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*REVIEW*

# Developing an enhanced recovery after surgery program for oncology patients who undergo hip or knee reconstruction surgery

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## Abstract

Enhanced recovery after surgery (ERAS) protocols are applied in orthopedic surgery and are intended to reduce perioperative stress by implementing combined evidence-based practices with the cooperation of various health professionals as an interdisciplinary team. ERAS pathways include pre-operative patient counselling, regional anesthesia and analgesia techniques, post-operative pain management, early mobilization and early feeding. Studies have shown improvement in the recovery of patients who followed an ERAS program after hip or knee arthroplasty, compared with those who followed a traditional care approach. ERAS protocols reduce post-operative stress, contribute to rapid recovery, shorten length of stay (LOS) without increasing the complications or readmissions, improve patient satisfaction and decrease the hospital costs. We suggest that the ERAS pathway could reduce the LOS in hospital for patients undergoing total hip replacement or total knee replacement. These programs require good organization and handling by the multidisciplinary team. ERAS programs increase patient's satisfaction due to their active participation which they experience as personalized treatment. The aim of the study was to develop an ERAS protocol for oncology patients who undergo bone reconstruction surgeries using massive endoprosthesis, with a view to improving the surgical outcomes.

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**Core Tip:** Enhanced recovery after surgery (ERAS) pathways are applied to oncology patients undergoing primary total hip replacement or total knee replacement; and through evidenced practices are used by the multidisciplinary team, with the aim of reducing the perioperative stress and its effects. ERAS protocols have been reported to promote early recovery, early mobilization, early feeding, and better pain management with multimodal analgesia. ERAS pathways in orthopedic surgery, also, reduce postoperative length of stay, postoperative complications and mortality by 30 d after surgery, hospital costs, and readmission rate by 30 d after discharge.

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## INTRODUCTION

Orthopedic prosthesis has been used globally since the 1960s. The aim is to restore the function of the joint replaced and to improve the patient's quality of life[1]. The first primary hip arthroplasty with a metal prosthesis was performed in 1953 by the Englishman George McKee[2]. Since then, different interventions have been developed varying in terms of their design and construction material, for a number of joints, revolutionizing the specialty of orthopedics[3,4]. Nowadays, the use of orthopedic prostheses is very common. It is estimated that more than 600000 knee arthroplasties are performed in the United States each year[5].

Endoprostheses are used in two areas of orthopedics: (1) In reconstructions of joints, which have been damaged by trauma, degenerative or systemic diseases and need to be replaced by metal endoprosthesis (semi- arthroplasty of the hip, knee and shoulder, total ankle arthroplasty and total hip and knee arthroplasty) for better functional and long-term results[6]; and (2) In orthopedic oncology after tumor resection due to malignancies or, less often, benign diseases, where bone and tissue deficits are restored with extensive prosthesis. Until about 1970, the only treatment for bone tumors and soft tissue sarcomas was amputation, without improving patient survival though. Since then, rapid advances in prosthesis technological has allowed the rescue of limps, which in combination with chemotherapy have significantly improved the survival rate[7].

The idea of enhanced recovery pathways was first introduced by Kehlet in the late 1990s, improving the mental and physical effects of post-operative stress on the recovery and general clinical condition of a patient undergoing surgery[8,9]. The concept of fast-track surgery, as it is widely known, included a combination of minimally invasive surgical techniques, combined anesthesia and analgesia, early feeding and early mobilization[10,11]. It was initially applied to colorectal surgery and later to almost all general surgeries[12,13].

Nowadays, fast-track programs have evolved into enhanced recovery after surgery (ERAS) protocols applied by a variety of surgical specialties, including orthopedics. Studies have shown that ERAS protocols reduce length of stay (LOS) without increasing mortality, readmissions or complications rates, decrease hospital cost and enhance patient satisfaction[14,15].

ERAS protocols are intended to reduce perioperative stress, which causes metabolic and immune changes with side effects on the various body systems and increases susceptibility to post-operative infections[14,16,17]. This is achieved through a combination of multifactorial evidenced-based practices performed by various health

specialties collaborating in an interdisciplinary team (surgeon, anesthesiologist, nurse, physiotherapist, *etc*.). An ERAS protocol is divided into three phases: Pre-operative, intraoperative, and post-operative (Table 1). It often begins before the patient's admission to the hospital and continues after discharge. The active participation of patients is required throughout the program[17-19].

According to ERAS protocols, there are several components of perioperative care that affect stress response and accelerate recovery. These include pre-surgical counselling, short fasting period, early mobilization, bowel and bladder preparation, anesthesia and analgesia, thrombocytopenia, prevention of nausea and vomiting and fluid management[20].

## PRE-OPERATIVE PERIOD

### *Informed consent*

In order for the patient to follow an ERAS protocol, it is necessary to be informed about all the care practices they will receive, the expected results of their care and the active role they will play in the program, and be acquainted with all the members of the interdisciplinary team. Some patients feel reticent about new practices out of either ignorance or fear, so they disagree or need time to decide. The interdisciplinary team should answer each question of the patient and give them the written protocol instructions[16,20,21].

### *Patient's medical history and determination of vital signs*

After the diagnosis and before the surgery is decided by the surgeon, the multidisciplinary team meets the patient to determine their vital signs and identify any health conditions they may have that may be improved until the planned surgery[22,23]. Patients at high risk for post-operative complications are identified by calculating individual risk based on family history, symptoms, and health status measurement using specific questionnaires[24,25]. One such tool is the Revised Cardiac Risk Index (Lee Criteria), which assesses the risk of more serious heart events based on a history of ischemic heart disease, heart failure, stroke, insulin-dependent type II diabetes, serum creatinine > 177 μmol/L and high risk surgery[24,26-28]. There are many specialized tools for measuring a patient's physical function, severity of surgery and anesthesia, post-operative mortality and morbidity, as well as various measurements of frailty related to clinical outcomes from surgery, supported by the American Society of Anesthesiologists[26-28].

### *Counseling*

ERAS protocols aim to increase the patient's physiological and functional reserves before surgery, which is, in fact, their main difference from fast-track proto-cols[11,29,30]. Studies have demonstrated the effectiveness of targeted pre- operative counseling. In particular, to reduce the risk of respiratory complications, such as infection or atelectasis, and the risk of post-operative wound inflammation, pre-operative smoking cessation within 2-4 wk of surgery is recommended[31,32]. If this is not possible, then it is recommended to reduce the number of cigarettes *per* day rather than quitting smoking, as this would result in a reflex increase in secretions that would have the opposite effect. Patients who consume alcohol have a slow recovery and increased rates of post-operative complications, so it is recommended to follow alcohol withdrawal programs before surgery when possible[33-35].

### *Pre-operative fasting*

According to ERAS protocols, the routine of "being nil by mouth" from midnight before surgery to patients who are going to be operated is considered obsolete and incorrect. Fasting increases the peri-operative stress and its adverse effects as catabolism, insulin resistance and hyperglycemia[36,37]. ERAS protocols recommend shortening the pre-operative fasting time; clear fluid fasting for 2 h and solid food fasting for 6 h before surgery are enough for most patients. Patients with gastroparesis, esophageal achalasia or previous upper gastrointestinal surgery, morbid obesity and previous history of post-operative nausea and vomiting are excluded[38,39]. Pre-operative administration of oral carbohydrate drinks has been studied in recent years and shown to significantly improve insulin resistance without significant impact on the recovery time of patients undergoing hip or knee replacement surgery[40-42]. Although carbohydrate intake in orthopedic surgery has been shown to improve

**Table 1 Summary of enhanced recovery after surgery pathways for oncology patients who will undergo hip or knee reconstruction surgery**

| | |
|---|---|
| **Preoperative approach** | |
| Informed consent | Patient should be informed and consented about all the care practices he/she will receive, the expected results from his/her care, the active role he/she will have in the program and to meet all the members of the interdisciplinary team |
| Health history and determination of the patient's vital function | To determine patient's vital function and to identify any health conditions that can be improved prior to surgery. Patient of high risk are identified by calculating individual risk based history, symptoms, health status using specific questionnaires |
| Counseling | Targeted preoperative counseling. It is recommended to quit smoking 2-4 wk and drinking alcohol 4 wk prior to surgery |
| Preoperative fasting | ERAS protocols recommend 2 h of fasting from clear fluids and 6 h of solids prior to induction of anesthesia |
| Preoperative anemia management | Preoperative anemia should be evaluated and treated before surgery |
| **Intraoperative phase** | |
| Anesthesia protocol | Standard Anesthetic Protocol and neuraxial techniques as a part of a multimodal approach |
| | GA with TIVA using continuous drip infusion of Propofol and Remifentanil is recommended by ERAS pathways |
| Neuraxial anesthesia | The gold-standard of ERAS programs is the use of epidural or spinal anesthesia, but especially for hip or knee replacement surgery is not recommended as a routine alone |
| RA/analgesia | A multimodal approach to pain management with RA and MA is supported by ERAS protocols. Should not be considered as an alternative technique to GA, but as a complement to an integrated strategy |
| Intraoperative analgesia | The use of NSAIDs or COX-2 inhibitors is recommended for the treatment of pain, in combination with paracetamol, in order to significantly reduce the use of opioid drugs in the context of a MA |
| Optimal intraoperative fluid management | Optimal fluid balance is necessary to avoid over or under hydration. Intraoperative isotonic crystalline fluids are administered to maintain the homeostasis and the electrolyte balance at a rate of 3-5 mL/kg/h |
| Prevention and treatment of perioperative nausea and vomiting | It is recommended to administer IV ondansetron 4 mg before induction to anesthesia and metoclopramide 30 min before awakening. Especially for high-risk patients, a combination of 2-3 antiemetics is recommended (ondansetron, dexamethasone, droperidol) |
| | Chewing gum postoperatively appears to help mobilize the gastrointestinal system |
| Normothermia | Normal body temperature is achieved by the use of electric hot air devices (for the patient's body) and fluid warmer devices for the IV fluids or blood agents to 37-40 °C |
| | The temperature of the operating room should not be under 21 °C |
| Prophylactic anticoagulant treatment | Rapid mobilization, elastic anticoagulant socks and low molecular weight heparin anticoagulant therapy for 28 d in hip surgery and 14 d in knee surgery, are recommended |
| Antimicrobial prophylaxis | The most suitable antibiotic for prophylactic antimicrobial treatment is 1$^{st}$ or 2$^{nd}$ generation cephalosporin (cefazolin or cefuroxime) intravenously 30-60 min before the skin incision, as a single-dose, depending on the patient's weight (weight-adjusted dose) |
| Surgical management | The ERAS Society makes no recommendations for surgical technique |
| | However, it recommends avoiding the use of tourniquets and drains as a routine in all operations |
| **Postoperative phase** | |
| Postoperative analgesia | Effective postoperative pain management includes a combination of analgesic drugs with central and peripheral action |
| | Postoperative analgesia is determined and depends on the intraoperative analgesia plan and follows the same method used |
| | The use of paracetamol 1 gr in combination with lornoxicam or celecoxib/parecoxib is recommended |
| | Oral analgesia as soon as patients begins to eat |
| Postoperative fasting | Clear fluids or jelly 4-6 h post-surgery. Return to normal diet as soon as possible |
| Prevent falls after surgery | Many factors can contribute to the fall after TKA and THA, such as reoperation, elderly, female gender and comorbidities, which highlights the importance of establishing a multidisciplinary fall prevention program at every orthopedic ward |
| Physiotherapy approach | Physiotherapy, Kinessiotherapy, Strengthening |
| | Physiotherapy rehabilitation of the patient undergoing TKA or THA should begin much earlier than the day of surgery, as counseling |

| | |
|---|---|
| | After the physical evaluation, interventions are made to reduce BMI and increase muscle strength by increasing physical exercise and activity |
| | The procedure can be started up to 4 wk before scheduled surgery, with regular sessions aimed at early mobilization |
| | Respiratory physiotherapy with 3-flow spirometer |

ERAS: Enhanced recovery after surgery; TIVA: Total intravenous anesthesia; BMI: Body mass index; GA: General anesthesia; MA: Multimodal analgesia; NSAIDs: Nonsteroidal anti-inflammatory drugs; COX-2: Cyclooxygenase-2; TKA: Total knee arthroplasty; THA: Total hip arthroplasty; RA: Regional anesthesia.

patients' well-being, metabolism, and post-operative pain, it is not recommended as a standard practice[17,43,44].

### *Pre-operative anemia management*

Pre-operative anemia should be evaluated and treated before surgery. Pre- operative anemia is associated with increased rates of allogeneic transfusion, longer stay in hospital, increased risk of post-operative infection, higher post- operative morbidity, complications and readmissions[45,46]. Clinical intervention studies about pre-operative and post-operative treatment with iron (Fe) or erythropoietin have reported statistically and clinically significant reduction in allogeneic blood transfusions[46-48]. The algorithm used to detect and correct pre- operative anemia by ERAS certified centers was associated with a reduction in the rate of transfusions, LOS, hospital readmissions, admissions to intensive care units and hospital cost[49].

## INTRA-OPERATIVE AND POST-OPERATIVE PERIODS

### *Anesthetic protocol*

In order to extract comparable results from an ERAS protocol, a standard anesthetic protocol must be followed. However, this is not always possible (for various reasons), which causes problems with regard to the homogeneity of parameters and the quality of the study methodology, thus challenging its reliability[50,51]. General anesthesia (GA) with total intravenous anesthesia using continuous drip infusion of Propofol and Remifentanil is recommended by ERAS pathways. In vitro studies have shown the properties of propofol as an anti-inflammatory agent and as a stimulant of immune response with beneficial effects on cancer recurrence prevention[52-55]. Oncology patients have peculiarities compared to the rest of the population. They are usually patients with metastatic or primary disease who have undergone chemotherapy and/or radiotherapy and have increased risk of intraoperative complications, especially during bone reconstruction with endoprosthesis and use of bone cement [56]. After a systematic review and meta-analysis of anesthesia techniques used for total knee replacement (TKR) and total hip replacement (THR) in non-cancer patients, the choice of anesthesia type was based on the type of surgery and the patient's general condition[57]. The level of evidence was low for GA or neuraxial anesthesia (NA), but the recommendation strength for both types of anesthesia was strong for patients undergoing hip or knee arthroplasty[52,58].

### *Neuraxial Anesthesia*

The gold-standard of ERAS programs is the use of epidural or spinal anesthesia, but it is not recommended as a routine specifically for hip or knee replacement surgery[57, 59,60]. There is a strong recommendation from the ERAS society not to inject high doses of opioids into epidural or spinal cord to avoid the risk of respiratory depression, post-operative nausea-vomiting (PONV), pruritus and urinary retention [61-63]. Morphine in low doses (0.1-0.18 mg) prevents the risk of respiratory depression and provides an adequate analgesic effect compared with continuous local anesthetic infusion after peripheral nerve blocks (PNB). NA with morphine promotes early patient mobilization[64]. Recent clinical trials using non- opioid formulations, such as bupivacaine, have shown excellent results with minimal risk of complications [51,65].

In ERAS protocols for hip or knee replacement, NA is recommended for its superiority over GA in reducing the stress response and the insulin resistance[19,66]. NA offers great analgesic benefits and reduces LOS and hospital costs, but may cause side effects such as respiratory depression, PONV and pruritus, therefore not

recommended as a routine[19].

### Regional anesthesia/analgesia

Regional anesthesia (RA) can reduce the incidence of cancer recurrence due to reduced need for opioids, suppression of the sympathetic nervous system, reduction of perioperative stress, and immediate anti-inflammatory and anticancer effect on immune system[54,67,68]. Although there are many studies that support the positive effects of RA on cancer recurrence, more studies are needed to determine the effects of RA on orthopedic cancers. Data may be incomplete, as orthopedic oncology procedures often involve resection of large bones and/or muscle groups and can take up to 12 h, making GA more common[69]. However, these resections can be performed using RA, either alone or in combination with GA[55,69].

