Safety and Efficacy of Latitud™ Hip Replacement in Total Hip Arthroplasty: An Observational Study in Kazakhstan Running title: Safety and Efficacy of Latitud ™ Hip Replacement

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Running title: Safety and Efficacy of Latitud™ Hip Replacement

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Abstract:

Introduction: Total hip replacement (THR) is one of the most successful surgical procedures globally for managing end-stage hip osteoarthritis. Latitud™ hip replacement system is at the forefront of restoring mobility and improving patient outcomes. This study aimed to evaluate the safety and effectiveness of the Latitud™ hip replacement in total hip arthroplasty.

Methods: In this retrospective, single-centre, post-market, observational study, 150 patients who underwent total hip replacement and were treated in our hospital from 2018- 2020 were included. The primary outcome was the THR-related intra and postoperative complications and revision rate at 1-year follow-up. Secondary outcomes were other patient-reported outcomes, radiographic analysis, Harris hip score, adverse events, implant dislocation, and survivorship rate.

Results: The mean age of the patients was 53.90 ± 11.44 years. The surgical procedures were successful without any major complications. There was a significant ($p < 0.001$) improvement in the Harris hip score. No death was observed throughout the study. There was 1 (0.67%) intra-operative fracture, with the patient having a closed comminuted fracture of the upper and middle third of the left femur and anemia. Seven patients (4.67%) patients required postoperative blood transfusions. During the follow-up period, there was no revision surgery or implant dislocation.

Conclusion: This observational study suggests that the Latitud™ hip replacement system was favorable safety and effective in a real-world setting in Kazakhstan. The study showed promising results in pain alleviation, functional improvement, and implant survivorship.

Keywords:

Harris hip score, range of motion, surgery, total hip replacement

1. **Introduction**:

Hip fracture is a widespread and serious medical condition associated with impaired mobility, inhibited autonomy, increased morbidity, and mortality. The majority of hip fractures occur at either of the two locations, namely, intracapsular or extracapsular. Femoral neck fractures belong to the former category, whereas intertrochanteric and subtrochanteric fractures are extracapsular (1). Total hip replacement (THR) is an endoprosthetic joint replacement technique that has proved to be a highly effective intervention to mitigate pain and restore or improve mobility in patients with osteoarthritis or rheumatoid arthritis (2, 3). THR is also regarded as an effective and successful end-stage surgical procedure that can even reinstate athletic performances again, as supported by the evidence from surgeon-based outcome reports and gait analysis (4). However, it has emerged, through the use of patient-reported outcome measures, that there is a sizeable number of patients who continue to report pain and functional disability after THR (5). It is critical to identify possible causes, such as pre-operative pain sensitization, that contribute to the failure to benefit ratio from THR so that these factors can then be addressed with appropriate pre-operative intervention.

Hip prostheses are medical devices that function instead of a damaged hip joint. The hip anatomy is formed by a convex head of the proximal femur inserted into a concave acetabulum within the pelvis, fendered by articular cartilage within a synovial joint capsule, and it experiences substantial contact strains when loaded, which are activity-dependent. Studies have found that when individuals perform various activities, the highest hip contact force, reaching around 260% of their body weight, is experienced while descending stairs (6). On the other hand, the greatest torsional moment while wearing a prosthesis was recorded during unassisted gait and while ascending stairs (7). These

contact forces, in parallel with a predisposition to osteoarthritis, may cause serious arthritic pain as well.

Charnley's low-friction arthroplasty system of the 1960s survives today as a metal femoral stem component (cemented or uncemented), with stem and ball articulating against an acetabular component (cup), with a liner and a metal shell forged by crosslinked polyethylene (8). The prosthesis system can also have a locking ring, a bipolar ring, a prosthetic head, and a femoral stem. The Ti or Co-Cr alloy femoral stem may be cemented or press-fit into the targeted place. The Ti or Co-Cr alloy acetabular component may also be cemented or press-fitted into desired site, with optional screws to achieve initial stabilization. Efficacy of a hip prosthesis is predominantly affected by dislocation, resulting in component loosening, aseption, and debris wearing. Wear is a multifactorial event caused by prosthetic, patient, and surgical factors. Metal-on-metal bearings, which are relatively harder, have been linked to various adverse effects, including cytotoxicity, osteolysis, pseudotumor, Metallosis, and aseptic loosening. In contrast, ceramic-on-ceramic bearing surfaces, made of either alumina or zirconia, have a reduced risk of brittle fracture; however, they may produce squeaking sounds. Femoral component fatigue with or without torsion, femoral component corrosion, and wear characteristics are critical features to consider when evaluating hip prostheses.

In this study, we aimed to evaluate the safety and performance of the Latitud™ Hip Replacement System (Meril Healthcare Pvt. Ltd., Gujarat, India) used for THR.

2. **Materials and methods**:

2.1. Study design

In this retrospective, single-centre, post-market, observational study, 150 patients treated with the Latitud™ Hip Replacement System for total hip replacement between July 2018 and August 2020 at the National Scientific Center of Traumatology and Orthopedics in Kazakhstan were included. Any person suffering from marked osteoporosis, poor bone stock, and/or metabolic disorder leading to systemic degeneration of bone were excluded from the cohort. The study was performed to evaluate the safety and performance of the Latitud™ Hip Replacement System in a real-world scenario.

