Journal of Orthopedics

Article

IMPACT OF CAPUT-COLLUM-DIAPHYSEAL ANGLE ON FEMORAL STEM POSITIONING IN SHORT-STEM HIP ARTHROPLASTY PERFORMED WITH AN ANTERIOR MINIMALLY INVASIVE SURGERY

P. Antinolfi, L. Giorgini*, G. Ancillai, L. Lucchetta, F. Manfreda and A. Caraffa

Orthopedic and Traumatology Clinic, S. Maria della Misericordia Hospital, Perugia, Italy

**Correspondence to*:
Lorenzo Giorgini, MD
Orthopedic and Traumatology Clinic,
S. Maria della Misericordia Hospital,
Via G. Dottori,
06100 Perugia, Italy
e-mail: lorenzo.giorgini23@gmail.com

ABSTRACT

This study examines how variations in the Caput-Collum-Diaphyseal (CCD) angle impact femoral stem alignment in total hip arthroplasty (THA) using short stems in the anterior minimally invasive surgery (AMIS). The objective of this study is to evaluate whether native CCD angles in the varus or the valgus influence the postoperative stem alignment, especially deviations greater than 3°, which may affect clinical outcomes. Patients who underwent THA between July 2021 and July 2023 with primary hip osteoarthritis or avascular necrosis were included. Exclusion criteria were postoperative complications, reoperations, or missing radiographs. Postoperative CCD and stem alignment were measured from radiographs, and statistical analyses were performed to compare these variables using t-tests and Pearson's correlation. Of the 46 hips, 24 were in Group A, and 22 in Group B. Group B showed a better ability to restore the CCD angle ($p < 0.05$). Both groups demonstrated a significant Pearson correlation between native CCD and postoperative stem alignment (Group A: r -0.60;$p < 0.001$ and Group B r: 0.486;$p < 0.05$). The average deviation in stem alignment remained within 3° for both groups. Patients with a varus CCD angle were more likely to have the stem positioned in the varus, while those with a valgus CCD angle showed a slight tendency toward valgus stem alignment. Surgeons should carefully consider preoperative CCD angles to minimize malpositioning during AMIS procedures.

KEYWORDS: *Caput-Collum-Diaphyseal angle, total hip arthroplasty, THA, anterior minimally invasive surgery, AMIS, stem alignment, CCD*

INTRODUCTION

The anterior minimally invasive surgery (AMIS) in hip surgery has gained increasing recognition for its ability to limit soft tissue injury and to improve short-term clinical outcomes. This technique offers significant advantages over traditional approaches, including reduced blood loss, shorter hospital stays, and faster postoperative recovery (1-3).

Proper stem placement is a crucial step and it is influenced by the position of the lower limb, by the higher cortical stress applied to the femur, and by the difficulty in releasing the structures that facilitate the broach insertion (4).

Received: 6 October 2024
Accepted: 23 November 2024

For this reason, instruments dedicated to the AMIS approach were developed, and the implants were optimized with shorter stems to facilitate their insertion and reduce the removal of bone stock during femoral broaching. However, the uncomfortable positioning and the short stem with the femoral neck or metaphyseal fixation can lead to an increased malpositioning in the varus or the valgus (5, 6). In this context, the native Caput-Collum-Diaphyseal (CCD) angle of the femur is a crucial measurement (7, 8).

The literature emphasizes that no significant clinical or biomechanical effects occur when the stem axis deviates by less than 3° from the femur's native axis (7, 9).

This study aims to analyze how variations in the CCD angle influence the alignment of the femoral stem relative to the femoral axis in the context of the AMIS and the use of short-stem prostheses. The primary objective is to assess whether, based on a femur with varus or valgus CCD, the stem placement deviates more than 3° compared to the anatomical femoral axis (10).

MATERIALS AND METHODS

A retrospective observational study was conducted on all the patients who underwent Total Hip Arthroplasty (THA) through the AMIS approach treated in the Orthopedic Clinic of Perugia from July 2021 to July 2023.

Preoperative pelvic X-rays (both hips, anterior-posterior view, standing erect) were screened to test for THA and to include patients who had a diagnosis of primary osteoarthritis (Kellergen-Lawrence > grade 3) or avascular necrosis of the head of the femur.

Exclusion criteria were patients with low-grade primary osteoarthritis (Kellergen-Lawrence < grade 3), periprosthetic fractures, or patients who developed postoperative complications (infection or aseptic loosening). From a cohort of 81 patients, 44 patients met the inclusion and exclusion criteria, comprising a total of 46 hips.

Surgical technique

All procedures were performed via the AMIS approach, using non-modular, uncemented short-stem prostheses implanted by a single experienced surgeon. The patient was positioned supine on a standard operating table without traction. The surgical site was prepared using a three-step antiseptic scrub with alcohol disinfectant, and sterile draping with an adhesive film was applied.

A 7- to 10-cm incision is made 2 cm latero-distally to the antero-superior iliac spine towards the fibular head; care was taken to isolate the lateral femoral cutaneous nerve (LFCN).

The interval between the sartorius muscle medially and the tensor fascia latae laterally is developed with attention to ligate the anterior circumflex artery to prevent excessive bleeding. The capsule is exposed between the rectus femoris muscle medially and the vastus intermedius muscle laterally. A capsulectomy was performed with identification and later reinsertion.

Trial components and instruments designed for the anterior approach were always used before the final implantation. Intra-operative fluoroscopy was used, but not routinely.

The perioperative and postoperative protocols were standardized across all cases. This included a single-dose antibiotic administration of Cefazoline (2 g IV) given preoperatively, along with weight-bearing as tolerated starting from the first postoperative day. A post-operative radiograph was performed after the weight-bearing on the operated leg was done.

Radiographic evaluations

Radiographic evaluation was performed using only postoperative anteroposterior (AP) pelvic radiographs, as validated by Lu et al. (11). Radiographs were taken with the patient lying flat on the radiography table, with the pelvis and legs in a neutral position. The tube-film distance was set at 110 cm to include both hips, centering the beam on the symphysis. Each radiographic measurement was taken by three of the authors (G.A, L.G, and F.M) in a randomized and blinded fashion. The radiographs were analyzed and measured through the PACS (Impax Enterprise; Agfa, Mortsel, Belgium) program.

To determine the CCD angle, according to Merle et al. (12), as the angle between the femoral neck axis and the femoral shaft axis on the AP radiograph, the hip center of rotation (COR) was defined using a circular instrument that determines the diameter of the femoral head and its center then the anatomical axis of the femoral shaft was determined by using two bisections of the femoral shaft at different locations (Fig. 1). These patients were then divided into two groups based on the native CCD angle from the radiograph of the hip; A normal CCD angle was considered between 120°

and 135° (12-17). The series was divided into Group A, with a varus tendency (CCD ≤ 127°), and Group B (CCD ≥ 128°), with a valgus tendency.

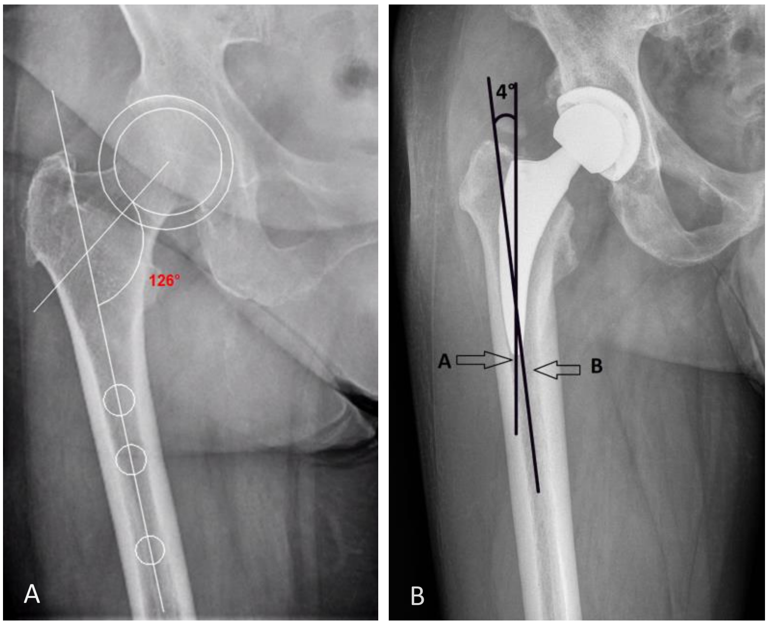


Fig. 1. ***A****): angle measurements of the CCD (caput-collum-diaphyseal);* ***B****): stem alignment angle* ***a****): stem axis;* ***b****): anatomical femoral axis.*

On postoperative radiographs, stem alignment was measured as the difference in degrees between the anatomical femoral shaft and the vertical axis of the stem. Negative values were considered for valgus stems.

Statistics

Statistical analysis was performed using SPSS (IBM Statistics). Native CCD and post-operative CCD were compared through a t-test analysis, and stem alignment was compared with a Pearson's analysis of the native CCD. A statistical confidence level of 95% was selected, and a p-value of < 0.05 was considered statistically significant.

RESULTS

After the radiological measurements, a total of 24 hips were assigned to Group A, and 22 to Group B. Results are shown in Table I.

Radiographic evaluations showed a greater ability to restore the CCD angle in Group B ($p < 0.05$). In comparison, Group A showed less ability to restore the same parameter while maintaining a significant correlation ($p < 0.001$).

Regarding the post-operative stem alignment, Pearson's r in Group A was -0.60 ($p < 0.001$), and in Group B was 0.486 ($p < 0.05$), also showing a significant correlation.

A native varus CCD angle resulted in an average varus stem implant, while a valgus-leaning CCD angle resulted in an average valgus stem implant (Group A: 1.5 in varus; Group B: 1.1 in valgus; $p < 0.001$). In neither group was an average deviation of more than 3° in varus or valgus measured.

Table I. *Results correlated with Native CCD.*

Group	Native CCD	Post-Operative CCD	p Value	Stem alignment	*Pearson's r
A (Varus ≤ 127°) N = 24	120.20 ± 2.5	130.29 ± 4.35	< 0.05	1.5 ± 2.0	-0.60 (p < 0.001)
B (Valgus ≥ 128°) N = 22	133.54 ± 5.0	129.18 ± 3.6	< 0.001	- 1.09 ± 1.77	0.486 (p < 0.05)

DISCUSSION

Proper reconstruction of hip geometry and femoral stem positioning in THA is critical as it affects clinical outcomes, dislocation risk, range of motion, bone impingement, abductor muscle strength, and polyethylene wear (18-20). In the literature, there is high heterogeneity for the cut-off values of varus or valgus stem alignment (9, 21, 22). The main reason for varus stem positioning is still a topic of debate. Reduced surgical exposure in minimally invasive approaches may lead to broaching in a more varus position (23).

Moreover, both Murphy et al. (24) and Luger et al. (10) stated that one of the main reasons for varus stem alignment could be the preoperative CCD angle, showing that low CCD angles and deformities like coxa vara, led to varus implantation.

The results of this study confirm that the native CCD angle of the femur can influence postoperative femoral stem alignment in AMIS approach surgeries using short stems. At the same time, a valgus-leaning CCD appears to influence valgus alignment, although in a less pronounced way.

The group with a preoperative varus-leaning CCD had greater varus stem positioning than those with a higher CCD. A statistically significant correlation analysis confirmed this finding. ($p < 0.001$).

Another aspect that emerged from the study is restoring the postoperative CCD, which is particularly significant in Group B ($p < 0.001$). Again, this suggests that despite a slight tendency for valgus stem alignment, overall positioning is easier to control than in patients with a varus CCD. However, usually in our surgical practice, the absence of collars with an angle below 126° is critical for a tailored stem alignment.

Some authors, however, tend to attribute femoral component malpositioning to the use of straight stems and a steep learning curve (25). In our case, these issues were avoided by including only short stems in the study and selecting patients treated by a single experienced surgeon rather than a group of professionals with varying levels of expertise; Others emphasize the importance of using offset instruments and (26) in our clinical practice, these instruments were routinely employed; however, no comparison with standard instruments was made, which could be a subject of future discussion.

Intraoperative fluoroscopy to evaluate component positioning was not routinely used in the cases included in the study. In the literature, few studies have analyzed this possibility, but they have not shown significant improvements in the final clinical and radiological outcomes (27). Nonetheless, further research could demonstrate that routine fluoroscopy use may significantly reduce implant malpositioning. In our case series, a traction table was never used; however, the literature reports that the outcomes and complications associated with the standard table and traction table are comparable (28, 29).

Some authors, such as Haversath et al. (21), have also identified the critical trochanter angle (CTA) as a predictor of varus stem alignment risk in anterior approach THA. Nevertheless, the literature shows that the CCD angle has a higher sensitivity, with only a marginally lower specificity, in predicting varus stem alignment in short-stem THA, making it a more reliable tool (7).

Several study limitations were addressed. Primarily, the patient inclusion criteria restricted the analysis to patients with primary hip osteoarthritis and avascular necrosis. Thus, caution is necessary when applying these findings to secondary osteoarthritis or other conditions with dysplastic features of the hip joint. Moreover, our study lacks clinical outcome measures or patient-reported outcomes, even though our analysis focused purely on radiographic assessments.

CONCLUSIONS

This study demonstrated how the native CCD angle of the femur significantly influences the postoperative alignment of the stem in THA, which performed an AMIS approach using short stems. Patients with a varus CCD angle were more likely to have the stem positioned in the varus, while those with a valgus CCD angle showed a slight tendency toward valgus stem alignment. Consequently, we hypothesize that a reduced preoperative CCD angle may be a risk factor for varus stem positioning in THA with short stems. Surgeons should pay particular attention to this parameter during preoperative planning for the AMIS approach and maintain the alignment deviation of the threshold 3°.

The data obtained by our study could provide valuable insights for future prospective studies aiming at a more detailed analysis of the femoral morphology and to the femoral stem alignment and its impact on long-term outcomes.

Funding
This research received no external funding.

Institutional Review Board Statement
The study is retrospective, and it follows the Helsinki ethical principles for appropriate medical research.

Conflicts of Interest
The authors declare no conflicts of interest.

REFERENCES

1. Ang JJ, James Randolph Onggo, Christopher Michael Stokes, Anuruban Ambikaipalan. Comparing direct anterior approach versus posterior approach or lateral approach in total hip arthroplasty: a systematic review and meta-analysis. *Eur J Orthop Surg Traumatol*. 2023;33(7). doi:https://doi.org/10.1007/s00590-023-03528-8
2. Bontea M, Bimbo-Szuhai E, Codruta Macovei I, et al. Anterior Approach to Hip Arthroplasty with Early Mobilization Key for Reduced Hospital Length of Stay. *Medicina-lithuania*. 2023;59(7):1216-1216. doi:https://doi.org/10.3390/medicina59071216
3. Komnos G, Manrique J, Foltz C, Klement MR, Restrepo C, Parvizi J. Transfusion Rates in Total Hip Arthroplasty Are lower in Patients with Direct Anterior Approach. *The archives of bone and joint surgery*. 2021;9(6):659-664. doi:https://doi.org/10.22038/abjs.2021.50237.2497
4. Lygrisse KA, Gaukhman GD, Teo G, Schwarzkopf R, Long WJ, Aggarwal VK. Is Surgical Approach for Primary Total Hip Arthroplasty Associated With Timing, Incidence, and Characteristics of Periprosthetic Femur Fractures? *The Journal of Arthroplasty*. 2021;36(9):3305-3311. doi:https://doi.org/10.1016/j.arth.2021.04.026
5. Kutzner KP, Pfeil J. Individualized Stem-positioning in Calcar-guided Short-stem Total Hip Arthroplasty. *Journal of Visualized Experiments*. 2018;132(132). doi:https://doi.org/10.3791/56905
6. Jacquel A, Le Viguelloux A, Valluy J, Saffarini M, Bonin N. A shortened uncemented stem offers comparable positioning and increased metaphyseal fill compared to a standard uncemented stem. *Journal of Experimental Orthopaedics*. 2019;6(1). doi:https://doi.org/10.1186/s40634-019-0197-1
7. Luger M, Feldler S, Lorenz Pisecky, Jakob Allerstorfer, Gotterbarm T, Klasan A. The "critical trochanter angle" does not show superiority over the CCD angle in predicting varus stem alignment in cementless short-stem total hip arthroplasty. *Archives of Orthopaedic and Trauma Surgery*. 2022;143(1):529-537. doi:https://doi.org/10.1007/s00402-022-04340-5
8. Berstock JR, Hughes AM, Lindh AM, Smith EJ. A Radiographic Comparison of Femoral Offset after Cemented and Cementless Total Hip Arthroplasty. *HIP International*. 2014;24(6):582-586. doi:https://doi.org/10.5301/hipint.5000160
9. Takada R, Whitehouse S, Hubble M, et al. DOES VARUS OR VALGUS ALIGNMENT OF THE EXETER STEM INFLUENCE SURVIVAL OR PATIENT OUTCOME IN TOTAL HIP ARTHROPLASTY? A REVIEW OF 4126 CASES WITH A MINIMUM FOLLOW-UP OF FIVE YEARS. *Orthopaedic Proceedings*. 2019;101-B:22-22. doi:https://doi.org/10.1302/1358-992X.2019.6.022
10. Luger M, Stiftinger J, Allerstorfer J, Hochgatterer R, Gotterbarm T, Pisecky L. High varus stem alignment in short-stem total hip arthroplasty: a risk for reconstruction of femoro-acetabular offset, leg length discrepancy and stem undersizing? *Archives of orthopaedic and trauma surgery*. 2021;142(10):2935-2944. doi:https://doi.org/10.1007/s00402-021-04176-5
11. Lu M, Zhou YX, Du H, Zhang J, Liu J. Reliability and Validity of Measuring Acetabular Component Orientation by Plain Anteroposterior Radiographs. *Clinical Orthopaedics & Related Research*. 2013;471(9):2987-2994. doi:https://doi.org/10.1007/s11999-013-3021-8
12. Merle C, Waldstein W, Pegg E, et al. Femoral offset is underestimated on anteroposterior radiographs of the pelvis but accurately assessed on anteroposterior radiographs of the hip. *The Journal of Bone and Joint Surgery British volume*. 2012;94-B(4):477-482. doi:https://doi.org/10.1302/0301-620x.94b4.28067
13. Roy S. Evaluation of Proximal Femoral Geometry in Plain Anterior-Posterior Radiograph in Eastern-Indian Population. *JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH*. 2014;8(9). doi:https://doi.org/10.7860/jcdr/2014/9269.4852
14. Rawal B, Malhotra R, Ribeiro R, Bhatnagar N. Anthropometric measurements to design best-fit femoral stem for the Indian population. *Indian Journal of Orthopaedics*. 2012;46(1):46. doi:https://doi.org/10.4103/0019-5413.91634
15. Rubin PJ, Pierre-François Leyvraz, Jean-Manuel Aubaniac, Jean Noël Argenson, Esteve P, B. De Roguin. The morphology of the proximal femur. A three-dimensional radiographic analysis. *J Bone Joint Surg Br*. 1992;74-B(1):28-32. doi:https://doi.org/10.1302/0301-620x.74b1.1732260
16. Mahaisavariya B, Sitthiseripratip K, Tongdee T, Bohez ELJ, Vander Sloten J, Oris P. Morphological study of the

proximal femur: a new method of geometrical assessment using 3-dimensional reverse engineering. *Medical Engineering & Physics*. 2002;24(9):617-622. doi:https://doi.org/10.1016/s1350-4533(02)00113-3
17. RC Siwach, S Dahiya. Anthropometric study of proximal femur geometry and its clinical application. *Indian Journal of Orthopaedics*. 2003;37(4):247.
18. Mahmood SS, Mukka SS, Crnalic S, Wretenberg P, Sayed-Noor AS. Association between changes in global femoral offset after total hip arthroplasty and function, quality of life, and abductor muscle strength. *Acta Orthopaedica*. 2015;87(1):36-41. doi:https://doi.org/10.3109/17453674.2015.1091955
19. Little NJ, Busch CA, Gallagher JA, Rorabeck CH, Bourne RB. Acetabular Polyethylene Wear and Acetabular Inclination and Femoral Offset. *Clinical Orthopaedics and Related Research®*. 2009;467(11):2895-2900. doi:https://doi.org/10.1007/s11999-009-0845-3
20. Sariali E, Klouche S, Mouttet A, Pascal-Moussellard H. The effect of femoral offset modification on gait after total hip arthroplasty. *Acta Orthopaedica*. 2014;85(2):123-127. doi:https://doi.org/10.3109/17453674.2014.889980
21. Haversath M, Lichetzki M, Serong S, et al. The direct anterior approach provokes varus stem alignment when using a collarless straight tapered stem. *Archives of Orthopaedic and Trauma Surgery*. 2020;141(6):891-897. doi:https://doi.org/10.1007/s00402-020-03457-9
22. Haversath M, Busch A, Jäger M, Tassemeier T, Brandenburger D, Serong S. The "critical trochanter angle": a predictor for stem alignment in total hip arthroplasty. *Journal of Orthopaedic Surgery and Research*. 2019;14(1). doi:https://doi.org/10.1186/s13018-019-1206-x
23. Gustke KA. Short stems for total hip arthroplasty. *The journal of bone and joint surgery*. 2012;94-B(11_Supple_A):47-51. doi:https://doi.org/10.1302/0301-620x.94b11.30677
24. Murphy CG, Bonnin MP, Desbiolles AH, Carrillon Y, Aït Si Selmi T. Varus will Have Varus; A Radiological Study to Assess and Predict Varus Stem Placement in Uncemented Femoral Stems. *HIP International*. 2016;26(6):554-560. doi:https://doi.org/10.5301/hipint.5000412
25. Nairn L, Gyemi L, Gouveia K, Ekhtiari S, Khanna V. The learning curve for the direct anterior total hip arthroplasty: a systematic review. *International Orthopaedics*. 2021;45(8). doi:https://doi.org/10.1007/s00264-021-04986-7
26. Di Martino A, Brunello M, Rossomando V, et al. Aesthetic Results, Functional Outcome and Radiographic Analysis in THA by Direct Anterior, Bikini and Postero-Lateral Approach: Is It Worth the Hassle? *Journal of Clinical Medicine*. 2023;12(3):1072. doi:https://doi.org/10.3390/jcm12031072
27. Bingham JS, Spangehl MJ, Hines JT, Taunton MJ, Schwartz AJ. Does Intraoperative Fluoroscopy Improve Limb-Length Discrepancy and Acetabular Component Positioning During Direct Anterior Total Hip Arthroplasty? *Journal of Arthroplasty*. 2018;33(9):2927-2931. doi:https://doi.org/10.1016/j.arth.2018.05.004
28. Lecoanet P, Vargas M, Pallaro J, Thelen T, Ribes C, Fabre T. Leg length discrepancy after total hip arthroplasty: Can leg length be satisfactorily controlled via anterior approach without a traction table? Evaluation in 56 patients with EOS 3D. *Orthopaedics & Traumatology: Surgery & Research*. 2018;104(8):1143-1148. doi:https://doi.org/10.1016/j.otsr.2018.06.020
29. Sarraj M, Chen A, Ekhtiari S, Rubinger L. Traction table versus standard table total hip arthroplasty through the direct anterior approach: a systematic review. *HIP International*. 2020;30(6):112070001990098. doi:https://doi.org/10.1177/1120700019900987

Article

INTERVENTIONAL THERAPIES IN FACET SYNDROME

M. Frigerio, M. Fenaroli, S. Tavelli and M. Patroni

Department of Neuroradiology, Clinical Institute, "Città di Brescia", Brescia, Italy

[*]*Correspondence to*:
Michele Frigerio, MD
Department of Neuroradiology,
Clinical Institute, "Città di Brescia",
Brescia, Italy
e-mail: michele_frigerio@hotmail.it

ABSTRACT

The facet joint syndrome represents a significant cause of chronic low back pain. This study outlines the available interventional treatments, as well as the potential role of ozonotherapy in the management of these patients. Additionally, an initial case series of patients treated with CT-guided intra-articular and deep paravertebral infiltration of an O_2-O_3 mixture is presented.

KEYWORDS: *Facet syndrome, low back pain, ozonotherapy, infiltrations, O_2, O_3*

INTRODUCTION

Low back pain (LBP) is a significant health issue that affects a large portion of the general population; it poses a substantial socio-health problem in Western countries, particularly in light of the progressive aging of the population. Lumbar facet joint syndrome represents a common cause of low back pain, which is often underdiagnosed and improperly treated. Some studies have shown a prevalence of 27-40% of pain arising from the facet joints in patients with LBP. This results in costs for society due to a lack of accurate diagnosis, excessive requests for radiological examinations, unnecessary surgeries, and loss of work capacity, making it the most significant source of healthcare expenditure in industrialized countries.

It is defined as unilateral or bilateral low back pain that radiates to the buttocks, groin region, and thighs up to the knee. The most common etiology is osteoarthritis (1, 2).

Many spinal structures can be responsible for pain; some conditions, such as herniated and protruded discs, can be easily diagnosed with neuroimaging studies; however, other conditions, including facet joint syndrome, are difficult to evaluate with diagnostic imaging alone. Although various diagnostic techniques exist, there is no effective correlation between clinical symptoms and the degree of spinal degeneration. Therefore, clinical evaluation and identification of painful trigger points remain fundamental for guiding treatment.

Interventional radiological treatments for lumbar facet joint syndrome begin with anesthetic joint blocks and steroid injections at the intra- or periarticular level and may escalate to neurolysis treatments (physical or chemical) (3). Infiltrative treatments with O_2-O_3 have demonstrated good efficacy in the treatment of low back pain over the years (4-8), particularly in cases of protrusions or herniated discs. They can be performed under radiological guidance or using anatomical landmarks. Radiological guidance ensures greater precision in needle placement and allows for assessment of gas distribution once injected, thereby increasing clinical efficacy and reducing the risk of complications in treatment. Furthermore, in conditions affecting the posterior compartment, infiltrative treatment with O_2-O_3 has also shown

Received: 6 October 2024
Accepted: 23 November 2024

effectiveness in managing patients with LBP; thus, radiologically guided infiltration of O_2-O_3 may constitute a valid supplementary and supportive alternative to other interventional treatments for patients with posterior compartment pathology, especially facet joint syndrome, considering its low cost, minimal complication rate, and ease of application (9, 10).