RA provides a greater advantage in joint reconstruction as it delivers sufficient anesthesia for orthopedic surgery and great post-operative analgesia, inhibits the release of stress hormones and reduces insulin resistance. A multimodal approach to pain management with RA and multimodal analgesia (MA) is supported by ERAS protocols[17,68]. RA always plays an important role in minimizing the intra- operative requirements for opioids and should not be considered as an alternative to GA, but rather as a complement to an integrated strategy[68].

Morphine has a negative effect on the functioning of the immune system and it is strongly recommended to minimize doses[70-72]. MA is of paramount importance in the perioperative period, because it helps to reduce the need for opioids[73]. Opioid sparing analgesia based on intravenous lidocaine, nonsteroidal anti-inflammatory drugs (NSAIDs) and ketamine has been found to maintain immune function[73].

RA seems to benefit most elderly and debilitated or seriously ill patients or those undergoing major orthopedic and thoracic surgeries[74]. Recent studies have shown that total arthroplasty may be possible with the use of RA in all age groups, regardless of the severity of the comorbidity[58,67].

ERAS programs significantly reduced the incidence of post-operative complications, such as myocardial ischemia and mortality, over a period of 30 d compared to conventional treatment[58,66].

### Intra-operative analgesia

For purpose of pain management, using a combination of NSAIDs or inhibitors of cyclooxygenase-2 (COX-2) with paracetamol (acetaminophen) is recommended to significantly reduce the administration of opioid drugs in the context of a MA[21,75,76]. Concomitant use of paracetamol and NSAIDs is the main axis of perioperative MA and one of the most important components of ERAS[73,76]. Studies have shown that MA has great analgesic effects on moderate pain and reduces the additional use of opioids after TKR and THR[57,77]. NSAIDs and COX-2 inhibitors are not recommended for patients with contraindications (allergy, pre-existing kidney disease, *etc.*)[78].

### Optimal intra-operative fluid management

Intravenous fluids and maintenance of normovolemia are very important for perioperative patients. Failure to maintain normovolemia may lead to increased morbidity/mortality, affect tissue oxygenation, increase post-operative cardiopulmonary complications, increase trauma inflammation and prolong hospital stay[17,19,21]. Intra-operative isotonic crystalline fluids are administered to preserve homeostasis and the electrolyte balance at a rate of 3-5 mL/kg/h. ERAS society recommends early transition from IV to PO fluid therapy within 24 h for patients undergoing major surgery[79].

### Prevention and treatment of PONV

PONV is undoubtedly an unpleasant adverse effect, which is experienced by 20%-30% of surgical patients and 70% of high-risk patients (patients with gastroparesis, esophageal achalasia, dysphagia, neurological diseases, gastrointestinal surgery, Whipple procedure, gastrectomy, *etc.*)[38]. For the prevention and treatment of PONV, it is recommended to administer 4 mg IV infusion of ondansetron before induction of anesthesia and metoclopramide half an hour before awakening. Especially for high-risk patients, a combination of 2-3 antiemetics is recommended. Such a combination may be ondansetron 4mg overnight, dexamethasone 4-5 mg after induction of anesthesia and droperidol 0.625-1.25 mg at the end of surgery[17,19,21,80]. Caution is needed in the use of dexamethasone as an antiemetic in oncology patients because of its potential immunosuppressive and hyperglycemic effects[81]. A recent study has

shown that dexamethasone significantly decreased the incidences of PONV as well as pain, improved respiratory parameters, and reduced the need for additional post-operative analgesic and antiemetic drugs[81]. It is worth noting that Gan *et al*[80] and Sherif *et al*[82] created a simplified PONV probability scoring system using only four risk factors: (1) Female gender; (2) Previous PONV history; (3) Smoking; and (4) Opioid analgesics[80,82]. Therefore, a combination of two drugs is recommended for patients with one or two risk factors, while for patients with more than two factors the recommendation is a combination of three drugs[80,83]. Finally, chewing gum post-operatively appears to help mobilize the gastrointestinal system[84].

### Normothermia

Hypothermia affects over 60% of patients. Maintaining body temperature at normal levels throughout the surgery has been shown to help reduce post- operative wound infection, intraoperative bleeding, cardiovascular complications, post-operative stress and its metabolic effects[85,86]. Prevention of perioperative hypothermia is achieved by using electric hot air devices for the patient's body and fluid heating pumps to administer intravenous fluids or blood products at 37-40 ℃ intraoperatively. The temperature in the operating room should be 21 ℃ for total joint surgeries[19,86-89].

### Prophylactic anticoagulant treatment

There is a significant correlation between deep vein thrombosis, pulmonary embolism and hip and knee replacement surgery, which can lead to post- thrombotic syndrome or even death[90]. The NICE guidelines recommend early mobilization and fast return to baseline activity[61], as well as low-molecular-weight heparin anticoagulant therapy for 28 d in hip surgeries and 14 d in total knee operations[90-92].

### Antimicrobial prophylaxis

One of the most serious and harmful post-operative complications in orthopedic surgery is bone tissue and prosthetic joint infections. Infection after THR or TKR surgery is called osteomyelitis and remains to date the worst complication to treat[21, 93]. Bone infection treatment often requires removal of the prosthesis in order to reduce osteolysis and inflammation[94-97]. Recommendation for prophylactic antimicrobial therapy is 1$^{st}$ or 2$^{nd}$ generation cephalosporin (Cefazolin, Cefuroxime) 30-60 min before the skin incision as a single-dose, depending on the patient's weight (weight-adjusted dose)[98].

### Surgical management

Although there are many comparative studies on surgical techniques and approaches to TKR and THR, we cannot conclude with certainty which technique is superior to all. ERAS society does not recommend a specific surgical technique[16].

ERAS protocols recommend avoiding the use of tourniquets and drains as a routine. It seems that tourniquet does not reduce the total blood loss from surgery, while increasing the risk of thromboembolic events, edema and complications[99-101]. Regarding wound drainage, studies show that not only does it not help prevent hematomas, but it also increases the risk of inflammation and blood loss because it eliminates the tamponade effect and may cause a retrograde infection[102-104].

### Post-operative analgesia

Effective post-operative pain management includes a combination of analgesic drugs with central and peripheral action, aimed at early mobilization and feeding. Once the patient begins to eat solid food, the IV analgesic regimen should be administered *per* os[19,36]. In ERAS protocols, MA is very important for pain management, enhanced recovery and patients discharge. MA significantly reduces the opioid requirements and helps reduce PONV, post-operative stress and the risk of complications[16,19]. The use of paracetamol in combination with lornoxicam or celecoxib/parecoxib is recommended. Paracetamol is very effective in acute post-operative pain without significant side effects and constitutes a key component of MA in all ERAS guidelines [17,78,105].

### Prevention of in-hospital falls after surgery

RA is responsible for in-hospital falls in post-operative patient after TKR and THR. Patients with GA have a higher rate of in-hospital falls compared to NA. The group of PNB has not been significantly associated with patients' falls[67], while PNB-induced quadriceps insufficiency is not the only cause for in-hospital falls[106]. Many factors can contribute to an in-hospital fall after TKR and THR, such as re-operation,

advanced age, female gender and comorbidities, which highlights the importance of establishing a multidisciplinary in-hospital fall prevention program in every orthopedic ward[35,107,108].

Multimodal post-operative analgesia, including RA or PNB techniques, in combination with goal-directed rehabilitation are important components that prevent in-hospital falls. This approach accelerates functional recovery and minimizes the risk of in-hospital falls, increases patient satisfaction and reduces overall hospital stay and costs[109,110].

## PHYSIOTHERAPY REHABILITATION

Physiotherapy rehabilitation of patients after TKR or THR surgery should begin much earlier than the day of surgery, in the form of counseling. After the physical evaluation, interventions are made to reduce body mass index and increase muscle strength by increasing physical exercise and activity[71,111]. The procedure can be started up to 4 wk before scheduled surgery, with regular sessions aimed at early mobilization. Patients are initially informed in detail about the surgery and the post-operative stage even with appropriate leaflets. If possible, patient counseling can be performed simultaneously to a group of people who will undergo surgery on the same day. At the same time, an exercise and stretching program can be implemented to strengthen the muscles of the lower extremities of patients, who learn how to perform it on their own[112,113].

Patients who have followed a counseling program delivered by the physiotherapist, have become more comfortable with the use of walking-aid, made the suggested interventions in the configuration of their residence so that it is safe for a faster return home and have returned home on the 3rd post-operative day without complications [114,115].

The strengthening part is very important because patients who are going to undergo TKR or THR surgery, already have deficient function of the quadriceps due to arthritis or cancer. This is caused by reduced functional use of the joint due to pain and atrophy. Muscle strengthening with progressively increasing resistance and neuromuscular electrical stimulation perioperatively have been shown to improve the functional performance of the quadriceps[116].

Pre-operative mobilization and strengthening seems to be crucial because there is a significant reduction in muscle strength and ability to perform the leg press test within the 1$^{st}$ week after surgery[117]. In fact, the decrease is not due to objective findings (inflammation, swelling) but subjective symptoms (insecurity, pain), which subside to such an extent when applying the pre-operative approach and early mobilization, that patients are discharged earlier and, in some cases, do not need post-operative physio-therapy other than an exercise routine they are trained to perform at home[118,119].

Psychological support of the patients from the interdisciplinary team is necessary, because it increases their sense of security and satisfaction[120]. The team reports on the benefits of early mobilization within 8-12 h after the surgery. Even patients who disagree or hesitate to follow the instructions of physiotherapists should at least agree to cooperate. Their initial reluctance is followed by surprise, as they experience less pain than they thought during the recovery period and are satisfied with their post-operative progress[121].

Early mobilization reduces the LOS as patients can be discharged sooner without increasing the risk of complications. Depending on the pain experienced by the patient, he or she may be able to stand or walk without aid on post- operative day 1 if the visual analogue scale score is lower than 5[122].

Pain management, reduced swelling, autonomous movement and normal mobilization with walking-aids are criteria for the patient's discharge from the hospital. Indicatively, following TKR the aim is for the patient to be able to lift their limb with stretched knee and achieve pain-free flexion to 90 degrees, while safe and controlled walking to and from the bed suffices after THR surgery[111,115,122]. Post-operatively, standard physiotherapy (kinesiotherapy) as well as other methods, including electrical stimulation, are applied in order to strengthen the muscles, increase the range of motion, reduce swelling and enhance independent gait[123,124].

All of the above ERAS pathways that developed for the rapid postoperative recovery of oncological patients undergoing Total Knee or Hip Reconstruction are summarized in Table 1.

## CONCLUSION

ERAS programs undoubtedly reduce hospitalization days without increasing the risk of complications or relapses and reduces hospital costs. These programs require good organization and handling by the multidisciplinary team. Nurses have a central role in the implementation of ERAS programs. ERAS programs increase the patient's sense of satisfaction due to their active participation which they experience as an individualized treatment. However, their implementation is not common practice in Greece, so additional multicenter clinical trials at are required.

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*REVIEW*

# Slacklining: A narrative review on the origins, neuromechanical models and therapeutic use

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## Abstract

Slacklining, the neuromechanical action of balance retention on a tightened band, is achieved through self-learned strategies combining dynamic stability with optimal energy expenditure. Published slacklining literature is recent and limited, including for neuromechanical control strategy models. This paper explores slacklining's definitions and origins to provide background that facilitates understanding its evolution and progressive incorporation into both prehabilitation and rehabilitation. Existing explanatory slacklining models are considered, their application to balance and stability, and knowledge-gaps highlighted. Current slacklining models predominantly derive from human quiet-standing and frontal plane movement on stable surfaces. These provide a multi-tiered context of the unique and complex neuro-motoric requirements for slacklining's multiple applications, but are not sufficiently comprehensive. This consequently leaves an incomplete understanding of how slacklining is achieved, in relation to multi-directional instability and complex multi-dimensional human movement and behavior. This paper highlights the knowledge-gaps and sets a foundation for the required explanatory control mechanisms that evolve and expand a more detailed model of multi-dimensional slacklining and human functional movement. Such a model facilitates a more complete understanding of existing performance and rehabilitation applications that opens the potential for future

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applications into broader areas of movement in diverse fields including prostheses, automation and machine-learning related to movement phenotypes.

**Key Words:** Slacklining; Neuromechanics; Human movement; Model; Balance; Rehabilitation



**Core Tip:** Slacklining is an ancient activity; however, modern scientific literature is very recent and limited. This paper explores slacklining's origins to provide background on its evolution and incorporation into prehabilitation and rehabilitation. Existing mechanical models and neurophysiological explanations are considered, summarised, and their applications and knowledge-gaps highlighted. Consequently, the need for improved understanding and descriptive and mathematical models are highlighted to ensure a multi-tiered understanding of slacklining's unique and complex neuro-motoric requirements for its multiple applications, including human functional movement. With understanding slacklining's history and fundamentals comes the potential for future broader applications for functional movement, prosthesis, automation, and machine-learning.

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## INTRODUCTION

Slacklining is defined as a complex neuromechanical task involving achievement of functional independence while maintaining dynamic stability through balance retention. This occurs from the interactions of the individual's whole-body where internal dynamics drive the response to external environmental changes, while treading on an unstable, three-dimensional moveable, tightened, webbing-band fixed at each end[1,2]. The concepts explored in this paper consider and address what slacklining is, and its historical origins, in order to provide essential background understanding of the activity and its evolution, recognition and progressive incorporation into prehabilitation and rehabilitation. With this background knowledge, the existing explanatory models can be considered, how they apply to an individual's capacity to achieve stability, and whether they provide a complete recognition and understanding of the explanatory control mechanisms for multi-directional instability and complex multi-dimensional movement. As such, they should be able to explain slacklining as a harmonious functional movement (HFM), namely the integrated interrelation of neural and muscular components to facilitate and enable a stable harmonized full-body functional movement[3]. Examining these current models enables the determination and recognition that there are knowledge-gaps, which indicates that existing models must be evolved and expanded in order to encompass the broad conceptual circumstances that achieve slacklining stability.

## THE ORIGINS AND ACTIONS OF SLACKLINING

As a trend-sport, modern slacklining is an adaptation of the ancient performing art of traditional rope-walking. Modern slacklining was initially started by climbers and outdoor enthusiasts in the 1960s and 1970s in the European Alps of Switzerland, France and Austria as well as in Yosemite National Park in the United States of America, where ropes and cables were replaced with adapted lightweight webbing and ratchet technology that incorporated an easier, safer and more elastic line[4,5]. Slacklining was originally termed "line-walking" or "funambulaire" (the precursor term to slacklining) in Latin European regions and "Jultagi" or "Eoreum" in Korea as a representation of Central Asia[5,6]. Slacklining has very ancient, established history

and cultural traditions. The earliest records are insinuated as being possible from approximately 40000 years Before Christ (BC) when man first invented ropes[7]. Consequently, the necessity and challenge arose to walk along these ropes to enable the completion of normal tasks in construction, movement along and between habitation sites such as cliffs and trees[8], for communication and social interaction such as crossing gorges as continues in the Russian Dagestan region, on the ropes of early Phoenician sailing vessels in ancient Crete around 1000 BC, and eventually for entertainment[4,9]. More direct inference is made at approximately 20000 BC where, "line-walking" or "funambulaire" was an established societal activity in pre-ancient Greece, China and the Korean Peninsula[4,6,10]. The earliest documentation appears to be in pottery and figurines of Cycladic acrobats from around 3000 BC[11]; and as a performance component of the ancient Greek Olympics from 776 BC and earlier Greek Games where the "Thaumatron" was awarded to those who performed a marvelous act or spectacle[6].

However, historical writings suggest the ancient Olympics were an extension of games from earlier periods, particularly the bronze age of Anatolia (3000-2500 BC), Crete (3000-1100 BC) and Mycenae (1600-1100), with some archaeological data suggesting games dated back to the 10$^{th}$ century BC[12]. Funambulaire was an integral social performing art from at least 3000 BC[4,6]; and demonstrated in the fresco paintings of Selini funambulist rope-walkers from the Villa of Cicero in Pompeii's ash covered ruins estimated as approximately 100-50 BC[13]. The natural progression from ropes and cables to ratchets and webbing reflects human evolutionary capacity found in multiple incorporations and replacements of traditional and established items into modern product developments and activities[8]. The graded incorporation into rehabilitation could have been initiated at any time, but medical literary writings insinuate at least around 150 Anno Domini (AD) during the period of Imperial Roman (31BC-AD476)[10,14], while the first published papers were in European sports science literature around 2009[15,16] (Figure 1).