As this is a retrospective analysis without any alteration in patient management, a waiver for written informed consent was obtained from the concerned Ethics Committee. The study followed all pertinent ethical standards, including ICH-Good Clinical Practice (GCP) ISO 14155:2020 and the Declaration of Helsinki (9).

2.2. Data collection and patient demographics:

Patient identities were anonymized, and data were collected as per applicable regulatory requirements. Baseline characteristics, demographics, procedural details, discharge summary, and primary and secondary outcomes data were obtained from the patients' medical records and documented using case report forms. The collected data included all the reported adverse or serious adverse events that took place either intra- or postoperatively. Also, any substance addiction was also recorded, if any.

2.3. Components of the Latitud™ Hip Replacement System:

The Latitud™ hip prosthesis system comprises an acetabular cup, outer polyethylene acetabular liner, locking ring, bipolar ring, prosthetic head, and femoral stem (cemented or uncemented) (Fig. 1).

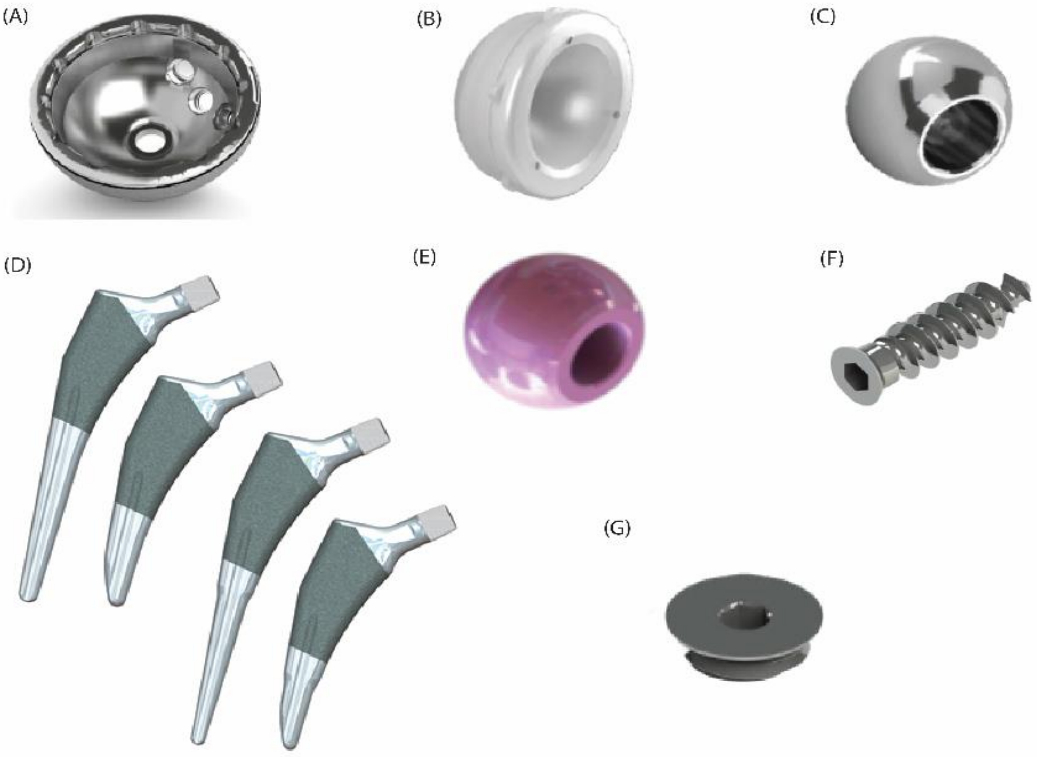

Figure 1- The components of Latitud™ Hip Replacement System: The prosthesis system is developed by the Meril Healthcare Pvt. Ltd., Gujarat, India. It consists of the following components: (A) Modular Shell (Viz. Acetabular cup); (B) Modular Liner (Viz. Acetabular Liner); (C & E) Modular Femoral Head; (D) Uncemented/ Cemented Femoral Stem; (F) Bone screw; (G) Apical hole occluder. The femoral stems are further classified into four types, namely, standard proximally coated stem (SPCS); standard proximally coated short stem (SPCSS), distally reduced proximally coated stem (DRPCS), and distally reduced proximally coated short stem (DRPCSS). SPCSS and DRPCSS are used for minimally invasive microplasty and SPCS AND DRPCS are designed to be used for full-length THR. All the femoral stems are available in two different variants of the neck, i) Standard variant with 128˚ and 132˚ offset angles and ii) lateral variant with high offset angle (132˚).

The acetabular cup or modular shell is made from the titanium alloy ELI (Ti_6Al_4V-Extra Low Interstitials) (ASTM F136) and is intended for cementless fixation within the prepared acetabulum. The outer surface of the modular shell is coated with commercially pure titanium to enhance fixation. The acetabular liner or modular liner

is made from highly crosslinked polyethylene (HXLPE) (ASTM F648). The modular femoral head is made from cobalt-chromium alloy (ASTM F 1537-1).

Femoral stems are available in two variants: uncemented femoral stem and cemented femoral stem. The uncemented variant is made from the titanium alloy ELI (ASTM F136) and coated with hydroxyapatite below the resection line to enhance proximal and distal stem fixation. The 12/14 taper of the Uncemented Femoral Stem is designed to mate with the modular femoral head. This variant is indicated for use without bone cement. The cemented variant is made from high-nitrogen stainless steel (ISO 5832-9:2019) and is designed to be fixed with bone cement. The 12/14 taper of the cemented femoral stem is designed to mate with the modular femoral head. The bipolar monoblock shell size ranges from 37 mm to 63 mm, while the modular femoral head size is either 22 mm or 28 mm (Table. 1).