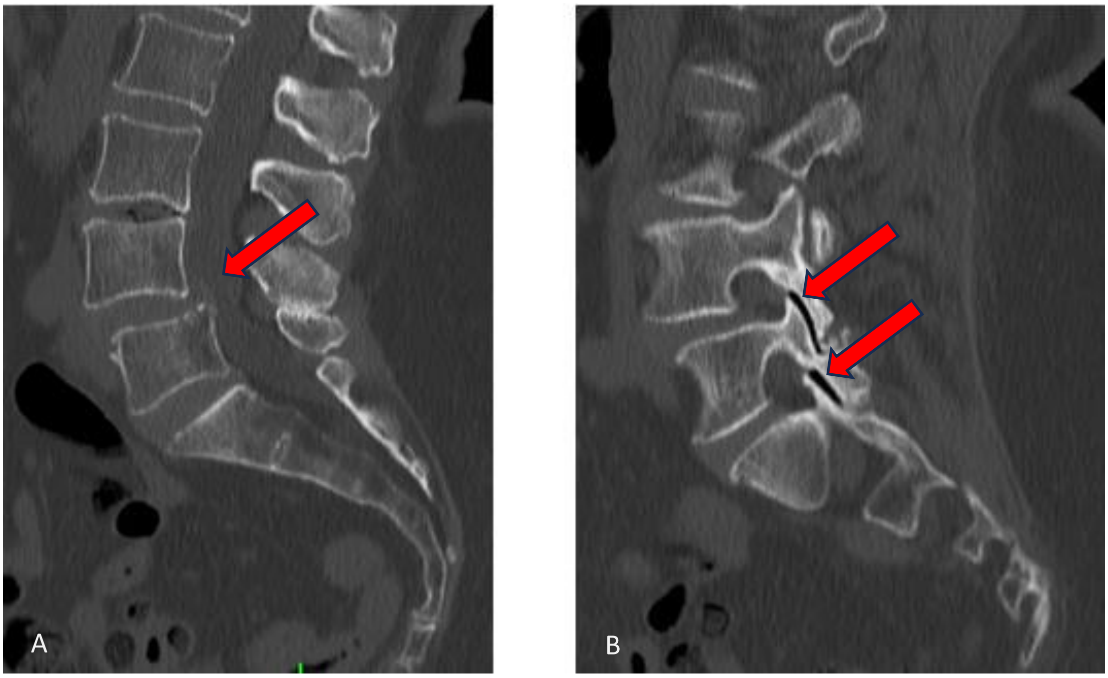
Facet joint syndrome includes localized pain with pseudoradicular irradiation and variability in territorial distribution; it typically involves one or both sides of the gluteal and trochanteric regions (from L4), the groin, and the thighs (L2-L5), terminating above the knee, without neurological deficits. Painful trigger points are often present at the site of interest. The pain is exacerbated during flexion-extension and rotation movements, improves with rest, and worsens in the morning and after periods of inactivity, leading to movement stiffness or after excessive physical exertion; it is aggravated by prolonged standing (11-20).

IMAGING

Pain originating from the zygapophyseal joints, however, is challenging to diagnose based solely on clinical findings, as symptoms and physical examination often lack specificity. This can lead to inefficient use of imaging studies, which may yield incidental findings that may be irrelevant in certain clinical contexts. Moreover, numerous pathological conditions (e.g., vertebral fractures, discopathies, neoplastic lesions) can initially present with overlapping clinical manifestations. Therefore, it is essential to make an appropriate choice of imaging in relation to the clinical context and to establish a clinico-radiological correlation to identify the potential cause of pain in the patient.

X-ray/CT

The initial radiological assessment of a patient with facet joint syndrome includes radiographic studies in the AP, LL, and oblique projections. This can be supplemented by a CT scan, which allows for better evaluation of the anatomy of the joint. Articular degeneration is manifested by narrowing of the joint space, subchondral sclerosis and erosion, the presence of calcifications in the joint capsule, cartilage thickening, hypertrophy of the articular processes and the yellow ligament, and osteophytes. Secondary signs include the presence of intra-articular gas degeneration, joint effusion, and degenerative spondylolisthesis. Synovial cysts may extend posteriorly but, in some cases, also anteriorly, involving the spinal canal or the neural foramen (Fig. 1. A-D).



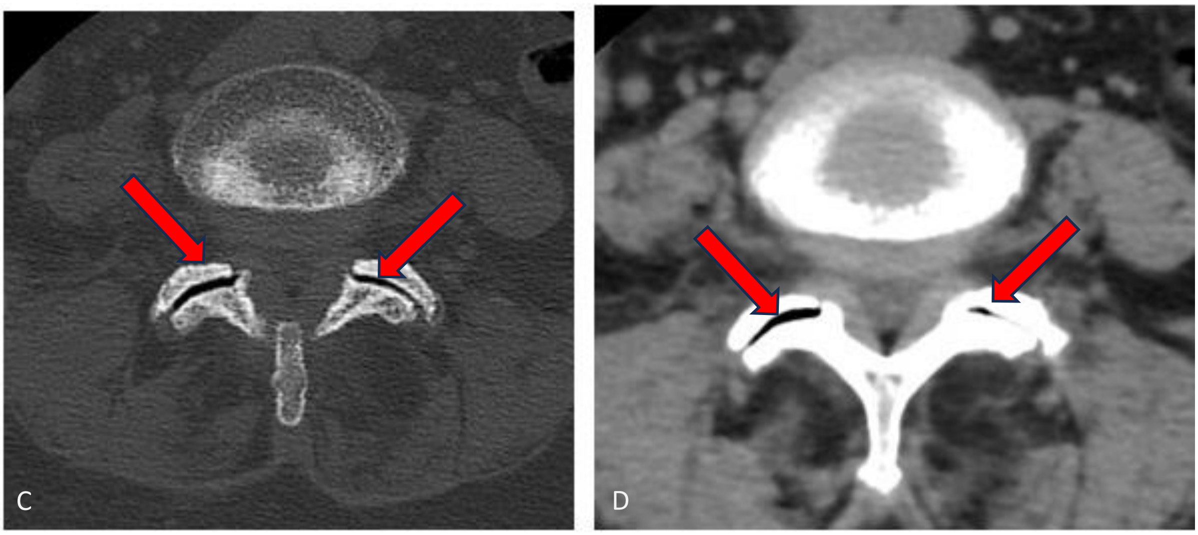


Fig. 1. ***A-B***: ***A***): *spondylolisthesis L4-L5;* ***B***): *facet joint hypertrophy and sclerosis;* ***C***): *axial CT with the bone algorithm: vacuolar degeneration of the facet joint;* ***D***): *axial CT with soft tissue algorithm: ligamentum flavum hypertrophy*.

MRI

MRI serves as a second-level modality in assessing patients with facet joint syndrome; compared to CT imaging, it allows for a better evaluation of the relationship between the joint and neural structures, particularly in cases of radicular compression due to foraminal or canal stenosis. Additionally, MRI facilitates the assessment of the inflammatory processes affecting the joint, including the synovium and adjacent bone, through the use of T2 sequences with fat saturation; subchondral edema is, in fact, present in 14-41% of patients with low back pain. The presence of diffuse joint effusion may suggest instability, although it is not specific to the site of origin of the pain (Fig. 2 A, B).

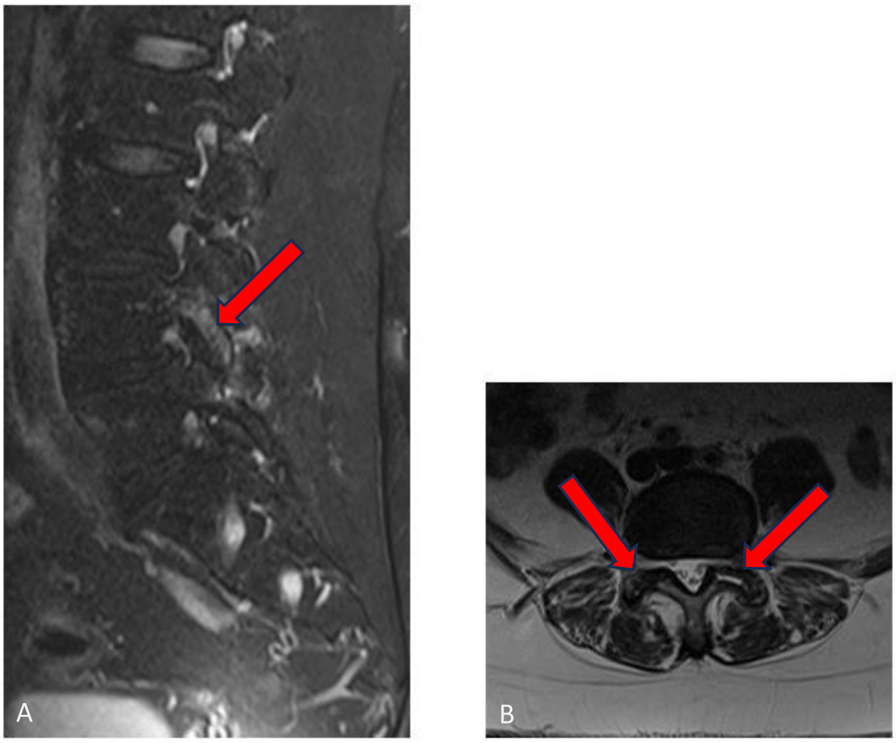


Fig. 2. *A-B: MRI sagittal (**A**), axial (**B**): facet syndrome (**arrows**).*

The study can be enhanced through the injection of a paramagnetic contrast agent with T1-weighted acquisitions with fat saturation (useful for the diagnosis of synovitis); it also allows for a better delineation of the inflammatory status of the degenerative process, thereby aiding in the identification of the therapeutic target for percutaneous treatments. However, administering gadolinium in this context is not routine and is reserved for selected cases.

INTERVENTIONAL TREATMENTS

First-line therapy is conservative, involving pharmacological approaches with the administration of NSAIDs (non-steroidal anti-inflammatory drugs) and muscle relaxants, followed by systemic corticosteroids if necessary. In cases of ineffectiveness, various percutaneous treatments may be implemented, depending on the operator's experience. Imaging-guided techniques enhance technical and clinical efficacy while reducing potential complications, such as hemorrhage, infections, and vasovagal syncope.

Medial branch blocks

Since it is often not entirely clear whether a facet joint is painful or not based on clinical assessment or imaging, a controlled nerve block can assist in the etiological diagnosis of low back pain. However, it does not address the pathogenesis of the pain.

There are several open questions:

- *degree of response:* authors do not fully agree on the clinical criteria for response to nerve blocks; some consider a response positive if there is a complete reduction of pain, while others do so for partial reduction;
- *target of the block:* it is currently believed that blocking the medial branch is more specific than intra-articular injections, and this target is thus utilized in selecting patients who are candidates for neurolysis;
- *number of blocks and levels:* various authors suggest performing blocks in two different sessions. Additionally, due to the dual innervation of the facet joint, the diagnostic block should be performed at a minimum of two levels per single block;
- *type of drug to be injected and volume:* diagnostic blocks include local anesthetics (lidocaine and/or bupivacaine); some authors find it advantageous also to combine steroids. There is no consensus on the volume of anesthetic to be injected, with recommendations varying from 0.25 ml to 0.5 ml per single block. However, there are potential false positives for various reasons: placebo effect, diffusion of the injected drug to other structures that may also be responsible for pain, and excessive administration of local anesthetic.

Articular steroid injections

The infiltrations of the articular facets include long-acting steroids and local anesthetic. They can be performed intra-articularly, periarticularly, or along the medial branch of the dorsal ramus, using radiographic, CT, or ultrasound guidance (Fig. 3 A, B).

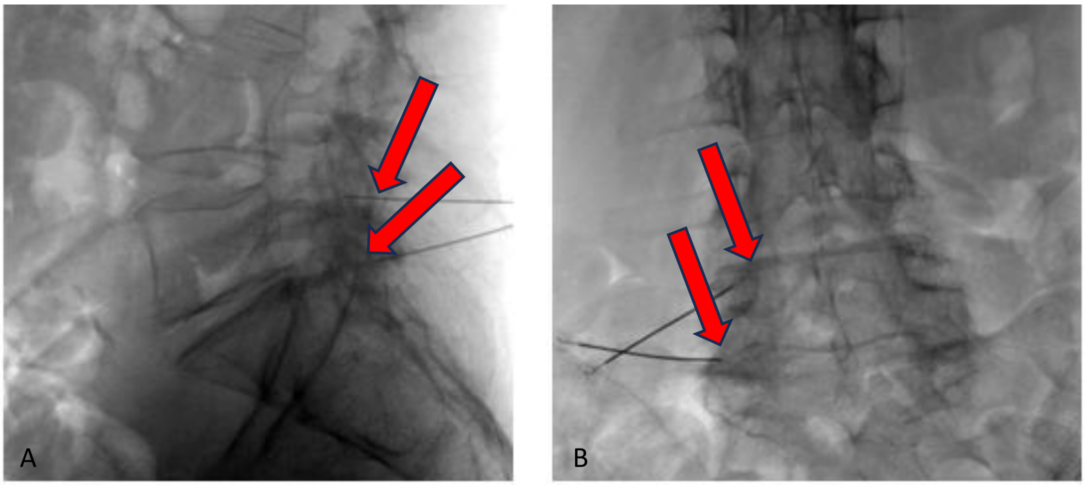


Fig. 3. *LL X-ray (**A**) and AP X-ray (**B**): assessment of proper needle positioning for treatment of the facet joints (**arrows**).*

Steroids allow for the interruption of nociceptive inputs at both central and peripheral levels and reduce the pro-inflammatory environment present in the affected joint; a short- to medium-term reduction in pain can be achieved with these treatments (4). Multilevel injections have demonstrated greater efficacy compared to single injections; however, the long-term efficacy is limited. No significant differences exist in the treatment site, as no real difference in outcomes has been observed between intra-articular and periarticular injections.

Neurolysis

It is performed on patients who have had a positive response in cases of anesthetic nerve block. When conducted after proper patient selection, it allows for pain reduction, improvement in disability, and decreased reliance on analgesics. However, regardless of the technique employed, it does not provide a definitive resolution of pain, as the damaged nerve may potentially regenerate. Two main techniques of physical neurolysis are primarily utilized:

- *radiofrequency:* this technique involves positioning an electrode under radiological guidance, followed by releasing a sinusoidal current. It can be performed as either ablative or pulsed radiofrequency, the latter allowing the avoidance of any potentially damaging effects on the nerve roots and possible spinal instability due to muscle denervation. Literature data demonstrate a significant reduction in pain in approximately 90% of patients with a duration of effect lasting up to 12 months. Potential complications include painful dysesthesia or cutaneous hyperesthesia, formation of neuromas, deafferentation pain, and accidental damage to the nerve root;
- *cryoneurolysis:* this technique consists of applying cold to the nerve to induce denaturation through the rapid decompression of a gas released at the tip of the needle. An ice ball is formed at the needle tip, which leads to a conduction block. Similar to radiofrequency, the success of the treatment relies on appropriate indication and patient selection. It shows results that are substantially comparable to those of radiofrequency. The advantages include being reversible, repeatable, and having a lower incidence of complications.

Surgery

There is no compelling evidence regarding the role of surgery in degenerative facet joint pain. In cases of spondylolisthesis, surgical intervention may be warranted if interventional therapies have failed, utilizing treatments such as lumbar decompressive laminectomy and arthrodesis. Other surgical treatments include endoscopic neurotomy.

OZONE THERAPY

Ozone therapy has progressively established itself in the treatment of spinal pain, primarily for cases of low back pain and sciatica due to herniated or protruded discs; the first use in this clinical field dates back to 1985, subsequently confirmed by numerous clinical studies that have supported its effectiveness both in alleviating symptoms and in progressively reducing the size of herniated disc tissue in follow-up imaging. The efficacy of the treatment has also progressively emerged in the management of non-discogenic pain caused by pathologies of the posterior compartment.

Over the years, infiltration treatments with O_2-O_3 have been performed with or without radiological control; in the former case, the gas injection is performed into the paravertebral musculature using anatomical landmarks, while in the latter case, radiographic, CT, or ultrasound guidance is employed to assess the correct positioning of the needle. A meta-analysis from 2021 showed that imaging-guided techniques provided a better reduction in pain compared to unguided methods, allowing for more accurate and deeper positioning of the needle; particularly, a greater difference in outcomes was noted in older patients, presumably due to anatomical changes related to osteoarthritis, scoliosis, vertebral collapse, etc., which may occur and thus make needle positioning even less accurate in unguided procedures.

Bonetti and colleagues (2, 4), demonstrated the efficacy of O_2-O_3 treatment in a cohort of 416 patients with pathologies of the posterior compartment, including facet joint synovitis, Baastrup's syndrome, spondylolysis, spondylolisthesis, and degenerative pathology of the facet joints, who were selected through accurate clinical and imaging evaluation. The subgroup of 326 patients with facet joint syndrome showed a significant reduction in initial pain in 74.5% of cases, even after a single treatment under CT guidance; in cases with insufficient reduction, a second infiltration further increased the percentage of clinical success, thus suggesting oxygen-ozone treatment as a valid alternative to other interventional and conservative treatments, given the minimal complication rate, low cost, and no exclusion for subsequent treatments such as steroid injections, radiofrequency, or surgical interventions.

Mechanism of action

The osteoarthritic degeneration of the facet joints begins at the level of the cartilage, leading to subsequent reduction of the joint space and increased vascularization, with multiple inflammatory mediators involved. In the late stages, this process culminates in articular hypertrophy, osteophyte formation, and progressive thickening of the subchondral bone tissue, resulting in sclerosis and erosion.

Various studies have demonstrated an increase in the infiltration of immune system cells and pro-inflammatory cytokines (TNF-α, IL-1β, IL-6, and prostaglandins) as well as enzymes contributing to cartilage degradation. In addition, anti-inflammatory cytokines and inhibitors of the aforementioned enzymes are upregulated in an attempt to generate a reparative response. Angiogenic factors are also present, which contribute to inflammation by enhancing the local influx of inflammatory cells and promoting neurogenesis.

Moreover, the development and progression of osteoarthritis are associated with an increase in oxidative stress and overproduction of reactive oxygen species (ROS). In normal cartilage, chondrocytes produce low levels of ROS, maintaining a balance with the body's physiological antioxidant systems, thus contributing to the maintenance of cartilage homeostasis, modulating the aging and apoptosis of chondrocytes, as well as the synthesis of the extracellular matrix. In osteoarthritic cartilage, abnormally high levels of ROS are produced in response to increased mechanical stress, fluctuations in the partial pressure of oxygen, and immunomodulatory mediators; concurrently, a reduction in antioxidant enzymes is observed. The increase in oxidative stress subsequently leads to apoptosis and premature aging of chondrocytes and synoviocytes. It also causes the activation of NF-kB, which contributes to the increase of pro-inflammatory factors. Ozone therapy acts through various mechanisms:

- activation of cellular metabolism;
- reduction of the synthesis of pro-inflammatory cytokines and prostaglandins;
- increase in immunosuppressive cytokines;
- reduction of oxidative stress in response to chronic oxidative stress;
- improvement of oxygen supply to tissues.

In the clinical context of osteoarthritis, it acts as a regulator of the inflammatory response, enhancing the synthesis of TNF-β and reducing pro-inflammatory cytokines (TNF-α and IL-8). Furthermore, it intervenes in the regulation of the NF-kB pathway, through which the production of pro-inflammatory cytokines is favored, implicating the inhibition of extracellular matrix synthesis and resulting in cartilage damage, alterations in the cartilage matrix, and apoptosis. The NF-kB pathway is directly activated by ROS or through pro-inflammatory mediators such as TNF-α. O_2-O_3 directly reduces the production of ROS or indirectly inhibits TNF-α, thereby blocking the NF-kB pathway.

The administration of low doses of O_2-O_3 also stimulates the organism's response by inducing the production of antioxidant enzymes, enabling the organism to adapt to chronic oxidative stress, and normalizing the redox balance. Finally, it enhances the effective utilization of oxygen in the mitochondrial respiratory chain, stimulating glycolysis in damaged cells and thus preventing cellular death.

PRELIMINARY EXPERIENCE

We present a preliminary experience involving 11 patients with a clinical and radiological diagnosis of low back pain due to facet joint syndrome, treated with CT-guided deep periarticular and paravertebral injections of O_2-O_3.

Technique

- an anamnesis interview is conducted with the patient, highlighting any contraindications to treatment that may be present in the medical history (remote pathological anamnesis);
- the evaluation of the medical history is then performed (recent medical history), with particular attention to the onset of symptoms, location and characteristics of the pain, and any previous treatments (conservative or minimally invasive) undertaken;
- an assessment of the radiological documentation is necessary, including an MRI study of the lumbar spine or, if contraindicated or not feasible for other reasons, a CT study. The patient is informed about the mechanism of action and effects of the treatment with O_2-O_3, including the efficacy rate and possible rare side effects;
- informed consent is obtained through the patient's signature;
- the patient is then accompanied to the CT room, positioned in the prone position on the table;
- preliminary low-dose scans are obtained to determine the correct centration of the level of interest and measurement of the injection site (Fig. 5).

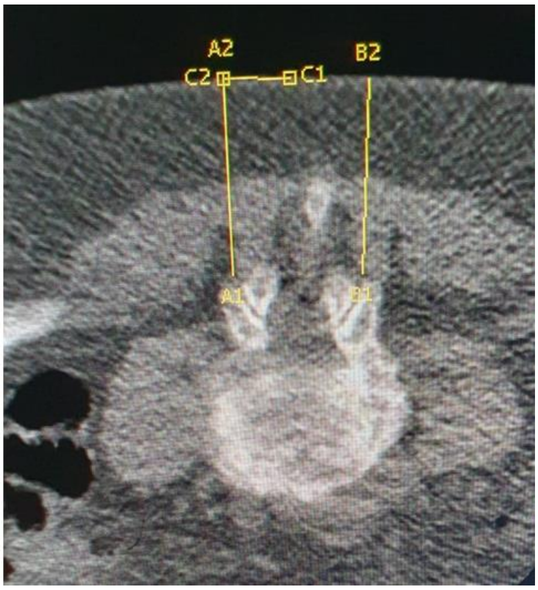


Fig. 5. *Preliminary CT scan prior to treatment.*

- marking on the patient's skin to identify the entry point based on the measurements taken, followed by disinfection of the skin with povidone-iodine and superficial anesthesia using ethyl chloride spray;
- placement of the needles (Fig. 6).

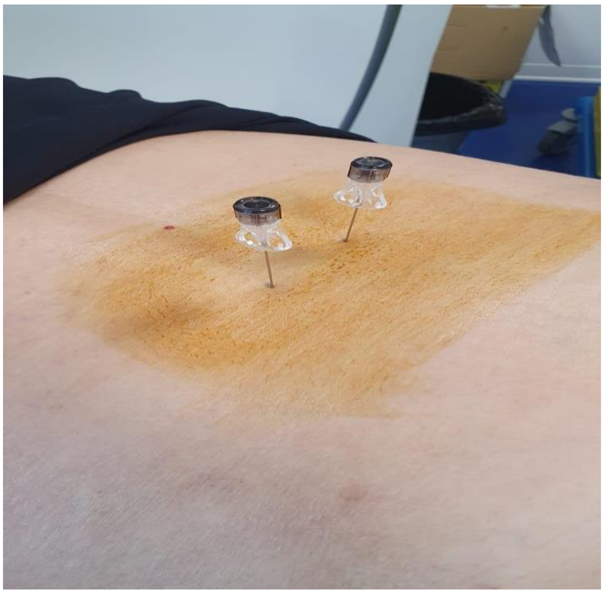


Fig.6. *Placement of the needles*

- verification of the correct positioning of the needle at the level of the joint interline through targeted CT scanning (Fig. 7).

Fig. 7. *CT control of needle positioning.*

- repositioning if necessary;
- using a sterile 20 ml syringe, inject 2-3 ml into the intra- and periarticular sites and 4-5 ml into the deep paravertebral site of a mixture of O_2-O_3 at a concentration of 25 µg/ml;
- withdrawal of the needle with compression;
- control with CT scans to verify the correct distribution of the gas (Fig. 8);

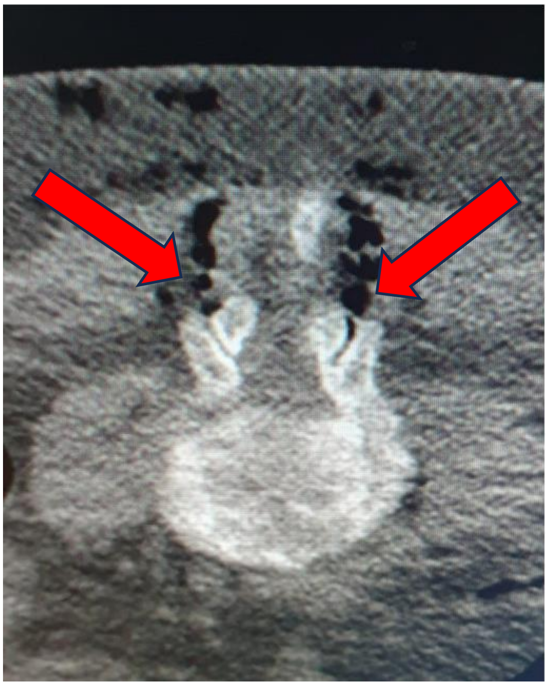


Fig. 8. *CT control of the distribution of the gaseous mixture O_2-O_3 (**arrows**).*

- implementation of physiotherapy treatment using a diamagnetic pump (CTU) or laser;
- clinical assessment of the patient's condition and discharge.

RESULTS

From January to May 2024, 11 patients (7 females and 4 males) with a clinical diagnosis of lumbar facet joint syndrome were treated. All patients underwent MRI or, if contraindicated or unavailable, CT imaging, which demonstrated radiological evidence of periarticular bone edema or other signs of joint overload. The treatment site was determined through clinical evaluation that identified a painful trigger point correlated with radiological findings; treatments were administered in a single session across a minimum of 1 level to a maximum of 3 levels.

Patients underwent a minimum of 2 to a maximum of 4 injections, with the treatment proposed at time 0, after 7-10 days, after an additional 15-20 days, and the last one after 20-30 days, within a total timeframe of approximately 2 months; in some patients, due to organizational reasons, the treatment intervals were extended beyond the initially agreed schedule.

In 8 out of 11 patients (72%), a reduction in pain of varying degrees was reported during the treatment, with the most significant improvement observed between the second and third injections, resulting in an overall subjective clinical improvement compared to the initial condition, a partial resumption of physical activity (commensurate with the patient's age), and a reported decrease in analgesic consumption. The total number of procedures was agreed upon with the patient based on clinical response.

The three cases of clinical failure were characterized as follows:

- a patient with a neurological condition, with a long history of low back pain and multiple prior treatments, underwent bilateral injection at 3 levels (L3-L4, L4-L5, and L5-S1); after the first treatment, there was a worsening of symptoms in the 5 days following;
- a patient with a depressive syndrome, suffering from chronic pain for years, received 2 injections without clinical benefit, after which she chose to discontinue treatment;
- a patient with chronic pain for years experienced mild improvement after the first 2 treatments; however, following physical exertion, symptoms recurred during the execution of the third injection, which proved to be ineffective. The scheduled fourth injection was canceled and replaced with a periarticular steroid injection.

No significant post-procedural complications were observed.

DISCUSSION

The data present in the literature support the possibility of using infiltrative treatments under radiological control with O_2-O_3 in patients with lumbar facet joint syndrome. CT guidance ensures correct positioning and identification of the injection site, as well as verification of the distribution of the medical gas, increasing the treatment efficacy rate while minimizing the risks of accidental puncture of neural or vascular structures and the rate of complications. The use of a low-dose scanning protocol significantly reduces the risk associated with the administration of ionizing radiation, which is considerably lower than the safety benefits provided by radiological guidance for the procedure.

Deep periarticular and paravertebral infiltration guided by CT has proven to be easily and swiftly applicable and has not shown technical issues compared to other infiltrative procedures such as medial branch blocks or corticosteroid injections; intraarticular injection in some patients has proven challenging due to the presence of osteophytes that hindered access to the joint space, as well as due to the presence of joint sclerosis, which prevented direct injection or minimized the quantity injected.

Given the progressive improvement observed with subsequent infiltrations, it may be advisable to propose to the patient a guided CT treatment cycle consisting of a minimum of two sessions and a maximum of four, as the most significant results have been noted between the second and third treatments. To reduce the risk of post-treatment pain, particularly in cases of multiple injections across several levels, it may be prudent, especially during the first treatment session, to reduce the injection volumes.