## SLACKLINING: EXERCISE, REHABILITATION AND THERAPY

### *Slacklining in exercise and rehabilitation*

The incorporation of such a fundamental yet physically complex recreational or cultural activity into the fields of therapy and rehabilitation is another evolutionary reflection. Slacklining, as therapy, has only been formally investigated and documented in the published scientific literature over the last decade[15-17]. There is anecdotal evidence of slacklining's therapeutic use since the 1970's and 1980's as both prehabilitation and rehabilitation for Alpine sports and athletes. This includes Ingemar Stenmark for downhill slalom ski[15], within Australia's competitive surfing community and elite training programs that led to the high performance center at Casuarina on the Australian East Coast[2], and for rock-climbing[17,18]. However, its first recorded application may be inferred from the Greek-Roman physician Galen-of-Pergamon from 150-200 AD. Galen is recognized as the father of "Exercise in Medicine"[10,19] with over 500 medical Treatises[20] that provide potential documentation for the use of rope walking for rehabilitation and prehabilitation purposes. The texts considered[21-23] do not mention rope walking specifically as an activity, but such an activity or exercise is highly likely to have been used and can be insinuated from the following knowledge: rope walking was, as mentioned, an accepted and integral activity within Imperial Roman Society[4,6]; Galen is considered the "father of rehabilitation" who advocated the importance of exercise, his texts and teaching were the recognized authority for almost 1600 years[24], particularly for exercise and health [22,25]. Galen wrote extensively on knee injuries including loss of function and balance in athletes and Gladiators, noting that knee muscle control required considerable time to regain due to loss of muscle activation, with "wasting in the absence of local muscle or nerve damage"[24], a reference to arthrogenic muscle inhibition (AMI)[6,11,14,18]. Galen prescribed exercise for rehabilitation and prehabilitation as essential for "… health and good condition"[26], and "… strength for function"[19,22]. Consequently, though not specific in detail, slacklining could have occurred through the informal or guided inclusion of an existing, recognized and challenging balance activity. Consequently, the incorporation of slacklining into rehabilitation may not be "that" recent, but actually date back some 2000 years.

### *Slacklining and arthrogenic muscle inhibition*

The discussion of AMI is an important consideration as slacklining appears to negate

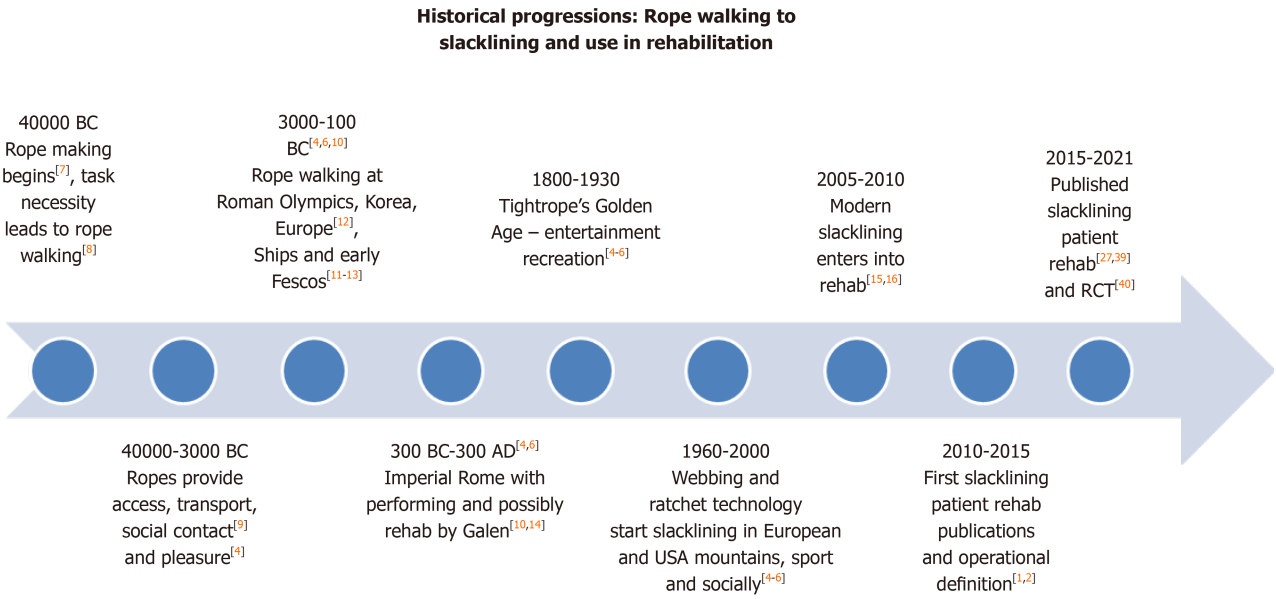


**Figure 1 Historical progressions: Rope walking to slacklining and use in rehabilitation.** BC: Before Christ; AD: Anno Domini.

the local muscular inhibitory action, particularly in the knee quadriceps[2] and potentially in the spinal lumbar multifidi[27]. AMI is defined as muscular activation failure, about a damaged or distended joint, due to ongoing neural activation deficit [28,29]. AMI has been well recognised since at least the 19th century as having a central-neural basis[30], being a consequence of articular sensory receptor discharge from joint afferents[31] due to swelling, inflammation, joint laxity[32] and tissue damage. The presence of AMI is consistent across different joints and joint pathologies, particularly the knee[29,30,32,33], hip[34], elbow[35], shoulder[31] ankle[36] and intersegmental spinal muscles[37]. Evidence indicates that with AMI, supra-spinal pathways potentially play a significant role through inhibitory down regulation that affects central nervous system (CNS) neural inhibition, that in-turn prevents full muscle activation. This is in conjunction with spinal reflex contributions through the Group-I non-reciprocal inhibitory pathway reflexes including the flexion and Gamma (γ)-loop[28]. Today, the full understanding of AMI remains incomplete and is the subject of significant investigative research[38]. However, slacklining's recognized effect in over-riding this down regulation, in the lumbo-pelvic[27] and lower limb regions[2,18] is gradually being recognized and is a significant advancement in anatomical and condition specific regional rehabilitation[39,40].

### *Slacklining as therapy*

The therapeutic direction of slacklining has evolved over the past decade to become an adjunct in both injury prevention, such as falls in the elderly[41], and specific sports including judo[42], basketball[43], badminton[44], handball[45], and football/soccer [46]; as well as in rehabilitation[2], including orthopedics[2,27], neuro-logy[27,39,40], sports training[47], general physical training[46] perfor-mance[43], and recreation[5]. This inclusion of slacklining with other prevention and rehabilitation themes derives from the triad of sensory system contributors of proprioception, vision, and vestibular somatosensory inputs[48]. This is a consequence of the unique properties of slack-lining[2] due to its distinct action from other conventional balance activities[49] and apparatus[41,43] as a composite-chain activity, *i.e.* there is a weak link in the kinetic chain resulting in abnormal motor synergy patterns due to the contact surface of the loaded limbs having free, partially supported but unstable movement on a recoil resistance surface[50]. The coupling of these qualities and the CNS contributors results in slacklining having four integrated qualities[2]: Balance - the equilibrium control regulating the body's segmental dynamic movement and center-of-mass (CoM) within the base of support[51]; postural control - the body's positional control in space[52]; muscle strength - the muscular generated forces[43,53]; and neuromechanical demand - the integration of neurobiology and biomechanics[1].

## MATHEMATICAL AND GENERAL MODELS THAT EXPLAIN SLACKLINING

### *Manifold models*

It is recognised that the neuromechanical control strategies employed during slacklining are not fully understood[54]. Several detailed proposed models seek to explain slacklining and predominantly utilise a conceptual "manifold model". However, the term manifold has two denotations: firstly, within a general context as a "conceptual dimension inside a general discussion"; and secondly, within a mathematical context as a "mathematical subset with lower dimension inside a mathematical model"[55]. The latter context is a defined shaped space where all activity and analysis occurs[56], which for slacklining likely simulates a saddle-shape within ordinary task space[57]. This saddle-manifold is shaped concave in the dimensions of the direction of the slackline (X) and convex in the direction of its lateral shift (Y) and the dimension of gravity or sag (Z)[58,59].

Scientifically and mathematically a "manifold" has the same or lower dimensionality as the underlying mathematical model, though mathematically the number of dimensions possible is arbitrary. Each point within the manifold has its own "homeomorphic" space. Consequently, a "bi-continuous function" exists between all points being on both a continuum in a given direction, while concurrently having an opposing continuous inverse function[60]. The manifold model concept was initially proposed within robotics as the "self-motion manifold"[61], and, subsequently applied to human movement and functional tasks as the "un-controlled manifold" (UCM) model[62]. Such a model suitably explains quiet-standing[58,59] and simple functional frontal plane movements *e.g.,* walking and postural sway[57,63], but was not proposed for complicated tasks involving dynamic contact, *e.g.,* slacklining[1,54].

The UCM may still, however, provide a potential solution as it proposes a motor control strategy for redundant systems by using the abundant solutions inherent to them[62]. This postulates that the task redundant space of the effector is not homogeneous, but structured according to task requirements[61,64]. Consequently, the UCM model may be expanded to accommodate slacklining as the increased variability and redundancy found in such challenging actions can be redistributed, allowing acceptable levels of task variability to be maintained[56,65].

In human quiet-standing and frontal plane movement on stable surfaces, the Newtonian equations in classical mechanics of an inverted pendulum are generally considered acceptable mechanical models for self-balancing[51,59,66]. These considerations are critical in acknowledging "how" the body estimates its current orientation in space, in order to, subsequently, generate the corrective stabilizing actions required to maintain what is a mechanically unstable upright stance. However, for slacklining, this model is not suitable. The base is not fixed: Consequently, body neuromechanical dynamics are coupled with the slackline's external dynamics, and the natural actions and subsequent responses of body-sway[1,54,67].

### *Application of the manifold model to slacklining*

To consider these attributes within a global encompassing model to describe slacklining as a dynamic and changing series of quantitative factors, Paoletti *et al*[1] proposed that "an optimal strategy is achieved" for self-balance. This is through the consideration of a nonlinear model that accounts for potential parameter coupling and overall CNS performance delays that occur on multiple time scales. These can be visualized as a system with passive coupled dynamics working in unison with sensory modalities, enabling orientation and activated motor coordination of the body to be self-directed or "inferred". In Serrien *et al*[68], where the balance strategy was examined within an "expanded manifold of a higher dimension" that the subjects must remain within, this approach in turn enabled the model to account for coordination from the perspective of "self-organizing maps"[68]. This model-modification allowed an entire kinematic chain response where equilibrium is achieved as an integrated CNS solution to the presented task-environment-subject dependent situation and allows for a large set of degrees of freedom (DoF) that facilitate understanding of postural control within the human motor system[69]. Additional perspectives from Vallery *et al*[53] clarify that these neuromuscular actions involve a decoupling of the stance leg/s, and its produced vector forces from the residual body, through muscular co-contraction at the hip. This is augmented by arm movement and bimanual arm coordination[70] that act as the primary initial compensatory reaction to CoM displacement[47], and in turn the arms concurrently provide angular momentum influences[54].

## BALANCE AND HARMONIOUS FUNCTIONAL MOVEMENT

In the balance model for achieving slackline independence through human HFM, the manifold's defined space contains variables with a significant set of DoF that contribute to particular movements or functions[69], some of which provide the amalgamation of stability and mobility[3] through CNS control[56]. Consequently, the model's manifold contains both stable controlled variables and unstable un-controlled variables, where no action control is required as a task-variable's position is not affected[62]. Any given set of CNS controlled DoF that provide stability, consequently, have variables separated into two orthogonal/opposing-directional subspaces: one with actions that have no effect (on the controlled variables); the other with orthogonal-subspace actions that do[62]. If variability in the controlled subspace is smaller than that of the opposing orthogonal-subspace, then the CNS, and, consequently, stability control, is unaffected[56]. These manifold models simplify reality[1] and enable a mathematical representation and analysis. They also provide insight into what CNS control aspects are present when postural balance strategies are implemented[71,72], and that all responses occur within physically defined boundary limitations[47].

## SUMMARY

The outlined existing hypothetical models of slacklining describe the neuromechanical control strategies that achieve this activity, predominantly through use of a conceptual "manifold" that simulates a "saddle-shaped" task space[58,59]. Through the use of classic mechanics this is envisaged as a self-balancing mechanical model of an inverted pendulum[51,66]. These concepts critically acknowledge spatial orientation and subsequently corrective stabilization actions. However, this is generally hypothesized around a stable or fixed base which is inadequate for a body dynamically coupled with external changes and response actions[1,54,67]. Consequently, there is a knowledge-gap and a required evolution and expansion of these ideas, not only from the perspective of mechanics[1,51,54], but also from that of the neurological[73] and biopsychosocial[74] constraints of the individual.

## PHYSICAL FORCES AND ORDINARY SPACE

### *Existing models of harmonious functional movement*

Models of human HFM and self-balancing generally consider two concurrent spheres of input: firstly, mathematical mechanical precision models bound by classical mechanics equations and; secondly, supplementary sensory and motoric neural control[47,67]. The mechanical models were initiated over the last 600 years, most likely from Da Vinci's documented model proposition: "motion is created by the destruction of balance, that is, of equality of weight, for nothing can move by itself which does not leave its state of balance, and that thing moves most rapidly which is furthest from its balance"[75]. In contrast, the importance and relevance of the control aspects of a neural source were not proposed till the mid to late 1800's, when the understanding of sensory input and neural latency were detailed in seminal German publications.

The initial aspects of sensory control include the perspective of frames of reference as used by the nervous system, and the kinematic constraints that these place upon any control aspect. Initially, this came from the role of vision and was established from Donders[75]' Law, namely "that there is a unique orientation of the eye when looking in any specific direction"[76]. This was supplemented by Listing's law which "… specifies what this orientation is"[77,78], being a principle that governs eye movements through the three dimensional (3D) planes of horizontal, vertical, and torsional, and is actively implemented by a neural mechanism[79]. Fick[79] proposed that Listing's law enhanced motor efficiency by "minimizing the rotational eccentricity of the eye"[80]. This sensory-motoric control system was quantified by von Helmholtz [80] who measured the time delay that occurs due to the finite speed of neural signal transmission, where response time is dependent on the input-output delays of single neurons and neural chains. Donders[81] furthered these control phenomena in his work related to "The speed of mental processing", which determined a relationship was present between an individual's "choice-response" and the number of stimuli

present[82]. This was, subsequently, supported and progressed by Merkel[82] who defined that "the response time is longer when a stimulus belongs to a larger set of stimuli". This eventually led to Hick's Law[83], or the Hick-Hyman Law almost 100 years later that proposed "…information is intimately concerned with reaction time" and describes "… the rate of gain of information", and assesses the involvement of "cognitive capacity"[84].

The Hick-Hyman Law denotes that the time an individual requires for decision-making results from the choices available, and will increase logarithmically with the number of choices. In slacklining, these choices increase dramatically compared to simple frontal plane movements[54,57,63]. Consequently, transmission rates vary significantly between cell types and transmission mediums being affected by neuron size, the presence of axon myelination and its composition[85], sheath number, length, thickness and distribution[86], the size and distance between nodes of Ranvier, types of intervening synapses and how many occur between the CNS and peripheral receptors, and the stimuli strength, and quality[85,87]. The sphere of task control and the time-delay present is due to the sensory and motoric neural pathways necessary signaling processes, such that delay increases as the system and its requirements become more complicated[58,73]. This accounts for the balance organ with the integrated labyrinthine and vision systems that are adapted to account for these time delays[67], and ensure the essential limitations necessary for the human body to remain stable[64].