Table 1: Size specifications of the bipolar monoblock and modular femoral head components of Latitud™

Bipolar monoblock Shell Size (mm)	Modular femoral Head Size (mm)
37	22
38	22
39	22
40	22
41	22
42	22
43	22
44	28
45	28
46	28
47	28
48	28
49	28
50	28
51	28
53	28
55	28
57	28

59	28
61	28
63	28

2.4. Surgical procedure:

The surgical team performed the procedure through the "Transgluteal" approach, the second most common technique after the "posterior" approach (10). It is formally known as the Direct Lateral Approach (DLA), which was modernized by Hardinge in 1982 (11). In this approach, the patient was positioned either in the supine or lateral decubitus formation, which was mentioned in the order of preference by the lead surgeon. While performing intraoperative imaging, the patient was positioned on a standard OR or radiolucent table. A bump was placed under the pelvis at the anterior superior iliac spine (ASIS) position to create space for femoral displacement during acetabular exposure, and a roller bar was placed under the ipsilateral calf to stabilize the leg.

The incision had started proximal to the anterior-middle third of the greater trochanter (GT) and extended distally in line with the femur. The fascia lata and iliotibial band (ITB) were incised, and the gluteus medius was split at the junction of the anterior-middle thirds using blunt dissection. The anterior structures were elevated subperiosteally, and the femoral neck osteotomy was performed after dislocating the hip.

Acetabular exposure was achieved using three retractors, and routine acetabular preparation was carried out. For femoral preparation, the leg was placed in a figure-four position, and the proximal femur was lateralized using retractors to visualize the femoral shaft direction and version. After component placement, the anterior flap was

repaired, and the fascia lata, ITB, and gluteus maximus were closed, followed by subcutaneous tissues and skin closure.

2.5. Excepted outcomes:

We divided the expected outcomes of the study into primary and secondary outcomes. The primary outcome was a composite of intra-operative complications, postoperative complications, and revision rates. Intra-operative complications included events like fractures and neurovascular injuries during the surgery. The postoperative complications encompassed incidents like aseptic loosening, infection, and pain. The revision rate indicated the percentage of participants needing component removal or replacement. Additionally, in the secondary outcomes, the implant dislocation, survivorship, radiographic analysis, Harris Hip Score, mobility assessment, length of hospital stay, and adverse events were evaluated. Collectively, these outcomes would inform the safety and success of the hip replacement procedure.

2.6. Clinical follow-up & assessment:

At the time of reporting, the patients had at least 1.5 to 2 years of follow-up. After THR, patients typically undergo routine follow-up assessments, including X-ray imaging and clinical examinations. During these clinical examinations, the active range of motion (AROM) of the hip joint was evaluated (12, 13). The AROM was calculated using a goniometer at the baseline and after the procedure to determine the alteration in the movement of the acetabular joint. We carried out the neutral-zero method in three different planes of movement, i.e., flexion/extension, abduction/adduction, and supine internal/external rotation. Maximum ROM was measured by the point of soft tissue

resistance. It is based on three hip-specific parameters, e.g., abduction/adduction, internal/external rotation, and flexion/extension (14).

For the measurement of abduction/adduction angle, the patients were rested in the supine position, and the arms of the goniometer were aligned in the anterior/posterior axis (x-axis) alongside the anterior midlines of the pelvis and femur. The patient was requested to abduct and adduct the hip as per their abilities actively, and goniometric angles were recorded for both movements. In order to determine the rotational angles in the superior/inferior axis (y-axis), the patients were positioned in a sitting or prone (face down while lying) posture with hip and knee flexed at a 90˚ angle. The goniometric measurements were taken to ensure the maximum possible internal and external rotations. Patients were placed in a supine position while lying on their back to assess the flexion/extension angle on the medial/lateral axis (z-axis). The goniometer arms were aligned with the lateral midlines of the pelvis and of the femur, and the angles were recorded upon maximum flexing and extending.

A visual assessment of the patient's gait pattern is also performed as part of each clinical examination. The gait pattern provides insights into the function of the hip joint under normal loading conditions.

The Harris Hip Score (HHS) was used to evaluate the functional outcomes of the patients before and after the implantation. On a scale of 0 to 100 points, the HHS can evaluate pain, daily living abilities, and hip function by assessing the range of motion (ROM) (15-17). It is based on the following four vertices of measurements:

i. Pain: The HHS evaluates pain severity and its impact on activities. The Harris Hip Pain Scale, or Harris Pain Scale, is considered a part of HHS and not separately. This domain contributes 44 points to the total score. The scoring

pattern is as follows: 0 points indicate disabling pain, 10 points refer to marked pain, 20 points are given for moderate pain, 30 points identify mild pain, patients with slight and/or occasional pain are given 40 points, and no pain corresponds to 44 points.

ii. Function: It assesses daily activities such as walking, stair use, public transportation, and sitting. Function contributes 47 points, with 14 points allocated to activities of daily living and 33 points to gait.