CONCLUSIONS

The limited follow-up period did not allow for the evaluation of medium- and long-term effects of the treatment and the potential need for a repetition of the infiltration cycles. Despite the low number of patients treated and the short follow-up duration, considering the preliminary results achievable with this methodology and the extremely low complication rate, it can be suggested that O_2-O_3 infiltrations guided by CT, both peri- and intra-articular, be used as a first-line therapy in patients diagnosed with facet joint syndrome who are poorly responsive to medical therapy. In particular, compared to intra-articular treatment with corticosteroids combined with anesthetic injections, O_2-O_3 does not present systemic side effects (e.g., hypertension, elevated blood glucose levels, etc.) or local effects (such as periarticular accumulation and calcifications) and has no risk of allergic reactions; compared to neurolysis procedures, it also offers the advantages of reduced costs, the possibility of outpatient treatment, and speed of execution.

REFERENCES

1. Breivik H, Collett B, Ventafridda V, Cohen R, Gallacher D. Survey of chronic pain in Europe: Prevalence, impact on daily life, and treatment. *European Journal of Pain*. 2006;10(4):287-287. doi:https://doi.org/10.1016/j.ejpain.2005.06.009
2. Bonetti M, Zambello A, Leonardi M, Princiotta C. “Not just herniated disc” back pain: Outcome of oxygen-ozone treatment in selected applications. *Journal of Ozone Therapy*. 2021;4(5):1. doi:https://doi.org/10.7203/jo3t.4.5.2020.10811
3. Datta S. Systematic Assessment of Diagnostic Accuracy and Therapeutic Utility of Lumbar Facet Joint Interventions. *Pain Physician*. 2009;2;12(2;3):437-460. doi:https://doi.org/10.36076/ppj.2009/12/437
4. Bonetti M, Fontana A, Biagio Cotticelli, Volta GD, Massimiliano Guindani, Leonardi M. Intraforaminal O2-O3 versus Periradicular Steroidal Infiltrations in Lower Back Pain: Randomized Controlled Study. *AJNR: American Journal of Neuroradiology*. 2005;26(5):996.
5. Latini E, Curci ER, Nusca SM, et al. Medical ozone therapy in facet joint syndrome: an overview of sonoanatomy, ultrasound-guided injection techniques and potential mechanism of action. *Medical Gas Research*. 2021;11(4):145-151. doi:https://doi.org/10.4103/2045-9912.318859
6. Travagli V, Bocci V, Borrelli E, Zanardi I. The usefulness of ozone treatment in spinal pain. *Drug Design, Development and Therapy*. 2015;9:2677. doi:https://doi.org/10.2147/dddt.s74518
7. Paoloni M, Di Sante L, Cacchio A, et al. Intramuscular Oxygen-Ozone Therapy in the Treatment of Acute Back Pain With Lumbar Disc Herniation. *Spine*. 2009;34(13):1337-1344. doi:https://doi.org/10.1097/brs.0b013e3181a3c18d
8. Bellomo RG, Paolucci T, Giannandrea N, Pezzi L, Saggini R. Ozone Therapy and Aquatic Rehabilitation Exercises to Overcome the Lumbar Pain Caused by Facet Joint Syndrome – Case Report. *International Medical Case Reports Journal*. 2020;13:171-176. doi:https://doi.org/10.2147/IMCRJ.S247697
9. Manchikanti L. Comprehensive Evidence-Based Guidelines for Interventional Techniques in the Management of Chronic Spinal Pain. *Pain Physician*. 2009;4;12(4;7):699-802. doi:https://doi.org/10.36076/ppj.2009/12/699
10. Rimeika G, Saba L, Arthimulam G, et al. Metanalysis on the effectiveness of low back pain treatment with oxygen-ozone mixture: Comparison between image-guided and non-image-guided injection techniques. *European Journal of Radiology Open*. 2021;8:100389. doi:https://doi.org/10.1016/j.ejro.2021.100389
11. Kalichman L, Li L, Kim DH, et al. Facet Joint Osteoarthritis and Low Back Pain in the Community-Based Population. *Spine*. 2008;33(23):2560-2565. doi:https://doi.org/10.1097/brs.0b013e318184ef95
12. Borenstein D. Does osteoarthritis of the lumbar spine cause chronic low back pain? *Current Rheumatology Reports*. 2004;6(1):14-19. doi:https://doi.org/10.1007/s11926-004-0079-z
13. Hatice Lakadamyalı, Nefise Çağla Tarhan, Tarkan Ergün, Banu Çakır, Ahmet Muhteşem Ağıldere. STIR Sequence for Depiction of Degenerative Changes in Posterior Stabilizing Elements in Patients with Lower Back Pain. *American Journal of Roentgenology*. 2008;191(4):973-979. doi:https://doi.org/10.2214/ajr.07.2829
14. Schinnerer KA, Katz LD, Grauer JN. MR Findings of Exaggerated Fluid in Facet Joints Predicts Instability. *Journal of Spinal Disorders & Techniques*. 2008;21(7):468-472. doi:https://doi.org/10.1097/bsd.0b013e3181585bab
15. Pathria M, Sartoris DJ, Resnick D. Osteoarthritis of the facet joints: accuracy of oblique radiographic assessment. *Radiology*. 1987;164(1):227-230. doi:https://doi.org/10.1148/radiology.164.1.3588910
16. Weishaupt D, Zanetti M, Boos N, Hodler J. MR imaging and CT in osteoarthritis of the lumbar facet joints. *Skeletal Radiology*. 1999;28(4):215-219. doi:https://doi.org/10.1007/s002560050503
17. Anaya JEC, Coelho SRN, Taneja AK, Cardoso FN, Skaf AY, Aihara AY. Differential Diagnosis of Facet Joint Disorders. *RadioGraphics*. 2021;41(2):543-558. doi:https://doi.org/10.1148/rg.2021200079
18. Manchikanti L, Hirsch JA, Falco FJ, Boswell MV. Management of lumbar zygapophysial (facet) joint pain. *World Journal of Orthopedics*. 2016;7(5):315. doi:https://doi.org/10.5312/wjo.v7.i5.315
19. Konin GP, Walz DM. Lumbosacral Transitional Vertebrae: Classification, Imaging Findings, and Clinical Relevance. *American Journal of Neuroradiology*. 2010;31(10):1778-1786. doi:https://doi.org/10.3174/ajnr.A2036
20. Bogduk N, Wilson AS, Tynan W. The human lumbar dorsal rami. *Journal of anatomy*. 1982;134(Pt 2):383-397.

Journal of Orthopedics

Comparative Study

AUTOMATING FRACTURE DETECTION: BENCHMARKING LANGUAGE MODELS AGAINST SPECIALIZED AI IN PLAIN RADIOGRAPHS

N.G. Biavardi[1], G. Placella[1], M. Alessio Mazzola[2], M. Conca[2], S. Mosca[1], V. Salini[1]

[1]Vita-Salute University, IRCCS San Raffaele Hospital, Milan IT
[2]IRCCS San Raffaele Hospital, Milan IT

Correspondence to:
Mattia Alessio Mazzola, MD
IRCCS Ospedale San Raffaele,
Unità Clinica di Ortopedia e Traumatologia
Via Olgettina 60,
20132, Milano, Italy
e-mail: mattia.alessio@hotmail.com

ABSTRACT

This study aims to compare the diagnostic capabilities of the emerging natural language AI model, ChatGPT, with Qure.ai, an established reference standard AI model, in the classification of fractures from plain radiographs. Employing a retrospective cross-sectional design, this diagnostic accuracy study was set in the Orthopedic Department of IRCSS San Raffaele Milano. A sample of 200 de-identified anteroposterior and lateral femur radiographs was utilized, equally divided into fractured and normal. Two AI models independently evaluated the radiographs, classifying them as fractured or normal, against the radiologist reports serving as the reference standard. The reference standard AI, Qure.ai, exhibited a marginally superior sensitivity (0.89 vs 0.73, $p<0.01$) and overall accuracy (0.92 vs 0.84) compared to ChatGPT. Both models demonstrated high specificity (>0.90), with the reference AI achieving closer-to-ideal diagnostic discrimination (AUC 0.92 vs 0.84). Fracture complexity diminished accuracy, and a strong inter-model concordance was noted. Both AI models showed a performance surpassing established clinical benchmarks, with the reference AI model slightly outperforming ChatGPT. The study's robust methodological framework offers essential insights for the clinical application of AI in radiographic fracture diagnosis. Further studies, particularly expanded multi-center trials, are recommended to validate these findings.

KEYWORDS: *artificial intelligence, AI fracture detection, ChatGpt, LLM, femur fracture*

INTRODUCTION

Quickly recognizing femur fractures (FF) in a clinical setting is crucial in emergency care medicine. The femur is identified as the most frequently fractured long bone, often requiring surgical intervention, which underscores the criticality of accurate diagnosis and prompt management (1). The predominant approach to managing femoral shaft fractures is intramedullary femoral nailing (IMN), which is hailed for favorable clinical outcomes and union rates. Nevertheless, this method is not devoid of perioperative complications, thereby necessitating meticulous recognition and management strategies to mitigate such adversities (2).

Received: 13 August 2024
Accepted: 18 September 2024

Literature has explored different facets of FF recognition and management. An accurate assessment of FF requires a thorough consideration of loads, physiological and morphological parameters, and their interplay (3). The usage of AI in interpreting orthopedic X-rays has shown remarkable promise in enhancing the accuracy and efficiency of fracture diagnosis. These AI algorithms, hinging on vast datasets of annotated images, have exhibited prowess in accurately classifying and diagnosing abnormalities (4).

Furthermore, the emergence of advanced language models like ChatGPT has marked a notable milestone in medical practice. A digital assistant should represent a reliable solution to support physicians in clinical decisions. The early applications of ChatGPT have shown a promising capacity in automating written responses to medical queries, with performance on medical exams nearing the passing threshold, making it a potential asset in medical education and research (5).

FFs are a common injury associated with significant morbidity and healthcare costs (6). Early and accurate diagnosis is critical for prompt treatment and positive patient outcomes. However, manually reviewing imaging studies to identify fractures is time-consuming and subject to human error and fatigue. There is a need for reliable automated tools to assist clinicians in fracture recognition (7). Recent advances in artificial intelligence (AI) show potential, but rigorous validation on diverse clinical datasets is lacking. In a narrative review, the application of deep learning to fracture detection on radiographs and CT examinations was discussed, shedding light on the value deep learning brings to this field and hinting at the prospective directions of this technology (8).

The aim of this study is to evaluate and compare the performance of ChatGPT versus Qure.ai, an established reference model, for classifying FF from x-ray images. Secondary aims are to quantify the sensitivity, specificity, and accuracy of both models relative to radiologist interpretation of imaging studies, to assess how factors like fracture characteristics impact classification accuracy, to analyze agreement with radiologist judgment and clinical usefulness, and to provide robust evidence to guide safe and effective integration of AI for augmenting fracture identification.

MATERIALS AND METHODS

Study Design and setting

The study design is summarized in Fig. 1.

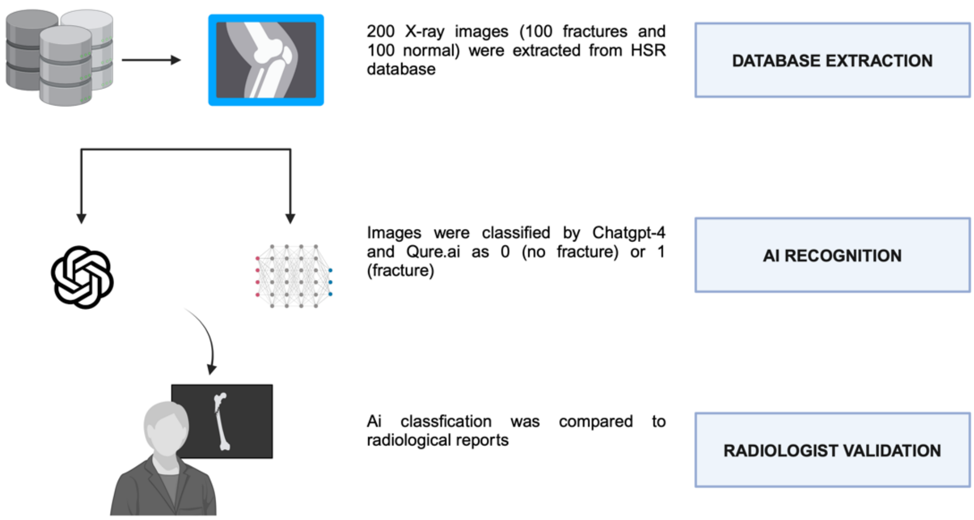


Fig. 1. *A cross-sectional study was conducted at the Orthopedic Department of San Raffaele Milano Hospital*.

The study incorporated 200 X-ray images of the femur, of which 100 were positive cases for fractures, and 100 were negative cases. The sample size was determined based on statistical power analysis to ensure adequate power to detect clinically meaningful differences in the performance metrics between the two AI models (9). All images were anonymized to ensure patient confidentiality.

Eligibility criteria

The inclusion criteria encompassed X-ray images of the femur with both anteroposterior and lateral views. Exclusion criteria included poor-quality images and those with foreign objects or artifacts. X-ray images were retrieved from the hospital's radiology database and subjected to image preprocessing to enhance visibility and standardize dimensions. Corresponding radiology reports were used as the gold standard for validation.

The primary dependent variables were the accuracy, sensitivity, specificity, and concordance of each algorithm. The independent variable was the algorithm used for image analysis, either ChatGPT Image Recognition or Qure.ai.

Two algorithms, ChatGPT Image Recognition and Qure.ai, were employed for image analysis. Each algorithm independently analyzed the set of 200 X-ray images. The results were then compared to the standard radiology reports to evaluate the algorithms' performance metrics.

Statistical analysis

Descriptive statistics, including frequencies, percentages, means, and standard deviations, were calculated for all study variables. Inferential statistical tests were performed. All statistical tests were two-sided, and a significance level of $p<0.05$ was adopted.

RESULTS

The study retrospectively analyzed 200 de-identified X-ray images demonstrating FFs sampled from the clinical data repository. The cohort encompassed diversity across age, gender, fracture locations, and other parameters. Two artificial intelligence models - ChatGPT and Qure.ai - were utilized to classify images as either fractured or normal. Their predictions were compared to radiologist interpretations, considered the reference standard. Results are summarized in Table I.

Table I. *The table summarizes key performance metrics for ChatGPT and Qure.ai in detecting PFF. Qure.ai outperformed in sensitivity, accuracy, and radiologist agreement, while both models showed high specificity. McNemar's test indicated significant differences and strong inter-model agreement was confirmed by Bland-Altman analysis*.

Metric/Analysis	ChatGPT Value	Qure.ai Value	Significance in Study
Sensitivity	0.73 (95% CI 0.644-0.810)	0.89 (95% CI 0.828-0.948)	Higher sensitivity in Qure.ai suggests better performance in detecting true positive PFF.
Specificity	0.95 (95% CI 0.899-0.989)	0.95 (95% CI 0.899-0.989)	Both models demonstrated high specificity, indicating low rates of false positives.
Accuracy	0.84 (95% CI 0.785-0.890)	0.92 (95% CI 0.885-0.955)	Qure.ai showed marginally higher accuracy, although the largely overlapping CIs indicate that the differences may be statistically insignificant.
McNemar's Test	Chi-Sq: 12.34, p=0.0004	Chi-Sq: 12.34, p=0.0004	The significant p-value suggests non-random discrepancies between the two models, emphasizing the need for careful model selection.
Cohen's Kappa	0.68	0.84	Indicates substantial-to-nearly perfect agreement with radiologist interpretations, suggesting potential complementary roles for AI in clinical practice.
AUC (ROC)	0.84	0.92	Both models showed good to excellent diagnostic capabilities, with Qure.ai slightly outperforming.
F1 Score	0.82	0.92	Reflects patterns similar to overall accuracy. A t-test yielded a non-significant p-value of 0.56, suggesting the observed differences might be due to chance.
Bland-Altman Agreement	Mean diff: 0.0092	Mean diff: 0.0092	Demonstrates strong inter-algorithm agreement, suggesting either model could be a reliable diagnostic tool.
ANN Performance	Not applicable	Not applicable	A separate ANN model achieved an accuracy of 97.5% in mimicking radiologist decisions, suggesting the potential for complex diagnostic algorithms.

Performance metrics

Overall, Qure.ai marginally outperformed ChatGPT across the key metrics of sensitivity, specificity, and accuracy. Specifically, ChatGPT demonstrated a sensitivity of 0.73 (95% CI 0.644 - 0.810), specificity of 0.95 (95% CI 0.899 – 0.989), and overall accuracy of 0.84 (95% CI 0.785 – 0.890). In comparison, Qure.ai exhibited numerically superior metrics with a sensitivity of 0.89 (95% CI 0.828 – 0.948), identical specificity of 0.95 (95% CI 0.899 – 0.989), and marginally higher accuracy of 0.92 (95% CI 0.885 – 0.955).

Sensitivity evaluates the proportion of true positives correctly identified, which is clinically important to minimize false negative findings that could delay diagnosis and treatment. While both models performed well, Qure.ai's higher sensitivity indicates it may be better suited for settings where maximal fracture detection is paramount. The identical specificities suggest both models effectively ruled out false positives. When considering overall accuracy across both positive and negative cases, Qure.ai again achieved slightly enhanced performance. However, the largely overlapping confidence intervals indicate that differences may fall within the realm of statistical variation.

Comparative analysis

To formally compare differences between ChatGPT and Qure.ai, McNemar's test was conducted given the paired nature of the data. This yielded a statistically significant chi-square value of 12.3 ($p<0.001$), providing evidence to reject the null hypothesis of no difference between the models' performances. The significant p-value implies that discrepancies in the tools' abilities to identify the neck of the femur (NOF) accurately are unlikely due to chance alone. Clinically, this suggests that the choice of AI system could substantively influence diagnostic outcomes, warranting careful validation and selection.

Inter-rater reliability

Inter-rater reliability was assessed between the AI tools and radiology reports via Cohen's kappa. The coefficient was 0.68 for ChatGPT, indicating substantial agreement with radiologist interpretations. Meanwhile, Qure.ai achieved a kappa of 0.84, suggesting almost perfect agreement. The higher kappa for Qure.ai suggests its classifications more closely mirrored those of experienced clinicians reviewing the imaging studies. Both values support potential complementary roles for AI in clinical practice, subject to appropriate oversight.

Diagnostic performance

To evaluate the models' capacities to discriminate NOFs from normal studies, receiver operating characteristic (ROC) curves were generated, and the area under the curve (AUC) was calculated. ChatGPT achieved an AUC of 0.84, while Qure.ai showed an AUC of 0.92 (Fig. 2).

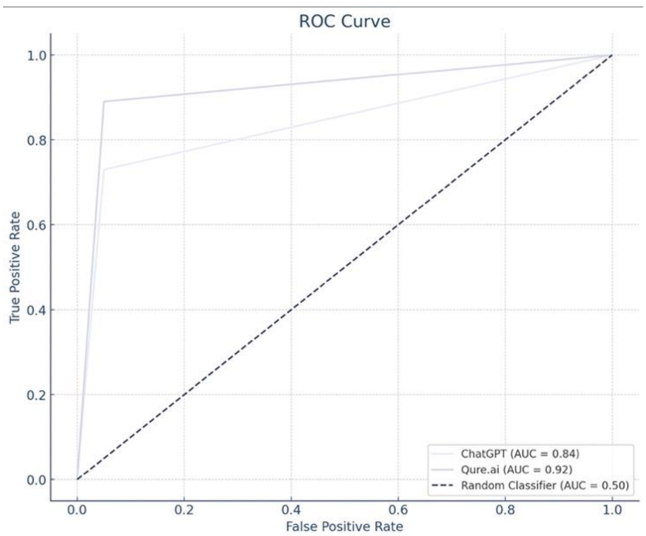


Fig. 2. *ROC curve representing the true positive and false positive rate of ChatGPT and Qure.ai.*

Both models exhibited good to excellent diagnostic discrimination based on conventional ROC interpretation schemas. However, Qure.ai again demonstrated slightly enhanced performance, nearing ideal fracture identification. The ROC curves provide insight into the tradeoffs between sensitivity and specificity at different classification thresholds.

F1 score analysis and hypothesis testing

The F1 score, calculated as the harmonic mean of precision and recall, provides a singular balanced measure of classification performance. Scores for ChatGPT and Qure.ai mirrored the patterns observed for overall accuracy. Specifically, ChatGPT registered an F1 score of 0.82 compared to 0.92 for Qure.ai. To determine if differences reached statistical significance, a two-sample t-test was conducted. This yielded a non-significant p-value of 0.56 ($t = -0.70$). Therefore, there is insufficient evidence to conclude that the observed divergence in F1 scores exceeds chance variation at the $\alpha = 0.05$ significance level.

Agreement analysis

Bland-Altman plotting was utilized to assess the agreement between ChatGPT and Qure.ai's individual fracture classifications (Fig. 3).

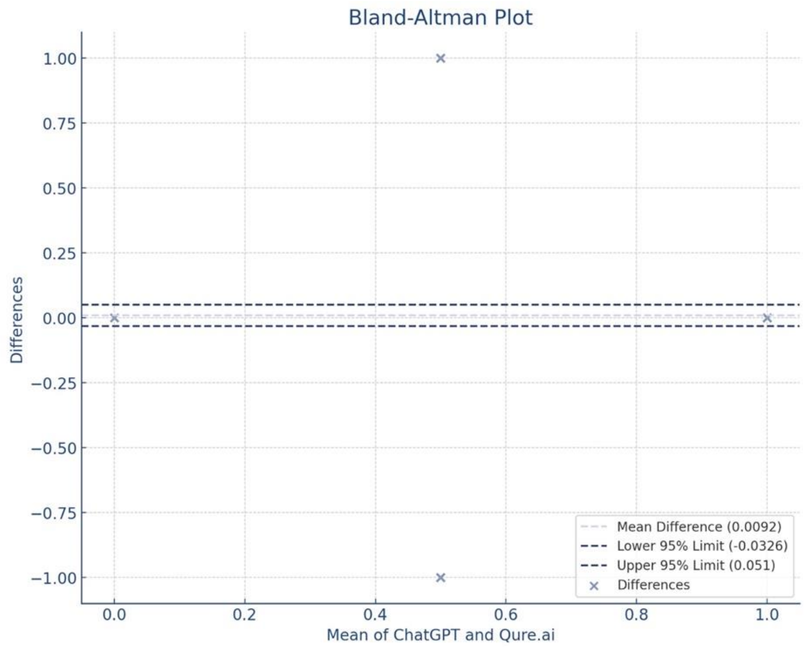


Fig. 3. *Bland-Altman plot illustrating the agreement between ChatGPT and Qure.ai in fracture classification. The mean difference is negligible, and 95% of differences fall within a narrow range, indicating strong inter-algorithm agreement.*

The mean difference between the two algorithms' predictions is remarkably small, approximately 0.0092. This negligible difference suggests a high degree of concordance between ChatGPT and Qure.ai in fracture identification. The scatter points are uniformly distributed across the plot without any discernible pattern of clustering or trend. This uniformity suggests that the differences between the two algorithms are random and not influenced by any systematic bias. The strong inter-algorithm agreement implied by the plot indicates that either algorithm could potentially serve as a reliable tool for the automated identification of fractures.

Decision curve analysis was performed to determine the clinical usefulness and net benefit of the models across different threshold probabilities for recommending treatment. The net benefit curves for ChatGPT and Qure.ai were strikingly similar across the spectrum of threshold values. This suggests both models may have analogous utility in guiding clinical decision-making for suspected FFs, though direct outcome data is needed.

Artificial neural network

The developed Artificial Neural Network (ANN) aims to predict radiologist classifications of fractures with an accuracy of 97.5%. It utilizes a multilayer perceptron architecture comprising an input layer, two hidden layers, and an output layer (fig. 4).

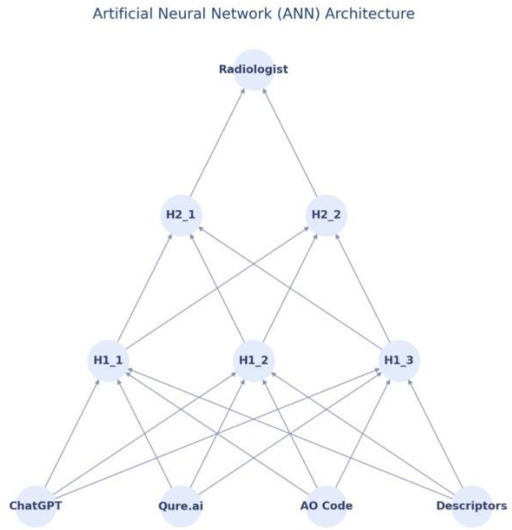


Fig. 4. *ANN architecture visualizes a four-node input layer, two hidden layers, and a single-node output layer. The model achieves a 97.5% accuracy in predicting radiologist fracture classifications, highlighting its effectiveness in capturing complex relationships among variables*

The input layer has four nodes: ChatGPT Prediction, Qure.ai Prediction, AO Classification System, and Basic Descriptors like patient demographics. The two hidden layers further refine these inputs, capturing intricate relationships among variables. The output layer represents the radiologist's fracture classification, serving as the target outcome for the model.

The high accuracy achieved by this ANN model suggests its potential effectiveness in a clinical setting for fracture identification. By leveraging multiple types of data, the network can mimic the complex decision-making process of radiologists with a high degree of accuracy. This could facilitate more accurate and rapid diagnoses, enhancing patient care and resource allocation in healthcare settings.

DISCUSSION

This study provides salient insights into the comparative performance of ChatGPT and Qure.ai for the automated classification of FF from plain radiographs. Across key performance indicators, i.e., sensitivity, specificity, and overall accuracy, Qure.ai marginally surpassed ChatGPT. Nevertheless, it is noteworthy that both computational models exhibited proficiency that surpasses established benchmarks in the extant literature, albeit requiring further validation for clinical applicability (10, 11).

In the benchmark tests, Qure.ai manifested a sensitivity of 0.89 compared to ChatGPT's 0.73. This distinction reached statistical significance, thereby suggesting that Qure.ai is potentially better suited for clinical workflows where maximizing the detection of true fractures is imperative (11). The ramifications of missed or delayed diagnoses can be severe, leading to inappropriate clinical management and suboptimal patient outcomes. These observations are consistent with the findings of Guermazi et al., who reported a significant 10.4% improvement in fracture detection sensitivity when AI was used to assist radiographic interpretation across multiple anatomical regions (10). However, another study still showcased a modest superiority of human radiologists over standalone AI (12). Both models showcased high specificity, indicating a minimal propensity for false positives that could trigger unnecessary clinical interventions. This high specificity is parallel to the findings by Hussain et al., who also reported a high specificity greater than 0.90 for both AI systems under investigation (11).

As for overall accuracy, Qure.ai slightly outperformed ChatGPT with scores of 0.92 versus 0.84, respectively. While these figures are promising, they still call for cautious interpretation given the proposed minimum accuracy thresholds for secure clinical AI integration, which range from 0.90 to 0.96 (11). The largely overlapping confidence intervals further substantiate that the current evidence is insufficient to assert that the observed differences in accuracy are statistically significant.

