Article

ASSESSING SPINOPLASTY IN RELATION TO SINGLE AND DOUBLE INTERSPINOUS SPACER APPLICATIONS: A STRATEGY FOR AUGMENTING POSTERIOR ARCH STABILITY AND PREVENTING SURGICAL FAILURE

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ABSTRACT

Lumbar spinal canal stenosis (LSCS) is among the most prevalent degenerative conditions in older individuals. Treatment failure can occur, typically associated with bone remodeling or fractures of the spinous processes. Polymethylmethacrylate (PMMA) augmentation of the posterior arch (spinoplasty, SP) has recently been suggested for cases of neoplastic involvement. This investigation assessed the effectiveness of SP as a preventive therapy prior to the placement of an interspinous spacer (IS). Additionally, we explored the possibility of addressing patients who had previously received IS implants that subsequently failed by introducing a second spacer at the same level alongside accessory SP. Between January 2009 and August 2021, 593 patients with LSCS were treated with CT-guided percutaneous IS implantation in our facility. Starting from January 2011, all patients diagnosed with osteoporosis underwent prophylactic SP before the spacer's insertion. Furthermore, in cases of re-stenosis attributed to bone remodeling and/or fractures, a second similar device was placed after strengthening the spinous processes with PMMA, aimed at reopening the stenotic spinal canal. Among patients who received prophylactic treatment before spacer placement, no re-stenosis was noted during the follow-up period of three to twelve months. Patients who underwent secondary spacer implantation at the same level following posterior arch augmentation once again reported alleviation of symptoms, with no further bone remodeling detected during follow-up evaluations. In conclusion, prophylactic SP prevents the failure of individual spacers due to bone remodeling/fractures and facilitates failure repair through the introduction of a second spacer at the same level.

KEYWORDS: *spine, lumbar canal stenosis, spacer, prophylaxis*

INTRODUCTION

Lumbar spinal canal stenosis (LSCS) ranks as one of the most common degenerative disorders in senior patients, typically causing neurogenic claudication, numbness, and weakness in the lower limbs, potentially resulting in paraparesis (1). Chronic radicular nerve ischemia, secondary to compression of the radicular veins associated with the spinal canal

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and/or foraminal stenosis, is often cited as the root cause of these symptoms, while distraction of the posterior arch frequently presents a solution to the condition, as supported by various biomechanical studies (2, 3). Although conventional surgical decompression is viewed as a definitive solution for LSCS, percutaneous interspinous spacers (IS) have recently emerged as a treatment option, promoting distraction of the spinous processes, alleviating the compression caused by interspinous ligaments, and mitigating the progressive syndrome while alleviating lower limb radiculopathy (4, 5). Furthermore, the indications for IS implantation have recently expanded to include lumbar discogenic pain, facet joint syndromes, disc herniation, and low-grade instability (6).

Unfortunately, approximately 7% to 13% of patients treated with IS report early recurrence of symptoms due to fractures and/or remodeling of the posterior laminae, often linked to localized bone tenderness (such as osteoporosis or excessive stress overload), which diminishes the distraction achieved previously, including in patients treated with innovative soft non-metallic polyetheretherketone (PEEK) devices (7). Vertebroplasty is widely recognized as the preferred technique for strengthening vertebral bone, and numerous applications beyond the vertebral bodies (e.g., sacral fractures and tumoral involvement of the posterior arch) have been suggested (8-17). This study investigated the potential of preventing bone remodeling of the laminae in osteoporotic patients slated for IS implants through pre-operative posterior arch augmentation [spinoplasty (SP)] using prophylactic CT-guided Polymethylmethacrylate (PMMA) injection into the posterior arch. Additionally, we considered treating patients who previously received traditional IS implants that later failed by performing localized SP and placing a second IS device anteriorly or posteriorly to the initial implant at the same level.

MATERIALS AND METHODS

Between January 2009 and August 2021, 593 patients with LSCS underwent CT-guided percutaneous IS implantation at our department. The ages of the patients varied from 56 to 82 years (mean age 73 years). Among them, 505 patients presented symptoms related to spinal canal stenosis (11 at L2/L3, 102 cases at L3/L4, and 379 at L4/L5, with 13 cases involving both L3/L4 and L4/L5 levels). At the same time, 88 exhibited severe localized foraminal stenosis (24 cases with unilateral, and 64 with bilateral stenosis) related to LSCS, as well as grade I spondylolisthesis (47 patients) with or without (41 patients) disc degeneration. All patients were subjected to clinical evaluations, and assessments of the quality of life and self-rated pain were conducted using a visual analog scale (VAS). The pre-operative average VAS score was 8.4.

Additionally, pre-operative EMG evaluation of the lower limbs and a lumbar CT-MR examination were conducted. We utilized two different types of PEEK-coated IS devices: one featuring a pair of metallic wings for encasing the spinous process (In-Space®, Synthes-DePuy, Switzerland) and a second comprising a fully PEEK spiral body without external wings (Helifix®, Alphatec, CA, USA). The size of the IS varied between 8mm and 14mm (9 patients received 8mm devices, 162 patients received 10mm, 388 patients received 12mm, and 34 patients received 14mm devices), with each patient treated at a single level. At the same time, dual-level treatment was performed only in four cases. The procedure was conducted under local anesthesia with analgosedation (18), directly within a CT suite, where CT scans were used to place the K-wire in the selected interspinous space via a posterolateral entry, employing a small skin incision measuring 5-10 mm. A C-arm mounted on the CT cradle served as a radiological guide for the placement of progressive dilators (ranging from 8 mm to 14 mm depending on the situation), culminating in the insertion of the IS device under fluoroscopic direction. The total duration of the procedure was approximately 30 to 45 minutes.

To prevent IS treatment failure linked to osteoporosis, starting in January 2011, all candidates for IS implants underwent a bone mineral density scan (BMD) to identify any osteoporotic conditions. Out of the 593 patients, 149 (approximately 25.1% - Group A) had severe osteoporosis, necessitating prophylactic posterior laminae augmentation with PMMA before the placement of IS implants.

Follow-up clinical evaluations were conducted at one, three, and 12 months post-procedure. In 65 out of 593 patients treated before January 2011 (approximately 11% - Group B), symptoms initially resolved after one month (with a mean VAS value of 1.7), only to return, with the VAS score rising back to 7.4 over one to twelve months (mean three months). All patients experiencing recurrent symptoms underwent a new CT examination (spiral CT, 1mm thickness, sagittal 2D reconstructions, mA rates lowered to a minimum of 20 mA), which revealed bone remodeling of the spinous processes, encasing the IS, thus restoring original stenosis. For patients in Group A, posterior arch augmentation was performed under CT guidance using a C-arm technique, whereby a 13G needle was introduced into the spinous processes in a sagittal orientation (123 patients) or through a parasagittal oblique route (31 patients), injecting 1-2 cc of PMMA into the laminae.

The IS device was introduced immediately afterward, according to the previously outlined technique. 54 out of the 65 Group B patients who suffered a failure of their initial IS treatment due to bone remodeling were offered prophylactic

SP treatment along with the insertion of a second IS device at the same level as the preceding one, aimed at elevating the interspinous space once more. All patients underwent SP treatment following the previously described procedure, with particular care taken regarding the targeted area for PMMA deposition (immediately above and below the site designated for the second implant). Subsequently, the second IS was introduced, with three cases inserted posteriorly and twelve cases placed anteriorly, based on the available space as indicated by pre-operative 2D CT reconstructions (Fig. 1, 2A, B). Follow-up CT studies were conducted at one, three, and twelve months, adhering to the established protocol.

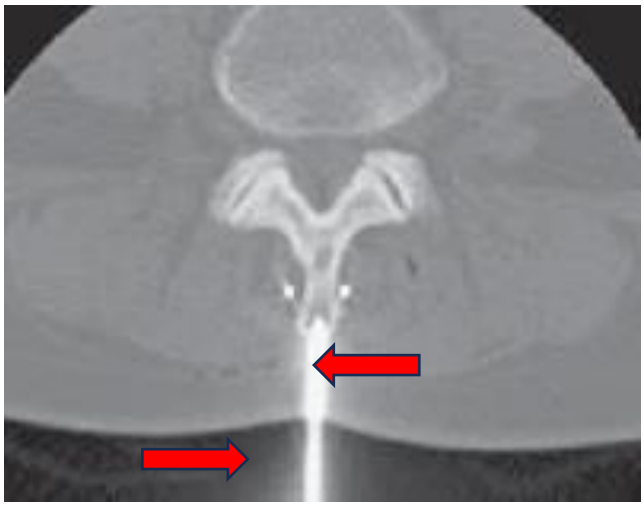

Fig. 1. *Posterior arch augmentation was performed by introducing a Jamshidi needle into the spinal processes at the L3 and L4 levels (**arrows**).*

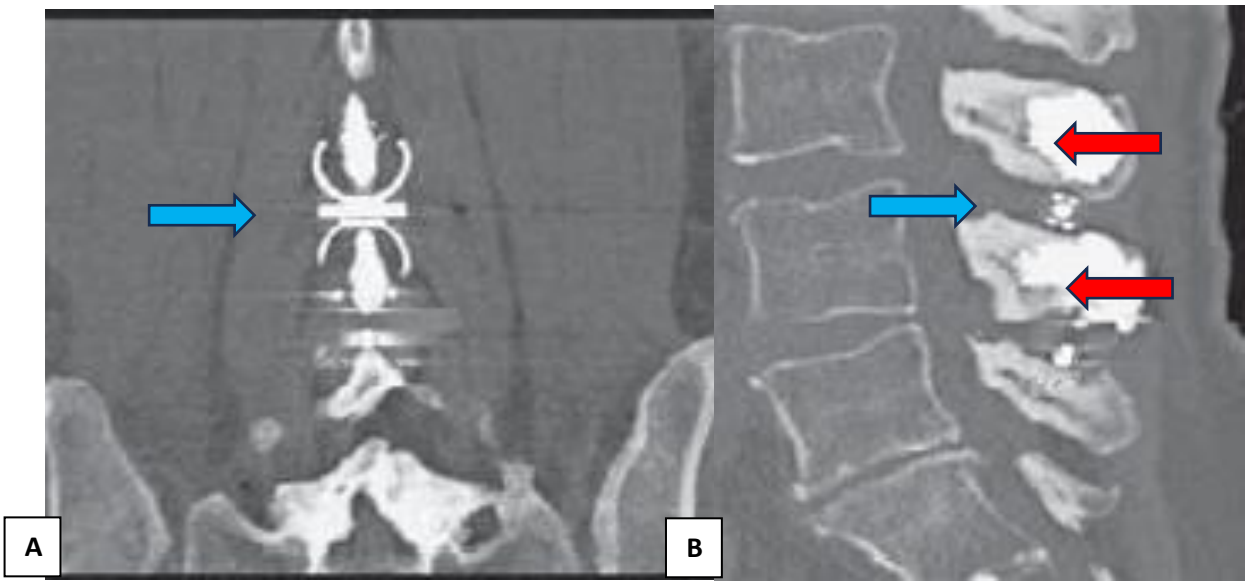

Fig. 2. ***A**): CT coronal view; **B**): sagittal view; After PMMA injection (**red arrows**), a new device (InSpace®, fully Peek, bilateral metal fins) was introduced at the L3/L4 level (**blue arrows**).*

RESULTS

No complications related to PMMA injection were reported among patients in Group A who underwent prophylactic SP, and minimal extra-lamina leakage was observed in just one patient, who exhibited no symptoms attributable to the slight paraspinous leakage. There was no recurrence of LSCS-related symptoms reported during follow-up evaluations spanning three to twelve months, with the mean value on the VAS scale dropping to 2. Follow-up CT examinations

revealed sustained distraction of the interspinous space and foramina at the treated level, with no remodeling of the posterior arch occurring thanks to PMMA augmentation at the final one-year follow-up control (Fig. 3, 4, 5 A-B). In the 65 patients who received a second IS device at the same level (Group B), the symptoms that recurred after the initial IS implant failure were completely resolved following the second treatment (prophylactic SP combined with IS implantation), and they remained asymptomatic at the follow-up checkup encompassing one to twelve months. No further symptoms were observed in patients with dual IS implants.