In terms of climbing stairs, 4 points are given for the activity without the support of a walking stick or railing, followed by 2 points given for the same activity with the aid of a railing or cane. For those who need another person's support for the same task, 1 point is given, and the inability to do the task by any means results in a 0 score.

Sitting activity earns points between 0 and 5 for either comfortably seated in an ordinary chair for 1 hour (5), sitting on a high chair for 30 min (3), or being unable to sit comfortably in any chair (0).

The transportation sub-domain is scored from 0 to 2 points. While the complete inability to board any public transport confers 0 points, boarding with moderate or no difficulty earns 1 and 2 points, respectively.

The walking ability assessment is sub-categorized into the walking distance and walking aids. In the case of walking distance, 0, 2, 5, 8, and 11 points are given for inability to walk, indoor walking, walking for two to three blocks, walking for six blocks, and walking for more than six blocks, respectively. One block is considered equivalent to 100 yards.

iii. Range of Motion: It takes into account all the ROM-related angles of movements, for instance, flexion, extension, abduction, adduction, internal

rotation, and external rotation. ROM contributes a maximum of 5 points towards HHS. The scoring for each of the parameters is as follows: 0 point (0° to 30°), 1 point (31° to 60°), 2 points (61° to 100°), 3 points (101° to 160°), 4 points (161° to 210°), and 5 points (211° to 300°).

iv. Deformity: This aspect evaluates hip flexion, adduction, internal rotation, and extremity length discrepancies. Deformity has a maximum score of 4 points. Wearing socks/shoes falls under the deformity criterion. Fixed flexion deformities of ≤30˚ and ≥30˚ are scored 1 and 2, respectively. Similarly, fixed adduction deformities of ≤10˚ and ≥10˚ are given 3 and 4 points, respectively. The absence of any deformity earns no points.

Patients were also assessed for any potential adverse events related to the THR procedure.

2.7. Statistical analysis:

All statistical analyses were performed using GraphPad Prism 8.0.2 (GraphPad Software Inc., Ca, USA). Measurement data are shown as the mean and standard deviation. Measured data were analyzed using the student's t-test in a grouped analysis between the paired samples. Venny 2.1 was used to build the Venn diagram (18). A p-value of <0.05 was considered statistically significant for all analyses.

3. **Results**:

3.1. Clinical and demographic parameters of the patients:

We included 150 patients of different ethnicities and age groups in our study cohort (Table. 2). The patients had several orthopedic-related and unrelated prevalent complications as found by their medical history and physical examinations. There were

seventy-four male and seventy-six female patients of different races. Both female and male patients were found to have higher BMI values. Eleven patients (7.33%) had alcoholism, and nine patients (6%) were tobacco smokers at the time of admission. Eleven patients had less than 10˚ fixed internal rotation, and less than 30˚ fixed flexion contracture was observed in twelve patients. Internal rotation in extension was also restricted to 10˚ in twelve patients. An abduction angle of less than 10˚ was recorded in eight patients. Lumber or lumbosacral osteochondrosis, sciatica, dysplastic coxarthrosis, post-traumatic aseptic necrosis, ankylosing spondylitis, and rheumatoid polyarthritis are some of the causative co-morbidities leading to the acetabular (ball-socket) joint degeneration, requiring the surgical replacement. Most patients (n = 90) had right-side hip replacement, followed by left-side hip replacement in fifty-two patients. Only eight patients had both hip joints replaced.

Table 2: The demographic and clinical details of the patients from the Latitud™ THR prosthesis study cohort

Patient variables	Specifications (n=150)
Gender	Male = 74 Female = 76
Age	Male: 52.6 ± 11.0 Female: 55.2 ± 11.8
Ethnicity	Kazakh: 83 Russian: 66 Ukrainian: 1
Race	Asian: 82 European: 68
BMI	Male: 26.49 ± 4.15 Female: 27.31 ± 5.09
Affected hip joint (Acetabulam)	Right: 90 Left: 52 Both: 8

Medical History	Telangiectasia of the lower extremities (2) Cardiac Ischemia (1) Angina Pectoris (5) Gastritis (6) Diabetes Mellitus Type 2 (5) Ventral Hernia (1) Right-Sided Direct Inguinal Hernia (1) Acute Respiratory Disease (1) Acute Sinusitis (1) Anemia (2) Ankylosing Spondylitis (axial form) (1) Spinal Osteochondrosis (3) Sciatica (left) (1) Hereditary Sensory Neuropathy (2) Rheumatoid Polyarthritis (1) Bechterew's Disease (2) Longitudinal intervertebral ligament Ossification (1) Bone Ankylosis (2) Atherosclerotic Cardiosclerosis (1) Normosystolic Constant Form (1) Obesity (14) Chronic viral Hepatitis C (1) Hypothyroidism (6) Allergic reaction (3) Chronic Catarrhal Gastroduodenitis (1) Gastritis (6) Congestive Heart Failure (3) Cholelithiasis (2) Chronic Pyelonephritis (1) Chronic Cholecystitis (3) Chronic Pancreatitis (2) GERD (1) IHD (3) Arterial Hypertension (35)
Substance dependency	Alcoholism (11) Tobacco smoking (9)