This is particularly relevant for more complex movements, such as those that occur on unstable surfaces, at higher speeds and require greater skill, with slacklining being such an example. Accordingly, in human movement, the more complex the task and the more stimuli present, the slower the action[17,88] or the greater the response time, Fitts's[88] Law (Table 1), and the higher the neuronal firing rate[1]. Further considerations are the large variation in effects of normal and pathological ageing[85] on human mechanical structures[67,86], neural system time delays[64]; and that injured tissue and individuals at the global level (such as neurological conditions) will not be able to achieve the required levels of adaptation, and, consequently, the individual will exhibit postural deficiency or balance loss[53,89,90]. The overall consequence is a simplified large-scale time-delayed model that provides insight from classical mechanics into the integrated functioning of the body systems and organs that support the theories and hypotheses of "integrated control"[48,67].

The subsequent progressions in the mathematical mechanical human movement and self-balancing models came at the start of last century when Graham-Brown[90] reported on "dynamic principles involved in progression". He stated that: "The cycle of progression may be supposed to commence at a point at which one of the limbs is perpendicular to the ground. The "initial velocity" then carries the body past this point, and it then falls forwards along the circumference of a circle the radius of which is the limb in contact with the ground". Over the last half century there has been further evolution and progression with Bresler *et al*[91] who remarked that the "Dynamic balance of the "head, arms and trunk" about the supporting hip is dependent upon the control of pelvic motion by the hip musculature"; while Saunders *et al*[92] recognised the significance of "Pelvic lateral tilt (being) identified as one of the primary determinants of gait".

In 1971, Adams[93] proposed the Classical model of "…a closed-loop theory for learning simple movements", that incorporated feedback, error detection and error correction as key elements. This model required that the output of the system had feedback, and compared the reference for error detection and, if necessary corrected for this to provide the resulting movement, such that it was "… self-regulating by compensating for deviating from the reference". More recently, MacKinnon *et al*[50] described "Control of whole body balance in the frontal plane during human walking" through the model of the "inverted pendulum" which relies on the principles of equations from classical mechanics. This model was progressed through a series of evolving modifications to account for the influence of both random disturbance and control torque. This neurologically controlled delay is effectively present at the ankle joint due to the concurrent relationship between: the passive stiffness from the visco-elastic nature of the muscle-tendon-ligament complex; and the active modulating influence of regional muscles[73]. This is supplemented by the triceps surae muscles that maintains balance by "predictively controlling the proximal offset of the spring-like element in a ballistic-like manner"[94,95].

Within the mechanical model it is also critical to consider that the inherently unstable upright position, where the smallest deviation eliminates equilibrium, is retained through uniformity between retarding and controlling forces[67,96]. These provide contributing components that can be low-level, such as passive ankle stiffness,

**Table 1 Glossary of definitions and explanation of scientific terms**

| Scientific Term | Explanation/definition |
|---|---|
| Fitts Law | Time to accomplish movement linearly increases with the logarithm of the index of the task difficulty |
| Hopf bifurcation point | A critical point where a system's stability switches and a periodic solution arises |
| Two-thirds Power Law | Expresses the robust local relationship between the geometrical and temporal aspects of human movement |
| Elliptic geometry | Non-Euclidean (or non-ordinary) geometry stating that there are no lines parallel to any given line, this is an example of Riemannian geometry |
| Affine Transformations | A transformation that preserves lines and parallelism |
| Equi-affine Transformations | a transformation that preserves areas, in addition to lines and parallelism |
| Temporal Segmentation | The central or brain action of breaking down motion sequences into different actions |
| Isochrony Principle | The duration of voluntary movement remains approximately constant across a range of movement distances; that is, movement duration is independent of movement extent |
| Kinematic redundancy | Kinematic redundancy occurs when a manipulator has more degrees of freedom than those strictly required to execute a given task. Additional active joints and interlinked segments improve both mobility and the available degrees of freedom |
| Inter-segmental law of coordination | A kinematic law that describes the coordination patterns among the elevation angles of the lower limb segments during locomotion (Borghese). It is reliant on accurate progressive timing of muscular contractions in adjacent segments and appendages |

*vs* high level, such as the growth-rate of the gravitational toppling torque[58,95]. Together these forces are considered a simple closed-loop control model[48] as a progression of Adams "closed loop" model[94]. A further mechanical model input consideration integrates neural sensory aspects, where feedback mechanisms are based predominantly on body-sway motion[63] from balance perturbations[97]. These evoke "sensory weights", a form of neural control representing comparative contributions of each sensory systems and integrated as a "package"[48]. This provides an internal estimate of orientation[71], where the assessed and adjusted responses are determined by how these inputs contribute to the total balance system as a single component[1]. Consequently, this "package" is itself dynamic and varies sufficiently to ensure equilibrium and prevent instability from corrective actions being either over- or under-produced[48]. The inputs themselves therefore exhibit bi-fold competing variations, due to the quality of the sensory information received. This is a consequence of changes in: (1) The external environmental conditions; and (2) The internal conditions affected by injury, neurologic disorders[90,98], or other psychosocial factors[65,74]. In the presence of a moving platform, as with slacklining, the vestibular and somatic sensory feedback is more highly weighted; while in quiet-standing the proprioceptive and visual systems are dominant[71]. Further, during afferent motor control the CNS creates "muscle synergies" where groups of muscles are combined as a common neural signal to control a range of movements which can be modulated differently by each individual, consequently demonstrating the neuromuscular capacity for adaptive strategies to facilitate stability while slacklining [99]. This reinforces the findings of neuroplastic change, automatic or "packaged" signals[48,71], engrams[100] and homunculus smudging[37], all of which occur as a response to complex, demanding, balance challenge activities[100], which will, consequently, include slacklining[2,101].

The consequential reactive motoric action that produces the stability, in the mechanical paradigm perspective, is achieved through the generation of joint torques that appropriately correct for any deviations from a desired orientation[48,72]. The original perturbation changes are detected primarily by inputs from the visual, proprioceptive, and vestibular sensory sub-systems[67,71], with the resultant reflex delay[1,72] enabling a "Hopf bifurcation point"[2] (Table 1). This achieves a temporary, though dynamic, "solution" for equilibrium and self-balance, with suitable active control strategies[58,67]. This "equilibrium solution" is explained by both the mechanical and sensory aspects within a "saddle-like" 3D phase-space that is characterized by geometrical properties and spatial relations of position and velocity[58]. It is achieved through the optimal parity between two competing manifolds: one which is stable along the saddle and provides slow convergent motion in a direction toward the equilibrium; and the other which is unstable and provides divergent spiral motions such as pitch, roll, and yaw[97] about the axis of the phase planes, which further increase the number of dimensions and DoF present, as these actions occur in

directions away from the equilibrium[58]. This "solution" is overseen by an intermittent "proportional and derivative" feedback system controller, that is characterized by the switching function at the "Hopf bifurcation point" in such a way that the proportional and derivative control is "off" when the net force is near the stable manifold of the saddle and is "on" in all other circumstances. This controller is able to use considerably smaller regional space and feedback parameters, which make it more robust[58] in the designated phase plane, as it exhibits the "two-thirds power law"[3] (Table 1) scaling regimes typically found in physiological sway movements in humans. Concurrently, the nominal equilibrium state is itself surrounded by a "dead zone" that reflects the time-delay from the sensory neural control inputs[72] that will allow a motoric reaction[64] that provides spontaneous movement patterns, like sway, to occur[95]. As a simple feedback loop system, this can provide an acceptable model for dynamic stability to ensue[52,58]. It also accounts for: Age-related differential findings due to physiological change - such as passive joint stiffness and damping from osseous degeneration, and proprioceptive delay, which affect center-of-pressure-based sway behaviors[57,66]; plus notably increased "noise" from larger amplitude, plus false and extraneous input signals[57,73] that can all be viewed from a "classical mechanics" influence perspective[67].

Any integrated mechanical and sensory model must also consider and discuss optimization approaches occurring, concurrently, within both aspects of the model, and that account for the "smoothness" or "flow" of HFM[3,102], *e.g.*, compare a curve joining multiple points to a series of straight lines. This smooth, HFM is a consequence of the process of "speed-curvature coupling"[103] which is optimized by the coordinated brain action of sensory and motoric control under the influence of pre-planning and "temporal segmentation", the process that "…identifies motion breakpoints and separates the different constituent phases"[104]. These sensory considerations are based on the mechanical assumptions of Riemannian or elliptic geometry[4,103] (Table 1). There is also a need to consider geometrical transformations that are both "affine"[5] (Table 1) and "equi-affine"[6] (Table 1), particularly in unstable settings, such as on a slackline, where the involved rotation, translation and shearing actions are both achieved and minimized in order to provide constant speed [102], such as occurs in the jerk response or Hoffman reflex[105].

This is of significant importance in relation to sensory input, particularly visual processing, as it confirms that "temporal segmentation"[7] (Table 1) of movement control complies with "equi-affine geometry"[103]. This geometrical transformation consequently accounts for the "two-thirds power law", which governs the relationship between the geometrical and temporal parameters of human movement. This is centrally represented in "motion-planning"[61] and "human vision processing" and ensures that the "Isochrony principle"[8] (Table 1) is upheld[103]. This, consequently, allows for the application of differentiable manifolds of higher dimensions, an important consideration for complex activities on unstable mobile surfaces, such as slacklining. The consideration of these additional aspects within a mechanical model clarifies that human locomotion complies with the principles of "Kinematic redundancy"[9] (Table 1); and the "Inter-segmental law of coordination"[10,103] (Table 1).

Together, these multiple aspects and considerations form the sensory and motoric neural control sphere, as noted previously from 18$^{th}$ Century German scientists, concepts that were, subsequently, integrated with the mechanical sphere. In unison they explain functional independence and balance control as the aforementioned closed-loop feedback system[94], with parity between the different integrated sensory orientation source information on one hand, and system feedback control constraints on the other[48]. However, such a conceptual model and presentation of balance, functional independence, and postural control, is only truly valid on stable surfaces [58]. When unstable surfaces, such as a slackline, are considered in such models, then further descriptive initiates, progressions, and evolutions are required[1,54] to account for the dynamic changing postures and positions[2,27,106]. This has led to the concept of "dimensionally-bound" manifold models, which require that the size-volume of the manifold is expanded. This accounts for the patterns of movement, control and balance-retention, that require higher levels of complexity within the significant DoF available for human motor system postural control[54].

## THE CURRENT DESCRIPTIVE MODEL OF SLACKLINING

The concept of functional independence and self-balance being explained by

dimensionally bound models, with expanded size-volume, takes into account activities such as slacklining that are significant progressions from those found in quiet-standing and simple frontal plane walking. This complexity occurs through the forces being produced more rapidly with the requirement for greater control occurring through smaller, more precise action-reaction dissipation[68]. There is a simultaneous reduction in both frequency and velocity in most available DoF, coupled with increased control of range of motion (RoM)[69]. This expanded manifold model allows greater distance in the Y and Z dimensions for any given X dimension position, but is limited by the physical constraints of the given slackline length (X dimension), its width and how far it can be moved laterally (Y Dimension) and the elastic-stretch that enables an optimal sag (Z Dimension). Consequently, a minimal effort or energy expenditure must be achieved and utilized to maintain stability in the presence of any perturbation[47]. This is consistent with the strategies of quiet-standing and stable surface walking[70]. However, any perturbation must be limited within the Y Axis, or lateral component of movement, to a distance in the order of 10 cm, for novices to moderate skilled slackliners, if control and balance on the line is to be retained[47]. Expert slackliners appear to exhibit greater lateral movement limitations within an expanded manifold[69].

This 3D model form has been envisaged and detailed with mathematical equations to validate positions[1,58]. However, to compound the descriptive difficulty of the model, it must be recognized that the optimal adopted strategy is individually selected. It can only be one of two methods prior to the introduction of any perturbation: (1) Two feet on the slackline, including use of an unloaded limb to touch and stabilize the line; or (2) One foot[2,5], with the other not touching but as a counter-balance that indirectly affects the manifold of the contacted and weight bearing foot [47]. In recognition of this deficiency the model was subsequently modified[54] through introducing a regional decoupling at the hips of the arms and trunk from the legs. This then accounted for the discrepancy that action-reaction forces generated by the arms, trunk, or free leg, could influence the point of contact, without moving the foot or changing the anterior-posterior direction by virtue of sheer forces, and ensures the principle of "energy optimization" was maintained[54]. This then allowed for individual joint torque and segmental interplay, where there is task distribution between the legs as the ultimate dissipater of the force vectors *via* the CoP dynamics at the foot/feet, but decoupled at the hips from the trunk and arms that influence, but do not control, angular momentum[47].

This 3D model then has the context that simulates the following example: an inverted pendulum[51] (the person), mounted on a cart (the slackline), that is moving on a circular or elliptical track[1] (the physical finite 3D ordinary space limitations of possible slackline movement), to a maximal distance from the slackline contact point [47] during instantaneous stability. Concurrently, the segments of the arms and trunk facilitate angular momentum control, and are decoupled by muscular co-contraction at the hips from the stance leg/s, that dynamically direct the vector forces[54].

The acquired movement control to achieve balance on a slackline is a set of self-learned patterns[96]. These form an instantaneous but fluid and interactive dynamic saddle-shaped manifold[58] that the individual must remain within to ensure stability [69] through balance control[66]. Stability is retained by the production of forces that are pro-active and re-active to those of the slackline's 3D reciprocal forces at and through a point/s of fixed contact with the body *via* the foot[47] or feet[47]. Consequently, the slackline's reactionary forces line of action always passes through the subject's contact foot/feet and cannot be influenced without a dissipated moment from the force vector. This force, *via* the foot to the leg, is in the X-dimension or anterior-posterior direction[54], the Y-dimension of lateral deviation within the physical limit of the slackline's topographical space[47], and the Z-dimension of available sag or reactionary bounce[107]. These forces form within the "high-dimensional manifold" "… in which the subjects have to stay in order to maintain balance"[68].

The expansion of this manifold can be learnt, with the improved balance then interpreted as enabling an increased RoM before the manifold edges are reached and balance is lost. Because the expanded manifold's edge is now further, the frequency of movement change is lower, as the need to adapt or change is less, which in-turn leads to a reduced velocity of motion and less kinetic energy being required when reaching the manifold's edge. Consequently, maintaining balance is easier and the energy used to counter the perturbation is dissipated in a stepwise manner[47,97].

## FACTORS THAT NECESSITATE CHANGES TO THE CLASSICAL MECHANICS MANIFOLD MODEL

Currently, the models of HFM and self-balance are limited to those described above. They can account for all available DoFs as found with dynamic unpredictable movement on unstable surfaces that consider and account for kinematic redundancy in consort with inter-segmental coordination.

This can be summarised as follows: An integrated mathematical mechanical precision model, bound by classical mechanics equations in parity with sensory and motoric neural controls that approximates a dynamic "saddle-like" phase-space, high-dimensional manifold characterized by two internal competing manifolds of convergent and divergent motion.

This hypothetical model facilitates understanding the mechanisms for independent HFM and balance. These mechanical and neural components increase their complexity when considering the influence of "qualitative-implicit-knowledge", such as the physics of gravity[108]. Generally, the brain hypothetically uses a qualitative internal model that incorporates classical mechanics-based equations from its existing knowledge of gravity and time as a multi-faceted perspective that include a quantified unit and both a spatial and cortical experience, even if this knowledge is quantitatively based[108]. This supplements sensory information when estimating more complex activities that involve external components, and not simply a body activity in isolation, including interceptive actions like hitting or catching[109]. However, when performing a "catch" in zero-gravity, movement is initiated earlier[109] as "qualitative-implicit-knowledge" is relied upon to pre-empt and approximate interceptive timing through pre-information that compensates for "no-gravity"[108]. This is analogous to core muscle pre-activation when using a limb. Further, "qualitative-implicit-knowledge" is influenced by the individual's psychological state, motivation level, past activity-specific experience, the social context where the activity is performed and the presence of positive support or negative perceived social pressure to participate or "perform" [53,74]. Current movement models do not accommodate or acknowledge these additional aspects. By considering a highly skilled complex activity, such as slacklining as opposed to quiet standing, the intent is to consequently, recognize the areas of knowledge-gap so an evolved and expanded hypothetical model and paradigm can be proposed.