Our findings are consonant with a growing body of literature emphasizing the indispensability of rigorously evaluating AI systems on heterogeneous datasets before their clinical incorporation (10, 11). The narrative of comparable or superior AI performance to human radiologists, as echoed in 61 of the 81 studies identified in a systematic review by

The BMJ, underscores the potential of AI, albeit also highlighting the necessity for rigorous, real-world clinical evaluations to ascertain the reliability and robustness of AI systems (13). Although performance metrics were robust on the initial dataset used in this study, broader testing on more extensive and diverse samples from various institutions is essential. This will account for increased variability attributable to technical and demographic factors, thus corroborating the models' robustness and reliability.

A limitation of our study was the exclusive utilization of anteroposterior and lateral radiographic views. Additional radiographic projections could potentially enhance diagnostic accuracy. Future research endeavors should extend to assessing performance across multiple imaging modalities such as CT and MRI. This notion aligns with the work of Guermazi et al., who found that AI's performance varied across different anatomical regions and that multiple fractures per patient remained a relative weakness for both human and AI interpretation (11).

In conclusion, our study contributes an objective framework for transparently benchmarking AI systems using impartial local data to clarify realistic capabilities and limitations. Both ChatGPT and Qure.ai show promise in augmenting fracture detection capabilities. The imperative for continued rigorous evaluation and direct correlation with patient outcomes cannot be overstated, as this will elucidate the most appropriate pathways for clinical integration and optimize the potential of human-AI collaboration in enhancing musculoskeletal imaging.

CONCLUSIONS

This study sought to rigorously benchmark the emerging AI system ChatGPT against the established FF classifier Qure.ai using local clinical data.

In a head-to-head comparison, both models demonstrated strong capabilities, with Qure.ai achieving a marginally higher sensitivity of 0.89 versus 0.73 for ChatGPT and overall accuracy of 0.92 versus 0.84. Specificity was high for both at 0.95. Statistical tests affirmed that Qure.ai's superior sensitivity was a significant differentiator. Bland-Altman analysis demonstrated strong inter-algorithm agreement in fracture classifications.

For clinical integration, Qure.ai currently appears better positioned to maximize safe fracture detection based on higher sensitivity and near-perfect agreement with radiologists. However, both systems exhibited competency exceeding established performance minimums, contingent on expanded validation.

This rigorous benchmarking provides vital insights into strengths, limitations, and appropriate applications to guide safe AI adoption. Both ChatGPT and Qure.ai show immense promise for augmenting FF identification. Continued transparent evaluation and correlation with clinical impacts will further elucidate optimal collaborative roles for AI and physicians in enhancing patient care.

Disclosure
No funding was received for this study. The authors have no relevant financial relationships to disclose.

Conflict of interest statement
The authors have no conflicts of interest to disclose.

REFERENCES

1. Ghouri SI, Asim M, Mustafa F, et al. Patterns, Management, and Outcome of Traumatic Femur Fracture: Exploring the Experience of the Only Level 1 Trauma Center in Qatar. *International Journal of Environmental Research and Public Health*. 2021;18(11):5916. doi:https://doi.org/10.3390/ijerph18115916
2. Gupte D, Axelrod D, Worthy T, Woolnough T, Selznick A, Johal H. Management of Femoral Shaft Fractures: The Significance of Traction or Operative Position. *Cureus*. 2023;15(1). doi:https://doi.org/10.7759/cureus.33776
3. Awal R, Ben Hmida J, Luo Y, Faisal T. Study of the significance of parameters and their interaction on assessing femoral fracture risk by quantitative statistical analysis. *Medical & Biological Engineering & Computing*. 2022;60(3). doi:https://doi.org/10.1007/s11517-022-02516-0
4. Sharma S. Artificial intelligence for fracture diagnosis in orthopedic X-rays: current developments and future potential. *SICOT-J*. 2023;9:21-21. doi:https://doi.org/10.1051/sicotj/2023018
5. Sedaghat S. Early applications of ChatGPT in medical practice, education, and research. *Clinical Medicine*. 2023;23(3):clinmed.2023-0078. doi:https://doi.org/10.7861/clinmed.2023-0078
6. Alnemer MS, Kotliar KE, Neuhaus V, Pape HC, Ciritsis BD. Cost-effectiveness analysis of surgical proximal femur fracture prevention in elderly: a Markov cohort simulation model. *Cost Effectiveness and Resource Allocation*. 2023;21(1). doi:https://doi.org/10.1186/s12962-023-00482-4

7. 7.Thian YL, Li Y, Jagmohan P, Sia D, Chan VEY, Tan RT. Convolutional Neural Networks for Automated Fracture Detection and Localization on Wrist Radiographs. *Radiology: Artificial Intelligence*. 2019;1(1):e180001. doi:https://doi.org/10.1148/ryai.2019180001
8. Kalmet PHS, Sanduleanu S, Primakov S, et al. Deep learning in fracture detection: a narrative review. *Acta Orthopaedica*. 2020;91(2):215-220. doi:https://doi.org/10.1080/17453674.2019.1711323
9. Goldenholz DM, Sun H, Ganglberger W, Westover MB. Sample Size Analysis for Machine Learning Clinical Validation Studies. *Biomedicines*. 2023;11(3):685. doi:https://doi.org/10.3390/biomedicines11030685
10. Guermazi A, Tannoury C, Kompel AJ, et al. Improving Radiographic Fracture Recognition Performance and Efficiency Using Artificial Intelligence. *Radiology*. 2022;302(3):627-636. doi:https://doi.org/10.1148/radiol.210937
11. Hussain A, Fareed A, Taseen S. Bone fracture detection—Can artificial intelligence replace doctors in orthopedic radiography analysis? *Frontiers in artificial intelligence*. 2023;6. doi:https://doi.org/10.3389/frai.2023.1223909
12. Oren O, Gersh BJ, Bhatt DL. Artificial intelligence in medical imaging: switching from radiographic pathological data to clinically meaningful endpoints. *The Lancet Digital Health*. 2020;2(9):e486-e488. doi:https://doi.org/10.1016/s2589-7500(20)30160-6
13. Nagendran M, Chen Y, Lovejoy CA, et al. Artificial intelligence versus clinicians: systematic review of design, reporting standards, and claims of deep learning studies. *BMJ*. 2020;368:m689. doi:https://doi.org/10.1136/bmj.m689

Observational Study

SUCCESSFUL USE OF OXYGEN-OZONE THERAPY UNDER CT GUIDE ASSOCIATED WITH ALPHA LIPOIC ACID + PALMITOYLETHANOLAMIDE AND MYRRH IN A 3-YEAR COHORT OF PATIENTS WITH FIRST-DEGREE SPONDYLOLISTHESIS SECONDARY TO SPONDYLOLYSIS

M. Bonetti[1*], M. Frigerio[1], G.M. Ottaviani[2], G. Pellicanò[3], M. Muto[4], S. Miglio[5] and F. Maffezzoni[5]

[1]Department of Neuroradiology Clinical Institute, "Città di Brescia", Brescia, Italy;
[2]Department of Emergency Spedali Civili di Brescia, Brescia, Italy;
[3]Department of Neuroradiology, Hospital Authority, Careggi University, Florence, Italy;
[4]Department of Neuroradiology Cardarelli Hospital of Naples, Naples, Italy;
[5]Specialist Clinic Oberdan, Brescia, Italy

Correspondence to:
M. Bonetti, MD
Department of Neuroradiology,
Clinical Institute, "Città di Brescia",
Via Bartolomeo Gualla 15,
25128, Brescia, Italy

ABSTRACT

In recent years, there has been an increase in reports on the use of oxygen-ozone therapy for the treatment of non-discogenic low back pain. The aim of our observational study was to compare the therapeutic efficacy of combined oxygen-ozone treatment with the oral administration of 800 mg/day of alpha-lipoic acid (ALA), 600 mg/day of palmitoylethanolamide (PEA), and 200 mg of myrrh in patients with first-degree spondylolisthesis secondary to spondylolysis, against the results obtained with oxygen-ozone treatment alone. From March 2021 to March 2024, we recruited 286 patients diagnosed with first-degree spondylolisthesis secondary to spondylolysis, confirmed through CT and/or MRI studies. All patients were experiencing low back pain and sciatica. Specifically, we treated 161 men and 125 women, aged between 36 and 74 years (mean age: 47.6). All participants in the study received Oxygen-Ozone Therapy, monitored by CT, along with an oral regimen of alpha-lipoic acid (ALA), palmitoylethanolamide (PEA), and myrrh, taking two capsules per day for 30 days. The 286 treated patients were evaluated at the time of recruitment using the Visual Analog Scale (VAS). Clinical outcomes were assessed in the long term at six months, utilizing both the VAS and the modified MacNab method. The results obtained were then compared with those reported in the literature for patients receiving only oxygen-ozone treatment under CT guidance. The VAS questionnaire showed satisfactory clinical results after treatment (M = 8.47, SD = 0.76 pre-treatment; M = 2.48, SD = 1.32 after treatment). These data were also confirmed using the modified Mac Nab method, with which we obtained an excellent result in 185 (64.70%), while in 40 it was satisfactory (13.95%). Out of 286 patients, 38 patients (13.3%) did not report any benefit as reported by the VAS test. These results were then compared with those reported in the literature with oxygen-ozone treatment alone. In light of the results obtained from our observational study involving 286 patients, we compared our findings, combining Oxygen-Ozone Therapy under CT guidance with oral administration of ALA, PEA, and myrrh, to data reported in the literature regarding oxygen-ozone therapy alone. We conclude that this combination therapy results in further improvement over the already excellent outcomes achieved with oxygen-ozone treatment alone. Therefore, we consider this therapeutic combination of ALA, PEA, and myrrh to be a valid alternative to standalone oxygen-ozone therapy.

KEYWORDS: *oxygen, ozone, ozone therapy, spondylolysis, spondylolisthesis*

Received: July 2024
Accepted: 7 September 2024

INTRODUCTION

Oxygen-Ozone (O_2-O_3) therapy for herniated and protruding discs has become a consolidated clinical practice and is utilized in many countries as a first-line therapeutic approach for patients suffering from this condition. Introduced for the first time in 1985, numerous case studies have been published over the years, reporting positive results ranging from 75% to nearly 90% in the treatment of low back pain, with or without sciatica, due to herniated discs (1-11). In the last fifteen years, many reports have also highlighted excellent therapeutic outcomes achieved with O_2-O_3 therapy in treating pathologies of the posterior spinal compartment (12-21).

In fact, there can be numerous etiologies linked to the vertebral pathology of the posterior compartment: pathology of the articular facets, spondylolysis-olisthesis, stenosis of the spinal canal, radicular cysts, intra and interapophyseal synovitis, Baastrup syndrome, etc. (1-3, 6, 8, 9, 11, 16, 17, 20, 21). It is, therefore, essential to reach a precise diagnosis formulated after a careful objective examination and supported by appropriate instrumental tests, such as (in addition to standard spinal radiographs) Computerized Axial Tomography (CT) and/or Nuclear Magnetic Resonance (MRI) (18) (Fig. 1 A-E, Fig. 2 A-C).

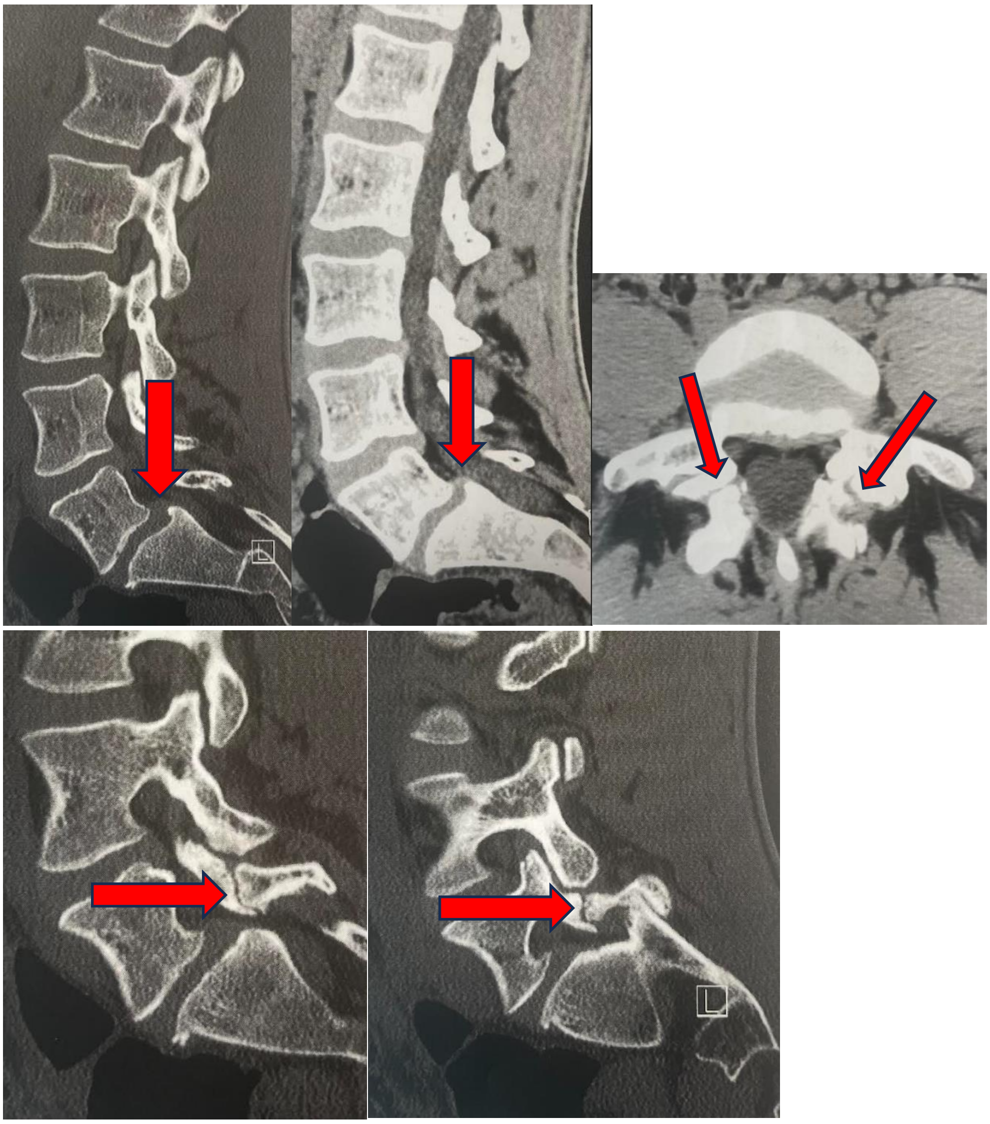


Fig 1. *Meyerding grade I anterolisthesis of L5 on S1 with bilateral isthmic lysis.* ***A-B****): sagittal reconstructions with algorithms for both bone and parenchyma documenting the listhesis of L5 on S1 (****arrows****);* ***C****): axial projection documenting bilateral isthmic lysis (****arrows****);* ***D-E****): sagittal reconstructions with algorithms for bone right (****D****) left (****E****) isthmic lysis (****arrows****).*

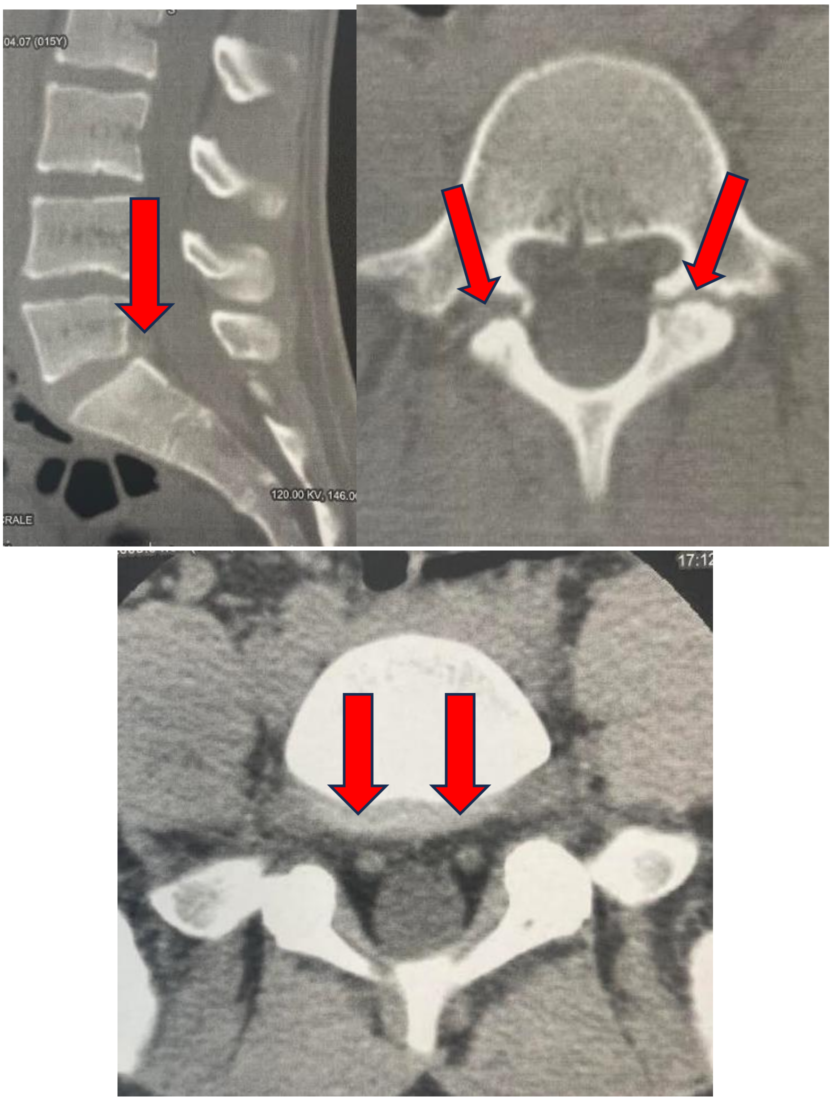


Fig 2. ***A***): *millimetric anterolisthesis of L5 on S1 (**arrows**);* ***B***): *bilateral isthmic lysis (**arrows**);* ***C***): *accompanying bilateral paramedian median protrusion (**arrows**).*

As indicated in scientific literature, the therapeutic action of the O_2-O_3 mixture (1-21) is well-established. Furthermore, several studies have also considered the therapeutic potential of ALA, PEA, and myrrh when administered orally in the management of pain (22-37).

ALA has been shown to reduce oxidative stress, thereby preventing damage from oxygen free radicals and providing thioctic acid with a broad spectrum of antioxidant activity (22-35). In contrast, PEA functions as a biological modulator that promotes the physiological response of tissues (36-39). MyrLiq® myrrh is a dry extract derived from the gummy resins of *Commiphora myrrha*, characterized by a high content of bioactive furanodienes, which are preserved through a patented extraction process that maintains the properties of the original raw material (40-42).

In the observational study, the authors present results from treating patients with low back pain and/or sciatica secondary to first-degree spondylolisthesis with associated spondylolysis, which may be responsible for the observed symptoms. The outcomes of CT-guided O_2-O_3 therapy were compared with those from a combined treatment regimen that involved O_2-O_3 therapy, along with oral administration of ALA, PEA, and myrrh over a 30-day period within a three-year cohort. Patients were evaluated long-term, six months post-treatment.

The research design aims to explore the integration of two therapeutic approaches. This association has begun to be studied (21), driven by the intention to optimize patient recovery through a combined approach that addresses immediate symptoms and underlying pathogenic factors.

Long-term observation of patients, six months post-treatment, allows for the assessment of not only the immediate efficacy of the combined therapy but also its sustainability over time. This research design intends to provide more detailed clinical evidence and better understand the mechanisms through which these substances can work synergistically, thus offering a more comprehensive framework for treating chronic pain related to spondylolisthesis and spondylolysis.

MATERIALS AND METHODS

In this observational study, we evaluated the therapeutic efficacy of treatment in patients with first-degree spondylolisthesis (antelisthesis less than 33%), bilateral isthmic lysis (Fig. 2 A-B-C), and associated disc pathology (herniated disc or protrusion). The treatment comprised oxygen-ozone therapy administered under CT guidance, combined with alpha lipoic acid (ALA), palmitoylethanolamide (PEA), and oral myrrh for 30 days in a cohort of patients.

Clinical evaluations were conducted using the Visual Analog Scale (VAS) questionnaire and the modified MacNab method both prior to treatment and six months post-therapy. We then compared the results of our treatment approach with those reported in the literature for cases that involved only CT-guided infiltrative treatment with oxygen-ozone therapy.

Infiltration technique

Following the acquisition of written informed consent from the participants, the appropriate injection level was determined based on comprehensive neuroradiological findings and the presenting clinical symptoms. This selected level was further confirmed through preliminary computed tomography (CT) scans conducted with the patient positioned in the prone stance, enabling accurate identification of the needle entry point.

Subsequently, the skin over the targeted site was meticulously disinfected with a polyvinylpyrrolidone iodine solution, after which local anesthesia was administered via ethyl chloride spray to ensure patient comfort during the procedure. A CT-guided puncture was then executed utilizing 22-gauge needles, with real-time CT guidance employed to verify the precise positioning of the needle within the anatomical structures (Fig. 3, 4).

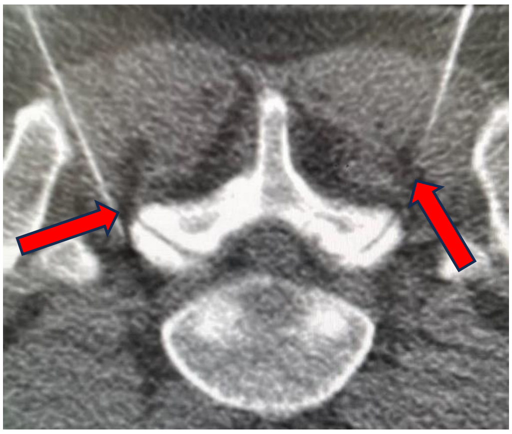


Fig 3. *CT scan check of correct needle placement (**arrows**).*

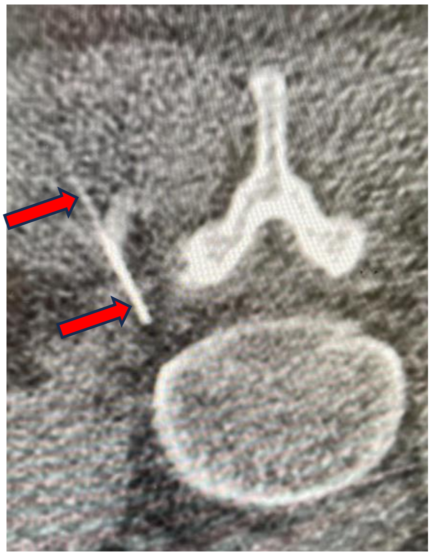


Fig 4. *CT scan check of correct needle placement (**arrows**).*

To uphold stringent aseptic standards, a 10 ml polyethylene syringe was prepared, containing a 3 ml oxygen-ozone gas mixture at 25 µg/ml concentration. This mixture was injected through a microporous filter to minimize any potential contamination risk during the procedure.

Following the infiltration, additional CT scans were performed to confirm the correct distribution of the gas mixture at the designated treatment site, ensuring that the therapeutic agent was adequately administered (Fig. 5, 6). Post-procedure, the patient was observed for approximately 30 minutes to monitor for any immediate adverse effects or complications, after which they were safely discharged.

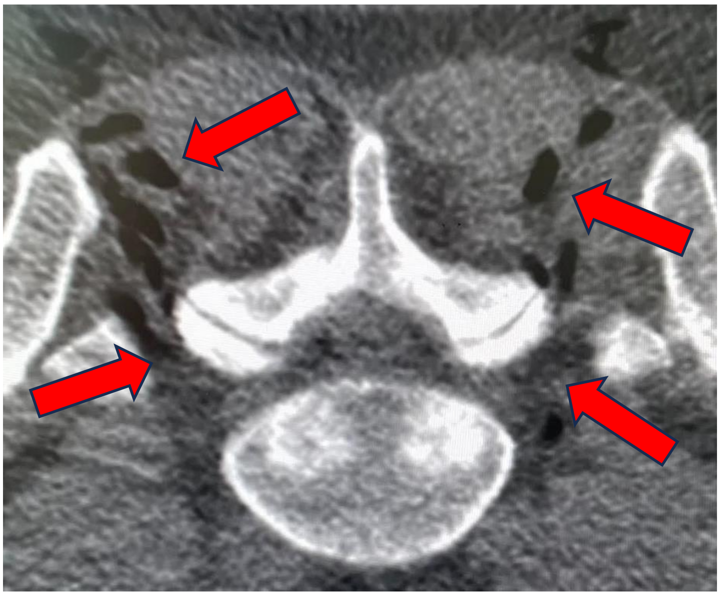


Fig 5. *Control of the gas mixture distribution at the foraminal level and in correspondence with the paravertebral muscles (**arrows**).*

The clinical outcomes in all patients were assessed through long-term follow-up over six months. This evaluation was conducted using a modified version of the McNab method (Table I). The Visual Analog Scale (VAS) questionnaire was utilized to quantify pain levels.

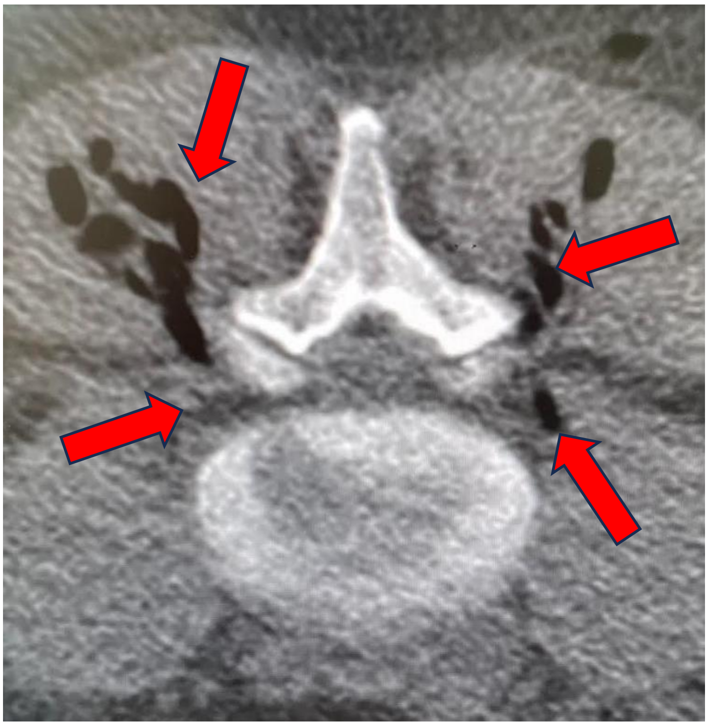


Fig 6. *Control the gas mixture distribution at the foraminal level and in correspondence with the paravertebral muscles (**arrows**).*

Table I. *Modified McNab method.*

Items	Explanation
a) Excellent	Resolution of pain and return to normal activities performed prior to the onset of pain.
b) Good or Satisfactory	Pain reduction greater than 50%.
c) Fair or Poor	Partial pain reduction of less than 50%.

RESULTS

Analysis of results

After therapy with local O_2-O_3 infiltrations and the use of ALA, PEA, and myrrh, as for the experience of pain measured by the VAS scale, the ratings before treatment ranged from 7 to 9, with a mean score of 8.47 (SD = 0.76), while after treatment the mean score was 2.48 (SD = 1.32). Only 38 patients (13.3%) reported no benefit, as indicated by VAS scores that were unchanged (Table II, III).