3.2. Procedural outcomes of the THR:

One hundred and fifty patients (100%) survived the surgical procedure and the postoperative period until the last follow-up (approximately 2 years). The mean duration of surgery was 56.5 ± 14.2 min (range: 40-85 min). The total length of hospital stay ranged from 8 to 24 days, with a mean of 12.2 ± 2.4. No patients suffered from a

neurovascular injury during the implantation of the Latitud™ System or any other serious adverse events, like death. No technical difficulties were reported during the implantation of the system. In terms of postoperative complications, patients suffered from minor side effects related to the THR procedure. Pain was the most common procedure-related complication in all patients that eventually subsided, followed by bleeding in seven patients (5%) (Fig. 2. A). Although seven patients required a postoperative blood transfusion, only one patient was reported as severely anemic related to the arthroplasty procedure, and the same Subject (0.7%) had suffered from a fracture, requiring additional surgical repair procedures. The sole event of an intraoperative fracture was specifically a periprosthetic fissure of the upper and middle third of the left femur due to impaired bone mineral density (osteoporosis). Eventually, bone fusion happened in the same patient (Fig. 2. A-B).

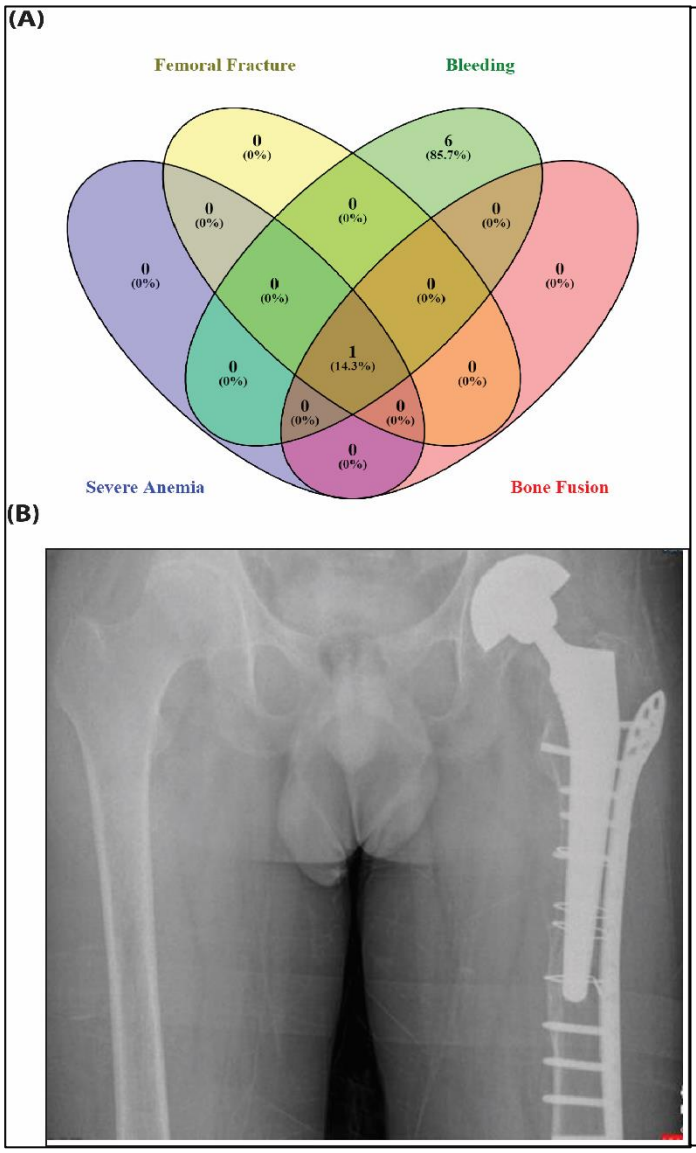

Figure 2. (A) The Venn diagram encompassed all the intra and postoperative adverse events and complications. The peri-operative complications were not very serious in nature and were mainly pain (n=150) and bleeding (n=7). Femoral fracture happened intra-operatively in one patient and it had a bone fusion at the site of fracture later. **(B)** The radiograph image of a patient showed femoral fracture and a hip fracture osteosynthesis with a plate and 4 wire cerclages. The patient had chronic osteoporosis and also suffered from severe bleeding postoperatively.

This complication was addressed by providing additional extraosseous mobilization with a locking plate and cerclage. As there were no postoperative complications, no additional treatments or actions were required.

3.3. Postoperative modulations of hip joint-related symptoms:

At the time of discharge, the majority of the patients did not have any additional health concerns and rather had the earlier symptoms improved. Pre-operatively, patients had varying degrees of limp, with scores ranging from 0 to 11 (5.92 ± 1.76). More than a third of the patients (35%) had no or slight limp, with scores of 8 or 11. However, post-replacement, all of them regained their walking ability without any limp, having scores