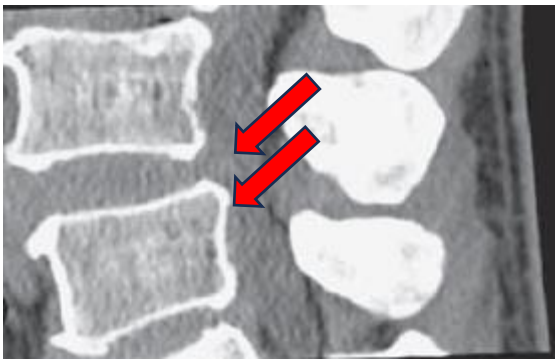

Fig. 3. *Re-treating spinal canal stenosis recurrence related to bone remodeling. Preliminary CT scan documents segmental canal stenosis (**arrows**).*

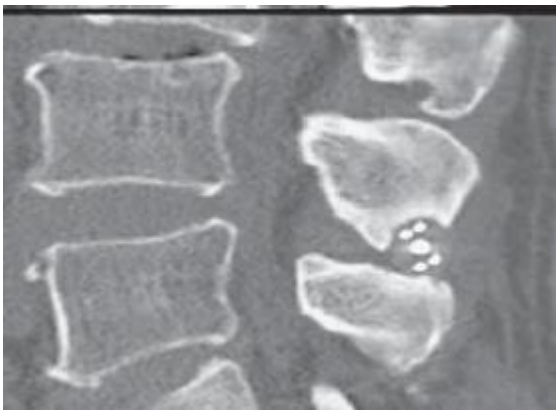

Fig 4. *After 60 days, because of the spinous process of bone remodeling, the patient experienced a recurrent syndrome related to re-stenosis.*

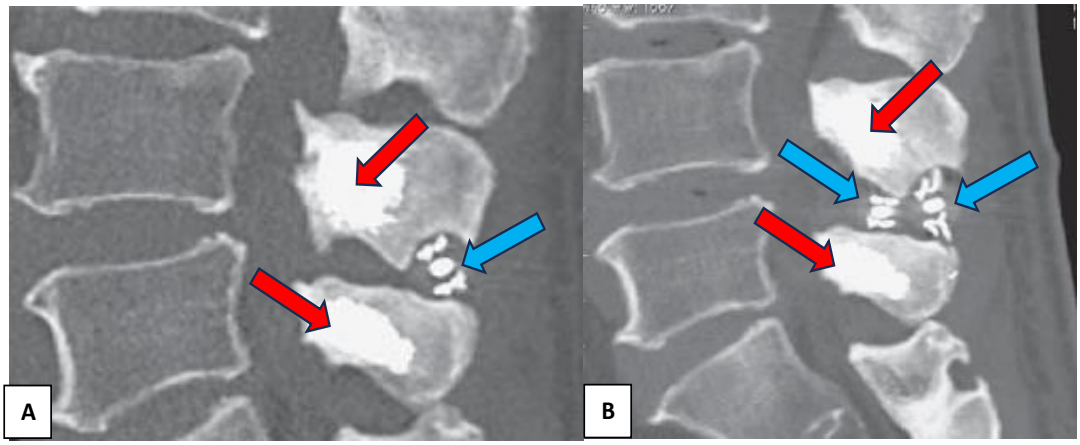

Fig. 5. ***A, B)****: Planning a second IS introduction anteriorly to the former, PMMA augmentation (****red arrows****) was obtained in the anterior half of the laminae and spinous process, then the guidewire was placed anteriorly to the first spacer, and a second device was finally deployed, reopening the interspinous space (****blue arrows****).*

DISCUSSION

Biomechanical research emphasizes the notion of "dynamic stabilization" of the posterior arch, circumventing the need for posterior fusion: the insertion of IS reduces discal loading, thus avoiding local anterior spinal column stress, aligning with contemporary concepts of the "functional spinal unit" (19-24). While traditional posterior stabilization and fixation techniques utilizing open surgery have been employed for several years, interest has surged in developing percutaneous stabilization systems. Fully percutaneous procedures have the significant advantage of minimizing surgical duration and postoperative recovery time and do not necessitate general anesthesia, proving to be well tolerated and accepted by patients. Previously, older, fully titanium devices were replaced by PEEK-coated IS, which was aimed at reducing mechanical stress between the device and the bony posterior arch. Nevertheless, complications related to remodeling of the posterior laminae, along with a return to original stenosis, may arise even in these cases. Augmentation of the pedicle and transverse processes has been documented, demonstrating pain relief in neoplastic involvement without reported complications (21). The posterior arch of the vertebra can be easily fortified through PMMA injection, achieved by placing a 13 to 15G needle into the spinal processes along the midline or employing a parasagittal oblique approach to reach the laminae directly (8).

A small volume of PMMA (generally between 1 to 3 cc) introduced under fluoroscopic guidance is straightforward to perform, and the PMMA remains within the spongy bone due to the laminae's thick cortex. By implementing prophylactic SP, IS placement has been sustained in our patient cohort, eliminating the risk of recurrent syndromes even after one year of follow-up. Introducing an IS following SP does not require a different approach or specific precautions. Currently, in cases of spacer failure due to remodeling and/or fracture of the spinous processes, more invasive open surgical interventions are commonly perceived as the sole recourse to decompress the spinal canal once more. Surgical decompression typically entails bilateral laminectomy and posterior interbody fusion with the application of screws and rods under general anesthesia. Complications associated with scarring and/or osteoporosis have been reported with conventional surgical methods (22-24). For this reason, re-treatment utilizing local anesthesia is advisable, particularly in elderly patients.

In our cohort of patients experiencing failure with previously implanted IS devices, we achieved resolution of recurrent LSCS by repositioning a second device at the same level, with spinous processes safeguarded through prophylactic posterior arch augmentation. While deploying a second IS device at the same level is not extensively documented in the literature, the technique appears straightforward for patients with prior IS implant failures and adequate space adjacent to the former spacer. When adequate distraction is accomplished through the placement of a second device,

both clinical symptoms are markedly alleviated or vanish entirely, thereby yielding new decompression of the central spinal canal and/or foramina.

CONCLUSIONS

Posterior arch augmentation emerges as a promising technique to avert IS failures in patients with spinal canal stenosis undergoing percutaneous spacer placement. It represents a user-friendly technique suitable for all patients at risk of fractures or bone remodeling resulting from osteoporosis or other skeletal stress conditions. The failure of a previously implanted IS device related to bone remodeling or fracture in patients without prophylactic SP can be effectively addressed through targeted SP and inserting a second IS device, restoring distraction and mitigating the recurrent clinical syndrome associated with re-stenosis.

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Evaluation Study

ASSESSMENT OF SURGICAL DECISION-MAKING FOR FRACTURES AROUND TROCHANTERIC NAILS: VERGILIUS CLASSIFICATION SYSTEM VALIDATION

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ABSTRACT

The increasing incidence of fragility fractures, particularly those affecting the proximal femur, has led to a rise in patients with fixation implants and peri-implant fractures. These secondary fractures, occurring around implanted devices such as intramedullary nails, present significant challenges in diagnosis and treatment. A novel classification system, the Vergilius Classification, was developed to provide a structured approach to peri-nail fractures, incorporating fracture location, morphology, fragment count, and healing status of previous fractures. This study aimed to evaluate the agreement among medical professionals in applying this new classification system. A total of 35 medical professionals, including physiatrists, trauma surgeons, and radiologists, participated in the study. They were asked to classify 15 anonymized clinical cases according to the Vergilius system, and their responses were analyzed for accuracy, agreement, and face validity. The results showed a high level of agreement (80%) across most categories, with the location of the fracture, fracture morphology, and number of fracture fragments (2, 3, >3) demonstrating the strongest consensus. However, agreement regarding the healing status of previous fractures was lower. Participants rated the classification as clear, easy to use, and potentially beneficial in clinical practice. This study confirms that the Vergilius Classification System is reliable and applicable for peri-nail fractures. Future real-world cohort studies are needed to further assess its clinical impact.

KEYWORDS: *peri-implant, peri-nail, fragility, classification, extracapsular, hip fracture*

INTRODUCTION

With the constant increase in life expectancy and fragility fracture rates, a growing incidence of patients with fixation implants and peri-implant fractures is to be expected (1, 2). A possible definition of this type of injury is a secondary fracture occurring in patients who have been treated with a fixation device (such as an extramedullary plate and screws or an intramedullary nail) and that is still present in the bone. The most common fragility fracture is the proximal femoral fracture (PFF), commonly distinguished in intracapsular and extracapsular (3). These latter are generally treated using intramedullary nails. A constant increase in the incidence of peri-nail fractures is observed (2, 4-7).

Norris et al. analyzed over 13,000 patients in a systematic review, discovering that the incidence of secondary fractures around the nail was 1.7% (4). Very few guidelines exist for treating peri-nail fractures (6, 8, 9). Recently, we developed a new classification system; considering the increasing incidence of peri-nail fractures, there arises a need for an adequate description of these cases that might aid in diagnosis and treatment decision-making (2). After a consensus meeting, we developed a hierarchal classification system based on the fracture location, morphology, the number of fracture fragments, and the healing state of the previous fracture (Fig. 1, 2).

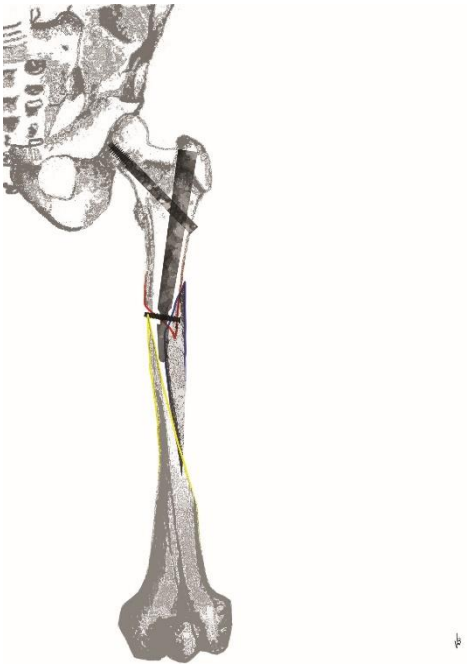

Fig. 1. *A drawing showing a BS3 peri-nail fracture.*

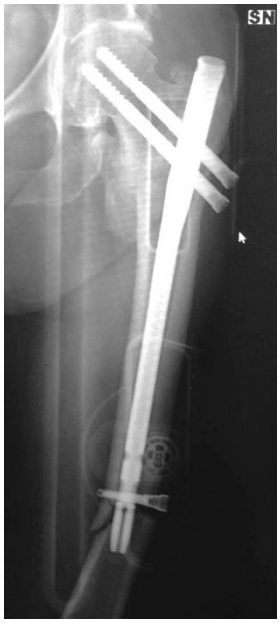

Fig. 2. *An X-ray showing a BO3 fracture. Note the small fragment around the distal screw apex.*

The objective of this study was to evaluate the concordance among a group of physicians in defining a fracture according to our new classification proposal.

MATERIALS AND METHODS

A total of 35 medical professionals were involved in this study: 10 physiatrists, 17 trauma surgeons, and 8 radiologists. Each participant was shown a brief presentation of the proposed classification system, with slides available throughout the study.

The primary aim of this evaluation was not to establish the ease of memorizing the classification but rather to determine the level of agreement among participants in defining individual cases. A further stratification was performed to evaluate the level of agreement for each specific category of participants. After presenting the Virgilio classification, each participant was invited to complete a form that included three different sections of questions.

Section 1: participant information

In the first section, questions regarding the participating physician were asked, including:

- the type of specialization obtained;
- the number of years in practice;
- the type of institution where they practice (Level I, II, III);

Section 2: clinical case evaluation

In the second section, 15 clinical cases of patients, strictly anonymized, were presented and previously selected by the authors of the study. Participants were to assess four essential parameters that define the Vergilius classification system:

- location of the fracture line: (A) fracture around the nail; (B) fracture around the distal screw; (C) fracture distal from the tip of the nail;
- morphology of the fracture: (S) spiral fracture; (O) oblique fracture; (T) transverse;
- number of fracture fragments: (2) two fracture fragments; (3) three fracture fragments; (3+) more than three fracture fragments;
- any prior consolidation of the fracture.

Section 3: classification feedback

In the third and final section, participants were invited to express their satisfaction with the classification using a score based on their responses to the following questions:

- did you find the classification clear?
- did you understand how to apply the classification?
- do you think this classification could be useful in clinical practice?
- does the classification adequately measure the properties of the fracture?

Parameters for evaluation:

1. accuracy: the authors of the classification stratify the cases and assess the percentage of correct classifications;
2. agreement percentage: this involves considering the percentage of participants who respond consistently to the clinical cases evaluated;
3. face validity: Two distinct Likert scales were used to evaluate clarity and understanding, requiring a score between 0 and 5. Face Validity was calculated as the average value of these indices.

Acceptable results defined at the start of the study:

- accuracy >80% for each individual case;
- agreement >80% for each individual case.

RESULTS

Of the 35 medical professionals initially involved in the study, 22 completed the evaluation protocol (65%). Of these, 12 were trauma surgeons (54.5%), 4 were radiologists (18.2%), and 6 were physiatrists (27.3%). 76% of the investigators reported to work in a high-volume hospital for trauma care. As a cumulative result, a good agreement between the observers was observed in 12/15 cases (80%). Regarding the subitems of the classification: the ABC (localization of the fracture line) reached the agreement in 10/15 cases; the SOT (fracture morphology) reached the agreement in 11/15 cases. The number of fracture fragments reached the agreement in 13/15 cases. Finally, the healing status of the previous fracture reached the agreement in 8/15 cases. Regarding face validity, 81% of the professionals found our classification clear, and 86.4% found it easy to use. According to 77.3% of professionals, the classification appropriately describes the characteristics of peri-nail fractures and would aid their daily practice.

DISCUSSION

The increase in life expectancy has led to a continuous growth of fragility fractures, especially those affecting the proximal femur (1, 10). These fractures are generally distinguished in intracapsular and extracapsular, presenting different clinics, patients' characteristics, treatment options, and outcomes (3). Extracapsular fractures are generally treated with intramedullary nailing (11). This technique presents some complications, including screw cut out, cut through, and nail failure (12). Among these, the secondary fractures arising along an implanted trochanteric nail are of growing interest (2). However, the exact incidence is unclear, considering these fractures are generally included among the peri-implant fractures (occurring around an implanted fixation device). The incidence in various studies ranged from 0% to 2.3% (11-14). Particularly, Parker et al., in a systematic review, found an incidence of 2.0% (39/1933) (12). Overall, the reported modern rates of peri-nail fractures have been 0% - 3.3% for short nails and 0% - 1.5% for long nails (11, 14). The reported incidence is of note, especially considering the high number of trochanteric nails implanted and comparing the incidence of periprosthetic fractures. These latter affect 1% of cases of primary total hip arthroplasty (THA) and 4% of revisions (15). Lindahl et al., through analysis of the Swedish hip prosthesis registry from 1979 to 2000, reported an annual incidence of 0.07% for the first 18 years, increasing to 0.1% by the end of the study period (16). The cumulative incidence was 0.4% for primary implants and 2.1% for revisions (16). Periprosthetic fractures accounted for 6% of the causes for revision (16).