Table II. *VAS test results before treatment.*

Instrument Scale	*Mean Score (Standard Deviation)*	*Range Of Scores*
VAS	8.47 (0.76)	7-9

Table III. *VAS test results after treatment.*

Instrument Scale	*Mean Score (Standard Deviation)*	*Range Of Scores*
VAS	2.48 (1.32)	1-7

Using the modified Mac Nab method in the long term (clinical follow-up at 6 months), 185 patients (64.70%) continued to report an excellent clinical result obtained with the therapy, while 40 (13.95%) reported a satisfactory result, and 61 (21.35%) were patients who had not experienced substantial benefits (Table IV).

Table IV. *McNab test results after treatment.*

	O_2-O_3 treatment and ALA+PEA+Mirrh in 286 patients		
outcome	*excellent*	*good*	*poor*
at 6 months	185 (64.70%)	40 (13.95%)	61 (21.35%)

In particular, the control CT in patients who, in addition to listhesis, presented a herniated disc (84 patients, 29.33% of the total) documented a complete dehydration of the hernia in 50 patients (17.48 % of the total), obviously without any change in the degree of listhesis. After six months, we requested a neurosurgical evaluation of the situation, and in 17 cases (5.94%), the neurosurgeon-surgeon colleague opted for a spinal stabilization intervention, while in 40 cases (13.99%), the patients continued exclusively a rehabilitation program of physiokinesitherapy.

DISCUSSION

In this observational study, we compared the results obtained with the combined treatment of oxygen-ozone under CT guidance associated with oral treatment with ALA+PEA+myrrh in 286 patients monitored six months after the end of therapy using both the VAS questionnaire and the modified Mac Nab method and then compared the results obtained with those recommended in the literature with oxygen-ozone treatment alone.

In literature, at a six-month clinical follow-up, studies analyzing the association between O_2-O_3, ALA, PEA, and myrrh demonstrated effectiveness from an exclusively analgesic perspective in 58.3% (21) of the treated patients. Our study achieved a therapeutic success rate of 78.65%.

In this regard, we believe that intraforaminal ozone administration in CT-guided mode guarantees perfect control of the needle path. In this regard, the possibility of curative oxygen-ozone is high for the improvement of local circulation with eutrophication in the proximity of the nerve root, compressed and suffering from both muscle spasms. It can normalize the level of cytokines and prostaglandins with anti-inflammatory and analgesic action. It increases the production of superoxide dismutase (SOD) with minimization of oxidizing reagents (ROS). Finally, the proximity to the herniated/protruded material causes accelerated dehydration or destruction of non-vascularized tissue that justifies the good final result.

Therefore, confirming how the rapid resolution of pain without complications, the ease of execution of the method and the complete control of the infiltration by CT allow today to propose the technique of oxygen-ozone therapy guided by CT as a method of choice among conservative therapies in the treatment of first-degree spondylolisthesis with associated spondylolysis.

The association with a minimally invasive therapy such as oxygen-ozone therapy under CT and the oral administration of 800 mg/day of ALA + 600 mg/day of PEA + 200 mg of myrrh to these patients can be considered an excellent therapeutic solution capable of further improving the good final clinical result with better control of symptoms. Certainly, this result is attributable to the combined action of ALA+PEA+myrrh which consists in further and effectively alleviating neuropathic symptoms.

Based on the results we obtained in this observational study on a sample of 286 patients, we believe this additional therapeutic option can be offered to patients with Meyerding's first-degree listhesis. We also believe that to obtain a satisfactory clinical result, a multidisciplinary therapeutic approach to this problem is highly effective and that the support of the physiotherapist colleague is essential to plan a subsequent postural re-education intervention aimed at maintaining the acquired therapeutic result over time. In cases where the therapeutic result has been poor or unsatisfactory, in addition to the intervention of the physiatrist colleague, a neurosurgical reassessment of the situation is essential to decide whether or not a spinal stabilization intervention is necessary.

CONCLUSIONS

In consideration of the findings from our observational study involving 286 patients who were evaluated six months post-therapy, we analyzed the therapeutic outcomes associated with a treatment regimen that incorporated O_2-O_3 therapy administered under CT guidance, in conjunction with the oral supplementation of ALA, PEA and myrrh.

Subsequently, we performed a comparative analysis of our results with existing data in the literature pertaining to the efficacy of O_2-O_3 therapy as a standalone treatment.

Our investigation indicates that the combination of these oral adjuncts, i.e., ALA, PEA, and myrrh, yields a significant enhancement of the already favorable outcomes observed with O_2-O_3 therapy alone. Thus, we can conclude that this integrated approach not only maintains but also amplifies the therapeutic benefits of O_2-O_3 treatment in patients with the specified conditions.

REFERENCES

1. Iliakis E. Ozone treatment in low back pain. *Orthopaedics.* 1995; 19:29-33.
2. Gualandi G, Bonetti M. Ossigeno-ozonoterapia nel trattamento della patologia dolorosa del rachide lombare: esperienza preliminare. *Acta Toxic. Therap.* 1996 17, 2-3: 261-264.
3. Iliakis E, Valadakis V, Vynios DH, Tsiganos CP, Agapitos E. Rationalization of the Activity of Medical Ozone on Intervertebral Disc A Histological and Biochemical Study. *Rivista di Neuroradiologia*. 2001;14(1_suppl):23-30. doi:https://doi.org/10.1177/19714009010140s105
4. Andreula CF, Simonetti L, Santis FD, Agati R, Ricci R, Leonardi M. Minimally invasive oxygen-ozone therapy for lumbar disk herniation. *American Journal of Neuroradiology*. 2003;24(5):996-1000.
5. Muto M, Andreula C, Leonardi M. Treatment of herniated lumbar disc by intradiscal and intraforaminal oxygen-ozone (O2-O3) injection. *Journal of Neuroradiology*. 2004;31(3):183-189. doi:https://doi.org/10.1016/s0150-9861(04)96989-1
6. Bonetti M, Fontana A, Cotticelli B, Volta GD, Guindani M, Leonardi M. Intraforaminal O(2)-O(3) versus periradicular steroidal infiltrations in lower back pain: randomized controlled study. *AJNR American journal of neuroradiology*. 2005;26(5):996-1000.
7. Bonetti M, Cotticelli B, Raimondi G, Valdenassi L, Richelmi P, Bertè E. Ossigeno-ozono terapia vs infiltrazioni epidurali cortisoniche. *Rivista di Neuroradiologia*. 2000;13(2):203-206. doi:https://doi.org/10.1177/197140090001300207
8. Bonetti M, Fontana A, Albertini F. CT-guided oxygen-ozone treatment for first degree spondylolisthesis and spondylolysis. *Springer eBooks*. 2005;92:87-92. doi:https://doi.org/10.1007/3-211-27458-8_19
9. Pellicanò G, Martinelli F, Tavanti VK, et al. The italian oxygen-ozone therapy federation (FIO) study on oxygen-ozone treatment of herniated disc. In: *International Journal of Ozone Therapy*. ; 2008.
10. Oder B, Loewe M, Reisegger M, Lang W, Ilias W, Thurnher SA. CT-guided ozone/steroid therapy for the treatment of degenerative spinal disease--effect of age, gender, disc pathology and multi-segmental changes. *Neuroradiology*. 2008;50(9):777-785. doi:https://doi.org/10.1007/s00234-008-0398-2
11. Xu L, Li Z-L, He X-F, et al. Evaluation of the Clinical Curative Effect of an O_2-O_3 mixture to Treat Lumbar Disc Herniation with Different Treatment Sessions. *Interventional Neuroradiology*. 2009;15(2):159-163. doi:https://doi.org/10.1177/159101990901500204
12. Steppan J, Meaders T, Muto M, Murphy KJ. A metaanalysis of the effectiveness and safety of ozone treatments for herniated lumbar discs. *Journal of vascular and interventional radiology: JVIR*. 2010;21(4):534-548. doi:https://doi.org/10.1016/j.jvir.2009.12.393
13. Magalhaes FNDO, Dotta L, Sasse A, Teixera MJ, Fonoff ET. Ozone therapy as a treatment for low back pain secondary to herniated disc: a systematic review and meta-analysis of randomized controlled trials. *Pain Physician*. 2012;15(2):E115-129.
14. Zhang Y, Ma Y, Jiang J, Ding T, Wang J. Treatment of the lumbar disc herniation with intradiscal and intraforaminal injection

of oxygen-ozone. *Journal of Back and Musculoskeletal Rehabilitation*. 2013;26(3):317-322. doi:https://doi.org/10.3233/bmr-130386

15. Bonetti M, Zambello A, Leonardi M, Princiotta C. Herniated disks unchanged over time: Size reduced after oxygen–ozone therapy. *Interventional Neuroradiology*. 2016;22(4):466-472. doi:https://doi.org/10.1177/1591019916637356
16. Bonetti M, Ottaviani GM, Fontana A, Pellicanò G, Della Gatta L, Muto M. Diagnosis and subsequent treatment with oxygen-ozone therapy of baastrup's disease. *Eur J Musculoskel Dis* . 2020;9(2):49-54.
17. Bonetti M, Zambello A, Princiotta C, Pellicanò G, Della Gatta L, Muto M. Non-discogenic low back pain treated with oxygen-ozone: outcome in selected applications. *Journal of Biological Regulators and Homeostatic Agents*. 2020;34(4 Suppl. 1):21-30. SPECIAL ISSUE: OZONE THERAPY.
18. Rimeika G, Saba L, Arthimulam G, et al. Metanalysis on the effectiveness of low back pain treatment with oxygen-ozone mixture: Comparison between image-guided and non-image-guided injection techniques. *European Journal of Radiology Open*. 2021;8:100389. doi:https://doi.org/10.1016/j.ejro.2021.100389
19. Krahulik D, Vaverka M, Hrabalek L, et al. Periradicular corticosteroid infiltration for radicular pain - comparison of Diprophos and Depomedrone and ozone effects. *Biomedical Papers*. 2021;167(1). doi:https://doi.org/10.5507/bp.2021.061
20. Bonetti M, Bragaglio G, Guarino G, Marchina I, Ottaviani G, Moretti M. Calcific post-epidural steroid infiltration epiduritis, when and if to treat with ozone therapy. *Eur J Musculoskel Dis*. 2022;11(2).
21. Bonetti M, Frigerio M, Ottaviani GM, Pellicanò G, Muto M. The treatment with oxygen-ozone therapy of first degree spondylolisthesis secondary to spondylolysis. Observational study on 168 patients. *Journal of Orthopedics*. 2023;15(2):67-73.
22. Park S, Karunakaran U, Jeoung N, Jeon JH, Lee IK. Physiological Effect and Therapeutic Application of Alpha Lipoic Acid. *Current Medicinal Chemistry*. 2014;21(32):3636-3645. doi:https://doi.org/10.2174/0929867321666140706141806
23. Mijnhout GS, Kollen BJ, Alkhalaf A, Kleefstra N, Bilo HJG. Alpha Lipoic Acid for Symptomatic Peripheral Neuropathy in Patients with Diabetes: A Meta-Analysis of Randomized Controlled Trials. *International Journal of Endocrinology*. 2012;2012:1-8. doi:https://doi.org/10.1155/2012/456279
24. Nagamatsu M, Nickander KK, Schmelzer JD, et al. Lipoic Acid Improves Nerve Blood Flow, Reduces Oxidative Stress, and Improves Distal Nerve Conduction in Experimental Diabetic Neuropathy. *Diabetes Care*. 1995;18(8):1160-1167. doi:https://doi.org/10.2337/diacare.18.8.1160
25. Laher I, Fasipe B, Faria A. Potential For Novel Therapeutic Uses Of Alpha Lipoic Acid. *Current Medicinal Chemistry*. 2022;29(35). doi:https://doi.org/10.2174/0929867329666221006115329
26. Costantino M, Guaraldi C, Costantino D, De Grazia S, Unfer V. Peripheral neuropathy in obstetrics: efficacy and safety of α-lipoic acid supplementation. *European Review for Medical and Pharmacological Sciences*. 2014;18(18):2766-2771.
27. Vafa Rahimi-Movaghar. The Major Efficient Mechanisms of Ozone Therapy are Obtained in Intradiscal Procedures. *Pain Physician*. 2012;6;15(6;12):E1007-E1010. doi:https://doi.org/10.36076/ppj.2012/15/e1007
28. Lehnert T, Naguib NNN, Wutzler S, et al. Analysis of Disk Volume before and after CT-guided Intradiscal and Periganglionic Ozone–Oxygen Injection for the Treatment of Lumbar Disk Herniation. *Journal of Vascular and Interventional Radiology*. 2012;23(11):1430-1436. doi:https://doi.org/10.1016/j.jvir.2012.07.029
29. Splendiani A, Perri M, Conchiglia A, et al. MR Assessment of Lumbar Disk Herniation Treated with Oxygen-Ozone Diskolysis: The Role of DWI and Related ADC versus Intervertebral Disk Volumetric Analysis for Detecting Treatment Response. *The Neuroradiology Journal*. 2013;26(3):347-356. doi:https://doi.org/10.1177/197140091302600316
30. Gallucci M, Limbucci N, Zugaro L, et al. Sciatica: treatment with intradiscal and intraforaminal injections of steroid and oxygen-ozone versus steroid only. *Radiology*. 2007;242(3):907-913. doi:https://doi.org/10.1148/radiol.2423051934
31. Perri M, Grattacaso G, Di Tunno V, et al. MRI DWI/ADC signal predicts shrinkage of lumbar disc herniation after O2–O3 discolysis. *The Neuroradiology Journal*. 2015;28(2):198-204. doi:https://doi.org/10.1177/1971400915576658
32. Leonardi M, Simonetti L, Barbara C. Effetti dell'ozono sul nucleo polposo: Reperti anatomo-patologici su un caso operato. *Rivista di Neuroradiologia*. 2001;14(1_suppl):57-59. doi:https://doi.org/10.1177/19714009010140s113
33. Leonardi M, Andreula C, Simonetti L. Percutaneous techniques for treating disc disease. *Functional Neurology*. 2003;18:242-244.
34. Leonardi M, Simonetti L, Raffi L, Cenni P, Barbara C. Mini-Invasive Treatment of Herniated Disc by Oxygen-Ozone Injection. *Interventional Neuroradiology*. 2003;9(2_suppl):75-75. doi:https://doi.org/10.1177/15910199030090s211
35. Dall'Olio M, Princiotta C, Cirillo L, et al. Oxygen-Ozone Therapy for Herniated Lumbar Disc in Patients with Subacute Partial Motor Weakness Due to Nerve Root Compression. *Interventional Neuroradiology*. 2014;20(5):547-554. doi:https://doi.org/10.15274/inr-2014-10078
36. Gatti A, Lazzari M, Gianfelice V, Di Paolo A, Sabato E, Sabato AF. Palmitoylethanolamide in the treatment of chronic pain caused by different etiopathogenesis. *Pain Medicine (Malden, Mass)*. 2012;13(9):1121-1130. doi:https://doi.org/10.1111/j.1526-4637.2012.01432.x
37. Paladini A, Fusco M, Cenacchi T, Schievano C, Piroli A, Varrassi G. Palmitoylethanolamide, a Special Food for Medical Purposes, in the Treatment of Chronic Pain: A Pooled Data Meta-analysis. *Pain Physician*. 2016;19(2):11-24.
38. Gabrielsson L, Mattsson S, Fowler CJ. Palmitoylethanolamide for the treatment of pain: pharmacokinetics, safety and efficacy. *British Journal of Clinical Pharmacology*. 2016;82(4):932-942. doi:https://doi.org/10.1111/bcp.13020
39. Artukoglu BB, Beyer C, Zuloff-Shani A, Brener E, Bloch MH. Efficacy of Palmitoylethanolamide for Pain: A Meta-

Analysis. *Pain Physician*. 2017;20(5):353-362.

40. Nomicos EYH. Myrrh: medical marvel or myth of the magi? *Holistic Nursing Practice*. 2007;21(6):308-323. doi:https://doi.org/10.1097/01.hnp.0000298616.32846.34
41. Shedoeva A, Leavesley D, Upton Z, Fan C. Wound Healing and the Use of Medicinal Plants. *Evidence-Based Complementary and Alternative Medicine*. 2019;2019:1-30. doi:https://doi.org/10.1155/2019/2684108
42. Batiha GES, Wasef L, Teibo JO, et al. Commiphora myrrh: a phytochemical and pharmacological update. *Naunyn-Schmiedeberg's Archives of Pharmacology*. 2022;396(3):405-420. doi:https://doi.org/10.1007/s00210-022-02325-0

Comparative Study

MODIFIED TRANDELTOID APPROACH *VS* THE DELTOPECTORAL APPROACH. A COMPARATIVE STUDY IN FRACTURES OF THE PROXIMAL HUMERUS

O. De Carolis[1], A. Benedetto[2], A. De Felice[1], V. Belviso[1], A. Pulcrano[2] and G. Solarino[2]

[1]Orthopaedic and Traumatology Unit, San Giacomo Hospital, Monopoli (Ba), Italy;
[2]Department of Translational Biomedicine and Neuroscience "DiBraiN", School of Medicine and Surgery, University of Bari, Orthopaedic and Traumatology Unit, AOU General Hospital of Bari, Bari, Italy

Correspondence to:
Andrea De Felice, MD
Orthopaedic and Traumatology Unit,
San Giacomo Hospital,
Largo Veneziani, 21,
70043 Monopoli (Ba), Italy
Email: andrea.defelice@asl.bari.it

ABSTRACT

Proximal humerus fractures often require open reduction and internal fixation using plates and screws. This study compares the deltopectoral approach (DP) and the modified transdeltoid approach (MDS) in 54 patients, evaluating clinical and radiographic outcomes, operative time, and complications. Clinical outcomes, assessed with the Constant-Murley Score and VAS scale, were comparable between the two approaches at 1, 3, and 6 months. Postoperative pain improved progressively, with no significant differences between groups. However, operative time was significantly shorter for the MDS group (65 ± 5 minutes) compared to the DP group (92 ± 4.3 minutes). Complications, such as malunion, avascular necrosis, and screw penetration, were minimal and showed no significant differences between approaches. Importantly, no neurovascular injuries were observed in any patients. In conclusion, DP and MDS approaches are safe and effective for treating proximal humerus fractures. The MDS provides a notable advantage in reduced operative time, making it a valuable alternative, particularly for fractures involving the posterior humerus. The choice of approach should consider fracture type and surgeon experience. Further research is needed to validate these findings.

KEYWORDS: *shoulder, deltoid-splitting approach, proximal humerus fracture, traumatology, deltopectoral approach*

INTRODUCTION

Proximal humerus fractures represent one of the most challenging injuries to manage in skeletal trauma, being the third most common fracture and accounting for approximately 4-10% of all fractures (1). The incidence, ranging between 31 and 250 cases per 100,000 inhabitants per year, steadily increases due to population aging. This type of fracture predominantly affects individuals over 60 years of age, with a female-to-male ratio of 4:1 in older women, often associated with osteoporosis. Conversely, high-energy fractures are more frequent in younger individuals and typically require more complex surgical treatments (2).

The treatment of proximal humerus fractures, particularly those involving the epiphysis or metaepiphysis, commonly relies on open reduction and internal fixation with plates and screws, although in some cases, especially in older patients with lower functional demands, the external fixation (3) or the reverse shoulder arthroplasty can be used

Received: 2 August 2024
Accepted: 15 September 2024

(4). Among the most widely used surgical options is the deltopectoral (DP) approach, which allows for extensive exposure of the anterior and lateral regions of the shoulder. However, this approach requires significant soft tissue dissection and muscle retraction to achieve adequate visualization, increasing the risk of devascularization of fracture fragments, particularly the humeral head. Furthermore, the DP approach does not provide direct visualization of the posterolateral portion of the humeral head, making it challenging to reduce large retracted fragments, such as the greater tuberosity, especially in muscular patients.

An alternative to the DP approach is the deltoid-splitting (DS) approach, which provides 270° exposure of the proximal humerus with less extensive soft tissue dissection. However, the traditional use of the DS approach has been limited by the perceived risk of injury to the anterior branch of the axillary nerve, particularly when distal extension of the split is required for plate placement. To overcome these limitations, a modified transdeltoid (MDS) approach has been developed, combining the advantages of the DS approach with greater safety for the axillary nerve, minimizing excessive retraction and preserving neurovascular integrity.

Classification and preoperative planning play a crucial role in the surgical management of these fractures. Standard radiographic methods are essential for initial assessment, but computed tomography (CT) with 3D reconstruction provides indispensable details for identifying fracture morphology and planning the intervention. Among the most commonly used classifications are the Neer classification (5), based on fragment displacement, and the Hertel classification (6), which integrates anatomical and vascular criteria, offering a more detailed understanding of fractures and their associated risks.

This study aims to compare the clinical and radiographic outcomes of patients undergoing surgical intervention using the MDS and the DP approaches. By analyzing intraoperative parameters, such as surgical time and complications, as well as clinical and radiological follow-ups at 1, 3, and 6 months, this study seeks to evaluate which approach ensures better results in terms of efficacy, safety, and preservation of shoulder function.

MATERIALS AND METHODS

The study included patients treated at the Orthopedics and Traumatology Units of the Policlinico di Bari and San Giacomo Hospital in Monopoli (BA) between November 2022 and March 2024.

Study design and patient selection

A total of 92 patients underwent surgical treatment for proximal humerus fractures with open reduction and internal fixation (ORIF) using PHILOS plates (Synthes Medical). Of these, 20 patients were excluded due to the absence of preoperative CT scans required for radiological classification. The remaining 72 patients had proximal humerus fractures classified as Neer type 3-4 (tuberosity displacement > 5 mm and humeral head angulation > 45°) by an experienced senior musculoskeletal radiologist.

Exclusion criteria included:

- absence of a preoperative CT scan;
- dislocations or open fractures;
- psychiatric disorders;
- associated injuries to the ipsilateral upper limb;
- comorbidities preventing surgery;
- polytrauma cases.

A total of 54 patients met the inclusion criteria and were enrolled after providing informed consent. Patients treated at the San Giacomo Hospital were operated on using the MDS approach, while those treated at the Policlinico di Bari underwent surgery using the DP approach. All surgeries were performed by two senior surgeons (DO and VG) specializing in upper limb trauma.

Study objectives

The primary objective was to evaluate whether one surgical approach provides superior clinical and radiographic outcomes by analyzing follow-up results at 1, 3, and 6 months.

The secondary objectives included:

1. comparing the operative time between the MDS and DP approaches;
2. analyzing postoperative hospital stays to determine differences in recovery time;
3. assessing postoperative pain levels using the Visual Analog Scale (VAS);

4. comparing functional recovery times using standardized scales, including the Constant-Murley Shoulder Score (7) and QuickDASH (8);
5. evaluating the incidence of reoperations in both groups.

Clinical protocol

Postoperative follow-ups were conducted at 1, 3, and 6 months. In some patients, the B-STEP protocol for the follow-up was used (9). The following evaluation tools were used:

- Constant-Murley Shoulder Score to assess shoulder function;
- Quick DASH to evaluate disability;
- VAS to measure pain intensity.

Complications such as infections, instability, and nerve injuries were recorded. Muscle strength in abduction was tested by measuring maximum resistance. Functional outcomes were classified based on the difference in Constant scores between the operated and contralateral shoulder:

- excellent: <11
- good: 11–20
- fair: 21–30
- poor: >30

Radiographic protocol

Radiographic assessments were performed preoperatively and at follow-ups using standard anteroposterior, transthoracic, and CT imaging. Postoperative radiographs evaluated malunion [defined using Beredjiklian criteria (10)] and other complications. Follow-up radiographs included anteroposterior views in neutral, internal, and external rotation.

Rehabilitation protocol

Post-surgery, all patients followed a standardized rehabilitation program. Pendulum exercises were initiated immediately after surgery, followed by supervised progressive range-of-motion and muscle-strengthening exercises, mainly targeting the deltoid muscle. Lifting heavy weights was discouraged during the recovery period. Periodic clinical and radiographic evaluations were conducted at 1, 3, and 6 months.

Statistical analysis

Descriptive statistics were used to summarize patient demographics and clinical data. Mean and standard deviation were calculated for continuous variables. The Student’s t-test was used to compare pre- and postoperative outcomes, with a statistical significance of $p<0.05$. Mean values for Constant-Murley, Quick DASH, VAS, and range of motion were rounded to two decimal places.

The results of this integrated protocol provided a comprehensive analysis of the comparative efficacy of the MDS and DP approaches for the surgical treatment of proximal humerus fractures.

DELTOPECTORAL APPROACH

The deltopectoral approach is widely used for open reduction and internal fixation of proximal humerus fractures. The incision, typically 10-12 cm long, extends from the coracoid process toward the humeral insertion of the deltoid, parallel to the deltoid muscle along the deltopectoral groove. The groove can be located by marking the skin to identify the "valley" of the interval. However, this incision crosses Langer's skin tension lines obliquely, potentially resulting in wider scar formation and less favorable cosmetic outcomes.

The richly vascularized subcutaneous adipose tissue can be exposed by retracting the pectoralis major medially and the deltoid laterally. A fat triangle in the proximal part of the dissection, extending obliquely across the incision, identifies the cephalic vein, which should be preserved to minimize postoperative arm edema. Preferably, the dissection is performed medially to the vein, with fewer branches than the lateral side.

The deltoid and pectoralis muscles are bluntly dissected to expose the clavipectoral fascia, which is incised laterally to the conjoint tendon and inferior to the coracoacromial ligament. Subacromial and subdeltoid spaces are carefully opened with adequate hemostasis to prevent excessive bleeding. Care is required to avoid injury to the posterior circumflex humeral artery during subdeltoid dissection. The subacromial bursa must be removed to visualize the rotator cuff adequately.

Visualization of the fracture

Lateral retraction of the deltoid with a modified Hohmann retractor and medial retraction of the conjoint tendon with a Langenbeck retractor allows visualization of the fractured humeral head. Particular attention is needed to protect the musculocutaneous nerve, which enters the coracobrachialis approximately 2.5 cm distal to the coracoid process. Excessive retraction under the conjoint tendon may cause neuropraxia of the nerve.

Abduction of the shoulder facilitates lateral exposure by reducing deltoid tension. Exposure can be improved if needed by partially releasing the deltoid or pectoralis major insertions.

Fracture reduction and fixation

Temporary reduction of the fracture is achieved by placing traction sutures on the osteotendinous junctions of the subscapularis, supraspinatus, and infraspinatus tendons. Kirschner wires may be temporarily used to maintain reduction. Once satisfactory reduction is achieved, the plate is placed along the lateral surface of the proximal humerus, aligned with the humeral shaft and lateral to the bicipital groove, ensuring proper alignment with the greater tuberosity.

This approach provides excellent exposure for managing complex fractures while requiring careful attention to neurovascular structures and the subacromial region.

MODIFIED TRANS-DELTOID APPROACH

The modified transdeltoid approach provides a minimally invasive alternative for open reduction and internal fixation of proximal humerus fractures. An 8 cm incision is made along the palpable anterolateral edge of the acromion, extending distally in line with the deltoid fibers.