of 8 or 11 (10.13 ± 1.41). The patients required various external support tools, such as canes or walking sticks, with scores ranging from 3 to 11 (6.22 ± 1.28). Following the surgery, most patients (95%) required no support or only a cane for long walks, scoring 7 or 11 (9.74 ± 1.98). The patients had covered limited distances by walking before arthroplasty, with scores ranging from 2 to 11 (6.40 ± 1.74). Postoperatively, 72% of the patients (n=108) could walk six blocks or more without difficulty, with an 11 score, and 84% could walk at least two to three blocks, with scores of 5 or 8. Overall, the mean increase in score was 9.95 ± 1.76. Earlier, the patients had difficulty putting on socks and shoes, with poor scores ranging from 0 to 4 (1.88 ± 0.81). Post replacement, most patients (96%) could put on shoes and socks with relatively more ease, scoring from 2 to 4 (3.88 ± 0.47). Prior to the hip joint replacement, patients had varying degrees of difficulty sitting, with scores ranging from 0 to 4 (3.00 ± 0.66). Later, all patients could sit comfortably in a standard-height chair without squatting posture, with scores of 2 to 5 (4.24 ± 0.68). With regard to using public transportation, the patients did not show any significant difference in scores, with a slight decrease after replacement (1.33 ± 0.47) compared to pre-operative performance (1.62 ± 0.52). After the surgery, most patients (98%) could use public transportation by themselves with moderate or no significant difficulty, having scores of 1 or 2 (1.33 ± 0.47). The ascent of stairs was difficult for patients with degenerated hips, with scores ranging from 0 to 4 (1.92 ± 0.35). Postoperatively, most patients (94%) could climb stairs normally without support and scored 4 (3.87 ± 0.50).

Upon clinical presentation of the patients suffering from hip joint damage, twelve patients had less than 30˚ of fixed flexion contracture. Post-THR, all the patients showed regained ability of fixed flexion contractures of more than 30˚. Pre-operatively, fixed internal rotation in extension limited up to 10˚ in eleven patients. Similar to

flexion, all the individuals were able to extend the fixed internal rotation greater than 10˚ during follow-up. A fixed abduction angle of less than 10˚ was observed in eight patients before the surgery. Postoperatively, all the patients were in remission from this deformity (Fig. 3. A). Pre-operatively, three patients had a limb length discrepancy or anisomelia of less than 3.2 cm (1.5 inches). The replacement successfully addressed this anomaly.

Upon analyzing the ROM in 150 patients, we found that overall, it improved significantly from 0.37 ± 0.25 prior to THR to 0.49 ± 0.37 ($p<0.01$) during the follow-up. However, further detailed investigation showed that the ROM score increased in 64 patients but deteriorated in 48 cases. No difference was observed in 38 patients (Fig. 3. B).

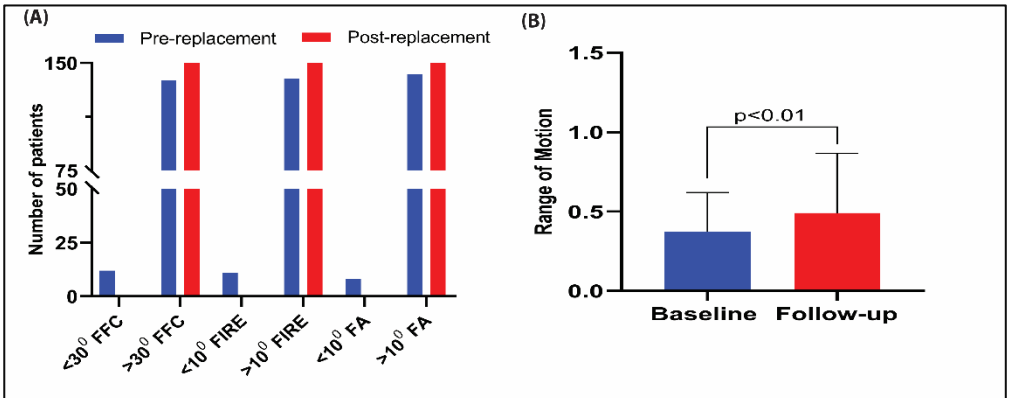

Figure 3. (A): Limitation of any particular range of motion is denoted as the fixed angle of movement. All measured fixed angles of movement, namely fixed flexion contracture (FFC), fixed internal rotation in extension (FIRE), and fixed abduction (FA) showed significant improvement post-THR. All the patients (n=150) were able to augment their range >30˚ for FFC and >10˚ for FIRE and FA. **(B)** We observed that there was a cumulative augmentation in ROM value by 1.31-fold ($p<0.01$) due to the successful implantation of Latitud™. However, it decreased in 48 cases by 2.78-fold, and increased in 64 cases by 2.92-fold. Both were found to be significant ($p<0.001$). Five patients did not have any observable change in ROM (0.3).

Pre-operatively, patients had limited flexion, with ranges from 70° to 110°. After replacing the acetabular joint, most of the patients (98%) achieved a better flexion range between 80° and 110°. At baseline, 8 patients had limited abduction, with ranges from 5˚-10˚, and 138 patients had their ranges recorded between 10° and 20°. Following the surgery, most patients (91%) had abduction ranges between 15° and 20°, and the rest were recorded as having a range between 10° and 15°, suggesting a remarkable improvement in abduction movement. Pre-operatively, patients had limited external rotation, wherein 48 and 98 patients had ranges of 5°-10° and 10°-15°, respectively. Postoperatively, 93% of patients showed external rotation between 10° and 15°, and the rest were found to have rotation between 5° and 10°. Patients with hip joint erosion had limited adduction ranges, such as 5° to 10° (21%) and 10° to 15° (79%). We found that

the majority of them (93%) had an adduction range between 10° and 15°, suggesting a betterment in the adduction range as observed before for other aspects of movement (Table 3).

Table 3: This is a comparison of alterations in different angles of movement, i.e., total flexion, total abduction, total external rotation, and total adduction, between pre- and post-hip replacement. All the parameters showed improvement with a better range of motion in each of the aspects.