Choosing the correct surgical strategy is essential to minimize the risk of new complications and to ensure the maximum chance of healing of peri-nail fractures; therefore, we developed an original hierarchal classification system based on a previous consensus meeting (2). The 'Vergilius Classification System' is based on the evaluation of those factors considered most important for the peri-nail fractures treatment according to the panel of experts:

- location of the fracture line: (A) fracture around the nail; (B) fracture around the distal screw; (C) fracture distal from the tip of the nail;
- morphology of the fracture: (S) spiral fracture; (O) oblique fracture; (T) transverse;
- number of fracture fragments: (2) two fracture fragments; (3) three fracture fragments; (3+) more than three fracture fragments;
- healing status of the previous extracapsular fracture: (n) fracture not healed.

Therefore, our classification system presents 54 potential categories in which the peri-nail fracture could be classified, and a single fracture could be described using 3 to 4 alphanumerical codes. According to Bernstein et al., a classification system should be reliable, simple, and the basis for treatment decision-making (17). After conceiving the Vergilius Classification System, we decided to evaluate its reliability and usefulness, as reported by those physicians who generally treat patients with peri-nail fractures. According to the present study, our classification system should be considered reliable, especially for the parameters of fracture localization (ABC), morphology (SOT), and fracture fragments (2, 3, +3). The evaluation of the healing state (n) of the previous fracture did not reach an agreement in most cases, raising some questions about its applicability. However, we considered that the quality of the imaging for some of the analysed x-rays was poor. In fact, the radiologists reach the highest percentage of agreement in the evaluation of this item. Although the usefulness of the 'Vergilius Classification System' needs cohort-based real-life studies, we consider of note that most of the evaluators found it clear, easy to use, and potentially useful in their daily practice thanking a clear description of the fracture.

CONCLUSIONS

Peri-nail fractures represent an emerging and dreadful complication of extracapsular fracture treatment. An appropriate classification of peri-nail fractures is mandatory for their adequate treatment. We developed a classification system based on the evaluation of fracture line localization, fracture morphology, number of fracture fragments, and healing state of the previous fracture. Our classification categorizes the peri-nail fractures in 54 different types. According to the present study the Vergilius Classification System was proved to be reliable and to have a potential impact in daily practice of the physicians involved in peri-nail fractures treatment.

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Retrospective Evaluation Study

DOCKING POINT NON-UNION TREATED WITH INTRAMEDULLARY NAILING: A RETROSPECTIVE STUDY

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ABSTRACT

Fracture septic nonunion is one of the most demanding complications for both the orthopedic surgeon and the patient, considering the need for several procedures that significantly impact patients' quality of life. Very often, fracture septic nonunion is associated with bone loss. External fixation through the Ilizarov principles promotes the filling of the bone gap thanks to distraction osteogenesis, a technique also known as bone transport. However, fibrous tissue frequently appears during the bone transport at the lower end, leading to a docking point nonunion. This study aimed to evaluate the outcomes of patients presenting with docking point nonunion treated using intramedullary nailing. We conducted a retrospective study on those patients treated with bone transport who developed docking point nonunion and treated with intramedullary nailing. For each patient, we collected demographic data, prior diagnosis, time to heal the initial injury, ASA score, and other recalcitrant lower limb discrepancies and malalignments. Specific questionnaires, including the Oxford Knee Score, Oxford Hip Score, AOFAS Foot Score, and ASAMI Scoring System, were used to evaluate the functionality of the affected limbs. This study included 8 patients (6 males and 2 females), aged between 23 and 65 years. Seven patients had a diagnosis of a tibial nonunion, and one had a femoral nonunion. Radiographically, all patients had a gap with an average length of 5.03 cm (range 2.14-10.1 cm). At the final follow-up, all patients showed difficulty walking on uneven surfaces but not on flat surfaces. All patients had limb length discrepancies, with an average of 1.5 cm (range from 0.5 to 3.5 cm). Five out of 8 patients presented with a slight malalignment: 3 in valgus and 2 in varus, with an average deviation of 5.8° (range 5-11°). The use of the Ilizarov bone transport, followed by intramedullary nailing, is effective in recovering bone loss and achieving complete healing of the docking point in a relatively short time. This approach is associated with a low incidence of post-traumatic deformities and preservation of limb functionality within a relatively short period.

KEYWORDS: *fracture, septic, bone loss, tibia, non-union, Oxford Knee Score, Oxford Hip Score*

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INTRODUCTION

Non-union defines a fracture that is not healed after 6-to-9 months and/or the absence of callus progression on sequential X-rays (1, 2). Septic nonunion is a condition that considerably affects the patient's quality of life, as it results in chronic pain and functional impairment (1, 3). The treatment is often difficult for both the patient and the orthopedic surgeon. Nowadays, various therapeutic strategies are available to address nonunion, ranging from conservative methods, including immobilization and bone stimulation, to pharmacological interventions with osteoinductive agents and extending to more advanced surgical options (1, 4-7). However, the key pillars in the management of septic nonunion consist of the surgical debridement of the fracture site, mechanical stabilization of the bone segment, and subsequent reconstruction using bone grafts or biomaterials aimed to restore the structural and functional integrity of the affected bone (1, 8). Among the many surgical techniques available, the Ilizarov method is particularly noteworthy (9). It is based on applying a circular external fixator that stabilizes the affected bone and encourages healing and tissue regeneration, exploiting the distraction osteogenesis observed in bone transport.

However, bone transport may take time, and one of the most prevalent complications encountered during this treatment is the nonunion of the docking point (3). This complication seems to be linked to the development of fibrous tissue over time between the osteotomy and the arrival of the transported bone segment at the endpoint of the transport. Currently, most authors recommend periodic evaluations of the docking point during bone transport and its debridement to remove fibrous tissue (3). The aim of this study is to evaluate the effectiveness of intramedullary nailing in treating docking point nonunion.

MATERIALS AND METHODS

We conducted a retrospective study on those patients with a septic non-union, treated with the bone transport technique complicated with a docking point nonunion treated with an intramedullary nail from 2010 to 2020. Each patient was evaluated through a comprehensive medical history and a detailed physical examination. The following data were collected: personal information, previous diagnosis, ASA score, healing time of the initial lesion, and any residual lower limb discrepancies and malalignment.

The primary endpoints were healing rate and time to healing (defined as the time elapsed between the surgery and the achievement of healing). Bone healing was defined as the union of at least three cortices. The secondary endpoints were related to limb function, evaluated using the Oxford Knee Score, American Orthopaedic Foot & Ankle Society (AOFAS) Foot Score, Oxford Hip Score, and the Association for the Study and Application of the Method of Ilizarov International and External Fixation (ASAMI) Scoring System.

RESULTS

Eight patients met the inclusion criteria, 6 males and 2 females, aged between 23 and 65. Seven of 8 patients had a tibial nonunion, while the other had a femoral nonunion. The previous fractures were all open, except in one case (Patient No. 2, Male, 48 years old). The affected limb was the left in 50% of the cases and the right in the remaining 50%; in all cases, the bone transport method was used, with an external fixator followed by an intramedullary nail. The mean bone gap before the start of the treatment was 5.03 cm (range 2.14 - 10) (Table I).

Table I. *Characteristics of the cohort and results of the proposed treatment.*

Id	Age	Sex	Asa	Non-union site		Open fracture (y/n)	Bone gap (cm)	Fracture healing (y/n)	Healing time (months)	OKS	AOFAS	OHS	Residual lower limb discrepancy (cm)	Residual malalignment	Residual deformity (degrees)
1	33	M	2	femur	distal third	Y	2.89	Y	11	24	NA	44	3	varus	10
2	48	M	1	tibia	distal third	N	3.72	Y	9	55	86	NA	1	varus	10.44

3	59	M	3	tibia	proxi-mal third	Y	7.47	Y	8	45	65	NA	0.5	valgus	5.19
4	62	M	2	tibia	distal third	Y	10.10	Y	8	6	10	NA	1,5	No	--
5	23	M	1	tibia	distal third	Y	2.63	Y	12	25	67	NA	0,5	No	--
6	65	M	3	tibia	distal third	Y	6.63	Y	7	25	49	NA	3,5	valgus	11
7	29	F	4	tibia	middl e third	Y	4.94	Y	5	24	61	NA	2	No	--
8	52	M	1	tibia	distal third	Y	2.15	Y	3	46	100	NA	0,5	valgus	10.38

NA: not available.

In all patients, complete healing was achieved after an average of 7 months. The shortest healing time reported was 3 months (Patient No. 7, Female, 29 years old). Regarding the secondary endpoints, the average Oxford Knee Score was 31 points, ranging from 6 to 55. The AOFAS Foot Scale averaged 62 points, ranging from 10 to 100. Regarding the patient who underwent femoral reconstruction, the Oxford Hip Score was 44 (Table I). Finally, the clinical and radiographic results according to the ASAMI Scoring System for the bone part were: excellent in 4 cases (50%), good in 2 (25%), fair in 0 (0%), and poor in 2 (25%) (Table II), while in the functional part of the ASAMI Scoring System, the results were: excellent in 2 cases (25%), good in 4 (50%), and fair in 2 (25%) (Table III).

Table II. *Results according to the ASAMI Scoring System – bone part.*

	Description	Patients
Excellent	Consolidation, absence of infection, deformity < 7°, lower limb length discrepancy <2.5 cm	4 (50%)
Good	Consolidation + two criteria among: absence of infection, deformity <7°, lower limb length discrepancy <2.5 cm	2 (25%)
Fair	Consolidation + one criterion among: absence of infection, deformity <7°, lower limb length discrepancy <2.5 cm	0
Poor	Lack of consolidation or refracture or consolidation + deformity >7° + lower limb length discrepancy >2.5 cm	2 (25%)

Table III. *Results according to the ASAMI Scoring System – functional part.*

	Description	Patients
Excellent	Active, no limping, minimal stiffness (extension deficit <15°, ankle dorsiflexion deficit <15°)	2 (25%)
Good	Active + one or two criteria among: limping, stiffness, hyporeflexia, pain	4 (50%)
Fair	Active + three or four criteria among: limping, stiffness, hyporeflexia, pain	2 (25%)
Poor	Inactive (difficulty performing normal daily activities)	0
Failure	Amputation	0

All patients showed a slight limb length discrepancy, with an average of 1.5 cm, ranging from 0.5 to 3.5 cm. Five patients presented a residual malalignment. Among these, the distribution is as follows: 3 patients with valgus, 2 with varus, and 3 with no deviation, with an average angle of 5.8 degrees, ranging from 5 to 11 degrees.

DISCUSSION

The results from this observational study suggest that the use of the intramedullary nail after bone transport and external fixation may represent a reliable treatment for fracture non-union complicated at the docking point. This study described a clear decision process for selecting the patients who followed a systematic protocol represented by the application of Ilizarov principles using a circular fixator for bone transport and subsequent nailing at the docking point. It has been shown that different fixator constructs can influence the outcome of the Ilizarov method (10, 11).

Our selection method allowed us to reduce variability among the patients by using the same type of fixator (Ilizarov circular frame), the same diagnostic criteria, and the same functional evaluation using appropriate scores. The patients were consistently monitored throughout the process to evaluate the functional recovery of the affected limb and the associated sequelae, as well as to assess the impact of these on each patient's quality of life (Fig. 1).

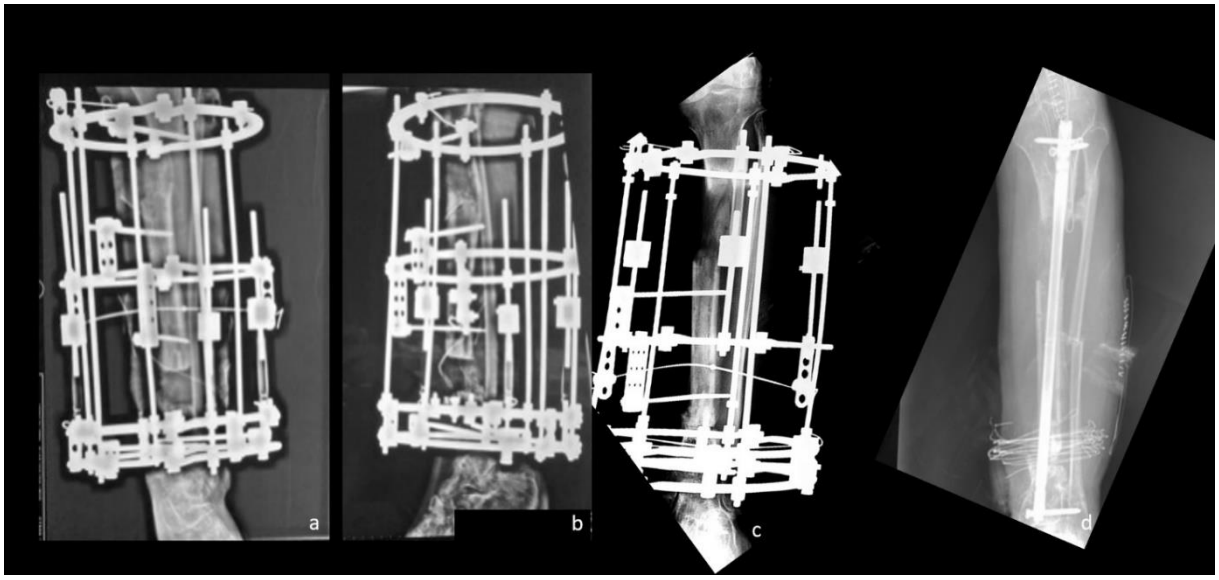

Fig. 1. *A clinical case showing the proposed treatment. In **a)** and **b)** anteroposterior and lateral X-rays during bone transport; **c)**: docking point nonunion; **d)**: intramedullary nailing of the docking point non-union.*

The use of the intramedullary nail was a breakthrough in the treatment of the docking point non-union (11), as also confirmed by our observations from both a radiographical and functional perspective. The average healing time (7 months) was relatively fast compared to other studies in the literature (11-13). For example, in the study by Sigmund et al. (9), the average healing time was longer (10 months), while it was 12 months in another study conducted by Lavini et al. (13).