Exposure and visualization

Once the proximal fibers of the deltoid muscle are exposed, the anterior, lateral, and posterior portions of the deltoid are identified. The fibrous raphe between the anterior and middle heads is divided along the fibers, creating a proximal window for visualizing the lateral wall of the humerus. The lateral portion of the deltoid displays an oblique orientation, running craniocaudally from posterior to anterior. Blunt dissection along the lateral and posterior heads of the deltoid creates a distal window, allowing visualization of the proximal metadiaphysis of the humerus.

For the proximal window, Hohmann retractors are placed anteriorly and posteriorly to the proximal humeral epiphysis, retracting the anterior and middle heads of the deltoid, respectively. Retractors separate the middle and posterior deltoid heads for the distal window, enabling access to the humeral diaphysis (Fig. 1).

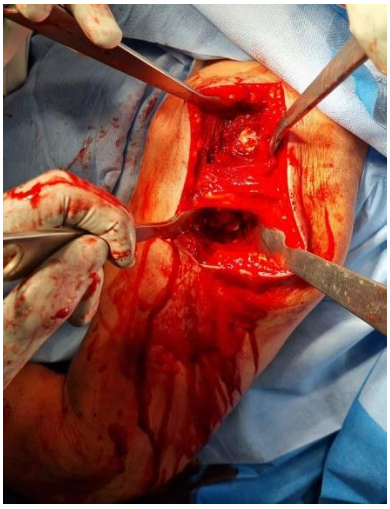


Fig. 1. *Development of the proximal and distal window.*

Fracture reduction and fixation

Through the proximal window, manipulation of the humeral head and reduction of the associated fracture is performed. Traction sutures are placed at the osteotendinous junctions of the subscapularis, supraspinatus, and infraspinatus tendons to reduce multi-part fractures. In cases of cancellous bone loss, artificial bone substitutes may be used.

Temporary Kirschner wires can be inserted to maintain fracture reduction without interfering with plate placement. The plate is slid through the proximal window along the bone plane, deep to the lateral deltoid head, and positioned on the lateral surface of the humerus. Proper alignment along the humeral shaft, the bicipital groove, and the apex of the greater tuberosity is confirmed.

Through the distal window, the reduction of metadiaphyseal fractures or placement of a clamp for humeral neck fracture management is achieved. The distal window also facilitates direct visualization of plate positioning along the humeral axis (Fig. 2).

Fig. 2. *Placement of the plate.*

Neurovascular safety

This approach avoids isolating the neurovascular bundle (NVB), including the anterior branch of the axillary nerve and the posterior circumflex humeral artery. The NVB is protected throughout by the lateral head of the deltoid.

Cranial mobilization of the lateral deltoid head enables the placement of screws in the calcar region of the humerus, providing secure fixation. This approach offers effective exposure for fracture management while minimizing soft tissue dissection and reducing the risk of neurovascular injury.

RESULTS

All 54 patients completed the follow-up at 1, 3, and 6 months, allowing for a comprehensive analysis of demographic, clinical, functional, and surgical outcomes.

Demographic and clinical data

The mean age was comparable between the two groups (65.71 ± 10.29 years for the DP group vs. 65.27 ± 9.59 years for the MDS group, p = 0.92), indicating that age did not significantly influence the outcomes. A significant difference was observed in gender distribution (p = 0.00002), with a slightly higher percentage of males in the DP group (44.8%) compared to the MDS group (40.7%). However, this difference did not appear to affect the primary clinical outcomes (Table I).

Table I. *Preoperative details of the analyzed samples.*

Patient details	Group DP (n=28)	Group MDS (n=26)	p-value
Age	65.71 ± 10.29	65.27 ± 9.59	0.92
Gender			0.00002
Male (%)	13 (44.8%)	11 (40.7%)	
Female (%)	15 (51.7%)	15 (55.6%)	
Neer's Classification			0.694
3 fragments	51.7%	51.9%	
4 fragments	44.8%	44.4%	
Side			0.00002
Right	55.2%	59.3%	
Left	41.4%	37.0%	
Days between fracture and surgery	3.25 ± 1.43	2.35 ± 1.90	0.052
Comorbidities	1.5	1.7	0.617

Outcomes

Tables II and III report results at 1- and 3-month follow-ups, whereas Table IV reports results at 6-month follow-ups.

Table II. *One-month follow-up.*

Outcome	Group DP	Group MDS	p-value
Relative Constant-Murley Score	22.28 ± 2.23	21.98 ± 2.20	0.8231
Internal Rotation	2.42 ± 0.24	2.48 ± 0.25	0.6784
External Rotation	2.46 ± 0.25	2.51 ± 0.25	0.7712
Strength Recovery (%)	21.33	21.00	N/A
Abduction	2.57 ± 0.26	2.58 ± 0.26	0.9546

Table III. *Three-month follow-up.*

Outcome	Group DP	Group MDS	p-value
Relative Constant-Murley Score	52.00 ± 5.20	51.28 ± 5.13	0.8341
Internal Rotation	5.63 ± 0.56	5.80 ± 0.58	0.6235
External Rotation	5.74 ± 0.57	5.87 ± 0.59	0.7632
Strength Recovery (%)	49.77	49.00	N/A
Abduction	5.99 ± 0.60	6.03 ± 0.60	0.9071

Postoperative complications

Postoperative complications were similar across the two groups. Major complications such as malunion, screw penetration, and avascular necrosis (AVN) showed no statistically significant differences ($p = 1.0$). Notably, no cases of axillary nerve paralysis or stupor were observed, addressing a common concern with the transdeltoid approach. These findings suggest that both techniques carry a low risk of complications.

Operative time

A significant difference was observed in operative time between the two approaches. The DP approach required a mean duration of 92 ± 4.3 minutes, while the MDS approach averaged 65 ± 5 minutes ($p < 0.05$). This demonstrates that the MDS technique is significantly faster without compromising functional or radiographic outcomes.

Pain assessment (VAS)

Pain levels, assessed using the Visual Analog Scale (VAS), showed progressive improvement in both groups over the follow-up period. At 1 month, mean VAS scores were 6.2 ± 0.6 for DP and 6.5 ± 0.7 for MDS ($p = 0.4572$), with no significant difference. By 6 months, pain levels were minimal, with VAS scores of 1.0 ± 0.3 for DP and 1.1 ± 0.4 for MDS ($p = 0.5913$), indicating comparable clinical outcomes in pain control (Table IV).

Table IV. *Final results of the study at 6 months.*

Outcome	Group DP	Group MDS	p-value
Relative Constant-Murley Score (mean ± S.D.)	74.27 ± 8.19	73.26 ± 8.02	0.8227
Degree of Functional Outcome			
	9	11	
Excellent	7	6	
Good	8	7	
Fair	4	2	
Poor	8.05 ± 0.95	8.28 ± 1.23	0.6428
Internal Rotation (mean ± S.D.)	8.2 ± 1.03	8.38 ± 0.9	0.7433
External Rotation (mean ± S.D.)	71.1	70.0	
Strength Recovery (%)	8.55 ± 1.19	8.61 ± 1.03	0.9132
Abduction (mean ± S.D.)			
	1	0	1
Malunion	0	1	1
Screw Penetration	1	1	1
AVN	92 ± 4.3	65 ± 5	significativa

Summary of results

Both the deltopectoral and modified trans-deltoid approaches provided similar functional and radiographic outcomes with low complication rates. The MDS approach demonstrated a significant advantage in operative time, making it a more efficient alternative without compromising patient safety or long-term results. These findings support the efficacy and safety of both techniques while highlighting the time-saving benefit of the MDS approach (Table V, Fig. 3).

Table V. *VAS evaluation.*

Follow-up	DP (mean VAS±SD)	MDS (mean VAS±SD)	p-value
1 month	6.2 ± 0.6	6.5 ± 0.7	0.4572
3 months	3.4 ± 0.5	3.6 ± 0.6	0.6087
6 months	1.0 ± 0.3	1.1 ± 0.4	0.5913

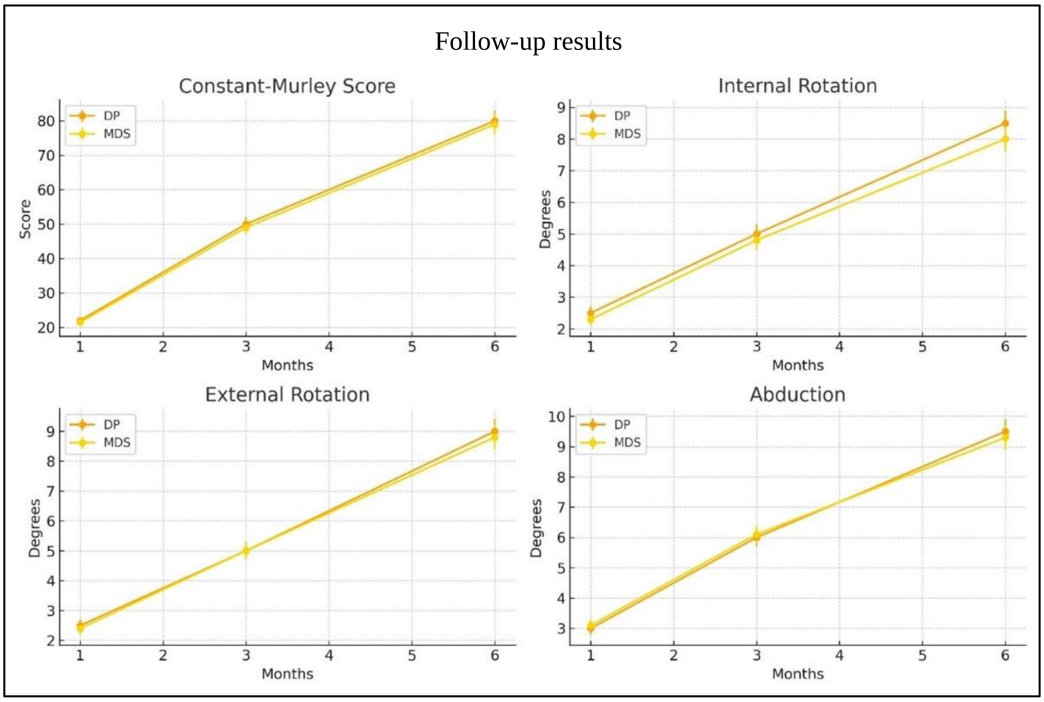


Fig. 3. *Clinical parameters compared.*

DISCUSSION

The DP approach has historically been the most commonly used technique for the treatment of proximal humerus fractures. However, its limited exposure can reduce posterior fragments, particularly the greater tuberosity (GT), which is challenging. In such cases, significant retraction of the deltoid is often required to access the posterolateral region of the proximal humeral epiphysis. The MDS approach was developed to address these limitations as a viable alternative for managing complex fractures.

The MDS approach provides direct exposure to the lateral surface of the humeral head, enabling 270° visualization while minimizing periosteal stripping and facilitating the reduction of the posterior GT fragment. Mobilization of the middle deltoid bundle allows direct access to the fracture lines, and the use of a wide-tipped Cocker clamp permits indirect elevation of the humeral head and temporary fixation with a Kirschner wire in the correct position relative to the glenoid. Hohmann retractors placed between the anterior and middle deltoid heads further assist in the reduction of the tuberosities. The plate is advanced along the lateral cortical surface of the proximal humeral metaphysis without compromising the neurovascular bundle during placement.

One technical issue encountered with the MDS approach is that the holes for the calcar and central screws in the plate are often obscured by the middle deltoid bundle. Mobilizing this bundle allows access to these holes without risking injury to the axillary nerve. Despite these technical peculiarities, our findings demonstrate that the MDS and DP approaches yield comparable functional outcomes and pain relief.

Follow-up data at 1, 3, and 6 months showed similar clinical results between the two groups, as measured by the Constant-Murley Score and the VAS. Both techniques proved to be safe and effective, with a minimal incidence of complications. Cases of malunion and avascular necrosis (AVN) requiring reoperations with reverse shoulder arthroplasty were exclusively observed in patients with four-part fractures, a type already associated with higher complication rates according to Neer's classification.

From a practical standpoint, each approach offers distinct advantages depending on the fracture’s location. The DP approach is preferable for anterior fracture-dislocations of the proximal humerus, providing superior visualization of the anterior aspect of the humeral head. Conversely, the MDS approach is better suited for fractures involving the posterior portion of the proximal humerus, enabling direct management of the posterior GT fragment, which is challenging to address with the DP approach.

Further studies are needed to evaluate whether implant removal following the MDS approach may present challenges. The dissection of the axillary nerve through scar tissue could prove difficult, potentially complicating implant removal.

Another critical distinction between the two approaches is operative time. The MDS approach allows for a faster procedure due to direct visualization of the fracture and more intuitive reduction maneuvers, requiring less fluoroscopy. This reduction in operative time may translate into lower surgical stress and reduced patient anesthesia duration (Fig. 4).

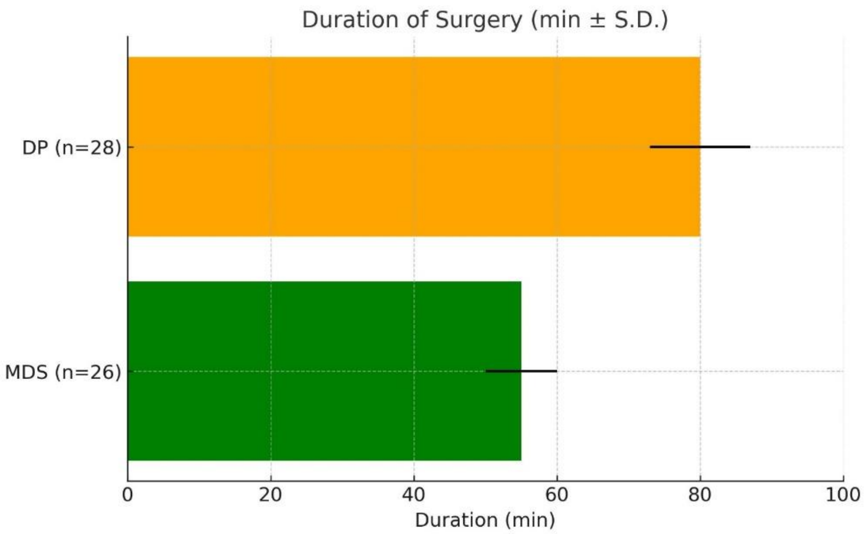


Fig. 4. *Intervention duration compared.*

Despite the strengths of our study, its retrospective design and relatively small sample size represent limitations. Nonetheless, it includes patients with complex four-part fractures as per Neer's classification, documenting the effectiveness of plate and screw fixation for these challenging injuries when performed by experienced surgeons.

In conclusion, both approaches are valid options for the surgical treatment of proximal humerus fractures. The choice of surgical approach, type of fixation, or materials (11) should be tailored to the specific fracture configuration and the surgeon's expertise. The MDS approach provides distinct advantages for posterior fractures and offers significant time efficiency without compromising safety or clinical outcomes.

REFERENCES

1. Court-Brown CM, Garg A, McQueen MM. The epidemiology of proximal humeral fractures. *Acta Orthopaedica Scandinavica*. 2001;72(4):365-371. doi:https://doi.org/10.1080/000164701753542023
2. Iglesias-Rodríguez S, Domínguez-Prado DM, García-Reza A, et al. Epidemiology of proximal humerus fractures. *Journal of Orthopaedic Surgery and Research*. 2021;16(1). doi:https://doi.org/10.1186/s13018-021-02551-x
3. Vicenti G, Antonella A, Filipponi M, et al. A comparative retrospective study of locking plate fixation versus a dedicated external fixator of 3- and 4-part proximal humerus fractures: Results after 5 years. *Injury*. 2019;50:S80-S88. doi:https://doi.org/10.1016/j.injury.2019.01.051
4. Maccagnano G, Solarino G, Pesce V, et al. Plate *vs* reverse shoulder arthroplasty for proximal humeral fractures: The psychological health influence the choice of device?. *World Journal of Orthopedics*. 2022;13(3):297-306. doi:https://doi.org/10.5312/wjo.v13.i3.297
5. Neer Cs nd. Displaced proximal humeral fractures. Part I. Classification and evaluation. By Charles S. Neer, I, 1970. *JBJS*. 1987;52(223):3-10.
6. Hertel R, Hempfing A, Stiehler M, Leunig M. Predictors of humeral head ischemia after intracapsular proximal humerus fracture. *Journal of Shoulder and Elbow Surgery*. 2004;13(4):427-433. doi:https://doi.org/10.1016/j.jse.2004.01.034
7. Vrotsou K, Ávila M, Machón M, et al. Constant–Murley Score: a systematic review and standardized evaluation in different shoulder pathologies. *Quality of Life Research*. 2018;27(9):2217-2226. doi:https://doi.org/10.1007/s11136-018-1875-7
8. Angst F, Schwyzer HK, Aeschlimann A, Simmen BR, Goldhahn J. Measures of adult shoulder function: Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) and Its Short Version (QuickDASH), Shoulder Pain and Disability Index (SPADI), American Shoulder and Elbow Surgeons (ASES) Society Standardized Shoulder. *Arthritis Care & Research*. 2011;63(S11):S174-S188. doi:https://doi.org/10.1002/acr.20630
9. Moretti L, Bizzoca D, Farì G, et al. Bari Shoulder Telemedicine Examination Protocol (B-STEP): A Standard Protocol for Personalized Remote Shoulder Examination. *Journal of Personalized Medicine*. 2023;13(7):1159-1159.

doi:https://doi.org/10.3390/jpm13071159

10. Beredjiklian PK, Hotchkiss RN, Athanasian EA, Ramsey ML, Katz MA. Recalcitrant Nonunion of the Distal Humerus. *Clinical orthopaedics and related research*. 2005;&NA;(435):134-139. doi:https://doi.org/10.1097/01.blo.0000157928.20381.46
11. Ceddia M, Solarino G, Tucci M, Lamberti L, Trentadue B. Stress Analysis of Tibial Bone Using Three Different Materials for Bone Fixation Plates. *Journal of Composites Science*. 2024;8(9):334-334. doi:https://doi.org/10.3390/jcs8090334

Case Report

REVISION WITH PROXIMAL TUBE REALIGNMENT SURGERY AND SOFT-TISSUE REBALANCING IS A VIABLE OPTION FOR PATELLAR INSTABILITY AFTER TOTAL KNEE REPLACEMENT IN SELECTED CASES

G. De Giosa*, F. D. Cannito, G. Giannini, C. Buono, S. Urga and G. Solarino

School of Medicine University of Bari "Aldo Moro", AOU General Hospital, Department of Translational Biomedicine and Neuroscience "DiBraiN" Neuroscience and Sense Organs, Orthopaedic & Trauma Unit, Bari, Italy

**Correspondence to*:
Giuseppe De Giosa, MD
School of Medicine,
University of Bari "Aldo Moro"
AOU General Hospital,
Department of Translational Biomedicine and Neuroscience, "DiBraiN"
Orthopaedic & Trauma Unit Policlinico
Piazza Giulio Cesare 11
Bari 70124, Italy
e-mail: degiosa_giuseppe@libero.it

ABSTRACT

Patellar instability is a complication after total knee replacement and a clear causative factor for patients' dissatisfaction. With modern implants, the design of the components does not appear to be a causative factor, as it can often be due to technical surgical errors such as the mispositioning of the components (mostly in internal rotation). To treat patellar instability and restore the proper geometry and biomechanics of the replaced knee, we performed the proximal "tube" realignment of the patella, as described by Insall. Preoperatively, knees were studied for any malrotation with CT, according to Berger's protocol. Satisfactory clinical outcomes were recorded, with no recurrence at the last follow-up, with the technique described and the use of a dome-shaped patellar component that can be forgiving for stability despite its propensity for increased contact stress.

KEYWORDS: *patellofemoral instability, TKA, arthroplasty, knee biomechanics, Insall, proximal realignment, TT-TG angle*

INTRODUCTION

Patellofemoral (PF) instability after total knee arthroplasty (TKA) has been reported in up to 20% of TKAs. Most often, it is caused by technical errors during surgery. Given the complexity of TKA biomechanics, several technical parameters are susceptible to error. Therefore, in most cases, PF instability cannot be traced back to a single cause. More likely, multiple contributors play a role (1, 2).

The major risk factors of PF instability after TKA are the following:

1. excessive preoperative valgus alignment;
2. individual components mispositioning;

Received: 13 August 2024
Accepted: 18 September 2024

3. improper patella preparation for prosthetic substitution;
4. soft-tissue imbalance.

Excessive preoperative valgus alignment leads to a mismatch of the trochlear groove and the extensor vector of the leg, the fact that encumbers proper patellar tracking and may cause the patella to tilt, subluxate, or even dislocate. A similar mechanism takes effect when a normal Q-angle is not restored. Especially patients with severe preoperative valgus or external rotational deformity, preoperative mal tracking, and loss of bone stock in the distal lateral condyle are at risk. In patients with pronounced preoperative valgus, the main culprit for this predisposition is usually the retraction of the lateral retinaculum.

Beyond the overall leg alignment, individual component positioning is the most important contributor. Internal rotation of the femoral or the tibial component, medialization of the femoral component and incorrect placement of the patellar component appear the most obvious. An internally rotated femoral component shifts the trochlear groove medially, thus increasing the distance to the patella, which tracks laterally relative to the femur. Through the tension exerted by the lateral retinaculum, the patella is pulled sideways. This may lead to patellar tilt, subluxation, or even dislocation. On the other hand, an internally rotated tibial component causes the tibia to rotate externally during knee flexion. This drives the tibial tubercle laterally, which increases the Q-angle and thus leads to lateral tracking. Depending on the severity, this may again lead to patellar tilt, subluxation, or dislocation (1, 3).

Placement of the prosthetic patella also plays a decisive role in determining PF stability. A patellar button that is too far laterally placed will increase the tension in the lateral retinaculum. This, in turn, can displace the center of the patella medially and thus lead to a lateral pull and subsequent lateral tracking with the known consequences (3, 4).

Resection of more bone from the medial facet is necessary to obtain a symmetric patellar cut parallel to the anterior surface since the medial facet is thicker than the lateral one in a normal patella. Overstuffing of the PF joint tightens the lateral retinaculum and increases the risk of lateral patellar tracking. In the knee with optimal femoral component size, this can be caused by increased thickness of the resurfaced patella. In the knee with an optimal patella size, this may be due to the use of an oversized femoral component (5, 6). Medialization of the patellar component on the cut surface of the patellar bone allows the patellar button to be centralized in the trochlear groove and improves patellar tracking by decreasing lateral patellar subluxation forces (1, 7).

CASE PRESENTATION

The case involves a 68-year-old female patient who underwent TKA surgery in March 2021 at another hospital and came to our attention one year after surgery due to knee pain and instability during daily activities. The Corin brand prosthesis used for TKA surgery consisted of a cemented size 4 femoral component, a cemented size 5 tibial component, and an 11-mm polyethylene insert. Preoperative X-rays taken in October 2022 (Fig. 1) and an objective examination performed demonstrated lateral patella instability. CT scan pointed a tibial tuberosity–trochlear groove (TT-GT) angle of 20.7°, which, together with the intra-rotation of the tibial component, justified the lateral dislocation of the patella. Clinically, the patient showed permanent patella instability in both knee flexion and extension (Fig. 2).

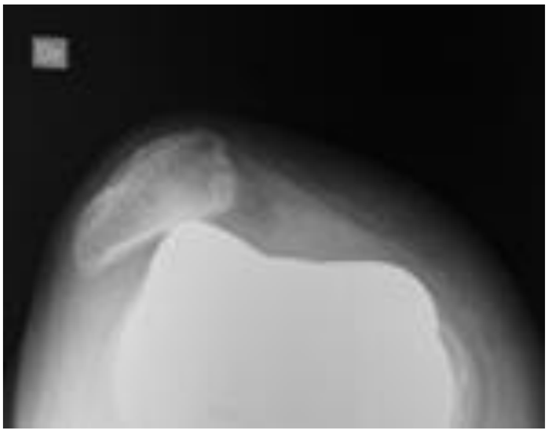


Fig. 1. *Preoperative X-rays, October 2022.*

Fig.2. *Pre-operative patellar lateral instability in extension and flexion*

The surgical procedure we chose involved Insall proximal realignment of the patella for recurrent dislocation or subluxation, consisting of a lateral release and advancement of the vastus medialis. First, a prosthetic 29x8 mm dome-shaped Nexgen All-poly patella was implanted to compensate for limited degrees of patellar tilt and rotation by maintaining acceptable contact congruency, especially in the mid-flexion range. Consequently, the proximal "tube" realignment was performed. A lateral parapatellar incision of skin and a detachment of the fibers of the iliotibial tract and the lateral retinaculum from the lateral patella were achieved, followed by a medial capsular incision extending from the quadriceps tendon over the patella into the patellar ligament. Finally, the vastus medialis was advanced and sutured onto the middle and distal aspects of the patella (Fig. 3). This surgical procedure ensured the achievement of patellar tracking, as confirmed by postoperative X-rays (Fig. 4).

Fig. 3. *Suture of the advanced vastus medialis on the middle-distal aspect of the patella.*

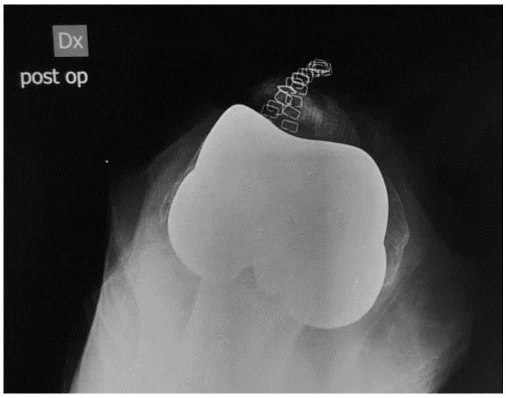


Fig. 4. *Post-operative X-rays: patellar tracking achieved.*

Fig. 5. *Three-month follow-up.*

At a six-week clinical follow-up, the patient showed complete extension and flexion of the knee in both seated and supine positions. During the early postoperative six weeks, the patient was instructed to wear a knee brace locked in extension with the recommendation of protected loading through crutches for the first four weeks. She kept the brace unlocked and rehabbed with the Kinetec CPM device 0-90° for the last two weeks. Six weeks after surgery, the patient was advised to wear a knee brace with a patellar hole for the subsequent six weeks. At the three-month clinical follow-up (Fig. 5), the complete flex extension of the knee was preserved, and a normal alignment of the prosthetic components with a slight lateral patellar dislocation in axial projection was appreciated on X-rays. Finally, one year after surgery, the patient reached a full range of motion of the knee with no pain and functional restrictions (Fig. 6).

Fig. 6. *One-year follow-up.*

DISCUSSION

According to the literature, component malposition during surgery is one of the most common causes of patellar instability (8-12). A tendency to place the components in internal rotation in the transverse plane increases the Q angle of the knee joint. It predisposes to lateral patellar mal-tracking and patellar instability (2). Radiographic evaluation of the patella primarily uses the lateral view and the sunrise or Merchant's view. Computed tomography is the most reliable method of assessing component alignment and positioning (13) and rotation. The latter is determined using 4 scans: the medial and lateral epicondyles, the tibial plateau immediately below the tibial base plate, the tibial tubercle, and through the tibial insert (14). The rotation of the femoral component is determined by measuring the angle formed by the line drawn through the medial and lateral epicondyles and the line connecting the posterior flanges of the implant. Tibial component rotation is determined by superimposing the geometric center of the proximal tibia onto the image with the tibial tubercle. On the patient's CT, we measured the tibial tuberosity (TT) to trochlear groove (TG) distance, given its diagnostic accuracy to guide the treatment of PF instability. After drawing the line along the posterior femoral condyles and the two lines perpendicular to it, the first bisecting the TT and the second bisecting the trochlear TG, we measured a TT-TG angle of 20.7° (Fig. 7).