## CONCLUSION

The successful achievement strategy that enables an individual to balance and remain on a slackline is currently explained as: A saddle shaped manifold model, where a moving inverted pendulum is subjected to self-generated and environmental forces within a defined 3D space, where the arm and trunk segments provide dynamic force influences but are decoupled from the hips and legs. This model integrates with gravity and the slackline's elastic reactive properties being governed by classical mechanics. However, there remains a knowledge-gap as this dynamic stability is transitory, momentary, and acquired through the integration of additional dimensions not hereto considered. Consequently, within the context of historical and contemporary slacklining, the existing models are insufficient for the required explanatory control mechanisms that can accommodate multi-directional instability and complex multi-dimensional human HFM. This knowledge-gap requires an evolved and expanded model in order to provide an explanation for the control mechanisms in place. This evolved model will represent multiple, integrated dimensions that will facilitate the understanding of existing performance and incorporate general and rehabilitation activity. With such a model these applications can be applied more broadly in the future to movement in diverse fields that would potentially include prostheses, mechanized automation, altered gravity, robotics, mechatronics, artificial-intelligence-driven movement and machine-learning related to movement phenotypes.

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*MINIREVIEWS*

# Off-the-shelf 3D printed titanium cups in primary total hip arthroplasty

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## Abstract

Three-dimensional (3D)-printed titanium cups used in primary total hip arthroplasty (THA) were developed to combine the benefits of a low elastic modulus with a highly porous surface. The aim was to improve local vascularization and bony ingrowth, and at the same time to reduce periprosthetic stress shielding. Additive manufacturing, starting with a titanium alloy powder, allows serial production of devices with large interconnected pores (trabecular titanium), overcoming the drawbacks of tantalum and conventional manufacturing techniques. To date, 3D-printed cups have achieved dependable clinical and radiological outcomes with results not inferior to conventional sockets and with good rates of osseointegration. No mechanical failures and no abnormal ion release and biocompatibility warnings have been reported. In this review, we focused on the manufacturing technique, cup features, clinical outcomes, open questions and future developments of off-the-shelf 3D-printed titanium shells in THA.

**Key Words:** Socket; Highly porous; Additive manufacturing; Ultraporous; Trabecular; Beam melting

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**Core Tip:** Three-dimensional printed titanium cups theoretically provide a porous, rough surface that improves local vascularization and osseointegration, while avoiding stress shielding because of the low elastic modulus. We herein discuss the manufacturing, main features, and clinical results obtained with 3D-printed titanium cups, with a focus on the open questions and possible future developments to improve this newborn device and technology.

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## INTRODUCTION

Acetabular component loosening is one of the most frequent reasons for revision in primary total hip arthroplasty (THA)[1]. Uncemented third-generation sockets were designed to improve local vascularization and the subsequent bony ingrowth promoted by the porosity of the cup surface and the biocompatibility of the metal alloy coating[2,3]. The long-term clinical and radiological performance and reliable safety profile of third-generation tantalum cups in primary THA is outstanding, even if some sporadic concerns have arisen after consulting registry data[4]. Highly porous titanium implants were developed based on the previous solid experience with third-generation, highly porous tantalum cups. The aim was to overcome drawbacks related to the cost of tantalum, which is a rare metal. 3D printed cups are a specific stand-alone type of highly porous titanium cups[2]. While they share the material and porosity with other highly porous titanium cups, because of additive manufacturing, 3D printed cups have larger pore sizes and higher porosity, reproducing trabecular bone-like elastic modulus in unique monoblock implants with no coatings[2]. 3D-printed cups may exhibit differences in the surface and beyond the surface with different biological advantages than traditionally manufactured highly porous titanium cups, including improved osseointegration, reduced stress shielding, and have unique failure modalities like cracking and ion release[2,5].

## MANUFACTURING TECHNIQUES

3D printed cups are produced using additive manufacturing, an industrial process that transforms 3D computer models into devices by layer-on-layer, titanium alloy powder-based fusion technology. This production method is very different from the manufacturing of traditional implants, usually by subtracting machinery and forming. Additive manufacturing is particularly suitable for custom made implants, complex geometries, and diverse surfaces, even with serial production. On the other side, conventional techniques are mainly limited to mass production and off-the shelf devices because of manufacturing constraints[5]. These features allow additive manufacturing devices to integrate surface porosity within a monoblock implant, which improves osseointegration and potentially reduces stress shielding by mimicking the stiffness of the periprosthetic bone (Figure 1). The additive manufacturing process is a powder bed fusion technology that adopts electron beam melting (EBM) and/or laser beam melting (SLM) energy sources for producing titanium alloy cups[6]. Both techniques start with a titanium alloy powder, whose chemical and physical properties are chosen as a function of the production technique and the powder bed fusion technology. The powder can be processed using a computer-aided design (CAD) model. The device is produced by a beam, with melting and bonding the powder layer after layer with precisely controlled cooling[ 5,6].

Some important differences exist between the two main additive manufacturing technologies. EBM technology is driven by a higher power source, requires a vacuum chamber at 600-1000°C, and is controlled by electromagnetic lenses that focus the beam, which is regulated by a deflection coil. A preheating scan is required, however,

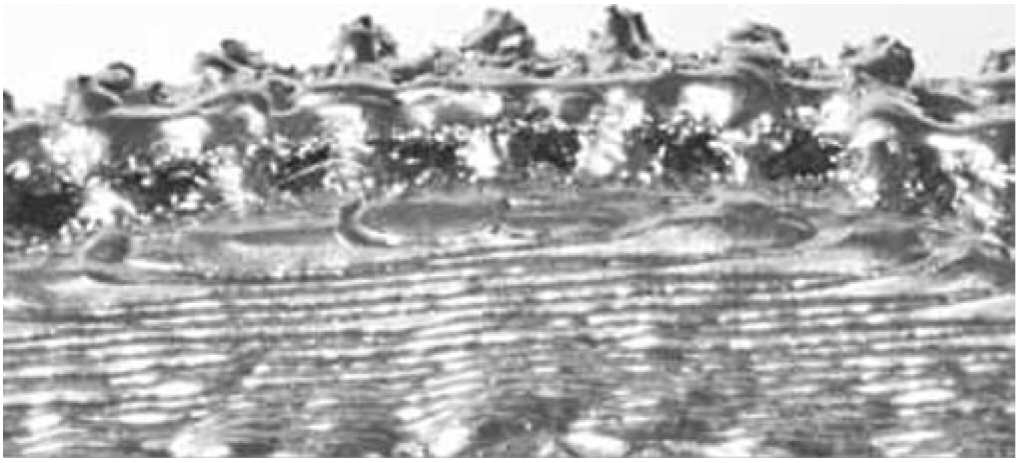

**Figure 1 Layer-by-layer additive manufacturing was used to produce a monoblock cup with an ultraporous surface (Ti-Por, Adler Ortho).** Courtesy of Adler Ortho.

the support during manufacturing is scarce because of the high speed and the vacuum environment. On the other hand, SLM is characterized by a much lower power source, is performed in a purified inert gas atmosphere at 200°C, and is controlled by a CAD mechanical mirror system. Preheating is not required, and the support during manufacturing is more intense. A most striking difference between EBM and SLM is the powder that is used. EBM used larger particles (45-150 μm *vs* 20-100 μm) and thicker powder layers (50-200 μm *vs* 20-100 μm)[5-7]. Post processing steps include cleaning (removal of excess powder), surface finishing, and thermal treatment, particularly for SLM.

The manufacturing technology has a noticeable impact on the final qualities of the device. The surface is rougher and the CAD design is more accurately reproduced after EBM manufacturing. Moreover, the mechanical properties of EBM devices are good because there are residual tensile stresses. The superior mechanical properties mean that heat treatment is not required, which reduces the manufacturing costs and makes EBM faster and more cost-effective than SLM[8]. The biocompatibility of the devices produced with the two different technologies is dependable, and neither dermal irritation nor delayed hypersensitivity were demonstrated in animals[6,9]. A comparative study cell reported that adhesion, proliferation, and activity were more pronounced in the SLM cohort[10].

## CUP FEATURES

A complete list of off-the-shelf 3D printed titanium cups is shown in Table 1. Nearly all the 3D printed cups have similar features, which include a porous surface structure of interconnected pores larger than 200 μm with a porosity higher than 50% (Figure 2). The elastic modulus and coefficient of friction were rarely provided by the manufacturers. Many cups had multihole designs with even augments, making the devices adaptable for massive bone stock loss and cup revision settings.

## PRECLINICAL STUDIES

Few preclinical studies of 3D printed titanium cups are available. Jahnke *et al*[11] compared the micromotion of 3D printed cups (EPore) and conventional sockets in sawbone models. The 3D printed cups had acceptable micromotion, lower than of conventional cups with low wall thickness. The investigators reported that the wall thickness, together with the highly porous surface, contributed to 3D cup stability, allowing peripheral micromotion of the sockets, and at the same time, provided rigidity with the thicker walls[11]. Dall'Ava *et al*[12] evaluated the outer surfaces of three off-the -shelf 3D printed titanium cups (Delta TT, Trident II Tritanium, and Mpact 3D Metal). The three cups have differences as wall thickness, pore size, porosity, and metallic structure. Some molten beads were present, with differences of size and density related to the production technology[12]. Dall'Ava *et al*[13] compared

**Table 1 Off-the-shelf 3D printed titanium cups that are commercially available**

| Cup | Manufacturer | Pore size (μm) | Porosity (%) | Design | Modularity | Notes | Available clinical studies |
|---|---|---|---|---|---|---|---|
| *Fixa Ti-Por* | Adler Ortho, Milan, Italy | 700 | 70 | Hemispherical | Yes | | Yes |
| *Agilis Ti-Por* | Adler Ortho, Milan, Italy | 700 | 70 | Hemispherical | No, Delta ceramic | Large ceramic-on-ceramic heads | No |
| *Polymax Ti-Por* | Adler Ortho, Milan, Italy | 700 | 70 | Hemispherical | No, XLPE | | Yes |
| *Omnia Ti-Por* | Adler Ortho, Milan, Italy | 700 | 70 | Hemispherical | Yes | Multihole, Ti augments | No |
| *Delta TT* | Lima Corporate, San Daniele, Italy | 640 | 65 | Hemispherical | Yes | Elastic modulus: 1.12 GPa | Yes |
| *Delta One TT* | Lima Corporate, San Daniele, Italy | 640 | 65 | Hemispherical | Yes | Multihole, Ti augments | Yes |
| *Delta Revision TT* | Lima Corporate, San Daniele, Italy | 640 | 65 | Hemispherical, triflanged | Yes | Commercially pure Ti, multihole, Ti augments | Yes |
| *SQRUM TT* | Kyocera, Kyoto, Japan | 640 | 60 | Hemispherical | Yes | Coefficient of friction: 1.09 | Yes |
| *Mpact 3D Metal* | Medacta, Castel San Pietro, Switzerland | 600-800 | 75 | Hemispherical | Yes | Multihole, Ti augments | No |
| *Trinity Plus* | Corin, Cirencester, United Kingdom | 300-900 | 50-90 | Hemispherical | Yes | Even multihole | No |
| *Ecofit Epore* | Implatcast, Buxtehude, Germany | 100-500 | 60 | Hemispherical | Yes | Multihole | No |
| *Redapt* | Smith and Nephew, Menphis, United States | 202-934 | 60-80 | Hemispherical | Yes | Multihole | No |
| *Trident II Tritanium* | Stryker, Mahwah, United States | 100-700 | 55-65 | Hemispherical | Yes | Laser rapid melting technology | Yes |
| *G7* | Zimmer, Warsaw, United States | 475 | 70 | Hemispherical | Yes | Even multihole shells | Yes |
| *3D ACT* | ITI Medical Equipment, Changzhou City, China | 600-800 | 80 | | Yes | Coefficient of friction: 1.08 | Yes |

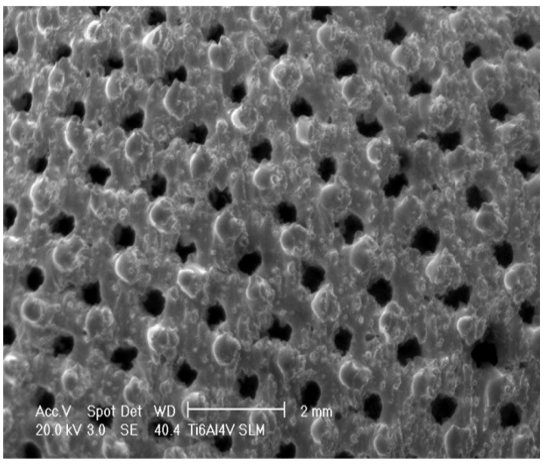


**Figure 2 The highly porous surface structure has a large number of deep, interconnected pores (Ti-Por, Adler Ortho).** Courtesy of Adler Ortho.

3D printed cups (Delta TT) with conventional cups (Pinnacle Porocoat, DePuy, United States). Pore size, porosity, and the mechanical features of the pores of the 3D printed caps and the conventional cups were significantly different. A visual assessment revealed higher percentages of bony attachment and tissue ingrowth for the 3D printed cups, but the differences comparison with the conventional sockets were not significant[13]. Hothi *et al*[14] compared three 3D printed cups with conventional

sockets. Two of the 3D-printed acetabular shells were produced by EBM (Delta TT and Mpact 3D) and one by laser rapid melting (Trident II Tritanium). Structural cavities were evident in all the 3D-printed cups and in none of the conventional sockets, with a significantly higher density, but no difference in cavity size, in the laser rapid melting socket. The presence of cavities was attributed to suboptimal manufacturing parameters, gas entrapment, or gaps in the starting powder beads[14].

## CLINICAL AND RADIOLOGICAL OUTCOMES

A systematic review of the outcomes and survivorship of 3D printed titanium cups in THA was conducted following retrieval of published studies indexed in the PubMed/MEDLINE database. {query box: ["highly" (All Fields) AND "porous" (All Fields)]} OR ["trabecular" (All Fields) OR "trabecularization" (All Fields) OR "trabecularized" (All Fields)] OR "pore" (All Fields) OR {"3D" (All Fields) AND ["printed" (All Fields) OR "printing" (MeSH Terms) OR "printing" (All Fields) OR "print" (All Fields) OR "printings" (All Fields) OR "prints" (All Fields)]} OR ["printed" (All Fields) OR "printing" (MeSH Terms) OR "printing" (All Fields) OR "print" (All Fields) OR "printings" (All Fields) OR "prints" (All Fields)] OR "3D printed" (All Fields) OR {["porosity"(MeSH Terms) OR "porosity" (All Fields) OR "porosities" (All Fields)] OR ["addit manuf" (Journal) OR ["additive" (All Fields) AND "manufacturing" (All Fields)] OR "additive manufacturing" (All Fields)]} AND "cup" (All Fields) AND ["hip" (MeSH Terms) OR "hip" (All Fields)] AND ["arthroplasty" (MeSH Terms) OR "arthroplasty" (All Fields) OR "arthroplasties" (All Fields)]; double check for 3D printed titanium cup brands, as listed in the paper by Dall'Ava: Ti-Por, Delta TT, Trinity, EcoFit, C-Fit, Mpact, Redapt, Trident, G7 {query box: Cup brand AND "cup" (All Fields) AND ["hip" (MeSH Terms) OR "hip" (All Fields)]}.

Ten papers were included. The two largest studies were registry reports, one from Registro dell'Implantologia Protesica Ortopedica (RIPO) and the other from the New Zealand arthroplasty registry. The RIPO registry study investigated the mid-term outcomes of 9864 Ti-Por cups, compared with other cementless cups (Figure 3). The non-stratified survival rates showed that the 3D printed cups had a significantly higher survival rate (98.7% *vs* 97.9%) at 7 years. The survival rates with cup aseptic loosening as the study end point showed that Ti-Por cups performed better than the other cementless cups (99.9% *vs* 99.5%). With similar articulation surfaces, Ti-Por cups achieved survival rates comparable to those of the control group[15].