For the functional assessment, as previously described, we used a series of scores specifically conceived for the function of the knee, ankle, and hip. Overall, the functional results were satisfactory in most cases. The sequelae analyzed in the follow-ups include limb length discrepancies and malalignments, which, from a broader perspective of the results described in the literature, represent minor complications. Indeed, considering various studies on the subject, many present much more troublesome complications, including recurrences of the infection (if any) that required unplanned reoperations, accompanied by recurrent infections during follow-up (12), as well as non-unions and failures at the docking site (13). Finally, but no less importantly, there have been cases of failure due to non-union of the regeneration (14-16).

On the other hand, in this study, we did not encounter these complications, partly due to the small sample size, the techniques we used (external fixator and subsequent intramedullary nail), and the multidisciplinary approach based on the contemporary evaluation of the orthopedic surgeon, the infectious disease specialist, and the radiologist. Nevertheless, as previously mentioned, complications still exist. Limb length discrepancies were observed in all patients during the follow-ups, with a minimum of 0.5 cm and a maximum of 3.5 cm, while malalignments were not found in all patients. Only three patients presented with valgus malalignment, two patients had varus malalignment, and the remaining

three had no malalignment. We addressed these issues with elevated footwear, which proved to be effective in correcting all the detected discrepancies, though two patients also required the use of a cane.

Regarding functionality, we found that 75% of patients had an excellent/good score on the ASAMI Scoring System, while 25% had a fair score. No patient had a poor score or required amputation. This indicates that all patients remained active. Additionally, 25% of patients reported no limp, pain, or stiffness; 50% experienced stiffness but no limp or pain; and only two patients, representing 25%, had limp, pain, and stiffness. Overall, we can conclude that in most patients, the function of the affected limb remained mostly preserved, and the aforementioned sequelae did not significantly affect their activities. Our study has some limitations, primarily due to the small sample size and the absence of a control group. However, we felt it necessary to apply strict inclusion and exclusion criteria to obtain a more homogeneous group, especially considering that the pathology studied is rarely observed. Moreover, the occurrence of docking point nun-union in the case of septic non-union is a dreadful but uncommon complication and there is no gold standard for its treatment

CONCLUSIONS

The bone transport method with external fixation, followed by the intramedullary nail, is effective in recovering bone loss and achieving complete healing at the docking point in a short period while maintaining the infection control of the affected bone. Furthermore, this combined approach is associated with mild post-traumatic deformities that seem to be correlated to limb function and patient satisfaction. Finally, the results confirm that the use of the intramedullary nail leads to very satisfactory outcomes in a relatively short time, a condition that, in our opinion, ameliorates patients' compliance and satisfaction with the treatment.

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Randomized Prospective Study

TO BRACE OR NOT TO BRACE? EARLY POSTOPERATIVE OUTCOME AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING A HAMSTRING GRAFT: A RANDOMIZED PROSPECTIVE STUDY

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ABSTRACT

The aim of this study is to compare the clinical outcomes of a consecutive series of 186 patients having been treated for anterior cruciate ligament reconstruction with a hamstring graft in whom a brace was used or not in the early postoperative period. A randomized prospective study of athletes undergoing anterior cruciate ligament reconstruction using the same surgical technique and the same graft (hamstring) was carried out. Three different groups were investigated: no brace, rigid brace in full extension (for 4 weeks), or articulated brace (0-90° for first 3 weeks then 0-120° for another week). All patients were assessed preoperatively and at follow-up for thigh muscle atrophy, range of motion, pain, quality of life, and subjective scores (Lysholm-Tegner score, IKDC score). Rehabilitation started at 2.2 ± 1.3 days after surgery. All of the athletes followed the same postoperative rehabilitation protocol with progressive daily sessions that ended 24 weeks after surgery. No significant differences were found concerning the use of a brace in early postoperative rehabilitation. At the final follow-up (24 weeks after surgery), side-to-side differences in laxity (as measured by KT-1000 arthrometer) between the involved and not-involved leg were 2.2±1.6 mm for NB (no-brace) group, 2.1±1.2 mm for AB (articulated brace) group and 2.3±1.3 mm for RB (rigid brace) group. There were no significative post-operative side-to-side differences in knee circumference between the three groups at 24 weeks follow-up (0.3±0.2 cm in the NB group, 0.2±0.2 cm in the AB group, and 0.1±0.4 cm in the RB group, respectively). Post-operative IKDC scores were 86.2±6 in the NB group, 82±12.6 in the AB group, and 81.6±13.2 in the RB group respectively. There was no significative difference in terms of ROM between the three groups at 6, 12, and 24 weeks and similar functional improvement as measured by Lysholm-Tegner activity score at the final follow-up. The present study did not show any difference in the rate of complications or residual laxity and clinical outcomes among the three groups. According to these data, postoperative bracing after anterior cruciate ligament reconstruction did not show any advantage and cannot be recommended.

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KEYWORDS: *anterior cruciate ligament, reconstruction, brace, rehabilitation, hamstring graft*

INTRODUCTION

The anterior cruciate ligament (ACL) tear is a common injury, mainly occurring in young and active athletes during sports that involve sudden stops with changes in direction or pivoting, such as soccer, basketball, or volleyball (1).

ACL tears account for 25 to 50% of all ligamentous knee injuries and are usually combined with other injuries, typically to menisci, cartilage, and/or collateral ligaments (2). The poor healing capacity of the ACL is one of the main reasons why the operative approach is currently the gold standard in athletes with ACL injuries (3).

ACL injuries were probably described for the first time by the Ancient Greeks (4) but the first attempt at ACL repair was described by Mayo Robson in 1895 using catgut ligatures (5). Primary ACL repair quickly became the gold standard for ACL lesions in the 1970s and 1980s (6-9). However, in the following years, several randomized controlled trials showed improved outcomes with reconstruction compared to primary repair. Therefore, from the beginning of the 1990s, open ACL repair was replaced by ACL reconstruction. Nowadays, between 60000 and 175000 ACL reconstruction procedures are performed each year in the United States (10). Several grafts have been proposed, including autografts (bone-patellar-bone, hamstrings, and quadriceps tendon), allografts, and synthetic grafts.

The rehabilitation protocols have significantly changed in parallel with the evolution of surgical techniques and fixation devices. In the last decades, there has been a general trend toward early mobilization and accelerated protocols with the final goal of returning to pre-injury activity at a high functional level as quickly as possible. However, rehabilitation must be effective and safe at the same time, and a real consensus on which is the most effective rehabilitation protocol is still missing, especially in patients with associated injuries (11). Post-operative immobilization with brace or other devices is one of the most discussed aspects. Knee bracing is used in up to 85% of patients to protect the repair and to prevent retears by reducing mechanical loads (12).

The type of bracing and the duration of its use are highly variable in literature with no unique protocol. Although the majority of surgeons are in favor of the use of a post-operative brace after ACL reconstruction, there is no scientific evidence to support its routine use. Postoperative bracing does not seem to be advantageous in terms of pain relief, stability, function, and rehabilitation (13-15). The present study aimed to compare the outcomes and complications associated with using an articulated brace, a rigid brace, or no brace in patients undergoing ACL reconstruction with a hamstring autograft.

MATERIALS AND METHODS

The present study was designed as a randomized prospective study according to the ethical recommendations of the Helsinki Declaration. All the enrolled patients were informed and spontaneously gave their own written consent. 186 patients undergoing ACL reconstruction with an autologous hamstring graft (performed by the same experienced surgeon) were randomly divided into three equally distributed groups: no brace (NB), articulated brace (AB), or rigid brace (RB) according to its use or not in the early postoperative rehabilitation period (4 weeks). The three groups were homogeneous in terms of age, gender, and delay between trauma and surgery (Table I).

Table I. *Baseline demographic data.*

	NB	AB	RB
Sex	46 M; 16 F	48 M; 14 F	50 M; 12 F
Involved knee	32 R; 30 L	34 R; 28 L	40 R; 22 L
Mean Age	24 years	26 years	25 years
Height	168 cm	166 cm	166 cm
BMI	22.4 Kg/m^2	24.2 Kg/m^2	24.6 Kg/m^2
Time between trauma and surgery	4.5 months	5.3 months	4.2 months
ROM	5-100°	4-96°	7-104°
Antero-posterior laxity (side-to-side difference)	5.2 ± 2.3 mm	4.9 ± 2.7 mm	5.3 ± 2.6 mm
Lysholm score	66	65	67
Tegner score (before trauma)	7	6	7
Graft diameter	8 mm	9 mm	8 mm

The diagnosis of ACL lesion was taken after clinical evaluation and MRI scan. The ACL reconstruction was performed using the same arthroscopic technique by the same senior surgeon under loco-regional or general anesthesia in all cases. Bone tunnels were performed with dedicated instrumentation in an anteromedial fashion (femur) and standard 55° (tibia). Hamstring tendons were fixed with a suspensory device (Smith & Nephew Endobutton®) on the femur and an absorbable screw (Smith & Nephew Biorci-HA®) on the tibia. Concomitant injuries such as cartilage or meniscus lesions were addressed (and recorded) during the same procedure. Exclusion criteria were meniscal sutures, other ligament reconstruction, skeletally immature patients, and patients with previous surgery on the index knee. Local intra-articular tranexamic acid injection was performed at the end of the surgery, and no closed suction drain was applied. All the patients received the same analgesic protocol (Acetaminophen 1 gr 3 times a day for 5 days) and were dismissed the day after surgery with a tolerance weight-bearing using two crutches.

Patients were included in one of the three groups by a random allocation performed with statistical software (Random Allocation Software v. 1.0 ®). In the NB group, all patients had their knees free of any restriction from the day of the operation and for the following 4 weeks. In the RB group, all patients had a Zimmer-type rigid brace (set at fixed 0° of extension) for the follow-up (FU) period (4 weeks). In the the AB group a DonJoy ® articulated brace was used in all cases (0-90° during the first three weeks, then 0-120° for the following week). The brace was worn upon waking during the early rehabilitation step (4 weeks). Rehabilitation started at 2.2 ± 1.3 days after surgery. All the patients received the same post-operative instructions and complied with the same rehabilitation protocol that ended 24 weeks after surgery (Fig. 1).

Phase I (weeks 0-4)

- Weight-bearing: as tolerated with two crutches
- Range of motion: active range of motion as tolerated (starting 7 days after surgery)
- Non-weight-bearing stretching of the gastrocnemius/soleus
- Straight-leg raise with the knee in full extension
- Electrical stimulation of the quadriceps
- Gluteal isometric and eccentric activation
- No hamstring stretching
- Ice packs for 20-30 minutes at a time

Phase II (weeks 4-6)

- Weight-bearing: as tolerated with two crutches (discontinue crutch use)
- Range of motion: work on progressive knee flexion – maintain full knee extension (prone assisted knee flexion and extension)
- Hamstring stretching and balance exercises
- Closed chain extension exercises
- Exercise bike – start elliptical trainer
- Progress to the weight-bearing stretch of the gastrocnemius/soleus

Phase III (weeks 6-16)

- Full weight-bearing (without crutches)
- Active full range of motion
- Hamstring strengthening
- Continue concentric and eccentric quadriceps, gluteals, and hamstring exercises
- Proprioception activities
- Single-leg drop landing (5 cm)
- Advanced closed-chain strengthening exercises
- Straight-ahead running (at 12 weeks)

Phase IV (weeks 16-24)

- Cutting exercises and sport-specific drills
- Sport-specific cardio training
- Jogging with directional change/uneven surface and with turns 90/180/360°
- Jogging and cutting with a 45° change of direction
- Acceleration and deceleration running
- Program for strength and endurance
- Outdoor cycling
- Return to sport at 5 months

Fig. 1. *Rehabilitation protocol: ACL reconstruction with hamstring autograft.*

Patients were blindly evaluated pre-operatively and post-operatively (at 2, 6, 12, and 24 weeks) by the same orthopedic surgeon using KT-1000 arthrometry, range of motion (ROM) exam, knee circumference, visual analogue scale (VAS), Lysholm score, Tegner activity score, and IKDC score. The same examiner recorded the same measurements at all follow-up evaluations. Passive knee joint stability (anterior displacement of the tibia relative to the femur) was measured and recorded by the same observer using the KT-1000 arthrometer (MEDmetric, San Diego, California) at the manual maximum force. The tests were performed with the patients in a supine position and the knee flexed at 20-30°,

recording the difference between involved and not-involved legs. Active ROM was measured using a goniometer with the patient in a supine position, while knee circumference was measured 2 cm proximally to the superior pole of the patella, comparing the results of both legs. All patients received a VAS to evaluate their perceptions of pain and discomfort in daily life. A VAS is a 100-mm long horizontal line with verbal descriptors (word anchors) at each end to express the extremes of the feeling. Patients put a cross on the line at the point that best corresponds to their actual pain (16-18).

Activity level was determined using the Lysholm score and Tegner activity score to document the pre-injury activity level and to compare it with the post-operative level (at 24 weeks follow-up). Lysholm knee scale (first described in 1982) (19) is a patient self-completed questionnaire including 8 items to describe daily living activities (limp, support, locking, instability, pain, swelling, stair climbing, and squatting). The total score is the sum of each response to the 8 items (with a maximum score of 100).

Tegner activity scale is a graduated list of activities of daily living, recreation, and competitive sports (with a score varying from 0 to 10): the patient is asked to select the corresponding activity level (20). Tegner activity scores have been developed to complement the Lysholm scale, based on observations that limitations in function scores (Lysholm) may be masked by a decrease in activity level.

The knee function was assessed using the International Knee Documentation Committee (IKDC) score; it is a 10-item questionnaire made up of three sections with both a subjective part and an objective evaluation form (21-23). The first section assesses symptoms such as swelling, stiffness, pain, locking, and giving way feeling. The second section evaluates daily activities and sport and the third assesses the knee function before and during the injury. The items are added to produce a single index (higher values indicate higher function levels and minor knee symptoms). IKDC can be easily scored using the online scoring sheet.