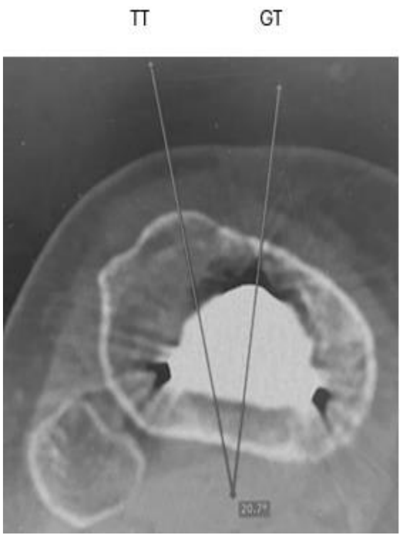


Fig. 7. *TT-GT angle measured on the pre-surgery CT scan.*

The femoral component showed no improper rotation in both pre-operative (CT scan) and intra-operative examination. Although we noticed an intra-rotated tibial component, which, together with the pathological TT-TG angle, might have warranted a total/tibial revision, we thought it worthwhile to perform soft tissue surgery as described by Insall and implant patellar prosthesis only since the femoral and tibial components were well fixed and stable. Axial radiographs of the patella in follow-up show slight lateralization of the patella. Still, despite this, the clinical examination is suitable, and the patient is pleased, has resumed normal activities of daily living, and no longer complains of pain and sensation of sagging/instability, which depicts the success of the choice of intervention.

CONCLUSIONS

Although patellar instability is a relatively uncommon complication after TKA surgery, its causes lie in multiple risk factors, such as preoperative anatomical conditions, intraoperative positioning of the prosthetic components, and unhealthy soft tissue. Before any prosthetic revision, techniques such as Insall proximal realignment of the patella should be considered, as they can provide satisfactory short- and long-term results.

REFERENCES

1. Malo M, Vince KG. The Unstable Patella After Total Knee Arthroplasty: Etiology, Prevention, and Management. *Journal of the American Academy of Orthopaedic Surgeons*. 2003;11(5):364-371. doi:https://doi.org/10.5435/00124635-200309000-00009
2. Eisenhuth SA, Saleh KJ, Cui Q, Clark CR, Brown TE. Patellofemoral Instability after Total Knee Arthroplasty. *Clinical Orthopaedics and Related Research*. 2006;446:149-160. doi:https://doi.org/10.1097/01.blo.0000214415.83593.db
3. Warschawski Y, Garceau S, Frenkel Rutenberg T, Dahduli O, Wolfstadt J, Backstein D. Revision total knee arthroplasty for patellar dislocation in patients with malrotated TKA components. *Archives of Orthopaedic and Trauma Surgery*. 2020;140(6):777-783. doi:https://doi.org/10.1007/s00402-020-03468-6
4. Merkow RL, Soudry M, Insall JN. Patellar dislocation following total knee replacement. *The Journal of Bone & Joint Surgery*. 1985;67(9):1321-1327. doi:https://doi.org/10.2106/00004623-198567090-00003
5. Grace JN, Rand JA. Patellar instability after total knee arthroplasty. *Clinical Orthopaedics and Related Research (1976-2007)*. 1988;237:184-189
6. Ferri R, Digennaro V, Panciera A, et al. Management of patella maltracking after total knee arthroplasty: a systematic review. *Musculoskeletal Surgery*. 2023;107(2):143-157. doi:https://doi.org/10.1007/s12306-022-00764-9
7. Matar HE, Illanes FL, Gollish JD. Extensive Proximal Extensor Mechanism Realignment for Chronic Patella Dislocations in Revision Knee Arthroplasty: Surgical Technique. *The Knee*. 2020;27(6):1821-1832. doi:https://doi.org/10.1016/j.knee.2020.09.018
8. Akagi M, Yoshitaka Matsusue, Mata T, et al. Effect of Rotational Alignment On Patellar Tracking in Total Knee Arthroplasty. *Clinical Orthopaedics and Related Research*. 1999;366:155-163. doi:https://doi.org/10.1097/00003086-199909000-00019
9. Anouchi YS, Whiteside LA, Kaiser AD, Milliano MT. The Effects of Axial Rotational Alignment of the Femoral Component on Knee Stability and Patellar Tracking in Total Knee Arthroplasty Demonstrated on Autopsy Specimens. *Clinical Orthopaedics and Related Research*. 1993;287:170-177. doi:https://doi.org/10.1097/00003086-199302000-00027
10. Healy WL, Wasilewski SA, Takei R, Oberlander M. Patellofemoral complications following total knee arthroplasty. *The Journal of Arthroplasty*. 1995;10(2):197-201. doi:https://doi.org/10.1016/s0883-5403(05)80127-5
11. Ma K. Patellofemoral complications following total knee arthroplasty. *Instructional course lectures*. 2001;50:403-407.
12. Leblanc Jm. Patellar complications in total knee arthroplasty. A literature review. *Orthopaedic review*. 1989;18(3):296-304.
13. Jazrawi LM, Birdzell L, Kummer FJ, Di Cesare PE. The accuracy of computed tomography for determining femoral and tibial total knee arthroplasty component rotation. *The Journal of Arthroplasty*. 2000;15(6):761-766. doi:https://doi.org/10.1054/arth.2000.8193
14. Berger RA, Crossett LS, Jacobs JJ, Rubash HE. Malrotation Causing Patellofemoral Complications After Total Knee Arthroplasty. *Clinical Orthopaedics and Related Research*. 1998;356:144-153. doi:https://doi.org/10.1097/00003086-199811000-00021

Narrative Review

THE CHOICE OF FEMORAL STEM IN THE PROXIMAL FEMORAL FRACTURE

M. Alessio Mazzola[1], G. D'Andrea[2], E. Ghezzi[2], G. Placella[2], S. Mosca[2] and V Salini[2]

[1]IRCCS San Raffaele Hospital, Milan IT
[2]Vita-Salute University, IRCCS San Raffaele Hospital, Milan, Italy

Correspondence to:
Mattia Alessio Mazzola, MD
IRCCS Ospedale San Raffaele,
Unità Clinica di Ortopedia e Traumatologia,
Via Olgettina 60,
20132, Milano, Italy
e-mail: mattia.alessio@hotmail.com

ABSTRACT

Proximal femoral fractures are common in elderly patients and are associated with significant morbidity and healthcare costs. Hip arthroplasty, including hemiarthroplasty and total hip arthroplasty, is a standard treatment for displaced femoral neck fractures, particularly in older adults. A critical aspect of these procedures is the selection of the femoral stem, which influences early mobility recovery and long-term implant outcomes. This review discusses the key considerations in femoral stem selection, including cemented versus cementless fixation, stem geometry, material composition, and modularity. Cemented stems are favored in elderly patients with osteoporotic bone due to their ability to provide immediate mechanical stability. In contrast, cementless stems are preferred in younger patients due to their potential for long-term biological fixation through osseointegration. Modular stems offer intraoperative flexibility but present a higher risk of mechanical complications. Femoral stem selection should be tailored to the patient's age, bone quality, and functional demands to minimize complications and optimize clinical outcomes.

KEYWORDS: *proximal femoral fractures, arthroplasty, hemiarthroplasty, total hip arthroplasty, stem*

INTRODUCTION

Proximal femoral fractures are among the most prevalent injuries encountered in the orthopedic field, especially in patients above 50 years old. The incidence of these fractures is 2-3 times higher in females compared to the male population (1). These fractures often result from low-energy trauma, such as a fall from a standing height, although can also occur due to high-energy trauma, especially in younger male individuals. Given the growth of the elderly population globally, the incidence of proximal femoral fractures, particularly hip fractures, continues to rise, contributing significantly to morbidity, mortality, and healthcare costs (2).

Various techniques and implants have been described to assist the management of proximal femoral fractures, with the primary goal of restoring function and mobility as quickly and safely as possible while minimizing complications and the need for reoperation.

Hip arthroplasty, either as hemiarthroplasty (HA) or total hip arthroplasty (THA), is the standard treatment for medial displaced femoral neck fractures (Garden type 3-4) among the elderly population. It has been demonstrated to promote quick mobilization and satisfactory long-term outcomes (3). The selection of the appropriate femoral stem is a

Received: 27 September 2024
Accepted: 10 November 2024

key aspect of this decision-making process, impacting both short-term outcomes, such as mobility recovery, and long-term consequences, such as implant survival and the risk of revision surgery (4).

Since this type of fracture primarily affects the elderly population, on the one hand, HA is indicated for very old patients due to poor bone quality and frailty; on the other hand, THA provides a reliable option for individuals with medial neck fractures who have painful hip osteoarthritis.

Internal fixation with cannulated screws or sliding hip screws is recommended in medial partial fractures or minimally valgus displaced fractures (Garden type 1 and 2) affecting young individuals with no signs of hip osteoarthritis (5). Delayed fracture treatment (more than 24-48 hours) should be treated with THA for compromise of the blood supply of the femoral head (6). A delayed internal fixation of medial fractures may lead to nonunion or avascular necrosis (5, 6). The choice of femoral stem approaching hip arthroplasty in medial femoral fractures is crucial.

This narrative review discusses the various femoral stem options available for treating proximal femoral fractures, their advantages and disadvantages, and the clinical implications of selecting the optimal stem for different patient populations.

Classification of femoral stems

The classification of femoral stems is key in determining the most suitable implant for a given patient. The classification system proposed by Radaelli et al. (7) describes 3 relevant characteristics of the femoral stem: geometry, location of modularity, and length. Each feature has significant implications for the surgical approach, postoperative recovery, and long-term outcomes.

The choice of femoral stem is especially important in the context of femoral fractures, where the condition of the surrounding bone and the patient's ability to bear weight postoperatively must be carefully considered. Stems are further classified by their method of fixation.

Cementless femoral stems rely on 3 key principles: achieving primary stability, facilitating mid-term biological fixation through osseointegration (bone growth occurs on the porous surface of the stem), and ensuring balanced femoral stress distribution for long-term survivorship. Most cementless femoral stems are made of either titanium aluminum vanadium alloy or cobalt-chrome molybdenum alloy.

In a randomized controlled trial, Healy et al. (8) demonstrated that titanium stems are associated with lower rates of stress shielding, reducing bone resorption around the implant. However, there is no significant correlation between titanium stem and thigh pain or functional outcomes.

Titanium alloy’s biocompatibility and its lower modulus of elasticity play a key role in promoting osteoinduction, osteoconduction, and oxygenation (9). In contrast, among the cobalt-chrome stems, there is a high risk of loosening and implant failure (8). Stainless steel, though available, is less commonly used due to its lower biocompatibility and susceptibility to corrosion (7-9). Radaelli cementless classification system (7) (Fig. 1) identifies 6 primary stem geometries and subtypes:

- Type A: flat taper – fixation achieved through medial to lateral metaphyseal cortical bone engagement and by 3-point fixation along the stem’s length;
- Type B: quadrangular tapers – fixation is obtained by filling the metaphyseal and proximal diaphysis in the coronal plane, with enhanced filling in the sagittal plane. This provides a more uniform load transfer on proximal cortical bone and high torsion stability;
- Type C: fit-and-fill – archives rotational stability through the complete filling of the metaphyseal canal and close engagement with the femoral cortex both proximally and distally;
- Type D: conical – short conical stems are designed for cases with abnormal proximal femoral morphology, such as development dysplasia of the hip or high valgus femoral necks. The fixation and rotational stability are reached at the level of the lesser trochanter. Short conical stems are typically monoblock, even if there has been a recent resurgence in the use of long monoblock, which is relatively simple to implant and avoid modularity complications;
- Type E: cylindrical - features a circular cross-section and aims for full diaphyseal engagement;
- Type F: calcar-guided short stems – designed to preserve bone stock and to restore physiological biomechanisms, resembling flat-wedge stems but they are smaller with a pronounced medial curve.

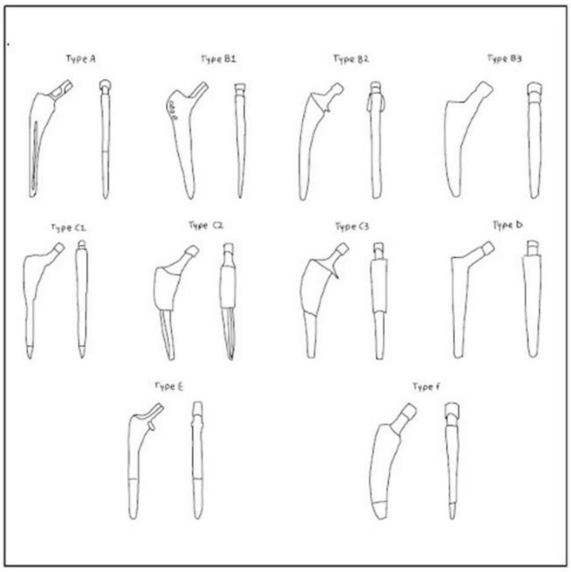


Fig. 1. *Schematic drawing representing Radaelli cementless classification according to femoral stem geometry.*

Anatomical femoral stems

Anatomical femoral stems are designed to closely mimic the natural anatomy of the femur closely, replicating its natural curvature. They are typically selected when preserving the natural biomechanics of the hip (10). Their anatomical shape promotes improved load transfer and alignment, resulting in a more physiological distribution of torsional forces. These stems are shaped to match the unique geometry of an individual's proximal femur, aiming to provide better fit and load distribution by replicating the natural curvature and contours of the femoral canal. Differing from straight or conventional femoral stems, anatomical stems often feature specific angulations and offsets that accommodate individual variations in femoral anatomy, such as femoral anteversion and medullary canal shape (10).

Anatomical femoral stems adapt proximal geometry with a curvature mimicking the natural anatomy of the metaphyseal region of the proximal femur. These stems provide excellent offset adjustment, improving stability and biomechanics, and distribute loads more naturally along the femoral canal, reducing stress shielding. The anatomical design aims to improve patient outcomes by reducing complications associated with implant misalignment and promoting better functional results (Fig. 2).

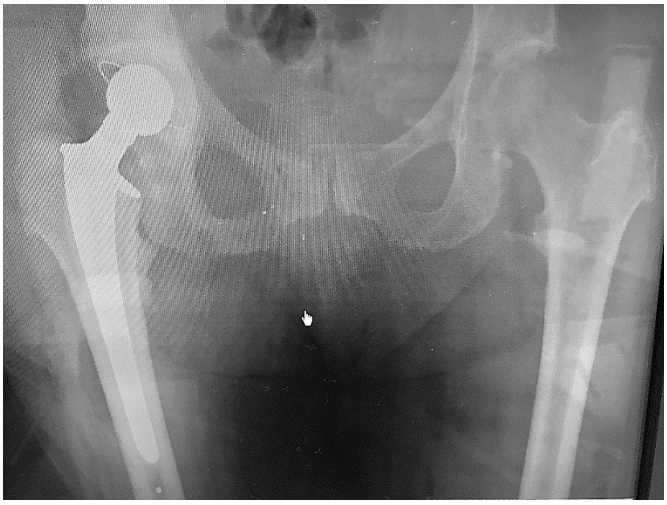


Fig. 2. *Post-operative X-ray of 80-year-old female patients after cemented THA with anatomical Lubinus II (Link, Hamburg, Germany) femoral stem for proximal femoral fracture.*

Monoblock versus modular stems

The choice between monoblock and modular stems can impact the surgical approach and the patient outcomes.

Monoblock stems, made of a single solid piece, reduce the risk of fretting and micromotion at the junctions but restrict the surgeon's ability to make intraoperative adjustments. In contrast, modular stems provide surgeons greater flexibility during implantation, offering customizable options for length and version and providing greater intraoperative adaptability. However, they may be more susceptible to mechanical issues such as modular devices, intraoperative fractures, modular junction fatigue fractures, corrosion, and higher implant costs (11).

Modular stems are seldom utilized to manage proximal femoral fractures but are particularly useful in revision or complex cases (Fig. 3).

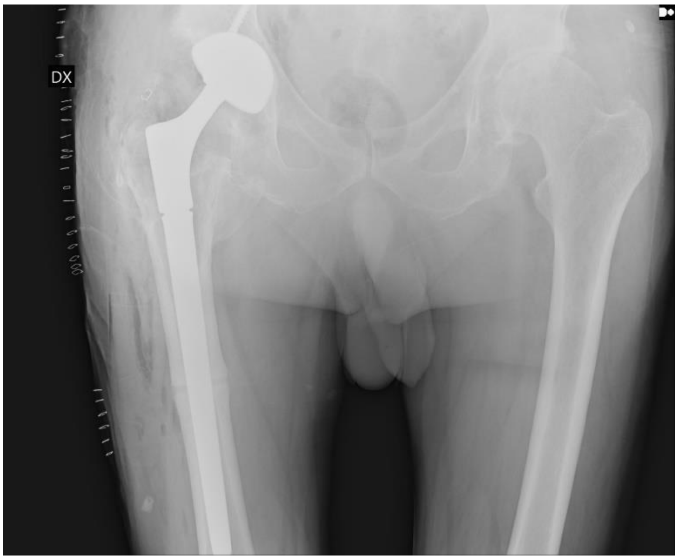


Fig. 3. *Post-operative X-ray of a 78-year-old patient who sustained displaced proximal femoral fracture 2 years after nailing of the proximal femur. Modular Lima revision stem (Lima Corporate, Villanova di San Daniele del Friuli, Udine, Italy) was chosen to manage proximal femoral weakening after nailing.*

Modular and monoblock stems in the revision setting showed similar re-revision rates and Harris Hip Scores for hip function. The intraoperative fracture rate was significantly higher with modular stems (11.6%) than monoblock stems (5.0%). Subsidence more significant than 10 mm occurred more frequently in the monoblock group. The application of extended trochanteric osteotomy was more popular in monoblock stems (22.7% vs 17.5%, $P = 0.003$). The incidence of postoperative complications, such as periprosthetic femoral fracture and dislocation, was similar between both stems. Overall, postoperative hip function and survivorship were similar between the modular and nonmodular groups (12).

Modular stems

Regarding stem modularity**,** femoral components have been designed to optimize limb-length equalization, femoral offset, femoral anteversion, impingement-free ROM, and soft tissue tension.

An increased femoral offset (perpendicular distance between the center of the femoral head and a line drawn down the center of the femoral shaft) has been shown to reduce the hip abductor force and hip reaction force without significantly impacting bone strains. Studies show no significant radiographic differences between increased- and standard-offset components, making the increased-offset approach a valuable option in improving hip joint mechanics without adverse effects on stability or bone integration. These biomechanical studies support using an increased-offset femoral component with cementless fixation (13). Common forms of modularity include head modularity, neck modularity, and subtrochanteric modularity.

- Head modularity allows for attaching different diameters and neck lengths to any given stem size or geometry. However, this type of modularity is associated with a higher risk of mechanical issues, such as dislocation, reduction, taper fracture, and corrosion;
- Neck modularity enables the adjustment of limb length and offset independently of stem size after fixation has been completed;
- Subthorcantheric modularity involves cylindrical or conical stems designed to achieve diaphyseal fixation. Most implant fractures occur at the junction between the osseointegrated distal and nonintegrated proximal parts. Bush et al. (14) recommended using longer proximal components to improve load transfer and reduce junctional strain. Notably, nonmodular stem fractures usually happen at the subtrochanteric level.

Stem length

Stem length plays a critical role in the final selection of femoral components. A short femoral stem is a type of hip implant shorter than traditional femoral stems ($\leq$ 120 mm). These stems are designed to preserve more bone in the proximal femur by occupying less space in the femoral canal. They aim to support a less invasive approach and allow for improved bone preservation, which can benefit younger or more active patients who may require future hip revisions (15). The short design is favorable for a minimally invasive approach and is well suited for a direct anterior approach in THA (16). The short stems reduce stress shielding, maintain a natural loading pattern, and promote patient recovery by reducing bone removal and trauma. They are especially suitable for younger or highly active patients and are increasingly utilized in modern hip replacement surgeries to enhance long-term outcomes and potential revision options (17).

The use of short stems in proximal femoral fractures is controversial. It should be limited to selected cases, such as younger patients with good bone quality, the integrity of the calcar region, and high functional demand (18) (Fig. 4).

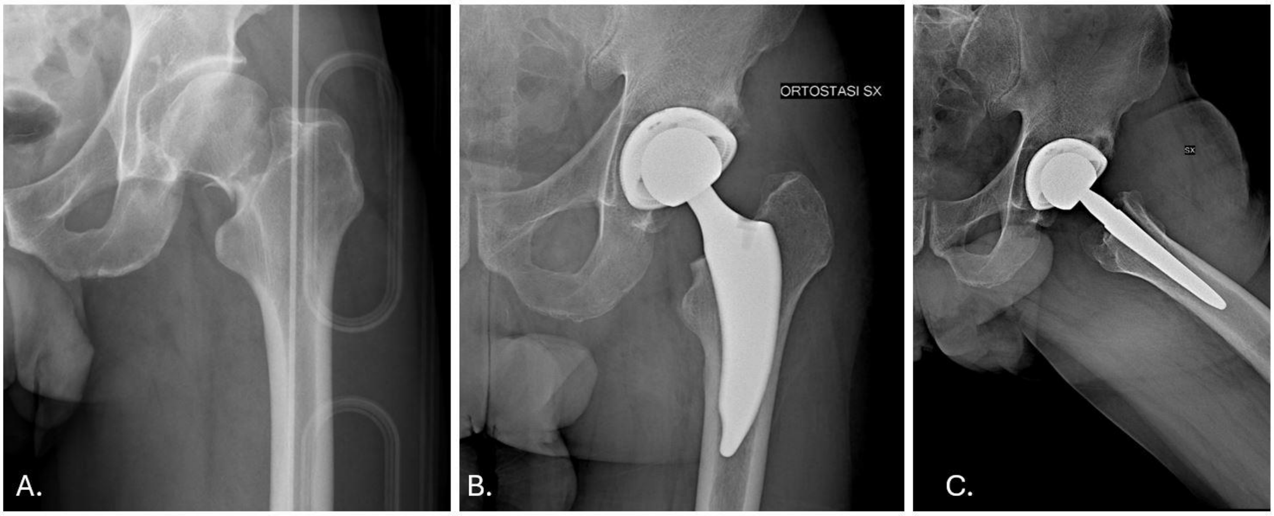


Fig. 4. *Preoperative X-ray of a 58-year-old man sustaining displaced medial proximal femoral fracture (**A**) 3 months anteroposterior (**B**) and axial (**C**) view after THA with Minima S short stem and Delta TT cup (Lima Corporate, Villanova di San Daniele del Friuli, Udine, Italy).*

Cemented versus cementless stems

Cemented femoral stems use bone cement (typically polymethylmethacrylate or PMMA) to secure the implant. This type of stem is often favored in elderly patients with poor bone quality, as the cement helps create a stable and immediate fixation. Cemented stems can also provide immediate weight-bearing capacity, which benefits patients with limited mobility. However, concerns have been raised about the potential for long-term complications with cemented stems, including cement fatigue and potential loosening over time. Furthermore, patients who underwent cemented fixation for proximal femoral fracture demonstrated significantly increased perioperative mortality, raising potential concerns about cementation in severely ill patients (19). Mabrouk et al. compared Polished Taper Slip (PTS) stems with composite beam (CB) stems, revealing a significantly higher risk of fracture in patients with underlying comorbidities who received PTS stems (RR:9.9; $p<0.001$) (20).

Cemented and cementless femoral stems each have several advantages and disadvantages. Cemented stems provide immediate stability, mainly among the elderly population with poor bone quality and lower complication rates, including reduced incidences of dislocation, loosening, and periprosthetic fractures. Additionally, cemented stems generally have lower revision rates (Fig. 5).

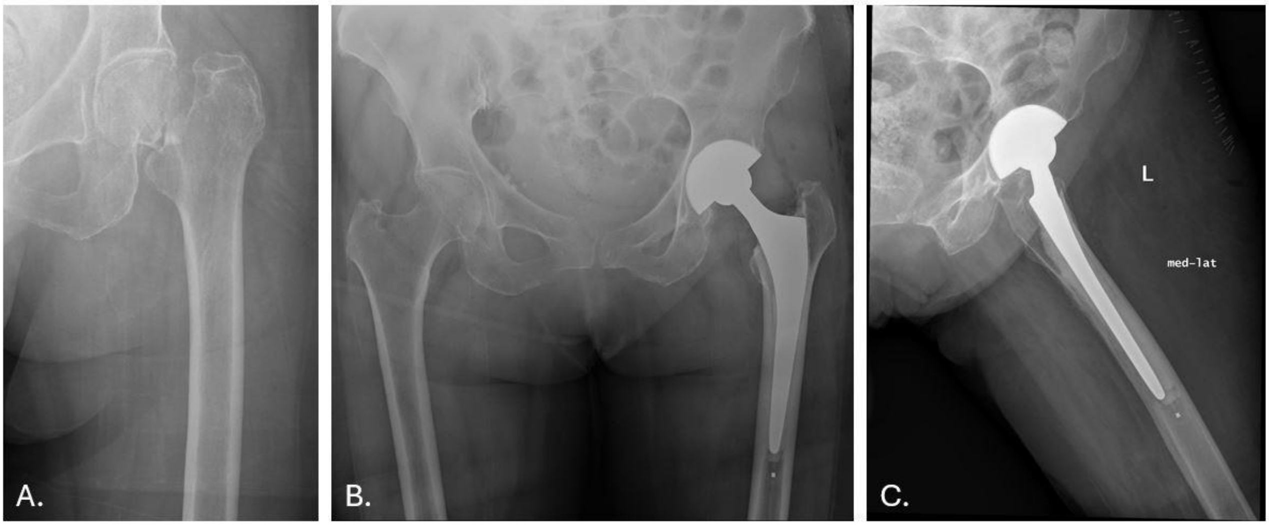


Fig. 5. *Preoperative X-ray of an 81-year-old female patient sustaining displaced medial proximal femoral fracture (**A**). Post-operative anteroposterior (**B**) and axial (**C**) view after cemented stem and uncemented cup THA with H-Max stem and Delta TT dual mobility cup (Lima Corporate, Villanova di San Daniele del Friuli, Udine, Italy).*

However, cement-related complications, such as embolism and cardiovascular risks, can occur, and the procedure typically involves longer operative time and more blood loss (20). On the other hand, cementless femoral stems offer the advantage of shorter operative times and less intraoperative blood loss, as well as eliminating the risks associated with bone cement. However, cementless stems carry a higher risk of early complications, such as dislocation, periprosthetic fractures, and loosening, particularly in elderly patients (20).

Overall, the choice between cemented and cementless stems depends on patient-specific factors such as age, bone quality, and the risk of complications(21) (Fig. 6).