Degree of movement	**Pre-replacement**				**Post-replacement**			
	Total Flexion (^{0}) (n=150)	**Total Abduction (^{0}) (n=146)**	**Total External Rotation (^{0}) (n=146)**	**Total Adduction (^{0}) (n=146)**	**Total Flexion (^{0}) (n=150)**	**Total Abduction (^{0}) (n=150)**	**Total External Rotation (^{0}) (n=150)**	**Total Adduction (^{0}) (n=150)**
5˚-10˚	—	8	48	31	—	—	11	11
10˚-15˚	—	74	98	115	—	13	139	139
15˚-20˚	—	64	—	—	—	137	—	—
70˚-75˚	2	—	—	—	—	—	—	—
75˚- 80˚	11	—	—	—	3	—	—	—
80˚-90˚	61	—	—	—	10	—	—	—
90˚-100˚	65	—	—	—	56	—	—	—
100˚-110˚	7	—	—	—	81	—	—	—

The pain score (HHPS) was higher after the replacement, 42.93 ± 1.77, compared to the baseline score of 11.45 ± 4.84 (n=150, $p<0.001$). This was indicative of less pain while performing mobility after the replacement procedure (Fig. 4. A). The mean pre-operative HHS was 42.3 ± 7.1 (range: 26-66), indicating poor hip function. At least a

year after the surgery, the mean postoperative HHS significantly improved to 91.1 ± 5.2 (range: 72-96) ($p<0.001$), highlighting superior functional outcomes (Fig. 4. B).

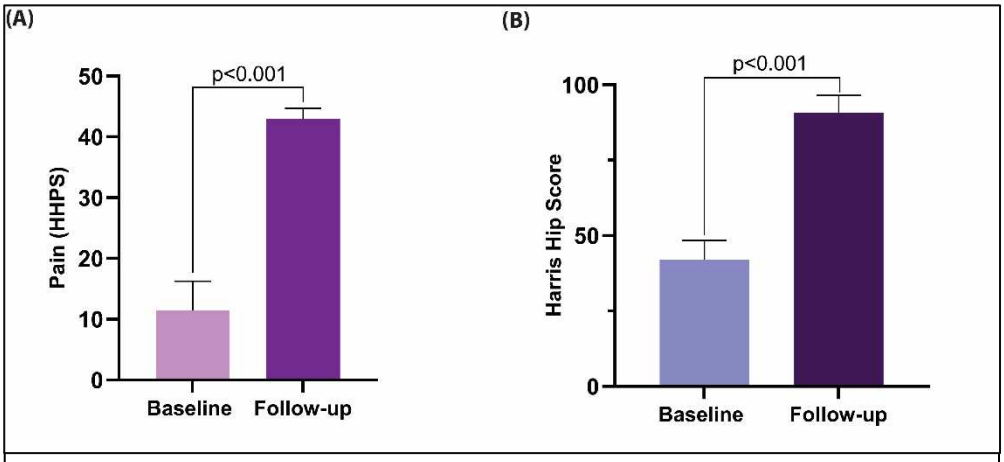

Figure 4. (A) The HHS-based pain score or HHPS is inversely proportional to the pain intensity while performing activities that involve hip joint mobility. The HHPS was enhanced by 3.75-fold at least 1 year after the implantation procedure ($p<0.01$). **(B)** Harris Hip Score assesses four domains, i.e., pain, function, range of motion, and absence of deformity. The HHS improved significantly by 2.2-fold post-THR ($p<0.001$). It was indicative of better functional range of the patients bearing the Latitud™ prosthesis.

4. **Discussions**:

With the ever-increasing burden of bone degeneration-associated diseases, total joint arthroplasty (TJA) is one of the most common orthopedic procedures (19). Two major types of TJA are total knee arthroplasty and total hip arthroplasty (THA) (20). THA or THR is on the rise, which is consonant with the fact that at least 10-15% of adults over 60 show some degree of OA (21). This study aimed to assess the safety and efficacy of the Latitud™ hip replacement system in THA performed on 150 patients from Kazakhstan over at least 1-year follow-up. A real-world study shows that the Latitud™ system is a promising option for THR, with promising pain relief, functional improvement, and implant survival results.

They underwent unilateral or bilateral total hip replacement and received a Latitud™ prosthesis through the DLA method, which provides good exposure to both the acetabulum and femur, allowing for better accuracy in component positioning and quicker restoration of hip biomechanics. Our cohort included patients with various conducive co-morbidities (e.g., rheumatoid polyarthritis, osteochondrosis, etc.) and risk factors (e.g., alcoholism and smoking) that can affect the overall health conditions of the individuals. Despite many potential hurdles, such as prevalent health conditions and the non-native study population compared to the origin of the device, the Latitud™ system showed favorable safety, with only one patient experiencing an intraoperative fracture due to pre-existing osteoporosis. The fracture was treated with a conservative approach, resulting in bone fusion. A few patients (5%) also developed postoperative bleeding, which was managed successfully with blood transfusion only. No incidence of neurovascular injuries was reported, and only one case of severe anemia requiring blood transfusion further supported the safety profile of the prosthesis. The device also improved the symptoms associated with degenerative hip joints, as established by the enhanced HHS index. Seeing these results in a real-world setting with a wide range of clinical challenges is encouraging.