The New Zealand registry compared 2192 3D-printed cups (1397 Delta TT cups, 640 Ti-Por, and 155 Polymax cups) and other cementless sockets (Pinnacle, Trident, and RM). The outcomes were similar in both cohorts with no differences in the revision rates and functional scores ($P$ = 0.058, hazard ratio: 1.29) while additive manufactured sockets were more frequently implanted in younger patients; the rates of aseptic cup loosening and deep infections were similar in both cohorts. Polymax cups achieved the lowest rates among the 3D cups[16].

Perticarini *et al*[17] published the first clinical and radiographic description of a 3D printed cup (Delta TT) cohort with a follow-up of 72 months. The clinical and radiographic outcomes of 134 THAs were satisfying, with 99.3% of the sockets radiographically stable at final follow-up. Only one case of aseptic cup loosening was reported. It occurred in a high-grade dysplastic patient, and was caused by the high dislodging forces of the lengthened abductor muscles (no femoral shortening was performed). The cup was successfully revised with another Delta TT device. The survival rate at mid-term was 99.3%[17].

Berend *et al*[18] evaluated 400 hips with G7 cups at a minimum follow-up of 1 year. Clinical and radiographic outcomes were satisfactory, with no radiolucent lines; two cup failures occurred because of impaired bony ingrowth[18].

Berend *et al*[19] updated the results of the previous case series at a minimum follow-up of 3 years in 152 implants. The clinical outcomes significantly improved, and the radiographic findings showed no radiolucent lines. The overall survival rate at 3.4 years was 99.5%, one case required cup revision because of failed bony ingrowth[19].

Massari *et al*[20] reported dual-energy x-ray absorptiometry outcomes of 3D printed cups (Delta TT): They found a reduction of bone mass density at 6 months, with slight recovery and stabilizing by 24 months. The bone mass variation was dependent on the body mass index. They reported also a significant clinical improvement with respect to the pre-operative status and no cases of failed cups[20].

Imai *et al*[21] compared the hip replacement outcomes of 101 3D printed cups (SQRUM TT) and 35 hydroxyapatite-coated sockets (SQRUM HA) in low-grade

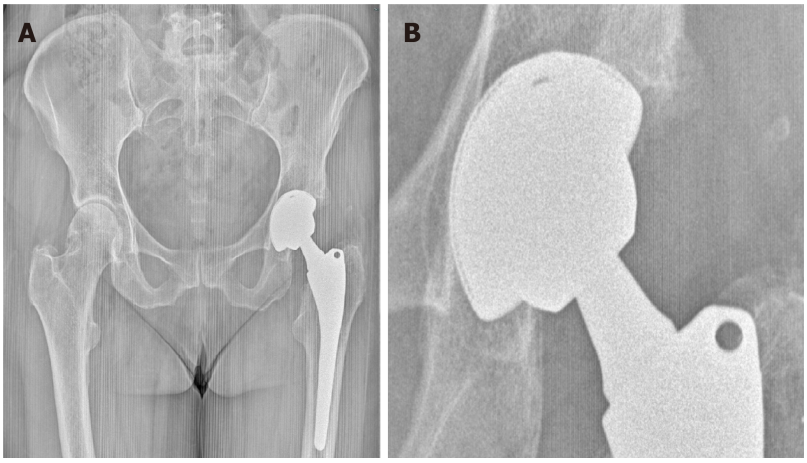


**Figure 3 A Ti-Por cup was implanted in a 59-year-old woman with primary osteoarthritis The socket has an hemispheric design with a rough surface with multiple spikes.** A: Primary osteoarthritis; B: The socket has a hemispherical design.

dysplastic patients receiving the same stems and the same bearings. The short-term clinical outcomes significantly improved in both the cohorts, achieving similar results. The radiographic 2-year outcomes showed that the 3D printed cups had a higher rate of radiolucent lines and fibrous ingrowth than the conventional hydroxyapatite sockets[21].

Bistolfi *et al*[22] evaluated the metal ion levels in the blood and urine in a cohort of 19 patients with conventional cups (Delta PF) and 19 with 3D printed cups (Delta TT). At 24 months, differences in the blood and urine levels of titanium, aluminum, and vanadium ions in of the two cohorts were not significant. A trend of decreasing ion levels was evident in both cohorts[22].

Castagnini *et al*[23] published a retrospective comparison of 24 metachronous bilateral THAs, a Ti-Por cup on one side and a hydroxyapatite-coated socket on the other side (Figure 4). The mid-term clinical outcomes showed comparable rates of cup loosening and radiographic osseointegration in both cohorts. The Ti-Por group had more evident medial stress shielding, but the difference was not significant ($P$ = 0.067). Neither was the decrease in acetabular radiographic density in the DeLee and Charnley Zone II[23,24].

Alamanda *et al*[25] used multiacquisition variable-resonance image combination magnetic resonance imaging to assess the radiological osseointegration of 3D printed cups, evaluating 19 Trident II Tritanium shells and 20 Trident sockets as a control group. The 3D cup cohort achieved significantly better outcomes in terms of bony ingrowth ($P$ = 0.009) with good osseointegration in 99.4% of the cases compared with 91.6% for the conventional cups. Only 0.6% of the bone-cup interface, measured in nine acetabular zones, were fibrotic compared with 8.3% of the conventional cups, mainly involving the central posterior zone[25].

The outcomes of 3D printed ACT sockets were retrospectively assessed in 108 hips by Geng *et al*[26] at an average follow-up of 48 months. A significant clinical improvement was observed, with 106 of 108 (91.3%) patients satisfied with the outcome. No acetabular cup failed: some transient radiolucent lines completely disappeared after 6 months. Radiographic signs of osseointegration were evident in all the cups. The overall survival rate was 99.1% at 72 months, with cup survival rate achieving 100%[26].

In summary, the clinical and radiological outcomes of 3D-printed titanium cups were dependable at mid-term, with large sized studies providing data not inferior to conventional cups. No mechanical failures were recorded and the metal ion release was reassuring. Some radiological findings of fibrotic ingrowth and radiolucent lines were also reported, making longer follow-up and more preclinical studies of 3D printed cups desirable.

## OPEN QUESTIONS AND FUTURE DEVELOPMENTS

The first open question about 3D-printed cups is about manufacturing. The layer-over-layer production and the highly porous structure may predispose to delamination and

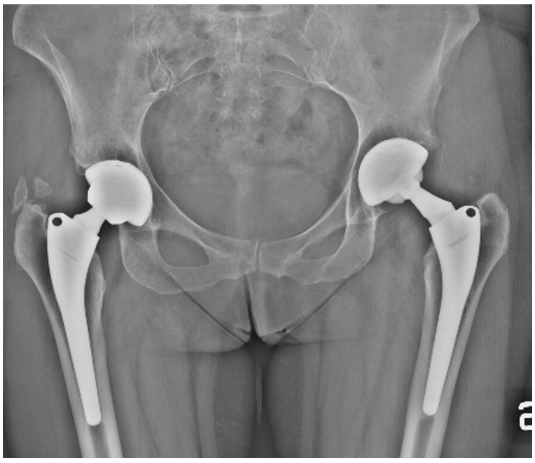

**Figure 4 A bilateral total hip arthroplasty, with a Ti-Por cup on the right and a hydroxyapatite-coated socket on the left.** The different surface roughness is evident. Both the cups had good radiographic osseointegration at 3 years.

fatigue fracture, and the findings about cavities are not reassuring[14]. Another concern is related to the balling effect of metallic droplets on the molten surfaces, potentially causing cracking and undesired roughness on the inner surface that compromises the locking mechanism and the liner seating, wear, and hardness. While some concerns of fatigue fractures and liner failures may be raised, to date no mechanical failures of 3D-printed cups have been reported, only a case of hemispherical modulus failure in a hip revision[27,28]. Similarly, no cases of delamination failure or mechanical problems related to the liner could be found.

The stress shielding and the fibrous membrane interface issues in the medial zone may be reasons of concern in 3D printed cups. It is likely that these findings are mainly related to the different stress distribution around the periprosthetic acetabular bone and the improved circumferential grip of the highly porous sockets. Thus, it can be hypothesized that a device with nonuniform porosity may reduce medial stress shielding and improve long-term osseointegration. However, in mechanical testing, Le Cann *et al*[28] demonstrated that the opposite condition (micro-roughness around the peripheral rim and macro-roughness on the rest of the cup) promoted better primary stability by reducing the damage of the supportive circumferential bone[28]. To date, many doubts exist about the optimal pore size, porosity, and porous surface extension of titanium devices although fundamental investigations addressing this topic were carried out in the 1980s for tantalum metal blocks[29-32]. Some investigators have reported that the use of pores that were too large could be detrimental for osseointegration by promoting fibrous tissue growth, at least for a short time[33]. Some data on ultraporous titanium cups are available from laboratory and clinical cohort studies, but no definitive conclusions can be drawn, as long-term follow-up is lacking and the tested populations are small.

Another aspect to be developed is related to the cup stabilization provided by high friction coefficients in highly porous devices. Theoretically, the high friction coefficient and the better initial scratch fit would improve primary stability, possibly enhancing the secondary bony ingrowth. Some investigators have found improvements with some less porous cups (plasma-sprayed devices)[34]**.** Unfortunately, there have been no supporting studies with definitive results comparing ultraporous cups and more recent surface textures, as described by Goldman *et al*[35]. In that study, ultraporous DePuy Gription cups did not provide better resistance to bending loads in comparison to standard DePuy Porocoat titanium bead sockets following implantation in seven cadaver models.

3D-printed cups have a good biosafety profile, that needs to be confirmed in large clinical studies[6,22]. More *in vivo* and long-term studies are needed to evaluate and compare the biocompatibility of 3D-printed medical devices, considering the possibility of immunological rejection and inflammatory reactions that can account for the failure of metallic implants.

To date, the optimal 3D printing technique is still unknown. The 3D printed cups that have been evaluated in preclinical studies differ in pore size, porosity and structure, and some features that are dependent on the manufacturing method[12]. Moreover, while additive manufacturing is a highly efficient method with up to a 50% reduction of production costs and up to a 75% reduction of raw material use, the fine

balance between efficiency and quality is yet to be determined[8,9,36]. More studies of the optimization of the energy requirements and scanning speed and their influence on the product quality and the subsequent need for post processing stages would be welcomed.

The possibility of achieving a good elastic modulus and a very highly porous surface makes 3D-printed cups particularly appealing for revision procedures when the bone stock is severely compromised. To date, short-term data on the use of 3D-printed cups are available in the literature; long-term data are lacking[37]. The preliminary short-to-midterm outcomes indicate that off-the-shelf 3D-printed titanium cups are dependable. Castagnini *et al*[38] reported no loosening of Ti-Por devices at a minimum follow-up of 5 years. Gallart *et al*[39] described two cases of Delta TT loosening out of 72 implants with augments, prevalently for revision hips, after more than 2 years. Steno *et al*[27] reported no re-revisions for loosening of Delta TT devices more than 3 years after implantation[27,38-40].

## CONCLUSION

In summary, 3D printed cups produced using additive manufacturing demonstrated reliable clinical and radiographic mid-term outcomes, even in large patient series. These implants also had a reliable safety profile. The metal ion levels and rates of deep infection were comparable to control groups, and no cases of mechanical failure were reported. Nonetheless, to date no clinical studies have demonstrated significantly better outcomes when compared with conventional cups with the same bearing forces. Clinical trials and registry studies with longer follow-up are required to confirm the theoretical benefits of 3D-printed cups in terms of osseointegration and a decreased rate of aseptic loosening.

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ORIGINAL ARTICLE

Case Control Study

# Evidence-based approach to providing informed consent for hip fracture surgery during the COVID-19 era

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## Abstract

### *BACKGROUND*

Hip fractures are the most common reason for inpatient orthopaedic trauma admission. Urgent surgical intervention for hip fractures has remained a clinical priority throughout the coronavirus disease 2019 (COVID-19) pandemic. Despite this, there is a paucity of clinical guidance addressing the informed consent process for hip fracture surgery in COVID-19 positive patients. This is of paramount medicolegal importance in a high-risk patient population.

### *AIM*

To quantify the additional perioperative risks for COVID-19 positive patients undergoing hip fracture surgery and provide clinicians with an evidence-based framework to establish an informed consent process.

### *METHODS*

Two hundred and fifty nine consecutive patients undergoing surgical intervention for hip fractures in four hospitals in the United Kingdom were recruited. 51 patients were confirmed positive for COVID-19. Predefined outcomes were analyzed over a 30-d postoperative period. COVID-19 positive and COVID-19 negative patients were compared after adjustment for confounding factors.

### *RESULTS*

COVID-19 positive patients had more intensive care admissions (27% *vs* 5%, $P < 0.001$), longer inpatient stays (median 23 d *vs* 9 d, $P < 0.001$) and a higher 30-d mortality (29% *vs* 10%, $P = 0.001$) than COVID-19 negative patients. Postoperative complications were evident in 74.5% of COVID-19 positive patients. 35.3% of

COVID-19 positive patients suffered postoperative lower respiratory tract infections with 13.7% developing acute respiratory distress syndrome (ARDS) and 9.8% experiencing symptomatic thromboembolic events.

*CONCLUSION*

The COVID-19 pandemic has created uncertainty in the medical community worldwide and poses unique challenges in providing informed consent for surgery. COVID-19 positive patients undergoing hip fracture surgery should be consented for the additional risk of postoperative complications (including lower respiratory tract infection, ARDS, deep vein thrombosis and pulmonary embolism), increased requirement for intensive care admission, longer inpatient stay and higher risk of mortality. Further, clinicians must be transparent about the potential for unknown risks as research into the long-term surgical outcomes of COVID-19 positive patients continues to evolve.

**Key Words:** COVID-19; Hip fractures; Mortality; Morbidity; Outcome assessment; Informed consent



**Core Tip:** Coronavirus disease 2019 positive patients undergoing hip fracture surgery should be consented for the increased risk of postoperative complications (including lower respiratory tract infection, acute respiratory distress syndrome, deep vein thrombosis and pulmonary embolism), increased requirement for intensive care admission, longer inpatient stay and a higher risk of mortality. It is medicolegally imperative that these risks are addressed as part of an informed consent process.

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## INTRODUCTION

Hip fractures are the most common reason for inpatient orthopaedic trauma admission, with an estimated 1.6 million cases globally *per* year[1]. Incidence has remained stable during the coronavirus disease 2019 (COVID-19) pandemic[2], and the British Orthopaedic Association continues to advocate urgent surgical intervention[3]. Patients are usually elderly with multiple comorbidities and poor physiological reserves[4]. Therefore, it is medicolegally imperative that the material risks inherent in hip fracture surgery for COVID-19 positive patients are addressed and quantified to facilitate an informed consent process.

A multi-center study from our institution reviewed outcomes in 422 hip fracture patients in the Greater London area and found postoperative 30-d mortality in COVID-19 positive patients was 30.5% compared to 10.3% in COVID-19 negative patients ($P < 0.001$). COVID-19 positive patients were also associated with increased perioperative morbidity, more admissions to the intensive care unit, and increased length of hospital stay compared to COVID-19 negative patients. However, there remains a paucity of focussed clinical guidance for providing informed consent for hip fracture surgery in COVID-19 positive patients. Davies reports that only one in 46 patients undergoing orthopaedic surgery was consented for the risk of complications secondary to COVID-19 infection[5]. This underscores the importance of establishing COVID-19 related perioperative risks in hip fracture surgery and providing clinicians with a clear structure to facilitate informed consent.

This study includes an additional 110 patients who were not included in the original multi-center review, and addresses the following objectives: Firstly we seek to quantify the additional perioperative risks for COVID-19 positive patients undergoing hip fracture surgery and secondly we develop an evidence-based framework for

anonymized.

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providing informed consent for hip fracture surgery during the COVID-19 pandemic.

## MATERIALS AND METHODS

### Study design

This retrospective cohort study included all patients undergoing surgical treatment for hip fractures at four National Health Service (NHS) hospitals between February 1–May 21, 2020. All adult patients undergoing operative treatment for a closed intracapsular, intertrochanteric or subtrochanteric hip fracture were included. Paediatric patients, open hip fractures, femoral shaft fractures (defined as 5 cm distal to the lesser trochanter) and periprosthetic femoral fractures were excluded. Research approval was obtained from respective departmental leads, and the NHS Research Ethics Committee decision tool excluded need for ethical review.