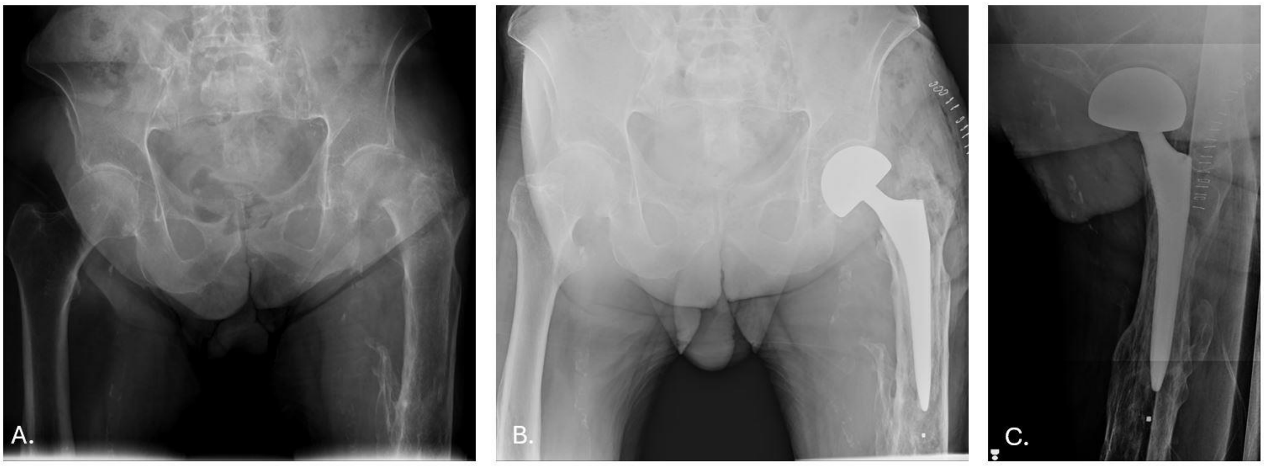


Fig. 6. *Preoperative X-ray of an 85-year-old male patient sustaining a displaced medial proximal femoral fracture in a previously healed shaft femoral fracture (A). The widening of the femoral canal, poor bone quality, and dysmorphic changes in femoral anatomy recommended a cemented stem. Post-operative anteroposterior (B) and axial (C) view after cemented HA with H-Max stem and bipolar head (Lima Corporate, Villanova di San Daniele del Friuli, Udine, Italy).*

Femoral stem in the treatment of proximal femoral fractures

When considering femoral stem selection in treating proximal femoral fractures, the surgeon must consider multiple factors, including the patient's age, bone quality, fracture pattern, and functional status (19-21). Proximal femoral fractures are more common in elderly individuals, many of whom present with osteoporosis. This poor bone quality often guides the decision toward cemented femoral stems, which provide immediate mechanical stability even in compromised bone conditions. Additionally, the high prevalence of comorbidities in this patient group necessitates a treatment strategy that allows for early mobilization to prevent complications such as deep vein thrombosis, pulmonary embolism, and pressure ulcers (22).

In younger patients with better bone quality, cementless femoral stems may be preferable due to the potential for biological fixation (20). The ability of the bone to grow into the implant provides long-term stability without the potential for cement-related complications. However, the surgeon must be mindful of the patient's activity level and expected functional demands. A younger, more active patient may place higher mechanical loads on the implant, necessitating a stem that can withstand these forces over an extended period (23).

The choice of stem length is also an important consideration. Standard-length stems are commonly used in hip arthroplasty procedures, but short stems are gaining popularity, especially in the context of femoral neck fractures (24). Short stems preserve more bone stock and may reduce the risk of periprosthetic fractures, a significant concern in elderly patients with osteoporotic bone. These stems are associated with less stress shielding and improved load transfer to the proximal femur, which may enhance functional outcomes. On the other hand, short stems require expert surgeons and younger patients with good bone quality and integrity in the calcar region, representing a reliable solution limited to selected cases. Long stems may be indicated in cases of extensive femoral damage or revision surgery, where additional support and fixation are required (25).

For patients with severe femoral fractures, including comminuted or highly displaced fractures, modular stems may offer a solution due to their versatility (26). The ability to adjust length and version intraoperatively allows the surgeon to optimize the fit of the implant and ensure proper alignment, which is critical for restoring function and reducing postoperative complications. However, using modular stems may increase the risk of mechanical complications, including stem loosening and junctional failure, particularly in patients with high physical activity levels.

Biomechanical considerations

The biomechanical properties of femoral stems are fundamental to their function and long-term success. Ideally, the stem should allow for physiological load transfer, minimizing stress shielding and promoting healthy bone remodeling.

Stress shielding refers to the reduction of bone density that occurs when the bone's mechanical load is transferred to the implant rather than being borne by the bone itself. This can ultimately result in the loosening of the implant and the need for revision surgery (27). The geometry, stiffness, and material of the stem significantly affect the load distribution between the femur and the implant.

Generally, titanium alloys are used for the femoral stems due to their lightweight, corrosion-resistant, and biocompatibility (28, 29). These alloys offer good dynamic mechanical strength and high success rates (30).

The prosthesis, when inserted, transfers the load from the femoral head and acetabular cavity at the hip to the prosthesis itself (31-33). This can affect the biomechanics of the joint and the surrounding bone. In particular, the stress applied to the bone may promote its physiological remodeling (34, 35).

When a prosthesis is introduced into the bone, the distribution of loads is altered, causing the atrophic bone to form in unloaded areas and denser bone in overloaded areas. This results from the different stiffnesses between the bone and the prosthetic materials, with metals having a higher stiffness, leading to stress shielding. To mitigate the effects of stress shielding, it is pivotal to design prostheses that better mimic the biomechanical properties of natural bone and allow for a more even distribution of mechanical load on the surrounding bone.

Tapered stems**,** for example, have been shown to offer more gradual force distribution, which can reduce the risk of stress shielding. These stems are designed to distribute stress more evenly across the proximal femur. They engage the proximal femoral bone more effectively, reducing the stress shielding risk and promoting better bone preservation. This design transfers less load to the distal femur and minimizes bone resorption in the proximal femur (36, 37).

In contrast, cylindrical stems tend to transmit more load to the distal portion of the femur, leading to higher rates of stress shielding in the proximal region. These stems often rely on distal fixation, which can exacerbate bone loss in the proximal femur over time. This design was more common in early prosthesis models. Another biomechanical consideration is the rotational stability of the implant, which is crucial for preventing implant loosening and ensuring long-term success.

Cemented femoral stems provide excellent rotational stability due to the rigid fixation achieved by the cement mantle. Acting as an intermediary between the stem and the bone, the cement fills irregularities, effectively preventing rotational and axial micromotions immediately after surgery. This solid fixation ensures strong short-term stability, which is crucial to avoid early implant loosening. However, the cement can degrade or weaken over time, especially in younger and active patients, leading to limited rotational stability and an increased risk of aseptic loosening.

In contrast, uncemented stems rely on achieving rotational stability through osseointegration, where bone tissue grows into or onto the stem surface, providing long-term biological fixation. Initially, these stems may exhibit more micromotion since they rely on a press-fit fixation, dependent on the mechanical friction between the implant and bone.

This can pose a risk of rotational instability until osseointegration is fully achieved. However, once bone growth secures the stem, uncemented implants offer superior long-term rotational stability, particularly with tapered or porous-coated designs that improve load distribution and bone-implant contact (38, 39).

Uncemented stems are typically favored for younger patients or those with good bone quality due to their long-term stability and lower risk of loosening over time. However, for patients with poor bone quality, the early stages of fixation can present challenges, as initial micromotion may lead to early implant failure.

Clinical outcomes and complications

Several clinical studies have examined the outcomes of different femoral stems in treating proximal femoral fractures, focusing on cemented versus uncemented designs. Cemented femoral stems are often recommended in elderly patients with osteoporotic bone because they provide immediate stability, reducing early postoperative complications such as implant loosening and dislocation. This is particularly important for older patients, as early mobilization and weight-bearing are crucial to avoid complications like bedrest-related issues or thrombosis (40). However, the long-term performance of cemented stems can be compromised due to cement fatigue, particularly in younger and active patients. Over time, the cement can degrade, increasing the risk of implant loosening.

In the study by Joshi et al. (41) on the long-term results of Charnley low-friction arthroplasty in young patients, cemented femoral stem failure in younger individuals was primarily attributed to cement fatigue and mechanical failure. Young and active patients typically place higher mechanical stresses on the implant and the surrounding cement mantle, which can lead to early degradation of the cement. Over time, this can result in loosening of the prosthesis. Additionally, the study highlights that the higher levels of activity in younger patients accelerate the wear and tear of both the implant and the cement, leading to higher failure rates compared to older, less active populations. The bone remodeling response also differs in younger patients, contributing to the risk of failure.

On the other hand, uncemented stems, which rely on biological fixation through osseointegration, tend to perform better in the long term in younger patients with good bone quality.

In the study by Flecher et al. (42), the authors highlight several reasons why cementless stems are preferred for hip arthroplasty in young patients. First, cementless stems facilitate osseointegration, allowing bone to grow into the implant, which provides a strong and durable fixation. Additionally, cementless designs typically have a lower modulus of elasticity, closely mimicking natural bone and reducing the risk of stress shielding. This characteristic promotes healthier bone remodeling and helps maintain long-term bone quality.

Periprosthetic fractures are a significant concern, particularly with uncemented stems, as inadequate initial fixation can lead to weakened bone around the implant and an increased fracture risk. Cemented stems, by contrast, distribute the load more evenly along the femur, potentially reducing this risk.

Edelstein et al. (43) analyzed a national Medicare sample and found that cementation of the femoral component can affect fracture and mortality risk. Their findings suggest that while cemented stems provide immediate stability, which may reduce the likelihood of periprosthetic fractures, they can still be associated with specific risks, particularly in the elderly with lower bone quality.

Conversely, Fleischman and Chen (44) discuss how uncemented stems are often linked to a higher incidence of periprosthetic fractures, especially if adequate initial fixation is not achieved. These fractures can occur due to insufficient bone support or excessive mechanical stress on the implant. The authors emphasize that careful surgical technique and considerations of bone quality and implant design are essential to minimize these risks. An alternative potential complication is implant loosening, which can occur with cemented and uncemented stems. Loosening can occur due to various factors, including poor initial fixation, bone quality, and mechanical stresses on the implant.

For cemented stems, loosening often results from cement degradation over time. The cement may fail to maintain a secure bond between the implant and the bone, leading to micromotion that compromises stability and can precipitate fractures. In the case of uncemented stems, loosening is primarily linked to inadequate osseointegration. If the bone fails to integrate with the stem properly, the implant may not achieve the necessary stability, increasing the risk of periprosthetic fractures (45).

Factors such as surgical technique, implant design, and patient factors like bone quality and activity levels are crucial in determining the likelihood of loosening. Dislocation is another complication that may occur following femoral stem implantation. Several factors, including implant design, surgical technique, and individual patient characteristics, influence the risk of dislocation.

The design of the femoral stem is critical; modular stems, for instance, allow for intraoperative adjustments that can optimize fit and alignment, thereby enhancing stability. These designs enable surgeons to tailor the components to the patient's anatomy, which can significantly reduce dislocation risk. Conversely, poorly designed stems or those with inadequate neck length may compromise stability and range of motion, increasing the likelihood of dislocation (46).

Surgical technique also plays an important role. Precise alignment and positioning of the femoral stem and acetabular component are essential for maintaining joint stability. Surgeons must carefully balance the surrounding soft tissues to avoid excessive tension or laxity, which can lead to instability and increase dislocation risk postoperatively (47).

Patient-specific factors further contribute to the risk. Muscle strength, coordination, and overall health significantly influence a patient's ability to stabilize the hip joint, especially during weight-bearing activities. Older patients or those with conditions such as obesity or neurological disorders may be particularly vulnerable to dislocation due to weaker musculature and impaired proprioception.

Finally, effective postoperative management is crucial for minimizing dislocation risk. Early mobilization, appropriate physical therapy, and patient education on hip precautions can strengthen surrounding musculature and enhance coordination.

CONCLUSIONS

The selection of the appropriate femoral stem for treating proximal femoral fractures is a complex decision that necessitates careful consideration of various factors, including patient characteristics, bone quality, fracture type, and the specific attributes of the implants. Cemented stems provide immediate stability and are particularly advantageous for elderly patients with compromised bone quality, ensuring a secure fit from the outset. In contrast, uncemented stems facilitate long-term biological fixation, making them a preferred choice for younger, more active individuals who require greater durability and resistance to wear.

The geometry and material composition of the femoral stem and the decision to use monoblock versus modular designs significantly influence the procedure's success. Key biomechanical factors, such as stress shielding, rotational stability, and load distribution, must be meticulously evaluated to minimize potential complications and enhance clinical outcomes.

In conclusion, the choice of the femoral stem should be individualized based on the specific needs of the patient and the characteristics of the fracture. A comprehensive understanding of the available stem options and their respective advantages and disadvantages is essential for obtaining optimal results in treating proximal femoral fractures.

Disclosure

No funding was received for this study. The authors have no relevant financial relationships to disclose.

Conflict of interest statement

The authors have no conflicts of interest to disclose.

REFERENCES

1. Zuckerman JD. Hip Fracture. *New England Journal of Medicine*. 1996;334(23):1519-1525. doi:https://doi.org/10.1056/nejm199606063342307
2. Alessio-Mazzola M, Traverso G, Coccarello F, Sanguineti F, Formica M. Dynamic hip screw versus intramedullary nailing for the treatment of A1 intertrochanteric fractures: A retrospective, comparative study and cost analysis. *Joint Diseases and Related Surgery*. 2022;33(2):314-322. doi:https://doi.org/10.52312/jdrs.2022.646
3. Rotini M, Farinelli L, Natalini L, et al. Is Dual Mobility Total Hip Arthroplasty Surgery More Aggressive than Hemiarthroplasty when Treating Femoral Neck Fracture in the Elderly? A Multicentric Retrospective Study on 302 Hips. *Geriatric orthopedic surgery & rehabilitation (Print)*. 2022;13:215145932210813-215145932210813. doi:https://doi.org/10.1177/21514593221081375
4. Springer BD, Hubble MJW, Howell JR, Moskal JT. Cemented Femoral Stem Fixation: Back to the Future. *The Journal of Arthroplasty*. 2023;38. doi:https://doi.org/10.1016/j.arth.2023.04.023
5. Bekeris J, Wilson LA, Bekere D, et al. Trends in Comorbidities and Complications Among Patients Undergoing Hip Fracture Repair. *Anesthesia & Analgesia*. 2019;132(2):475-484. doi:https://doi.org/10.1213/ane.0000000000004519
6. Sendtner E, Renkawitz T, Kramny P, Wenzl M, Grifka J. Fractured Neck of Femur. *Deutsches Aerzteblatt Online*. 2010;Epub 2010 Jun 11. doi:https://doi.org/10.3238/arztebl.2010.0401
7. Radaelli M, Buchalter DB, Mont MA, Schwarzkopf R, Hepinstall MS. A New Classification System for Cementless Femoral Stems in Total Hip Arthroplasty. *The Journal of Arthroplasty*. 2022;38(3):502-510.

doi:https://doi.org/10.1016/j.arth.2022.09.014

8. Healy WL, Tilzey JF, Iorio R, Specht LM, Sharma S. Prospective, Randomized Comparison of Cobalt-Chrome and Titanium Trilock Femoral Stems. *The Journal of Arthroplasty*. 2009;24(6):831-836. doi:https://doi.org/10.1016/j.arth.2008.06.035
9. Albrektsson T, Johansson C. Osteoinduction, osteoconduction and osseointegration. *European Spine Journal*. 2001;10(0):S96-S101. doi:https://doi.org/10.1007/s005860100282
10. Kim YH, Park JW, Jang YS, Kim EJ. Long-term clinical results and patient satisfaction of a metaphyseal-engaging anatomic cementless femoral component in total hip arthroplasty. *International Orthopaedics*. 2024;48(12). doi:https://doi.org/10.1007/s00264-024-06322-1
11. Carnovale M, Meo DD, Guarascio G, et al. Mid-Term Outcomes of a Short Modular Neck-Preserving Cementless Hip Stem: A Retrospective Study With a 6-Year Minimum Follow-Up. *Arthroplasty Today*. 2024;27:101387-101387. doi:https://doi.org/10.1016/j.artd.2024.101387
12. Wang D, Li H, Zhang W, et al. Efficacy and safety of modular versus monoblock stems in revision total hip arthroplasty: a systematic review and meta-analysis. *Journal of Orthopaedics and Traumatology*. 2023;24(1). doi:https://doi.org/10.1186/s10195-023-00731-5
13. Charles MN, Bourne RB, Davey JR, Greenwald AS, Morrey BF, Rorabeck CH. Soft-tissue balancing of the hip: the role of femoral offset restoration. *Instructional course lectures*. 2005;54:131-141.
14. Busch CA, Charles MN, Haydon CM, et al. Fractures of distally-fixed femoral stems after revision arthroplasty. *The Journal of Bone and Joint Surgery*. 2005;87-B(10):1333-1336. doi:https://doi.org/10.1302/0301-620x.87b10.16528
15. Falez F, Casella F, Papalia M. Current Concepts, Classification, and Results in Short Stem Hip Arthroplasty. *Orthopedics*. 2015;38(3). doi:https://doi.org/10.3928/01477447-20150215-50
16. Alessio-Mazzola M, Colombo P, Barducci N, et al. Direct anterior approach with conventional instruments versus robotic posterolateral approach in elective total hip replacement for primary osteoarthritis: a case-control study. *Journal of Orthopaedics and Traumatology*. 2024;25(1). doi:https://doi.org/10.1186/s10195-024-00753-7
17. Yan SG, Weber P, Steinbrück A, Hua X, Jansson V, Schmidutz F. Periprosthetic bone remodelling of short-stem total hip arthroplasty: a systematic review. *International Orthopaedics*. 2017;42(9):2077-2086. doi:https://doi.org/10.1007/s00264-017-3691-z
18. Gounot A, Charlot A, Guillon P, et al. The use of uncemented stems in femoral neck fractures in elderly patients: A comparative study of 671 cases. *Orthopaedics & Traumatology Surgery & Research*. 2024;110(4):103878-103878. doi:https://doi.org/10.1016/j.otsr.2024.103878
19. Fenelon C, Murphy EP, Pomeroy E, Murphy RP, Curtin W, Murphy CG. Perioperative Mortality After Cemented or Uncemented Hemiarthroplasty for Displaced Femoral Neck Fractures—A Systematic Review and Meta-analysis. *The Journal of Arthroplasty*. 2021;36(2):777-787.e1. doi:https://doi.org/10.1016/j.arth.2020.08.042
20. Mabrouk A, Feathers J, Mahmood A, West R, Pandit H, Lamb J. Systematic Review and Meta-Analysis of Studies Comparing the Rate of Post-operative Periprosthetic Fracture Following Hip Arthroplasty With a Polished Taper Slip versus Composite Beam Stem. *Journal of Arthroplasty*. 2023;39(1):269-275 Epub 2023 Jun 19. doi:https://doi.org/10.1016/j.arth.2023.06.014
21. Raja BS, Gowda AKS, Singh S, Ansari S, Kalia RB, Paul S. Comparison of functional outcomes and complications of cemented vs uncemented total hip arthroplasty in the elderly neck of femur fracture patients: A systematic review and meta-analysis. *Journal of Clinical Orthopaedics and Trauma*. 2022;29:101876. doi:https://doi.org/10.1016/j.jcot.2022.101876
22. Gjertsen JE, Nilsen D, Ove Furnes, et al. Promoting cemented fixation of the femoral stem in elderly female hip arthroplasty patients and elderly hip fracture patients: a retrospective cohort study from the Norwegian Arthroplasty Register and the Norwegian Hip Fracture Register. *Acta Orthopaedica*. 2024;95:130-137. doi:https://doi.org/10.2340/17453674.2024.40073
23. Flecher X, Pearce O, Parratte S, Aubaniac JM, Argenson JN. Custom Cementless Stem Improves Hip Function in Young Patients at 15-year Followup. *Clinical Orthopaedics and Related Research®*. 2009;468(3):747-755. doi:https://doi.org/10.1007/s11999-009-1045-x
24. Lee SJ, Yoon KS. Favorable Functional Recovery and Stem Stability after Hip Arthroplasty with a Short Metaphyseal Stem in Elderly Patients with Osteoporotic Femoral Neck Fractures. *Hip & Pelvis*. 2019;31(1):11. doi:https://doi.org/10.5371/hp.2019.31.1.11
25. Sahemey R, Ridha A, Stephens A, et al. Does size matter? Outcomes following revision total hip arthroplasty with long or primary stems: a systematic review and meta-analysis. *Arthroplasty*. 2024;Jan 9;6(1). doi:https://doi.org/10.1186/s42836-023-00228-w
26. Cacciola G, Braconi L, Bosco F, et al. Outcomes of modular stem for the treatment of periprosthetic femoral fracture: a systematic review of the literature. *Annals of Joint*. 2023;8:40-40. doi:https://doi.org/10.21037/aoj-23-27
27. J. Mark Wilkinson, Hamer AJ, Rogers A, Stockley I, Eastell R. Bone mineral density and biochemical markers of bone turnover in aseptic loosening after total hip arthroplasty. *Journal of Orthopaedic Research*. 2003;21(4):691-696. doi:https://doi.org/10.1016/s0736-0266(02)00237-1
28. Al Zoubi NF, Tarlochan F, Mehboob H, Jarrar F. Design of Titanium Alloy Femoral Stem Cellular Structure for Stress

Shielding and Stem Stability: Computational Analysis. *Applied Sciences*. 2022;12(3):1548. doi:https://doi.org/10.3390/app12031548

29. Cassar-Gheiti AJ, McColgan R, Kelly M, Cassar-Gheiti TM, Kenny P, Murphy CG. Current concepts and outcomes in cemented femoral stem design and cementation techniques: the argument for a new classification system. *EFORT Open Reviews*. 2020;5(4):241-252. doi:https://doi.org/10.1302/2058-5241.5.190034
30. Zajc J, Moličnik A, Fokter S. Dual Modular Titanium Alloy Femoral Stem Failure Mechanisms and Suggested Clinical Approaches. *Materials*. 2021;14(11):3078. doi:https://doi.org/10.3390/ma14113078
31. Mavčič B, Antolič V. Cementless femoral stem fixation and leg-length discrepancy after total hip arthroplasty in different proximal femoral morphological types. *International Orthopaedics*. 2020;45. doi:https://doi.org/10.1007/s00264-020-04671-1
32. Buks Y, Wendelburg KL, Stover SM, Garcia-Nolen TC. The Effects of Interlocking a Universal Hip Cementless Stem on Implant Subsidence and Mechanical Properties of Cadaveric Canine Femora. *Veterinary Surgery*. 2016;45(2):155-164. doi:https://doi.org/10.1111/vsu.12437
33. Toci GR, Magnuson JA, DeSimone CA, Stambough JB, Star AM, Saxena A. A Systematic Review and Meta-Analysis of Non-database Comparative Studies on Cemented Versus Uncemented Femoral Stems in Primary Elective Total Hip Arthroplasty. *The Journal of Arthroplasty*. 2022;37(9). doi:https://doi.org/10.1016/j.arth.2022.03.086
34. Jafari Chashmi M, Fathi A, Shirzad M, Jafari-Talookolaei RA, Bodaghi M, Rabiee SM. Design and Analysis of Porous Functionally Graded Femoral Prostheses with Improved Stress Shielding. *Designs*. 2020;4(2):12. doi:https://doi.org/10.3390/designs4020012
35. López-Subías J, Panisello JJ, Mateo-Agudo J, et al. Bone remodelling, around an anatomical hip stem: A one year prospective study using DEXA. *Revista Española de Cirugía Ortopédica y Traumatología (English Edition)*. 2021;65(1):31-40. doi:https://doi.org/10.1016/j.recote.2020.09.010
36. Freitag T, Bieger R, Kiefer H, et al. Biomechanics of a calcar loading and a shortened tapered femoral stem: Comparative in-vitro testing of primary stability and strain distribution. *Journal of Experimental Orthopaedics*. 2021;8(1). doi:https://doi.org/10.1186/s40634-021-00388-1
37. Ceddia M, Solarino G, Giannini G, De Giosa G, Tucci M, Trentadue B. A Finite Element Analysis Study of Influence of Femoral Stem Material in Stress Shielding in a Model of Uncemented Total Hip Arthroplasty: Ti-6Al-4V versus Carbon Fibre-Reinforced PEEK Composite. *Journal of Composites Science*. 2024;8(7):254. doi:https://doi.org/10.3390/jcs8070254
38. Bieger R, Ignatius A, Decking R, Claes L, Reichel H, Dürselen L. Primary stability and strain distribution of cementless hip stems as a function of implant design. *Clinical Biomechanics*. 2012;27(2):158-164. doi:https://doi.org/10.1016/j.clinbiomech.2011.08.004
39. Pilliar RM, Lee JM, Maniatopoulos C. Observations on the Effect of Movement on Bone Ingrowth into Porous-Surfaced Implants. *Clinical Orthopaedics and Related Research*. 1986;&NA;(208):108???113. doi:https://doi.org/10.1097/00003086-198607000-00023
40. Atik OŞ, Çankaya D. To cement or not to cement, that is the question in elderly! *Joint Diseases and Related Surgery*. 2021;32(2):277-278. doi:https://doi.org/10.52312/jdrs.2021.57900
41. Joshi A, Porter M, Trail I, Hunt L, Murphy J, Hardinge K. Long-term results of Charnley low-friction arthroplasty in young patients. *The Journal of Bone and Joint Surgery British volume*. 1993;75-B(4):616-623. doi:https://doi.org/10.1302/0301-620x.75b4.8331119
42. Gromov K, Pedersen AB, Overgaard S, Gebuhr P, Malchau H, Troelsen A. Do Rerevision Rates Differ After First-time Revision of Primary THA With a Cemented and Cementless Femoral Component? *Clinical Orthopaedics & Related Research*. 2015;473(11):3391-3398. doi:https://doi.org/10.1007/s11999-015-4245-6
43. Edelstein AI, Hume EL, Pezzin LE, McGinley EL, Dillingham TR. The Impact of Femoral Component Cementation on Fracture and Mortality Risk in Elective Total Hip Arthroplasty. *Journal of Bone and Joint Surgery*. 2022;104(6):523-529. doi:https://doi.org/10.2106/jbjs.21.00640
44. Fleischman AN, Chen AF. Periprosthetic fractures around the femoral stem: overcoming challenges and avoiding pitfalls. *Annals of Translational Medicine*. 2015;3(16):234-234. doi:https://doi.org/10.3978/j.issn.2305-5839.2015.09.32
45. Wagener N, Hardt S, Matthias Pumberger, Friederike Schömig. Comparative analysis of femoral bone loss: uncemented vs. cemented aseptic stem loosening in first-time revision surgery—a retrospective evaluation of 215 patients. *Archives of Orthopaedic and Trauma Surgery*. 2024;144(8):3427-3438. doi:https://doi.org/10.1007/s00402-024-05506-z
46. van Erp JHJ, Snijders TE, Weinans H, Castelein RM, Schlösser TPC, de Gast A. The role of the femoral component orientation on dislocations in THA: a systematic review. *Archives of Orthopaedic and Trauma Surgery*. 2021;142(6):1253-1264. doi:https://doi.org/10.1007/s00402-021-03982-1
47. Kunutsor SK, Barrett MC, Beswick AD, et al. Risk factors for dislocation after primary total hip replacement: a systematic review and meta-analysis of 125 studies involving approximately five million hip replacements. *The Lancet Rheumatology*. 2019;1(2):e111-e121. doi:https://doi.org/10.1016/s2665-9913(19)30045-1