Statistical analysis

The Mann-Whitney *U* test was used for the nonparametric measurements of the Tegner activity level score and VAS score. An analysis of variance for repeated measurements was used for parametric measurements of knee circumference, ROM, anteroposterior laxity, and IKDC. Analysis of covariance was used to adjust for any initial differences between the groups concerning the following covariates: age, gender, and activity level. Statistical significance was set at $p < 0.05$. All statistical analyses were carried out by an independent statistician and performed with the SAS (Statistical Analysis System) software (SAS Institute, Inc., Cary, North Carolina).

RESULTS

None of the patients was lost at the follow-up, and all completed the outcome measures. There were no significant differences concerning age, gender, activity level, range of motion, instability, and time from injury to operation at time 0 (before surgery) (Table I).

Meniscus injuries were reported in 28 patients in the NB group, 36 patients in the AB group, and 44 patients in the RB group: all these meniscus injuries have been treated with selective meniscectomy (Table II). Six patients developed postoperative complications (Table III).

Table II. *Associated lesions.*

Associated lesion	NB	AB	RB
Meniscus injuries (requiring meniscectomy) n.	28	36	44
Cartilage lesion (I-II Outerbridge grade) n.	24	28	36

Table III. *Post-operative complications.*

	Complication	Delay from surgery (weeks)	Group
1	Early Local infection	<2	NB
2	Early Local infection	<2	RB
3	Extension deficit	8	RB
4	Intraarticular loose body	12	AB
5	ACL re-rupture	20	NB
6	ACL re-rupture	22	AB

These included local infection in 2 patients (adequately treated with prolonged antibiotic therapy for 6 weeks), extension deficit in 1 patient (requiring arthroscopic arthrolysis), intraarticular loose body (requiring arthroscopic removal)

in 1 patient, re-rupture of the ACL due to a new trauma during sports activity in 2 patients (requiring a new ACL reconstruction). The average pre-operative side-to-side difference in laxity (as measured by KT-1000 arthrometer) between the involved and non-involved leg was 6.2±2.3 mm in NB group, 5.9±2.7 mm in AB group and 6.3±2.6 mm in RB group respectively. At the final follow-up, the corresponding values were 2.2±1.6 mm for the NB group, 2.1±1.2 mm for the AB group, and 2.3±1.3 mm for the RB group, respectively (Table IV). No statistically significant difference emerged between the 3 groups at each follow-up.

Table IV. *Anterior-posterior laxity (KT-1000 measurements): side-to-side difference measured pre-operatively and at 24 weeks follow-up.*

	Pre-op	Post-op (24 weeks)
NB	6.2 ± 2.3 mm	2.2 ± 1.6 mm
AB	5.9 ± 2.7 mm	2.1 ± 1.2 mm
RB	6.3 ± 2.6 mm	2.3 ± 1.3 mm

There was no significant difference in ROM between the three groups at 6, 12, and 24 weeks. At the last follow-up (24 weeks after surgery) the average extension in NB, AB, and RB groups were -3±1, -2±2, and -3±2 degrees, respectively, while the corresponding knee flexion values were 144±4, 144±3, and 146±5 degrees respectively (Table V).

Table V. *Range of motion (ROM) measured with a goniometer 24 weeks after surgery: extension and flexion.*

	Post-op extension	Post-op flexion
NB	-3° ± 1°	144° ± 4°
AB	-2° ± 2°	144° ± 3°
RB	-3° ± 2°	146° ± 5°

The side-to-side difference in preoperative knee circumference (measured 2 cm proximally to the patella) was 1,4 ± 0.8 cm in the NB group, 1.7 ± 1.0 cm in the AB group, and 0.8 ± 0.4 cm in the RB group. Corresponding values at 6 weeks FU were 1.2±1.2 cm, 1.4±0.6 cm, and 1.5±0.5 cm in the NB, AB, and RB groups, respectively. This difference kept on decreasing with time, and at 24 weeks follow-up, the side-to-side difference was 0.3±0.2 cm in the NB group, 0.2±0.2 cm in the AB group, and 0.1±0.4 cm in the RB group, respectively (Table VI).

Table VI. *Knee circumference was measured pre-operatively and at 6- and 24-week follow-ups, and there was a side-to-side difference.*

	Pre-op	6 weeks FU	24 weeks FU
NB	1,4 ± 0.8	1.2 ± 1.2 cm	0.3 ± 0.2 cm
AB	1.7 ± 1.0	1.4 ± 0.6 cm	0.2 ± 0.2 cm
RB	0.8 ± 0.4	1.5 ± 0.5 cm	0.1 ± 0.4 cm

VAS score demonstrated a progressive decrease in all groups at 6, 12, and 24 weeks after surgery. At 24 weeks of follow-up, the average VAS score was 0.3±1.8 in the NB group, 0.7±2.1 in the AB group, and 0.6±1.4 in the RB group, respectively (Table VII).

Table VII. *Visual Analogue Scale (VAS) measured at 6-, 12-, and 24-week follow-up.*

	6 weeks FU	12 weeks FU	24 weeks FU
NB	3.2 ± 0.6	1.6 ± 0.4	0.3 ± 1.8
AB	2.8 ± 1.2	1.4 ± 0.8	0.7 ± 2.1
RB	3.4 ± 0.8	1.8 ± 0.6	0.6 ± 1.4

The Lysholm and Tegner activity scores showed a functional improvement at the 24-week evaluation: Tegner's average value was 7 in the NB, 6 in the AB group, and 6 in the RB group (Table VIII).

Table VIII. *Lysholm-Tegner score measured pre-operatively and at 24 weeks follow-up.*

	Lysholm Pre-op	Lysholm Post-op	Tegner Pre-op	Tegner Post-op
NB	66	84	7	7
AB	65	82	6	6
RB	67	82	7	6

The baseline IKDC score was 29.4 ± 2.3 in the NB group, 27.4 ± 2.1 in the AB group, and 28.2 ± 1.6 in the RB group. Corresponding values at 24 weeks, were 86.2±6, 82±12.6 and 81.6±13.2. The difference between the NB group, the AB group, and the RB group was statistically significant ($p < 0.01$) (Table IX).

Table IX. *IKDC score measured before surgery and at 24 weeks follow-up.*

	Pre-op	Post-op (24 weeks FU)
NB	29.4 ± 2.3	86.2 ± 6.0
AB	27.4 ± 2.1	82.0 ± 12.6
RB	28.2 ± 1.6	81.6 ± 13.2

DISCUSSION

The most relevant finding of the present study is the absence of any significant difference in terms of clinical scores and complications related to the use of postoperative brace (AB or RB) or not (NB). There was no significant difference between them in terms of pain, complications, functional activity (sports practice or activity daily living), muscular strength, and knee stability. Antero-posterior residual knee laxity (measured with KT-1000 arthrometer) did not show significant side-to-side difference in the three groups. Clinical satisfaction was normally distributed in the three groups. Although no difference emerged, according to Lysholm-Tegner, the IKDC score showed better results in the braceless group (statistically significant).

These data are important since rehabilitation protocols after ACL reconstruction must be safe and effective. From the literature analysis, high variability in the composition and timing of rehabilitation phases emerges. To date, no consensus exists on the most effective rehabilitation protocol (11), and there is no scientific evidence to support the routine use of a post-operative knee brace (13-15). According to the present study, there is no evidence to support the use of a brace (articulated or not) or to keep the knee immobilized or immediately mobilized. The present data are similar to those reported in other previous studies where no significant difference emerged in terms of knee joint laxity, pain, and functional activity depending on the use or not of a postoperative knee brace (24-27).

Those surgeons who support the use of knee brace affirm it ensures normalized tibiofemoral joint mechanics, increased protection on the graft and minimized stress forces (translational, rotatory, and valgus loads) across the knee. These hypotheses have been confirmed in previous biomechanical studies, which show that bracing significantly decreases pathologic anterior displacement of the tibia relative to the femur (28). Another potential effect of bracing is its influence on knee proprioception. Birmingham et al. found that knee bracing did not improve balance testing with no significant effect on balance control in challenging balance tasks (29). Risberg et al. found that knee bracing did not improve the threshold to detect passive motion after ACL reconstruction (25). These results were comparable to those of Beynnon et al. (30), who demonstrated that functional bracing or neoprene sleeve applied to an ACL-deficient knee did not improve the threshold for detection of passive knee motion. On the other side, Salehi et al. (31) showed a significant effect of functional knee bracing on postural control in double-leg stance subjects with ACL reconstruction. Palm et al. (32) showed that elastic knee braces increased postural stability in patients with ACL rupture but reported no difference in postural stability between injured and uninjured legs in the braced protocol.

On the other hand, wearing a brace can be potentially detrimental since it may result in significantly increased thigh atrophy, potential loss of knee extension, increased fatigability during rehabilitation exercises, and decreased patient perception of maximal performance (13-15). The study by Muellner et al. (26) showed that bracing after ACL reconstruction (with patellar tendon) did result in an initial reduction in knee flexion with the use of a standard rigid brace. This drawback could be avoided with the hyperextension brace (13, 33).

Several studies on functional bracing have shown that it produces significantly more thigh atrophy at 3 months than did non-bracing (25, 34). However, the thigh atrophy was reduced when the brace was removed, with no difference 6 months after surgery. In addition, these studies showed that the use of prolonged knee braces resulted in significantly decreased quadriceps muscle strength (by 12% to 30%). Lindström et al. in a prospective randomized controlled trial (RCT) on knee bracing showed that the use of post-operative bracing had no effects on the extent of joint effusion at three months and on functional outcomes at twelve months (35). Mayr et al. (15), in an RCT, compared the clinical outcomes of the rehabilitation protocol after ACL reconstruction using a hard brace and a water-filled soft brace. Patients in the soft-brace group had significantly higher IKDC subjective ratings from 6 weeks to 12 months after surgery. Using the water-filled soft brace resulted in less swelling, extension deficit, and increased patient-measured outcome, with significantly higher Tegner activity scores and Lysholm knee scores. Despite these considerations, a survey by the

American Orthopaedic Society for Sports Medicine (AOSSM) showed that post-operative bracing is used up in 85% of patients undergoing ACL reconstruction (12).

However, this clear trend is not justified by any evidence reported in the literature. The systematic review by Wright and Fetzer found no difference in the use of post-operative bracing in terms of graft stability, postoperative ROM, pain, retear rate, or protection from a new injury (14). More recently, Kruse et al. concluded that a knee brace after ACL reconstruction is neither beneficial nor necessary (36). In addition, Lobb et al. (1) showed no evidence of advantages with knee bracing (0-6 weeks postoperatively) over the no-bracing option. Finally, the review by Rodriguez-Merchan (37) on 28 articles showed that postoperative bracing after ACL reconstruction does not help reduce pain and improve knee stability and function. The authors concluded that there is no scientific evidence to support the routine use of a knee brace in the rehabilitative postoperative course following ACL reconstructions.

The present randomized controlled trial had similar results. At the final follow-up (24 weeks), there was no difference in terms of ROM, thigh atrophy, complication rate, and function that emerged from the use of a knee brace (articulated or rigid). Interestingly, no difference emerged regarding residual laxity at the last follow-up.

Although the notable findings that may influence surgeons' daily practice, the present study has some limitations. The first one is that the follow-up is quite short, and longer follow-ups may have been useful in detecting any differences in retear rate. Finally, the present study is focused only on hamstring grafts. This fact has made the study more homogeneous but may have been a bias simultaneously, excluding the potential effects of knee bracing on other grafts.

CONCLUSIONS

The present study did not show any statistical evidence to support the use of a knee brace, either fixed or articulated in the first postoperative period after ACL reconstruction. Joint stability, range of motion, pain, quadriceps circumference, functional activity, and complication rate were similar in the three groups. Therefore the presumed protective role of knee brace and prolonged extension after surgery did not result in any clinical advantage nor the rate of complications and residual laxity. Surgical technique, based on the surgeon's experience, post-operative rehabilitation program, and patient's compliance to surgeons and therapist indications seem to be more relevant to achieve satisfactory results and avoid complications. Future studies should better define the role and importance of bracing after ACL reconstruction.

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Review

OZONE THERAPY IN THE TREATMENT OF CHRONIC LOW BACK PAIN: A LITERATURE REVIEW

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ABSTRACT

The treatment of low back pain (LBP) represents one of the most common therapeutic challenges in medicine. Various therapeutic modalities have been explored in an attempt to reduce pain and improve the quality of life for patients, including medications, physical therapy, surgical interventions, and minimally invasive treatments. One of the more recent approaches is the use of ozone, a gas with anti-inflammatory and analgesic properties, which is gaining attention as a therapeutic option for LBP. This literature review examines studies investigating the efficacy of ozone in the treatment of LBP, with particular emphasis on biological aspects, mechanisms of action, and clinical outcomes.

KEYWORDS: *ozone therapy, low back pain, lumbar disc herniation, ozone injection, peridural ozone therapy, intradiscal ozone injection, back pain treatment*

INTRODUCTION

Low back pain (LBP) is one of the most common conditions affecting the vertebral column. It represents a health problem that is significant not only from a clinical perspective but also socially and economically. Approximately 70% of the adult population has experienced at least one episode of LBP during their lifetime, with varying levels of severity, and it is the leading cause of absenteeism from work. The incidence of LBP peaks in the third decade of life; its prevalence increases until the ages of 60-65 years, after which it gradually declines (1-8).

In the majority of cases, it is not possible to identify a specific cause of LBP through clinical and radiographic investigations; rather, it is attributed to various issues affecting the musculoskeletal system (4, 7). The pathogenesis of LBP is indeed multifactorial: mechanical-compressive causes on the nerve root are associated with both cell-mediated inflammatory reactions and non-immunological responses secondary to bioumoral factors. Chronic LBP is frequently attributable to degenerative diseases of the bony and ligamentous structures. By the age of 49, approximately 60% of women and 80% of men exhibit osteophytes on radiological examinations and other early signs of spondylosis. By the age of 79, practically the entire population displays radiographic signs of degeneration (1-8).