### Patients

Of 259 patients were recruited. 51 patients were COVID-19 positive and 146 patients were COVID-19 negative. 62 patients were excluded as they were not tested for COVID-19. Patients were classified COVID-19 positive in the presence of clinical symptoms and a positive throat and nose swab assay using reverse transcriptase-polymerase chain reaction (RT-PCR) for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Patients were classified COVID-19 negative in the absence of clinical symptoms and a negative throat and nose swab assay using RT-PCR for SARS-CoV-2. Repeat swabs were performed if patients exhibited new or persistent symptoms.

### Data collection

The following predefined study outcomes were recorded by orthopaedic registrars using a standardized collection proforma: Patient demographics and baseline characteristics [age, gender, ethnicity, American Society of Anaesthesiologists (ASA) grade, comorbidities, dementia status, mobility]; preoperative factors (admission haemoglobin, admission leukocytes, RT-PCR SARS-CoV-2 swab results, associated injuries, systemic symptoms on admission, medical treatment on admission); operative factors (time from injury to surgery, type of anaesthesia, surgical procedure, grade of operating surgeon, operative time, intra-operative complications); postoperative outcomes (location of postoperative treatment, outcome at 30-d post-surgery and time from surgery to hospital discharge or mortality); and postoperative complications (COVID-19 positive patients). Outcomes were sourced from electronic medical records.

### Statistical analysis

Analyses of the demographics and baseline characteristics of COVID-19 positive and COVID-19 negative patients were performed using the unpaired *t*-test for continuous variables following normal distributions, and the Mann-Whitney U test for continuous variables not following normal distributions. Categorical variables were compared using the Chi-squared test except for variables with small sample sizes where Fisher's exact test was preferred.

Outcomes in COVID-19 positive and COVID-19 negative patients were compared statistically before and after adjustment for confounding factors exhibiting a difference between cohorts in the initial analyses ($P < 0.2$). Logistic regression was performed to analyze binary outcomes. Survival analysis was performed using Cox regression to compare length of inpatient stay. Patients who were still in the hospital and not ready for discharge when the data was finalized were censored. Patients who died were censored at the time of death.

Odds ratios were used to quantify the size of the association between each variable and outcome. The *P* value for statistical significance was set at < 0.05. The statistical analysis was performed using Stata version 15.1 (Stata Corp LLC, College Station, Texas).

## RESULTS

### Baseline characteristics and operative factors

There was no significant difference between COVID-19 positive and COVID-19 negative patients for age, gender, ASA grade, comorbidities, dementia, mobility or admission leukocyte levels. Admission haemoglobin levels were significantly reduced in COVID-19 positive patients (108 g/L *vs* 116 g/L, $P = 0.02$) (Table 1).

There was no significant difference between COVID-19 positive and COVID-19 negative patients for choice of anaesthesia, surgical procedure or grade of operating surgeon. COVID-19 positive patients had an increased waiting time from admission to surgery (3 d *vs* 2 d, $P = 0.03$) and reduced operative time (71 min *vs* 80 min, $P = 0.008$) comparative to COVID-19 negative patients (Table 1).

### The effects of COVID-19 on study outcomes

COVID-19 positive patients had more intensive care admissions (27% *vs* 5%, $P < 0.001$), longer inpatient stays (median 23 d *vs* 9 d, $P < 0.001$) and a higher 30-d mortality (29% *vs* 10%, $P = 0.001$) than COVID-19 negative patients (Table 2).

After adjusting for potentially confounding variables, odds of intensive care admission were 4.64 times higher (95%CI: 1.59-13.50, $P = 0.005$), and odds of 30-d mortality were 3 times higher (95%CI: 1.22-7.40, $P = 0.02$) in the COVID-19 positive cohort (Table 2).

Postoperative complications were evident in 74.5% of COVID-19 positive patients. 35.3% of COVID-19 positive patients suffered postoperative lower respiratory tract infections (LRTI) with 13.7% developing acute respiratory distress syndrome (ARDS). 9.8% of COVID-19 positive patients experienced symptomatic thromboembolic events with a 3.9% incidence of deep vein thrombosis (DVT) and a 3.9% incidence of pulmonary emboli (PE) (Table 3).

## DISCUSSION

Informed consent is grounded in the assumption that we as clinicians know the risks of a surgical procedure with a reasonable degree of accuracy, and are able to convey these risks to patients in order to facilitate a balanced decision on whether to proceed with surgical intervention. The COVID-19 pandemic has created uncertainty in the medical community worldwide and poses unique challenges in providing informed consent for surgery.

A hip fracture in the elderly population is a life-threatening injury. Despite advancement in prosthesis design, antibiotic prophylaxis and focussed rehabilitation, mortality following hip fracture surgery remains 7.9%-9.6% at 30 d and 22.8%-27.0% at one year[6,7]. Operative intervention is recommended to enable early mobilisation, provide effective pain relief and reduce mortality from complications secondary to prolonged bedrest[8].

COVID-19 positive patients had a higher 30-d mortality (29% *vs* 10%, $P = 0.001$) than COVID-19 negative patients. These findings echo other studies in Europe and America: Results from the Spanish Hip-COVID Observational Study illustrated a 14-d mortality of 30.4% in COVID-19 positive patients[9], while the 30-d mortality for COVID-19 positive patients following hip fracture surgery in New York was 52.9% [10]. It is therefore clear that a full and frank discussion about the increased risk of post-operative mortality must form an integral aspect of the informed consent process for COVID-19 positive patients undergoing hip fracture surgery.

Informed consent mandates exploration of alternative treatment options. Non-operative management of hip fractures typically requires a prolonged period of bedrest or traction. This may condemn patients to weeks of pain; the National Institute for Health and Care Excellence guidelines advocate even if a hip fracture complicates or precipitates a terminal illness, surgery should still be considered as part of a palliative care approach[8]. Prolonged bedrest increases the risk of complications such as pneumonia, urinary tract infection and pressure sores[11]. In studies prior to the pandemic, hip fracture mortality following non-operative management with bedrest was 63.6%-73.0% at 30 d and 84.4% at one year[12,13]. In patients managed non-operatively in the Spanish Hip-Covid Observational Study, the 14-d mortality was 67%[9]. These mortality rates are significantly higher than 30-d mortality rates reported in COVID-19 positive patients following hip fracture surgery. Therefore, COVID-19 positive patients who are medically fit for hip fracture surgery should be advised that existing literature does not support deviation from surgical intervention

**Table 1 Patient demographics and baseline characteristics**

| Variable | Category | COVID-19 negative (*n* = 146) | COVID-19 positive (*n* = 51) | *P* value[1] |
|---|---|---|---|---|
| Age | - | 77.3 ± 12.8 | 79.3 ± 11.0 | 0.31 |
| Gender, *n* (%) | Female | 92 (63) | 28 (49) | 0.08 |
| | Male | 54 (37) | 26 (51) | |
| ASA grade, *n* (%) | 1 or 2 | 46 (32) | 15 (29) | 0.64 |
| | 3 | 64 (44) | 20 (39) | |
| | 4 | 36 (25) | 16 (31) | |
| Number of comorbidities | - | 3.0 ± 1.5 | 3.3 ± 1.7 | 0.23 |
| Dementia, *n* (%) | No | 93 (64) | 36 (71) | 0.37 |
| | Yes | 53 (36) | 15 (29) | |
| Mobility, *n* (%) | Independent | 65 (47) | 18 (36) | 0.14 |
| | Stick | 48 (35) | 16 (32) | |
| | Frame | 26 (19) | 16 (32) | |
| Admission haemoglobin (g/L) | - | 116 ± 19 | 108 ± 18 | 0.02 |
| Admission leucocytes ($\times 10^9$/L) | - | 1.1 [0.8, 1.3] | 1.1 [0.7, 1.3] | 0.50 |
| Procedure, *n* (%) | Cannulated screw | 16 (11) | 4 (8) | 0.28 |
| | Dynamic hip screw | 29 (20) | 14 (28) | |
| | Intramedullary nail | 34 (23) | 11 (22) | |
| | Hemiarthroplasty | 56 (39) | 21 (42) | |
| | Total hip replacement | 10 (7) | 0 (0) | |
| Operative time | - | 80 [65, 102] | 71 [58, 83] | 0.008 |
| Surgeon level, *n* (%) | Senior house officer | 4 (3) | 0 (0) | 0.48 |
| | Registrar | 102 (70) | 32 (64) | |
| | Associate specialist | 11 (8) | 5 (10) | |
| | Consultant | 28 (19) | 26 (13) | |
| Admission to surgery (d) | - | 2 [1, 3] | 3 [2, 5] | 0.03 |
| Anaesthesia, *n* (%) | General | 80 (55) | 30 (61) | 0.46 |
| | Spinal | 65 (45) | 19 (39) | |

Summary statistics are: mean ± SD, median [inter-quartile range] or number (percentage).
[1]*P* values indicating the significance of the difference between coronavirus disease 2019 (COVID-19) positive and COVID-19 negative cohorts. COVID-19: Coronavirus disease 2019; ASA: American Society of Anaesthesiologists.

as the optimum standard of care.

COVID-19 positive patients had more intensive care admissions (27% *vs* 5%, $P < 0.001$) and longer inpatient stays (median 23 d *vs* 9 d, $P < 0.001$) than COVID-19 negative patients. Although often overlooked and not technically a prerequisite of the informed consent process, preoperative discussion regarding location of postoperative care and anticipated length of inpatient stay are invaluable in ensuring patients develop realistic expectations for their recovery. Further, providing a pragmatic estimation for duration of inpatient stay enables patients to prepare in advance for the logistical complexities of mandatory self-isolation post hospital discharge for COVID-19 positive patients. This is especially important when care arrangements need to be made for other vulnerable persons living at the same address as the patient.

Postoperative complications were evident in 74.5% of COVID-19 positive patients. 35.3% of COVID-19 positive patients suffered postoperative LRTI with 13.7% developing ARDS (Table 3). This reflects results from the CovidSurg collaborative which analyzed 835 COVID-19 positive patients undergoing emergency surgery and identified post-operative LRTI in 40% of patients with 14.3% developing ARDS[14].

**Table 2 Comparison of outcomes between coronavirus disease 2019 positive and coronavirus disease 2019 negative cohorts**

| Outcome | Analysis | Negative (*n* = 146), *n* (%) | Positive (*n* = 51), *n* (%) | Odds ratio[2] (95%CI) | *P* value |
|---|---|---|---|---|---|
| Intensive care | Unadjusted | 8 (5) | 14 (27) | 6.53 (2.55, 16.7) | < 0.001 |
| Admission | Adjusted[1] | - | - | 4.64 (1.59, 13.5) | 0.005 |
| 30-d mortality | Unadjusted | 14 (10) | 15 (29) | 3.93 (1.74, 8.89) | 0.001 |
| | Adjusted[1] | - | - | 3.00 (1.22, 7.40) | 0.02 |
| | | Negative (*n* = 146), Med [IQR] | Positive (*n* = 51), Med [IQR] | Hazard ratio[2] (95%CI) | |
| Length of stay | Unadjusted | 9 [7, 13] | 23 [19, 31] | 0.28 (0.18, 0.42) | < 0.001 |
| (d) | Adjusted[1] | - | - | 0.26 (0.17, 0.42) | < 0.001 |

[1]Adjusted for: gender, mobility, admission haemoglobin, operative time and time from admission to surgery.
[2]Expressed as outcome in the coronavirus disease 2019 (COVID-19) positive group relative to the outcome in the COVID-19 negative group.

**Table 3 Postoperative complications in coronavirus disease 2019 positive patients**

| Complication | *n* (%) |
|---|---|
| Lower respiratory tract infection | 18 (35.29) |
| Acute respiratory distress syndrome | 7 (13.73) |
| Sepsis | 7 (13.73) |
| Thromboembolic event | 5 (9.80) |
| Acute kidney injury | 5 (9.80) |
| Anaemia | 4 (7.84) |
| Myocardial infarction | 2 (3.92) |
| Urinary tract infection | 2 (3.92) |
| Cellulitis/wound infection | 2 (3.92) |
| Upper gastrointestinal bleed | 1 (1.96) |
| None | 13 (25.49) |

Prior to the pandemic, the rate of LRTI post hip fracture surgery was estimated to be 4.9%-7.0% with the combined incidence of atelectasis, respiratory failure, pulmonary embolism and ARDS at 4%[15,16]. It is theorised that fracture and surgical intervention may trigger an oxidative stress response promoting excessive inflammation and decreasing patients' immunity–increasing the likelihood of respiratory complications secondary to COVID-19 infection[17]. Therefore, COVID-19 positive patients undergoing hip fracture surgery must be consented for the increased risk of postoperative LRTI and development of ARDS.

The British Orthopaedic Association's blue book for the care of patients with fragility fractures reports a 3% incidence of symptomatic DVT and a 1% incidence of pulmonary embolism following hip fracture surgery[18]. In our study, 9.8% of COVID-19 positive patients experienced a symptomatic thromboembolic event with a 3.9% incidence of DVT, a 3.9% incidence of PE and a 1.96% incidence of cerebrovascular infarction. This corroborates findings from the CovidSurg collaborative where 2.2% of COVID-19 patients undergoing emergency surgery developed postoperative PEs[14]. In critically unwell COVID-19 positive patients, rates of thromboembolic events are even higher–with 25% patients admitted to an intensive care unit in Holland developing a DVT after 21 d[19].

Patients with hip fractures and COVID-19 infection automatically fulfil two of the three criteria in Virchow's triad for thrombus formation: Venous stasis due to immobility and hypercoagulability secondary to an inflammatory state[20]. Evidence suggests COVID-19 may also cause the third criteria: endothelial injury. It is proposed that serum levels of angiotensin 2 are elevated in COVID-19 positive patients stimulating production of reactive oxygen species responsible for the breakdown of nitric oxide which leads to endothelial dysfunction[21]. In the context of these studies,

it is prudent to consent COVID-19 positive patients undergoing hip fracture surgery for the increased risk of postoperative thromboembolic events, and to reiterate the importance of compliance with venous thromboembolism protocols.

In summary, COVID-19 positive patients undergoing hip fracture surgery should be consented for the increased risk of postoperative complications (including LRTI, ARDS, DVT and PE), increased requirement for intensive care admission, longer inpatient stay and a higher risk of mortality. Further, COVID-19 has enforced an additional requirement for the informed consent process: Transparency about the potential for unknown long-term risks and an honest admission of how little we currently understand as research into the long-term surgical outcomes of COVID-19 positive patients continues to evolve.

The principle strengths of this study are that a robust and comprehensive range of predefined study outcomes were recorded using a standardized collection proforma; the study collected data over a four month period from four NHS hospitals at the epicentre of the United Kingdom's COVID-19 outbreak providing a large sample size; only those patients with confirmed COVID-19 positive or COVID-19 negative swab assays were included rather than reliance on interpretation of vague and variable symptomatology; and the study included a control group of COVID-19 negative patients undergoing operative intervention in the same time period with outcome analysis including adjustment for confounding variables between cohorts.

This study has limitations which must be considered when interpreting findings. Diagnosis of COVID-19 was reliant on a positive throat and nose swab assay with a systematic review of the accuracy of COVID-19 tests establishing false negative rates between 2% and 29%[22]. Further, our study focussed exclusively on patients undergoing hip fracture surgery. This minimized demographic and surgical confounders, but makes the generalisability of our findings to other trauma or elective orthopaedic procedures unclear.

## CONCLUSION

COVID-19 positive patients undergoing hip fracture surgery should be consented for the increased risk of postoperative complications (including lower respiratory tract infection, ARDS, DVT and pulmonary embolism), increased requirement for intensive care admission, longer inpatient stay and a higher risk of mortality. Both clinicians and patients must acknowledge these risks as part of a detailed informed consent process.