A hip replacement is an operative intervention wherein the natural hip joint is surgically removed and substituted with an artificial prosthetic component to alleviate the pain associated with arthritis affecting the hip and address extensive structural damage to the hip joint. Once the compromised hip joint is replaced, it ensures mobility restoration and overall functional improvement for the individual. The patients who received the Latitud™ implant showed pain mitigation and a better range of movements. Virtually all the participants regained the ability to walk without a limp. Postoperatively, the majority of the patients started climbing stairs without support (94%), performed moderate-to-long (at least 200 yards) walks with little or no support (95%), and were able to wear shoes/socks

with relative ease (96%). As an exception, THR did not affect the ability to board public transport vehicles. All these factors significantly impact patients' quality of life, underscoring the superior performance of Latitud™ in uplifting patients' lifestyles. At the same time, the low incidence of adverse events indicated a greater safety profile. Only one case that experienced intra-operative fracture was already suffering from ankylosing spondylitis (grade 2) and osteoporosis. The patient also had moderate anemia and, probably as a result of that, suffered from a severe form of it. He also had hormone dependence and nephrogenic systemic fibrosis (NSF). However, we do not have any evidence to establish if hormone dependence and NSF have any etiologic effect on the peri-operative complications. HHS is a type of disease-specific health status scale used often to evaluate the total hip replacement outcome (22). In the world of evidence-based medicine, it holds significant value and, quite befittingly, has been in practice for more than 50 years (23). As a part of the HHS evaluation, the range of motion (ROM) analysis revealed significant improvements (n = 64) in flexion, extension, abduction, external/internal rotation, and adduction post-implantation. However, some patients (n = 48) showed a reduction in ROM, and the remaining cases (n = 38) were recorded to have no difference at all. However, an overall increase in HHS signified that the patients showed a significant cumulative functional improvement. Limb length discrepancy can be a potential complication post-THR since implant size can cause heterogeneity in the leg length (24). However, the length discrepancy was cured in three patients using the Latitud™ system. The limitation in the fixed angle movements was also reversed across all the patients after the procedure. The mean duration of surgery and total length of hospital stay were comparable to those reported in other studies, suggesting that the Latitud™ system can be implanted efficiently without prolonging the surgical time or hospital stay (25, 26).

A retrospective Global Burden of Disease (GBD) study on Kazakh people procured data on 56,895 patients afflicted by OA from the Unified National Electronic Health System of Kazakhstan. It found that people are at risk of developing gonarthrosis, with women having three times higher chances of developing the disease (27). Our study, therefore, has tested the Latitud™ system in one of the populations highly affected by degenerative bone disease. The limitations of the study were that it was a retrospective and single-center study. The comparison studies with other hip replacement systems would provide a more definitive understanding of the Latitud™ system's relative advantages and disadvantages. Instead, this mid-term follow-up study provides critical data that indicate a robust benefit potential in the long-term outcomes, such as implant survival rate and complication-free performance. Longer follow-up periods are needed to assess the long-term durability of the Latitud™ system. Inter alia, multicenter studies are necessary to confirm the generalizability of these findings to a broader patient population.

5. **Conclusion**:

Our study demonstrated that the Latitud™ hip replacement prosthesis system provides improved functional mobility to perform routine tasks while ensuring minimal or no occurrence of intra-/postoperative adverse events. Latitud™ system effectively reduced pain, improved walking ability, increased the range of motion, and corrected deformities in patients undergoing total hip replacement surgery. Hence, the Latitud™ system has shown promise as a safe and effective option for THA in this mid-term study after 1-2 years of follow-up.

List of Abbreviations:

THR Total hip replacement

RA rheumatoid arthritis

OA Osteoarthritis

ICH International council of harmonization

GCP Good clinical practice

SPCS Standard proximally coated stem

DRPCS Distally reduced proximally coated stem

DRPCSS Distally reduced proximally coated short stem

DLA Direct Lateral Approach

ASIS Anterior superior iliac spine

GT Greater trochanter

ITB Iliotibial band

AROM Active range of motion

HHS Harris Hip Score

GERD Gastroesophageal reflux disease

IHD Ischemic heart disease

HHPS Harris hip pain score

TJA Total joint arthroplasty

THA Total hip arthroplasty

6. Declarations

6.1. Ethics approval and consent to participate:

The study has been approved by the Ethics Committee for human subject participation (Vide. Commission Meetings on Ethics and Ethical Evaluation of Clinical Trials in RSE on REM, 12 May 2021. No. 07-02-05-08/0873U). All study-related results are permitted to be disseminated in an anonymized manner through peer-reviewed publications, conference presentations, and lay summaries.

6.2. Consent for publication:

Not Applicable.

6.3. Availability of data and materials:

Data sharing does not apply to this article as no datasets were generated or analyzed during the current study.

6.4. Competing interests:

K.S. is currently working with the company (Meril Life Sciences Pvt. Ltd.), which has sponsored this study.

6.5. Funding:

The expenses related to this study have been borne by Meril Life Sciences Pvt. Ltd. K.S., an employee of the sponsor company, was involved in the decision to publish the study findings.

6.6. Authors' contributions:

O.B. has conceptualized and designed the project. O.B., A.B., A.Bel. had performed the surgeries. T.B., D.O., A.Be., and K.P. had measured the parameters, collected data, and prepared the data collection sheet. K.S. had analyzed the data and written the manuscript.

6.7. Acknowledgements:

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