In 5-15% of cases, LBP is attributable to disc disease. The natural history of a herniated disc is generally favorable: it is common to observe symptom improvement over the months, with many episodes of LBP resolving spontaneously or with conservative therapies. Nevertheless, some studies have shown that LBP persists 12 months after onset in a percentage ranging from 37% to 54% of patients (1-8). In addition to pharmacological therapy and physiotherapeutic rehabilitation, ozone therapy has been proposed as an exclusive treatment or combined with the abovementioned therapies

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(9-22). Although its efficacy has been demonstrated in various clinical settings, ozone therapy remains virtually unknown to most clinicians.

Ozone and low back pain

Ozone is normally present as a gas in the atmosphere and comprises three oxygen atoms structured in a cyclic form. The medical device that generates ozone utilizes a high voltage gradient (5-13 mV) to produce the following reaction: $3O_2$ + 68400 cal → $2O_3$. The gas mixture commonly used in therapeutic applications comprises 95% oxygen and no more than 5% ozone. The mechanisms of action of ozone, specifically when utilized for the treatment of spinal disorders, include:

- intra- and trans-tissue oxygenation of the pathological site, resulting in a reduction of hypoxia and venous stasis;
- inhibition of the production of mediators in the inflammatory cascade and pain transmission;
- a direct effect of fragmentation of the mucopolysaccharides that constitute the nucleus pulposus of the intervertebral disc, facilitated by the rupture of water molecules. This leads to the lysis of the herniated disc and a reduction of symptoms resulting from nerve root compression (9, 15, 17, 19).

In the treatment of chronic LBP, it is advisable to use conservative or minimally invasive treatments as a first line of intervention. More complex procedures, up to surgical intervention, are frequently necessary but often display an unfavorable risk-benefit ratio. There are indeed numerous cases of recurrence post-treatment, which can culminate in Failed Back Surgery Syndrome (FBSS), with an incidence of 15%. Consequently, there has been a drastic reduction in spinal surgeries in recent years (7, 9).

In light of all this, ozone therapy represents an important therapeutic option. It can be employed as a first-line therapy or as an alternative to surgery in cases of conservative treatment failure. The current trend toward the administration of ozone therapy via intramuscular injection minimizes the invasive nature of the therapy, simplifies its management, preserves healthy tissue, and reduces the risk of infectious complications (9-22). Nevertheless, the role of ozone therapy in the treatment of chronic LBP remains a subject of ongoing discussion.

MATERIALS AND METHODS

This review aims to investigate the actual utility of ozone therapy, focusing on both observational and experimental studies in patients suffering from chronic LBP attributable to spinal pathologies. A bibliographic search was conducted in major scientific databases, including PubMed, Cochrane Library, Scopus, and Google Scholar. The search terms used included a combination of the following keywords:

- “ozone therapy”
- “low back pain”
- “lumbar disc herniation”
- “ozone injection”
- “peridural ozone therapy”
- “intradiscal ozone injection”
- “back pain treatment”

The inclusion criteria encompassed studies involving adults with LBP caused by conditions such as disc herniation or protrusion, treated with ozone therapy (either intradiscal or peridural), with primary outcomes being the reduction of pain and improvement in functionality. In the case of meta-analyses, studies that did not report long-term follow-up data (minimum of 3 months) or that exhibited significant methodological limitations were excluded. The search was limited to studies published between 2000 and 2022.

RESULTS

Ozone therapy has generated increasing interest in the management of LBP, particularly in patients with disc herniation or refractory chronic pain. Although numerous studies have suggested the efficacy of this treatment, the scientific evidence remains partial and presents significant methodological limitations. Below, each study included in the review is discussed in detail, highlighting strengths, weaknesses, and implications for clinical practice.

Andreula et al. (9) compared the effects of ozone therapy as a sole treatment or in combination with local injections of corticosteroids and anesthetics. The study included 600 patients with clinical symptoms arising from sciatic nerve compression and radiological evidence (CT or MRI) of disc herniation. 300 patients received intradiscal (4 mL)

and periganglionic (8 mL) injections of an O_2-O_3 mixture with an ozone concentration of 27 µg/mL. The therapeutic outcome was assessed at 6 months using a modified MacNab method. In the patients treated with ozone therapy, good symptom control was recorded in 70.3% of cases. The sequential administration of steroids and anesthetic increased the response rate to 78.3%. The difference between the two groups is statistically significant, highlighting that the primary impact on the outcome is attributable to ozone therapy.

Bonetti et al. (10) studied a sample of 306 subjects suffering from chronic low back or sciatic pain, with 166 cases attributed to discopathy and 140 to other causes. The sample was divided into two groups, which received either a CT-guided intraforaminal injection of an O_2-O_3 mixture or a periradicular steroid injection. Follow-up assessments were conducted in one week and six months to evaluate the short- and long-term effectiveness of the treatment. At the first follow-up, most subjects reported benefit, regardless of the treatment received. However, at six months, a statistically significant difference favoring ozone therapy was observed only in subjects with discopathy. Among those not affected by discopathy, therapeutic failure was reported in only 8.6% of subjects treated with ozone therapy, compared to 21.4% of those treated with steroids.

Gallucci et al. (11) compared the efficacy of intraforaminal and intradiscal administration of steroid, local anesthetic, and an O_2-O_3 mixture with injections of only steroids and anesthetic in subjects with sciatica due to disc herniation. In this randomized controlled study, 159 patients of both sexes across a wide age range (18-71 years) were investigated. The outcome was assessed using the Oswestry Disability Index (ODI), administered to patients prior to treatment and after 6 months. At follow-up, 74% of subjects who received ozone therapy in conjunction with steroid and anesthetic showed clinical improvement versus 47% among those who only received the two drugs.

Zambello et al. (12) conducted a randomized study involving 351 subjects suffering from chronic LBP. Subjects were treated with ozone therapy or epidural steroid injections. The study included a cross-over between the two therapies in case of therapeutic failure after 4 weeks of treatment. The therapeutic response was optimal or good in 47.3% of patients undergoing steroid treatment compared to 77.1% of subjects receiving ozone therapy. Only 11 subjects initially assigned to ozone therapy required therapeutic crossover compared to 38 initially treated with steroids. Among subjects receiving steroid therapy as a second-line treatment, only 36.4% reported symptomatic improvement compared to 70.8% of subjects who received ozone therapy after the failure of steroid treatment.

An important multicentric, double-blind, randomized study conducted in 2009 by Paoloni et al. (13) examined the efficacy of ozone therapy versus placebo. The control group received a simulated intramuscular paravertebral injection via skin puncture and manual pressure application at the lumbar level. Patients receiving ozone therapy showed a significant improvement in symptoms, as evaluated by the visual analog scale for pain (VAS), with an average score of 0.66 compared to 4.00 in the control group. Furthermore, 61% of treated patients reported long-term maintenance of analgesia (6 months) against 33% in the control group. The use of ozone therapy also resulted in a significant reduction in non-steroidal anti-inflammatory drug usage and an improvement in disability.

Zhang et al. (14) prospectively evaluated the efficacy of ozone therapy in a sample of 172 subjects with low back and sciatica pain. The sample was divided into two groups: the first received intradiscal and intraforaminal injections of O_2-O_3, while the second received the same therapy combined with 1 mL of betamethasone. Symptom evaluation was conducted via VAS and JOA score (Japanese Orthopedic Association LBP evaluation system) at three weeks, six months, and twelve months after treatment commencement. Favorable results were obtained in both groups, with a VAS score reduction from 7.68 to 2.17 in the first group and from 7.49 to 2.23 in the second. No statistically significant differences between the two groups were recorded. This study suggests that ozone therapy, associated with minimal side effects, could be proposed as a valid alternative to both surgical intervention and steroid therapy.

A prospective study by Melchionda et al. (15) compared the efficacy of ozone therapy (administered via paravertebral intramuscular injection) with conservative treatment based on non-steroidal anti-inflammatory drugs in patients with acute L5-S1 radiculopathy. 38 subjects were divided into two groups and clinically and neurologically examined after one, two, and four weeks, as well as after three and six months. MRI and electromyographic studies were conducted at baseline and after six months. Pain intensity and degree of disability were assessed using VAS and ODI scales, respectively. A statistically significant difference between the two groups was detected starting from the second week of treatment: 50% of subjects treated with ozone therapy reported freedom from pain symptoms compared to only 16.6% of subjects undergoing anti-inflammatory treatment. This trend was confirmed at the six-month follow-up (80% vs. 50%). No side effects were noted in the administration of ozone therapy in this study.

Rimeika et al. focused on the efficacy and safety of treatment with an oxygen-ozone mixture for LBP, particularly in the management of conditions like disc herniation (21). The meta-analysis included 45 articles comparing the efficacy of imaging-guided injection techniques with non-guided techniques. Parameters considered included pain reduction (measured using the VAS), improvements in functionality (using the Oswestry Disability Index - ODI), and the safety of

treatment by evaluating the presence of side effects. In all 45 articles included in the meta-analysis, ozone was administered as a gaseous mixture of O_2-O_3 with a concentration varying between 10 and 40 µg/ml; the injection of O_2-O_3 was paired with steroids in 8.3% of cases, anti-inflammatories in 2.2% of cases, and anesthetics in 13% of cases, while in 6.5% of cases, it was coupled with other techniques (radiofrequency thermocoagulation, collagen injection, bioresonance magnetotherapy, and/or electrical stimulation).

The imaging guidance used predominantly involved CT or fluoroscopy, with a single prospective study based on ultrasound guidance. Non-imaging-guided techniques were based on paravertebral-intramuscular injections using anatomical landmarks. The meta-analysis showed that both injection methods (with and without imaging guidance) led to significant improvements in the management of LBP. However, the analysis also revealed that imaging-guided techniques tend to yield better results, both in terms of pain reduction and functional improvement, compared to non-guided techniques.

In particular, patients treated with imaging-guided injections demonstrated greater precision in administering the oxygen-ozone mix, reducing the risk of improper administration and enhancing the drug distribution in the target area. Despite the superior efficacy of imaging-guided techniques, the overall findings suggest that non-guided injections can also represent a valid therapeutic option with a good safety profile but greater variability in results. The analysis also indicated that both methods are associated with fewer side effects compared to other invasive treatments such as surgery.

The article by Clavo et al. (22) presents a randomized, double-blind, controlled clinical study comparing the efficacy of ozone therapy to surgery for treating lumbar disc herniation. The study involved patients with symptoms refractory to conservative treatment for at least six weeks. Participants were randomized into two groups: one received intradiscal and paravertebral ozone therapy, while the other underwent standard surgical intervention for disc decompression. The evaluation of outcomes was based on pain measurement scales (e.g., VAS scale) and functional disability indices (e.g., Oswestry Disability Index) with regular follow-up intervals. The analysis showed that ozone therapy resulted in a significant reduction in pain and functional improvement comparable to those achieved with surgery but with lower associated risks and shorter recovery times. The percentage of patients reporting significant clinical improvement was similar in both groups. Furthermore, the complication rate was lower in the ozone-treated group compared to the surgical group.

DISCUSSION

Ozone therapy has been successfully utilized in recent years for the treatment of chronic low back pain originating from discopathy or other causes. In patients with herniated discs, ozone therapy has proven effective in reducing pain even after the failure of other conservative therapies. The cost-benefit ratio of this therapy is significantly favorable in light of its efficacy, low incidence of side effects, and the high prevalence of chronic low back pain in the general population. Consistent with the prevalence of specific pathologies, the majority of studies include patients suffering from chronic lumbosacral pain secondary to herniated discs. Other considered causes include spinal canal stenosis, facet joint osteoarthritis, disc protrusions with vertebral instability, and intervertebral osteochondrosis, among others.

As previously described, ozone is a strong oxidizing agent that contributes to the reduction of the herniated nucleus pulposus by acting on the proteoglycans that make up this structure. This suggests that the dimensional reduction effect may positively impact pain symptoms by alleviating compressive symptoms across various pathological contexts. This review confirms the substantial absence of side effects from the treatment thanks to the ozone concentrations used in therapeutic settings and the recent trend to prefer intramuscular injections over riskier transforaminal and intradiscal injections.

Moreover, injections can be repeated after a certain period on the same site. Adding to this is a positive economic consideration, as ozone therapy involves significantly lower costs compared to surgical treatment or prolonged pharmacological therapy. Therefore, ozone therapy can be considered a valid therapeutic option for the treatment of chronic low back pain in numerous pathological contexts, both as a first-line treatment and as an alternative to surgery in case of failure of other conservative strategies.

CONCLUSIONS

In conclusion, scientific evidence suggests that ozone therapy represents an effective therapeutic option for the treatment of chronic low back pain, particularly in patients with discopathy. This literature review indicates that ozone therapy can significantly contribute to pain reduction and improvement of patients' functionality, thereby enhancing their quality of life.

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Review

ADJUVANT OZONE THERAPY IN KNEE OSTEOARTHRITIS: A LITERATURE REVIEW

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ABSTRACT

The aim of this work is to evaluate data from the literature from 2013 to date on the application of oxygen-ozone therapy in the treatment of knee osteoarthritis to assess its therapeutic potential in comparison with other non-surgical treatment options.

KEYWORDS: *oxygen, ozone, therapy, osteoarthritis, knee, cartilage, degeneration*

INTRODUCTION

Osteoarthritis (OA) is defined as a degenerative joint condition of unknown etiology, which can be mono- or polyarticular in onset and is progressive in nature. It is characterized by alterations in articular cartilage and reactive bone formation at the subchondral level and the articular margins. The pathology is marked by progressive cartilage degeneration (where cartilage becomes softened and thins until complete erosion occurs, exposing the underlying bone), formation of periarticular osteophytes, and synovial and capsular inflammation. Clinical manifestations of OA include pain, functional limitation, joint swelling, and deformity. OA is associated with chronic joint inflammation that causes persistent oxidative stress (1, 2).

