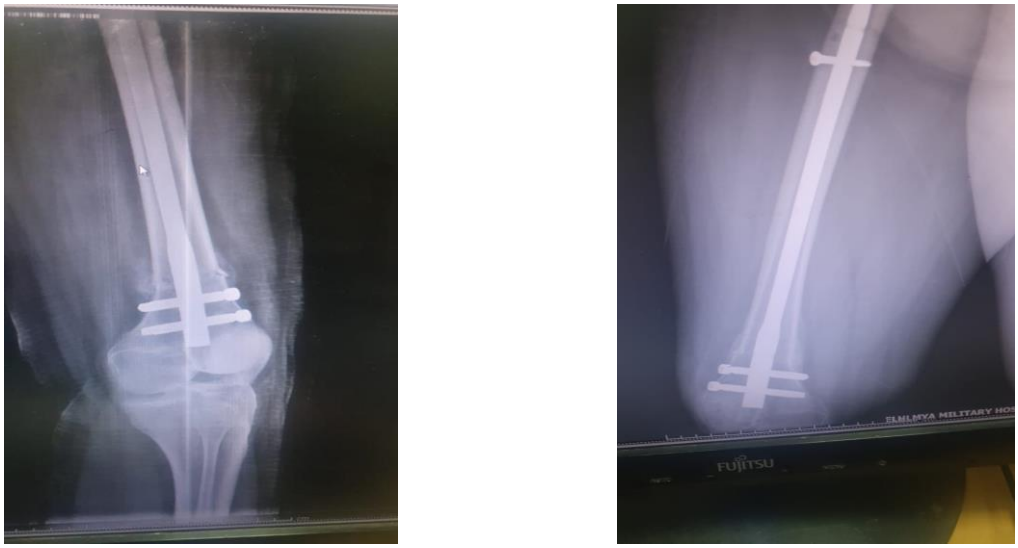

Fig. (6) AP x-ray showing distal femur after 6 months postoperatively.

Table (12) Demographic data and basic analysis.

	Our study	Hierholzer et al [10]	Henderson et al [9]	Gao et al [7]	Markmiller et al [8]
Total Number of cases	32	115	24	36	32
Mean Age	35.37 years in RN group 37.12 in LP group	54 years for both groups	63 years in RN group 65 in LP group	50.6 years in RN group 54.7 in LP group	43.7 years in RN group 57.2 in LP group
Gender	It was matched between both groups in all studies				
Mode of trauma **High energy**	65% of cases	57% of cases	Non-significant	69 % of cases	62.5% of cases
Low energy	35% of cases	43 % of cases		31 % of cases	37.5% of cases
Medical conditions and smoking	It was matched between both groups in all studies				

Retrograde Nails took 95.36+-16.3 minutes to perform, while LPs took 107.5+ 12.6 minutes. This difference is statistically significant (p value = 0.017).

5. Discussion

In our research, the age, gender distribution, kind of trauma, concomitant conditions, and amount of smoking were all same across the two groups.

According to previous investigations, these findings were in line with those of the other studies.

Due to its smaller sample size, our research found a larger number of high-energy traumas than the previous studies.

Gao et al. [7] found no statistically significant difference in mean operating time between the two groups (p = 0.106), with a mean duration of 87.4 minutes for the Retrograde Nail group and a mean time of 79.7 minutes for LP.

A statistically significant difference was seen between the Retrograde Nail group (142 minutes) and the LP group (155 minutes).

Due to open reduction rather than closed reduction employed in most instances of Gao and Markmiller's studies (17 out of 19 plate cases were treated by LISS approach, and all of them) in our investigation, the operational duration for the LPS group was much longer than in those studies.

Retrograde Nail group lost 258.1+ 147.23 cc of intraoperative blood, whereas the LP group lost 424.3 cc. This was a statistically significant difference (p value=0.003) in intraoperative blood loss.

Retrograde Nail group lost 298 cc of blood compared to 200cc of blood in the LP group, which is a substantial difference in intraoperative blood loss.

RN group blood loss was equivalent to previous research in our study. However, in our investigation, the use of open reduction approach resulted in a greater proportional increase in blood loss in the LP group.

The postoperative hospital stay in our research did not vary significantly between the two groups (p value=0.39). The average length of stay in the RN group was 2.58 days, whereas in the LP group it was 2.91 days.

We considered this to be a critical metric for assessing the impact of surgery on the patient's overall health, but no other research have addressed the issue of post-operative hospitalisation.

It took the Retrogade Nail group an average of 11.7+ 2.1 weeks to unite, compared to an average of 18.5+ 3.7 weeks for the LP group in our research (p value = 0.001).

A substantial difference in the median time to union between groups using Retrogade Nail and LP was found by Markmiller et al. [8].

There was no statistically significant difference in the time to union between the RN and the LP groups, according to Gao et al. [7].

Henderson and colleagues [9]; When a fracture is secured using locking plates rather than nails, the periosteal callus is much less prominent.

Hierholzer et al. [10] found no significant differences in the time it took for the groups to unite.

While the open reduction and periosteal stripping in LP instances, as well as Henderson et al's findings suggest, contributed to a shorter union time in the RN group, the reason for this finding is unclear. The shorter union time in the RN group was also seen in Henderson et al.

Because of the LISS approach used in these previous investigations, the plate group had similar union times to the RN group.

However, our research found that the RN group had higher LEFS score values, however this difference was not statistically significant (p value=0.89) between the two groups.

No statistically significant change in HSS scores (p = 0.406) was found by Gao et al.

Based on statistical analysis, there were no significant variations in the KOOS scores for daily living function or sports and leisure function between groups, according to Hierholzer et al.

Lysholm–Gillquist score was employed by Markmiller et al [8] to evaluate lower extremity function, however there was no statistically significant difference between the two groups.

It's clear from our study's findings and those of other researchers that fixation methods (RN or LP) and techniques (open or closed) are equally effective when carried out correctly.

A improved knee range of motion was seen in the Retrograde Nail group, however it was not statistically significant (p value=0.89). – The research

No significant difference (P=0.346) was found in the range of motion between the two groups (Gao et al (7)).

Results from our research and those of Gao et al (7) were comparable, with the RN group having superior outcomes, but it was not statistically significant. This may be because to the open reduction method used in the LP group, which opened the knee capsule.

There was no statistically significant difference in the complication rate between the two techniques in most research, including ours. However, the healing disturbance was the most obvious in ours (albeit not significant) and in Gao et al [7].

Table (13) comparison of data regarding postoperative complictions

	Our study	**Gao et al [7]**	**Hierholzer et al [10]**
Postoperative complications	Non- significant between both groups	Non- significant between both groups	Non- significant between both groups

6. Conclusion

Based on this study; accepted outcome had been achieved with both methods compared with results of previous studies. However in our series nail showed more favorable outcome, less surgical morbidities and better rehabilitation as evident. However, both systems require precise preoperative planning and advanced surgical experience to reduce the risk of post-operative complications. Clinical outcome may largely depend on surgical technique rather than on the choice of implant.

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