OA is a highly debilitating condition with significant socio-economic impact. The World Health Organization (WHO) estimates that globally, 25% of adults over the age of 25 experience pain and disability associated with this disease. It is one of the most prevalent and disabling conditions, affecting both sexes (with a higher incidence in females). The prevalence significantly increases after the age of 55. Although OA predominantly affects the elderly, younger individuals are not spared, and this disease is the leading cause of lost workdays.

Only 10-20% of individuals with radiological evidence of the condition exhibit signs and symptoms of the disease. OA affects women more frequently than men, particularly evident after the age of 55 when the highest number of OA cases is reported; prior to this, especially until the age of 45, OA affects men more frequently. Between the ages of 45 and 55, the incidence is almost equal in both sexes. The early onset in men may be attributed to occupational activities. At the same time, the more common occurrence in women after 55 may be linked to osteometabolic alterations related to post-menopausal hormonal changes (1, 2).

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Degenerative lesions affecting the joints are numerous and involve the cartilage, subchondral bone, and tendon insertions. Frequently, the degenerative process can be complicated by phases of joint inflammation, leading to swelling with effusion.

OA can be classified into primary forms, often affecting multiple joints, and secondary forms, which are more frequently localized. Primary OA has a genetic predisposition, and it is not uncommon to observe it in multiple family members. Secondary OA can also affect younger individuals and is often associated with trauma, obesity, malformations of the lower limbs, occupational exposures (such as using vibrating tools or repetitive tasks in non-physiological positions), and arthritis, among others.

The International Cartilage Repair Society (ICRS) classifies OA into four grades:

- Grade 0 (normal);
- Grade 1 (nearly normal: superficial lesion);
- Grade 2 (abnormal: lesion extending to 50%);
- Grade 4 (very abnormal: osteochondral lesion).

The most common symptom reported by patients with OA is pain, which worsens with activity and decreases with rest. As the disease progresses, symptoms may include stiffness, reduced joint range of motion, episodes of swelling due to joint effusion, and a grinding sensation during movement, leading to joint deformities (varus or valgus deviation in the knee).

Pain is the primary symptom that prompts patients to seek medical care. Diagnosis is based on the radiological appearance, which also helps determine the stage of the disease (1). Treatment is closely related to the clinical condition of the patient and is most effective and least invasive when initiated early. Traditionally, it consists of physical therapy (including exogenous and endogenous thermotherapy, massage therapy, cryotherapy, and electrotherapy), pharmacological therapy (NSAIDs, analgesics, adjuvants), intra-articular infiltrative therapy (corticosteroids, NSAIDs, hyaluronic acid, platelet-rich concentrates, anesthetics), and surgical therapy (arthroscopy, joint replacement surgery).

Infiltrative therapy is indicated for the treatment of all inflammatory (non-infectious) and degenerative joint conditions, including joint diseases (OA, arthritis) and soft tissue conditions (capsulitis, tendinitis, tenosynovitis, bursitis, fascitis, radicular syndromes, among others) (2).

The biological effects of ozone, such as anti-inflammatory action, anti-edematous effects, analgesic action, enhancement of and activation of microcirculation, tissue regenerative action, a direct effect due to its high oxidative potential, activation of cytokines and phagocytosis, and immunomodulation, indicate a rational and judicious use of ozone in appropriate and calibrated concentrations and quantities, with suitable routes of administration and under correct modalities, in combination with other substances (such as hyaluronic acid, collagen, PRP) for the treatment of knee osteoarthritis (3-9).

MATERIALS AND METHODS

The keywords used as search criteria were ozone therapy, medical ozone, knee osteoarthritis, hyaluronic acid, systematic review, meta-analysis, edited from January 2014. Scientific articles were obtained through PubMed, Embase, Cochrane, and ResearchGate. Preference was given to systematic reviews and meta-analyses. Additional consultation was made of orthopedic texts regarding the treatment of knee osteoarthritis and texts on oxygen-ozone therapy.

RESULTS

The common consideration across the evaluated studies, particularly the systematic reviews and meta-analyses, is the relative methodological quality observed in the analyzed articles, which partially affects the validity of the evidence regarding the efficacy of oxygen-ozone therapy in the treatment of knee osteoarthritis.

The eligibility criteria and subsequent inclusion of the articles reviewed led to a significant reduction in the available literature; thus, only 7 papers were selected (3-9).

DISCUSSION

Raeissadat et al. (3) identified a total of 231 articles, ultimately including 7 studies in their qualitative review (544 patients) and 5 studies (428 patients) in their quantitative analysis. Sconza et al. (4) included 11 studies (858 patients) from a pool of 116, while Arias-Vásquez et al. (5) selected 8 studies (335 patients) from 93.

The authors agree on the effectiveness of oxygen-ozone therapy in reducing pain associated with knee osteoarthritis, with results showing greater efficacy than placebo or non-invasive treatments. The therapy demonstrated results comparable to those of hyaluronic acid or platelet-rich plasma (PRP) in cases of moderate osteoarthritis (grades 1-3) and was noted to reduce pain more rapidly, particularly in short to medium-term (1-3 months) while also improving joint functionality. However, the long-term outcomes reported in the analyzed studies varied considerably.

Experimental studies on rats (6) demonstrated the non-toxicity of ozone injections in cartilage, comparing the effects histologically with mono-iodoacetate (MIA). These authors subsequently induced osteoarthritis in the knees of rats using MIA, which was treated with 50 µml of ozone at 30 micrograms/ml in the right knee and pure oxygen in the left knee, administered three times a week for three weeks. Histological evaluations conducted after the final administration revealed a beneficial effect on cartilage from the ozone injection after 8 days, with progressively diminishing effects noted in evaluations after 11 and 15 days post-injection, although still superior to oxygen injection.

The assessment of ozone efficacy compared to hyaluronic acid (7) did not reveal significant differences between the groups in pain reduction, improved stiffness, or functional enhancement. The combination of both treatments showed a significantly better outcome, particularly at the 2-month follow-up in patients with knee osteoarthritis, compared to treatment with only ozone or only hyaluronic acid (8).

Additionally, a comparison between PRP and ozone administration (9) demonstrated that both substances contributed to pain reduction, functional recovery, and improved quality of life. Ozone appeared more effective for intense pain relief, while PRP showed greater and more lasting effects on pain reduction and functional recovery. The combination of both treatments did not significantly alter the overall results.

CONCLUSIONS

Knee osteoarthritis is among the most prevalent musculoskeletal diseases. While symptoms may remain mild and stable over long periods, they are primarily associated with the degeneration of the articular cartilage. The condition also involves the formation of osteophytes, weakening of the subchondral bone, synovial inflammation, and alterations in the surrounding ligaments, tendons, and muscles.

Cartilage degeneration is triggered by elevated levels of inflammatory cytokines, which increase oxidative stress and metalloproteinase activity. Treating knee osteoarthritis with ozone is considered a safe and effective therapy due to its ability to activate Nrf2 (a signaling transducer), downregulate NF-kB, and modulate the NLRP3 inflammasome. The Nrf2 domain is responsible for activating the transcription of antioxidant response elements. The anti-inflammatory effect inhibits NF-kB, which activates pro-inflammatory cytokines such as TNF-alpha, IL-1 beta, and IL-8. Heme oxygenase-1, activated by Nrf2, inhibits NF-kB, thus blocking the pro-inflammatory cascade. Heme oxygenase-1 can also directly activate anti-inflammatory cytokines and increase endothelial progenitor cells. Furthermore, ozone treatment may diminish inflammation mediated by NLRP3, enhancing the antioxidant activity of Nrf2 and inhibiting apoptosis.

The correct selection of concentrations and appropriate volumes, the executor's skills, the use of suitable equipment, and adherence to hygiene and safety standards are essential elements for successful treatment. Literature indicates that the safest, sufficient, and most effective ozone concentrations range between 10 and 50 µml, with maximum anti-inflammatory effects observed at concentrations between 30 and 45 µml.

The duration of therapy typically varies from 6 to 10 weeks, with 1 to 3 sessions per week, depending on the patient's age, symptom severity, and disease stage. The use of ultrasound support can enhance effectiveness and precision, particularly in peri-articular and tendinous infiltrations.

There is an evident need for more precise, comprehensive, and exhaustive scientific evidence to consolidate the safety of ozone utilization and to develop further improved guidelines.

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Technical Note

SURGICAL TECHNIQUE FOR LATERAL EXTRA-ARTICULAR PARAPATELLAR APPROACH FOR TIBIA NAILING: A TECHNICAL NOTE

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ABSTRACT

The extra-articular lateral parapatellar approach is a surgical technique for tibia nailing, especially useful for the semi-extended knee position, leading to excellent control of the tip apex deformity of proximal shaft fractures. This approach employs a lateral incision near the patella to reach the antero-superior tibial angle, preserving the synovial layer and the intra-articular structures. Studies have shown that the extra-articular lateral parapatellar approach offers a superior knee function and minimizes anterior knee pain. Additionally, this approach correlates with a lower rate of painful hemarthrosis during the hospital stay, significantly enhancing patient comfort and recovery quality. The goal of this technical note is to describe in detail the extra-articular parapatellar surgical approach.

INTRODUCTION

Tibial shaft fractures are the most common type of long bone fractures, with an annual incidence of 16.9 per 100,000 (1). Males are most frequently affected, especially between ages 10 and 20, while the peak for females is between 30 and 40. These fractures primarily result from walking, indoor activity, and sports (2). Various surgical techniques for treating tibial shaft fractures include plates, intramedullary nails, and external fixations (3). Currently, the intramedullary nail is considered the gold standard, especially for tibial diaphyseal fractures.

In the present technical note, we examined the lateral extra-articular parapatellar approach (ELP), first described by Kubiak et al. in 2010. This technique allows for tibial nailing with medial patellar subluxation while preserving the synovium and without violating the articular surface, potentially reducing trochlear damage and mitigating concerns about intra-articular remaining debris of the supra-patellar approach (4). The purpose of this technical note is to describe in detail the ELP approach to tibial nailing in a semi-extended position.

Surgical technique

The surgical steps outlined in the images will be referenced throughout this paper. The indications and advantages of the technique are described in Table I. The contraindications and limitations are presented in Table II.

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Table I. *Indications and advantages of the ELP approach.*

Indications	-	**Tibial shaft fractures**
	-	**Proximal or distal fractures extension**
	-	**Semi-extended position requirement**
Advantages	-	Do not require special instruments
	-	Improved patello-femoral outcome
	-	Reduced anterior knee pain
	-	Lower incidence of painful hemarthrosis

Table II. *Contraindications and limitations of ELP.*

Contraindications	-	**Severe patello-femoral osteoarthrtitis**
	-	**Extensor mechanism disruption**
Limitations	-	Technically demanding
	-	Difficult clinical interpretation of proximal tibial rotation for the medial patellar subluxation

The patient is placed in a supine position on a radiolucent table, with a foam ramp under the leg. The knee is flexed to about 30 degrees. A clinical examination of the patellar glide over the trochlea is performed to evaluate parapatellar laxity. A 3 to 5 cm lateral parapatellar incision is performed (Fig. 1).

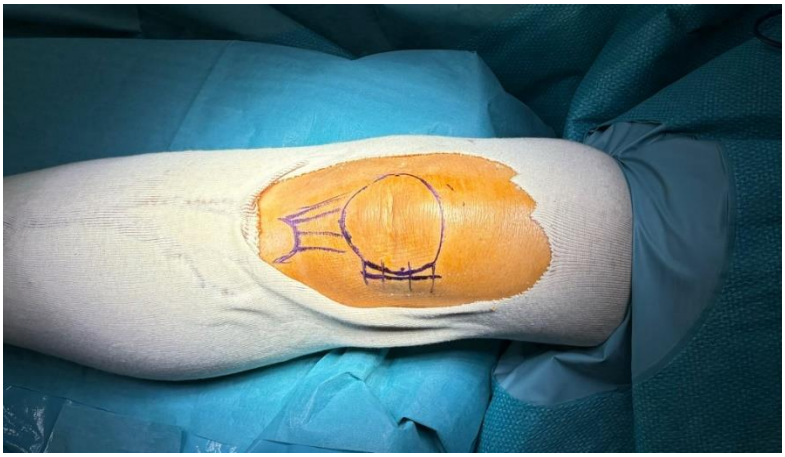

Fig. 1. *Patient set-up with details of the left knee and main surgical landmarks indicating the tibial tubercle, patellar tendon, and patella.*

Dissection is performed until the lateral retinaculum and the third and second layers of the lateral retinaculum are incised and dissected. The cauterization of the supero-lateral genicular artery is performed to avoid bleeding and impaired vision during the procedure. Subsequentially, the antero-superior angle of the tibia is bluntly palpated, and the synovial layer is carefully preserved to avoid intra-articular penetration (Fig. 2).

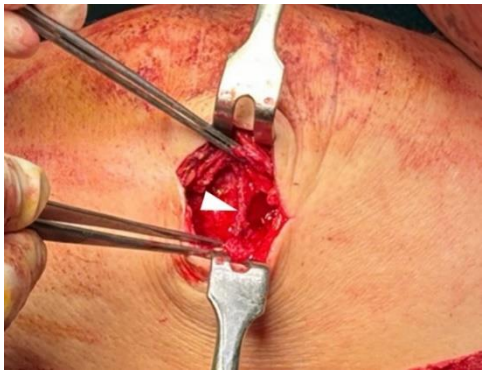

Fig. 2. *Surgical dissection of the third and second lateral retinacular layers and identification of the supra-lateral genicular artery (**white arrowhead**).*

The patella is then subluxated medially to facilitate access to the proximal tibia for guidewire insertion. A threaded guide pin is placed deep to the patellar tendon and superficial to the synovium (Fig. 3).

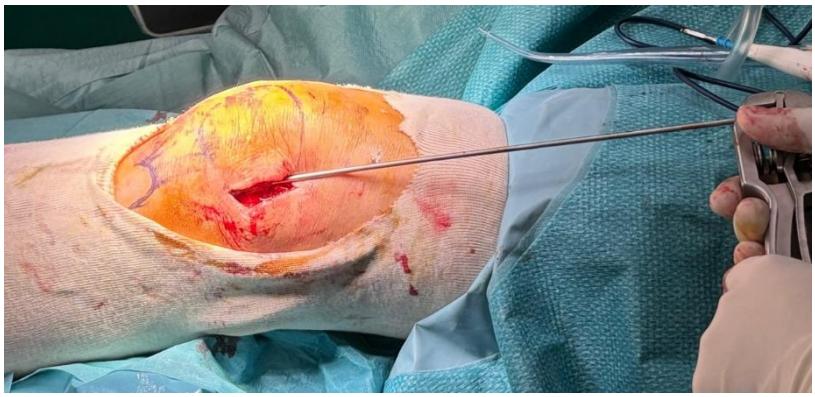

Fig. 3. *The guidewire is inserted, maintaining the axis of the tibial shaft and advanced approximately 8-10 cm.*

The entry point is crucial for positioning the tibial nail within the medullary canal and is essential for proper fragment alignment of proximal and metaphyseal fractures. In the anteroposterior view, the entry point aligns with both the axis of the intramedullary canal and the medial aspect of the lateral tubercle of the intercondylar eminence. In the lateral view, the entry point is positioned at the ventral edge of the tibial plateau and remains in line with the medullary canal. To confirm the accuracy, the position is checked using image intensifiers in AP and lateral views (Fig. 4).

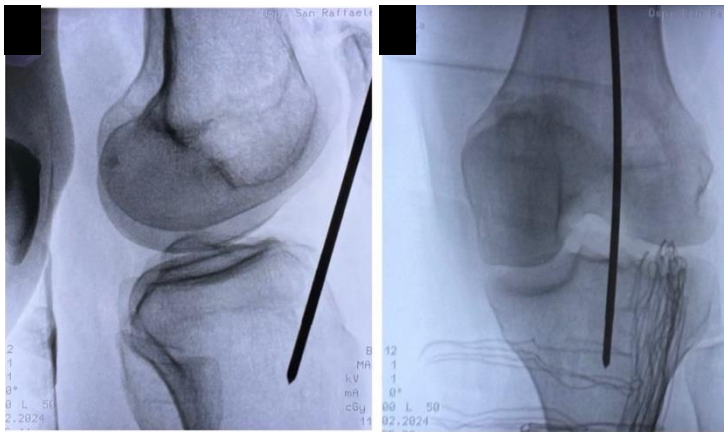

Fig. 4. *Fluoroscopic assessment of guide pin insertion.*

After proximal reaming, the fluoroscopy is used to advance the guidewire through the fracture and to the center of the ankle joint (Fig. 5).

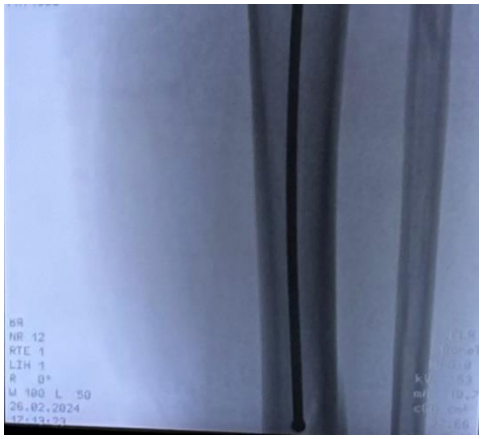

Fig. 5. *Intramedullary tibia guidewire.*

Proper fracture reduction with a Weber reduction clamp is an essential step of intramedullary nailing, as it aligns the fracture to facilitate guidewire placement, reaming, and nail insertion. Length, angulation, and rotation are all important to provide correct nail positioning (Fig. 6). The procedure is verified by using an image intensifier to ensure the accurate position throughout the procedure (Fig. 7).

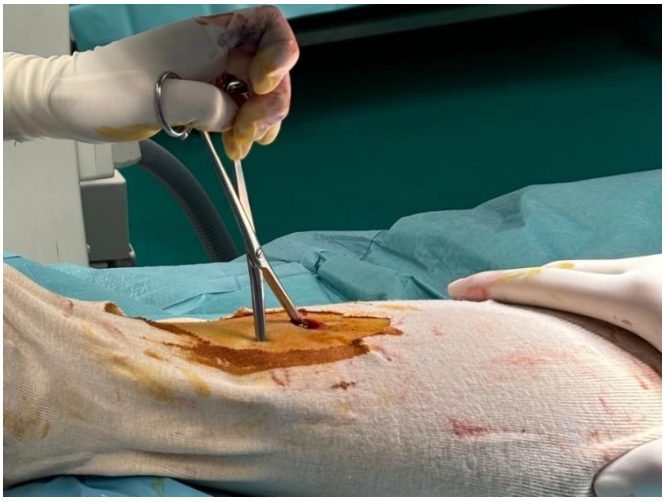

Fig. 6. *Oblique and spiral fractures can be reduced with Weber reduction clamps applied percutaneously perpendicular to the fracture line.*

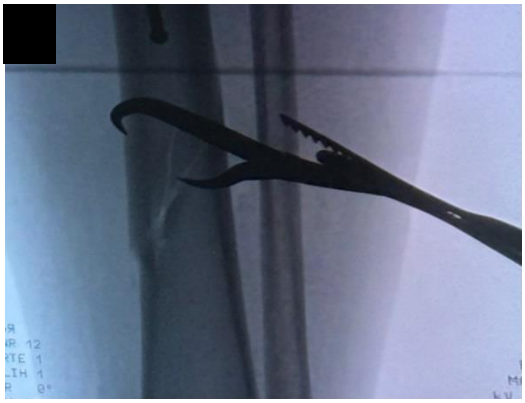

Fig. 7. *Fluoroscopic image of the reduction clamp used for percutaneous fracture reduction.*

Once the fracture has been reduced and stabilized with the Weber reduction clamp, the protective sleeve, and the cutter are placed over the guidewire. The medullary canal is reamed until the required diameter is reached. The guidewire and the cutter should not touch the posterior cortex. Depending on the diameter of the nail, the appropriate length and diameter are selected and placed within the intramedullary space.

Nail length can be estimated preoperatively; however, intraoperative measurements provide greater accuracy. The distance from the nail entry point to just above the ankle joint ensures the nail does not protrude above the bony surface. The nail diameter should be sufficiently large to provide an excellent fit and reduction. Reaming should be 1.5 mm greater than the nail diameter since the medullary canal is not perfectly straight. The nail is then inserted using the dedicated handlebar. With the insertion handle, the nail is carefully advanced into the medullary canal through slight rotational movements (Fig. 8).

The passage of the nail across the fracture is monitored by the fluoroscopy in two planes (AP and lateral) to avoid malignant and iatrogenic fractures (Fig. 9).

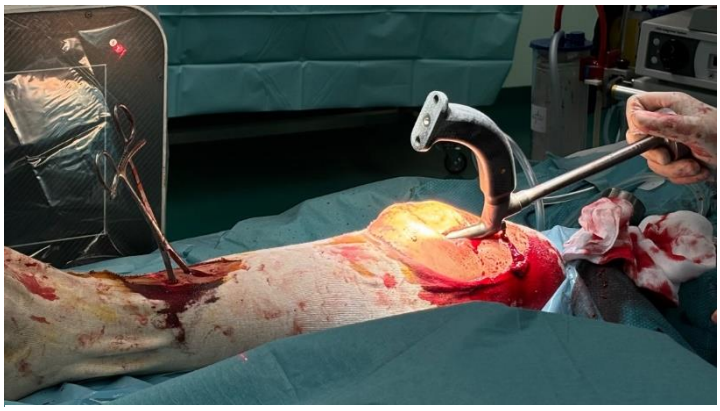

Fig. 8. *Insertion of the canulated nail over the guidewire by hand, or gentle hammering.*

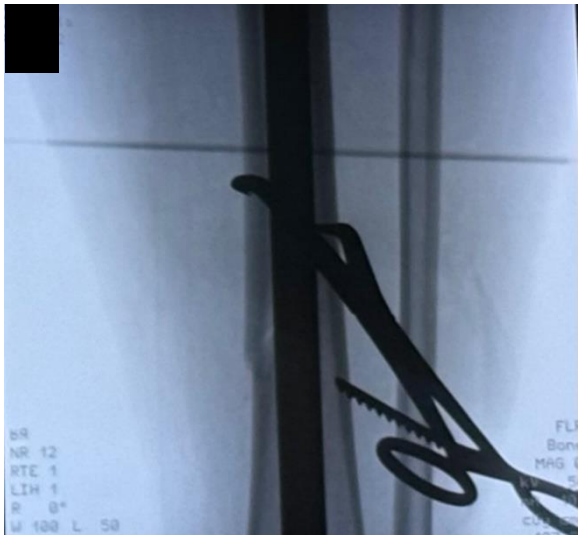

Fig. 9. *The nail is placed in the center of the distal tibia and the proper fracture alignment are maintained in placed by the forceps.*

Once the correct nail position is confirmed, proximal and distal locking screws are inserted, followed by the removal of the insertion handle. Both cortices are drilled until the drill bit just breaks through the far cortex (Fig. 10).

The number of locking screws is based on fracture pattern and fracture stability. Either 4.0- or 5.0-mm locking screws are used depending on the nail diameter. The next step involves performing distal locking. Typically, two distal locking screws are used for diaphyseal or proximal fractures, though if the pattern is length stable. The leg and the fluoroscope are properly positioned, and an incision is made under radiographic guidance. If correct, screw length is measured, the appropriate screw is inserted, and the proper placement is confirmed radiographically (Fig. 11).

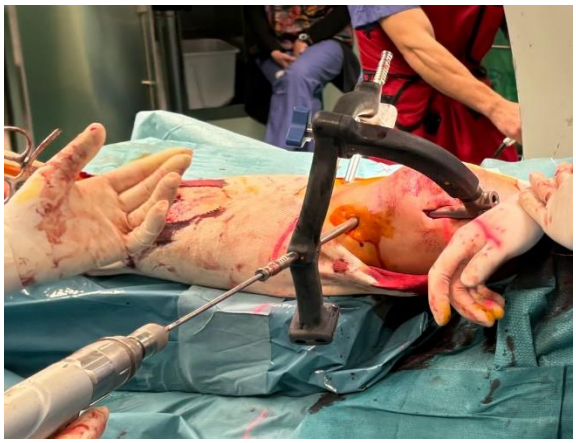

Fig. 10. *Guided insertion of proximal locking screws.*

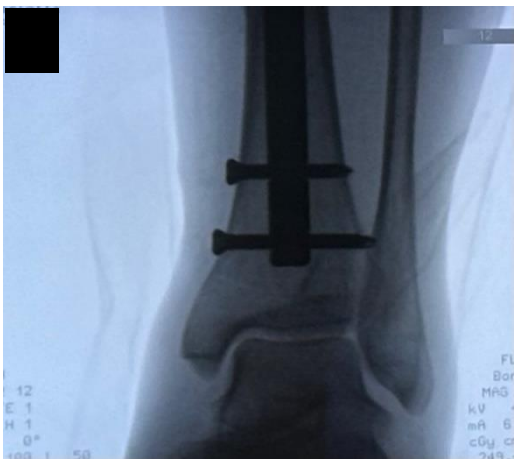

Fig. 11. *Fluoroscopy of distal locking screw.*

After the nail has been locked proximally and distally, the insertion point is irrigated to remove all reamer debris. Reticular tissues are sutured with interrupted absorbable wires. Skin and subcutaneous tissues are closed, and medication is applied (Fig. 12).

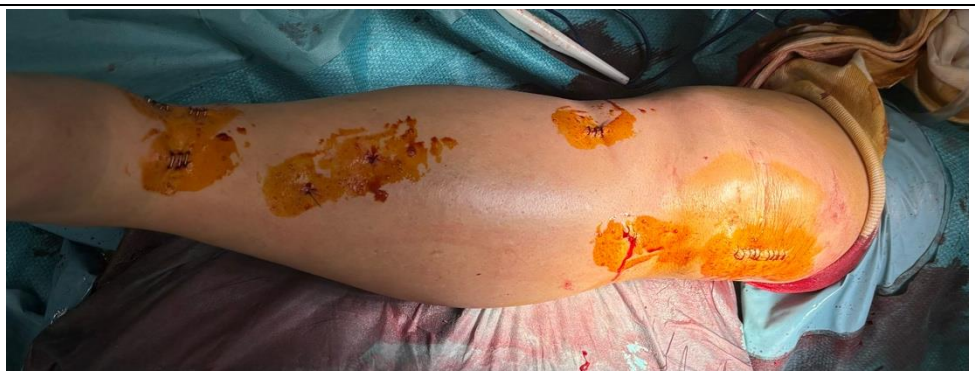

Fig. 12. *Final aspect of the left leg after tibia nailing through extra-articular lateral parapatellar approach.*

Immediately after surgery, it is essential to assess pain management, mobilization, infection prevention, and deep vein thrombosis prophylaxis, along with the early detection of complications (i.e., compartment syndrome). A key aspect of this technique is patellar subluxation, which facilitates tibial nailing in a semi-extended position. However, subluxation can lead to reamer impingement and iatrogenic injury of the patella and requires experience and confidence with the surgical technique.

CONCLUSIONS

The surgical technique for lateral extra-articular parapatellar approach for tibia nailing is a reliable technique in selected cases. However to our knowledge, additional case reports are needed to firmly establish the validity of this surgical approach.

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