## ARTICLE HIGHLIGHTS

### *Research background*

The incidence of hip fractures has remained stable throughout the coronavirus disease 2019 (COVID-19) pandemic, and urgent surgical intervention continues to be prioritized. However, there remains a persistent lack of clinical guidance addressing the subject of informed consent for COVID-19 positive patients undergoing hip fracture surgery. This is of paramount medicolegal importance in a high-risk patient cohort.

### *Research motivation*

The COVID-19 pandemic has created novel challenges and uncertainties in providing informed consent for surgery throughout the medical community. Hip fractures are the most common reason for inpatient orthopaedic trauma admission, with an estimated 1.6 million cases globally *per* year. Therefore, an evidence-based framework for facilitating an informed consent process for hip fracture surgery would provide clinicians with valuable support and clarity worldwide.

### *Research objectives*

This study had two primary objectives. Firstly, we aimed to quantify the additional perioperative risks for COVID-19 positive patients undergoing hip fracture surgery. Secondly, we sought to provide clinicians with an evidence-based framework for facilitating informed consent in COVID-19 positive patients undergoing hip fracture surgery.

### Research methods

Two hundred and fifty nine consecutive patients undergoing hip fracture surgical intervention in four hospitals in the United Kingdom were recruited. 51 patients were confirmed positive for COVID-19. Predefined study outcomes were recorded over a 30-d period using a standardized collection proforma. COVID-19 positive and COVID-19 negative patients were compared statistically before and after adjustment for confounding factors. Logistic regression was performed to analyze binary outcomes. Survival analysis was performed using Cox regression to compare length of inpatient stay.

### Research results

After adjusting for potentially confounding variables, in COVID-19 positive patients the odds of intensive care admission were 4.64 times higher (95%CI: 1.59-13.50, $P$ = 0.005) and the odds of 30-d mortality were 3 times higher (95%CI: 1.22-7.40, $P$ = 0.02). 75% of COVID-19 positive patients suffered post-operative complications. 35.3% experienced postoperative lower respiratory tract infections, 14.3% developed acute respiratory distress syndrome (ARDS) and symptomatic thromboembolic events were evident in 9.8%.

### Research conclusions

We conclude that the informed consent process for COVID-19 positive patients undergoing hip fracture surgery should discuss the additional risk of postoperative complications (particularly lower respiratory tract infection, ARDS, deep vein thrombosis and pulmonary embolism), increased requirement for intensive care admission, longer inpatient stay and higher risk of mortality.

### Research perspectives

This study contributes to the body of literature reporting short-term surgical outcomes in COVID-19 positive patients. Future research in this field should analyze long-term surgical outcomes in COVID-19 positive patients. In the interim, it is integral that clinicians are transparent with patients that long-term risks of surgery in COVID-19 positive patients remain unknown.

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ORIGINAL ARTICLE

Retrospective Cohort Study

# Dermatomyositis and polymyositis in total hip arthroplasty

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## Abstract

### *BACKGROUND*

Idiopathic inflammatory myopathies (IIM) are systemic autoimmune disorders such as dermatomyositis (DM), polymyositis (PM), inclusion body myopathy, and autoimmune necrotizing myopathy that, similar to osteoarthritis, affect quality of life and activities of daily living. Moreover, these patients are often burdened with chronic pain and disability; however, the outcomes and risk of total hip arthroplasty (THA) in this patient population remain unclear.

### *AIM*

To evaluate 90-d complications and costs in patients with these conditions.

### *METHODS*

A retrospective case control study was designed by accessing data from the Medicare dataset available on the PearlDiver server. Patients with IIM, here, those with DM and PM were matched based on possible confounding variables to a cohort without these diseases and with the same 10-year risk of mortality as defined by the Charlson Comorbidity Index Score (CCI). Univariate and multivariate analysis were performed to evaluate complications and t-tests to evaluate 90-d Medicare reimbursements as markers of costs after THA.

### *RESULTS*

The total sample was 1090 patients with each cohort comprised of 545. Females were 74.9% of the population. The mean CCI was 5.89 (SD 2.11). Those with IIM had increased rates of pneumonia [odds ratio (OR) 1.45, $P < 0.001$] and pulmonary embolism (OR 1.46, $P = 0.035$) and decreased hematoma risks (OR 0.58, $P = 0.00$). 90-d costs were on average $1411 greater for those with IIM yet not significantly different ($P = 0.034$).

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*CONCLUSION*

Patients with IIM have an increased 90-d rate of pneumonia and pulmonary embolism concomitant with a decreased hematoma rate consistent with their pro-coagulatory state. Further attention to increased resource utilization in these patients is also warranted.

**Key Words:** Dermatomyositis; Arthroplasty; Polymyositis; Outcomes; Charges; Reimbursement



**Core Tip:** Patients with dermatomyositis have an increased 90-d rates of pneumonia and pulmonary embolisms. The increased rates of these complications is concordant with a decreased hematoma rates consistent with the prothrombotic state of these patients. Surgeons should remember the implications of dermatomyositis when patients are undergoing total hip arthroplasty, and further discuss deep vein thrombosis prophylaxis.

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## INTRODUCTION

Preoperative patient expectations are an important factor in a patient's decision to undergo arthroplasty[1-3]. Such expectations are intimately related to, among other factors, the likely risks and benefits for an individual patient[1-3]. As a result, there is burgeoning interest in all surgical specialties towards quantifying the expected risks and benefits associated with a given procedure[4].

One particular population that has not been widely studied with respect to arthroplasty are patients with idiopathic inflammatory myopathies (IIM), a group of four rare, systemic autoimmune disorders [dermatomyositis (DM), polymyositis (PM), inclusion body myopathy, and autoimmune necrotizing myopathy] that share a number of clinical characteristics[5-7]. IIM patients have baseline increased risk of deep vein thromboses and death[5-9].

Degenerative joint disease is observed in up to 53% of patients with IIM[10]. It is unclear whether IIM directly contributes to joint degeneration[6,7]. High-dose corticosteroids are also often necessary to control major manifestations of IIM, which may result in osteonecrosis and eventual collapse and destruction of joints[9].

Despite the proven success of total hip arthroplasty (THA) in the general population, patients with IIM are amongst the most complex patients who undergo this procedure and there is a paucity in the evidence-based literature with regards to whether these patients experience a higher rate of complications, higher costs, or poorer outcomes following surgery[9,11,12].

The purpose of this study was to evaluate ninety-day complications and costs in patients with IIM, specifically DM or PM, undergoing primary THA for end-stage hip arthritis. The study hypothesized that patients with IIM would experience a higher rate of complications and higher costs following THA compared with the general population.

## MATERIALS AND METHODS

Given the low prevalence of IIM, a retrospective review was performed using a national database of surgeries and outcomes. A subset of the United States Medicare patient population was evaluated by way of the Medicare Standard Analytical Files. This dataset is available on the PearlDiver server (PearlDiver Inc., Colorado Springs,

CO, United States), a health insurance portability and accountability act-compliant and commercially-available software that allows for scrutiny of large number of records through International Classification of Disease, Ninth Revision (ICD-9) and Current Procedural Terminology (CPT) codes. This server contains over 50 million patient records and has been used extensively by various groups around the country to study a variety of conditions and diseases. No Institutional Review Board approval was required for this study, given the de-identified dataset.

Adult patients with a diagnosis of IIM were identified through ICD-9 710.3 (DM) and 710.4 (PM). These two specific conditions were used as a surrogate for IIM as a whole, given that the available IIM literature–particularly with respect to morbidity and mortality–tends to focus primarily on these two conditions. Cases of THA were identified through ICD-9 81.51 and CPT 27130. Hemiarthroplasty and revision procedures were excluded from the study. Included patients with IIM who underwent primary THA were then matched with controls at a one-to-one ratio through a well-established, comprehensive set of variables. These included age distribution, sex and Charlson Comorbidity Index (CCI). The CCI is a validated predictor of 10-year mortality and has been widely used across multiple medical specialties. Following the matching process, patient groups were compared with respect to age distribution, sex, geographic region where the procedure was performed, and specific comorbidities.

The outcomes assessed in this study included postoperative complications and costs. Diagnosis codes used to identify and compare complications in the postoperative period were similar to those used in previous studies and are reported in Supplementary material[13]. Reimbursement data for day-of-surgery and the ninety-day postoperative period were collected as a surrogate for costs[14]. The ninety-day timeframe was chosen as it is the most common time frame involved in bundled payment programs.

### *Statistical analysis*

All statistical analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria). Chi-square tests with Fischer corrections were used for dichotomous variables and paired *t*-tests were used for cost data after it was determined that the data was parametric through the Kolmogorov-Smirnov test. Multivariate regressions including age, gender, CCI and the presence *vs* absence of IIM were performed for each of the outcomes of interest, yielding an adjusted odds ratio (OR) with corresponding 95% confidence interval (CI). For all statistical analyses, the threshold for significance was established at $P \leq 0.05$. Unless noted otherwise, numerical values given were mean ± SD.

## RESULTS

Initial query of the database identified 78005 patients with a diagnosis of IIM and 1145631 cases of THA. After inclusion, exclusion, and matching criteria were applied, 1090 patients were captured for a final total of 545 patients in each of the two groups from 2005 to 2014.

The majority of patients were aged 69 and younger, with no significant difference in age distribution between groups (Table 1).

Females comprised the majority of patients in both groups, with 408 (74.9%) in each ($P = 1.000$). There were no significant differences between groups with respect to the geographic distribution of patients by region ($P = 0.185$).

The mean CCI was identical for both groups (5.89 ± 2.11; $P = 1.000$). Compared with patients with IIM, a significantly higher proportion of patients in the control group had diabetes mellitus (59% *vs* 44%; $P < 0.0001$), pulmonary disease (56% *vs* 46%; $P = 0.001$), and peripheral vascular disease (31% *vs* 30%; $P = 0.008$). Table 2 presents the pre-operative comorbidity profiles of both cohorts. Groups were otherwise similar with respect to comorbidities.

Multivariate regression analysis demonstrated that, compared with controls, patients with IIM had a higher risk of developing pneumonia (OR = 1.456, 95%CI: 1.170-1.812; $P = 0.001$) and pulmonary embolism (OR = 1.460, 95%CI: 1.026-2.077; $P = 0.035$) following THA (Table 3). Further, regression analysis demonstrated that patients with IIM had a lower risk of hematoma formation that became clinically significant compared with controls (OR = 0.582, 95%CI: 0.406-0.833; $P = 0.003$). Groups were otherwise similar with respect to risk of complications following THA.

When evaluating mean day-of-surgery reimbursements, there were no significant differences identified between IIM patients ($12952 ± $4002 *per* patient) and controls

**Table 1 Demographic factors for patients included in this study**

| | No. of IIM patients | No. of control patients | *P* value |
|---|---|---|---|
| Total number of patients | 545 | 545 | |
| Female patients | 74.90% | 74.90% | 1.000 |
| Age (yr) | | | |
| ≤ 64 | 24.4% | 23.6% | |
| 65-69 | 25.0% | 24.1% | |
| 70-74 | 19.1% | 19.7% | 0.993 |
| 75-79 | 17.1% | 18.1% | |
| 80-84 | 11.4% | 11.2% | |
| ≥ 85 | 3.1% | 3.4% | |
| Region | | | |
| Midwest | 23.1% | 26.8% | |
| Northeast | 18.5% | 21.5% | 0.1851 |
| South | 41.3% | 36.9% | |
| West | 17.1% | 14.9% | |

Reported percentages reflect the proportion of total patients in each of the two sample populations (*e.g.*, patients with idiopathic inflammatory myopathies or controls). IIM: Idiopathic inflammatory myopathies.

**Table 2 Additional comorbidities for patients included in this study**

| Comorbidity | Proportion of IIM patients without comorbidity | Proportion of control patients without comorbidity | *P* value |
|---|---|---|---|
| AIDS | 0.59% | 1.74% | 0.479 |
| Congestive heart failure | 29.66% | 30.68% | 1.000 |
| Depression | 37.3% | 40.52% | 0.402 |
| Diabetes mellitus[1] | 44.35% | 58.61% | 0.000 |
| SUD–Drugs | 6.31% | 7.96% | 0.910 |
| SUD–Alcohol | 2.35% | 4.2% | 0.716 |
| Hypertension | 89.43% | 92.19% | 0.112 |
| Hypothyroidism | 42.44% | 38.21% | 0.059 |
| Liver disease | 12.92% | 12.45% | 0.355 |
| Lymphoma | 3.38% | 4.63% | 1.000 |
| Metastatic cancer | 5.14% | 6.8% | 0.901 |
| Neurological disease | 13.07% | 13.6% | 0.742 |
| Pulmonary disease[1] | 45.96% | 55.86% | 0.001 |
| PVD[1] | 30.1% | 30.54% | 0.008 |

[1]Denotes significance, $P < 0.05$. Reported percentages reflect the proportion of total patients in each of the two sample populations (*e.g.*, patients with idiopathic inflammatory myopathies or controls) with the listed comorbidity. AIDS: Acquired immunodeficiency syndrome; SUD: Substance use disorder; PVD: Peripheral vascular disease; IIM: Idiopathic inflammatory myopathies.

($12445 ± $3857 *per* patient; $P = 0.299$). Similarly, mean ninety-day reimbursements were comparable for patients with IIM ($15530 ± $4901 *per* patient) and controls ($14480 ± $4525 *per* patient; $P = 0.140$).

**Table 3 Results of multivariate regression analysis to evaluate the relative risk of complications in patients with idiopathic inflammatory myopathies compared with controls following total hip arthroplasty**

| Complication | | OR (95%CI) | *P* value |
|---|---|---|---|
| Acute kidney injury | 0.034 | 1.035 (0.817-1.311) | 0.778 |
| Cardiac arrest | 0.315 | 1.370 (0.712-2.636) | 0.346 |
| Deep vein thrombosis | 0.423 | 1.526 (0.524-4.443) | 0.438 |
| Nerve injury | -0.966 | 0.381 (0.039-3.687) | 0.405 |
| Pneumonia[1] | 0.376 | 1.456 (1.170-1.812) | 0.001 |
| Pulmonary embolism[1] | 0.378 | 1.460 (1.026-2.077) | 0.035 |
| Urinary tract infection | 0.123 | 1.131 (0.931-1.374) | 0.215 |
| Wound disruption | -0.249 | 0.780 (0.485-1.253) | 0.304 |
| Hematoma[1] | -0.542 | 0.582 (0.406-0.833) | 0.003 |
| Transfusion | 0.060 | 1.062 (0.861-1.310) | 0.573 |
| Capsulitis | 0.355 | 1.426 (0.952-2.137) | 0.085 |
| Infection | -0.342 | 0.71 (0.442-1.139) | 0.156 |

[1]Denotes significance, $P < 0.05$. CI: Confidence interval; OR: Odds ratio.

## DISCUSSION

The results of this study support the hypothesis that patients with IIM experience a higher rate of ninety-day complications, namely pneumonia and pulmonary embolism, following THA. However, the study results also contradict part of our hypothesis in that costs (as represented by ninety-day reimbursements) were similar between patients with IIM and controls. Interestingly, there was one complication (clinically diagnosed hematoma formation) we identified that occurred less frequently in patients with IIM, likely given the pro-thrombotic state of these inflammatory conditions as discussed below. To our knowledge, this is the first study to comprehensively analyze the specific complications and reimbursements associated with THA in patients with IIM compared with patients in the general population with a matched comorbidity profile.

There are a myriad of disease manifestations, comorbidities, and medication side-effects that patients with IIM are susceptible to, which may place them at a higher risk of complications following arthroplasty compared with the general popula-tion[5-9,12,15]. One of the most feared and potentially devastating complications in arthroplasty is venous thromboembolism (VTE)[9]. Depending on the diagnostic study used and the chosen endpoint (*e.g.*, asymptomatic, symptomatic, fatal, *etc.*), the risk of VTE following lower-extremity arthroplasty has been reported to be less than 1%-2% when chemoprophylaxis is used[9,16,17]. It is well-documented that IIM carries a heightened risk of thromboembolic events, with one study reporting that these patients have an eight-fold higher risk of developing VTE compared with the general population[8]. Our study identified that patients with IIM demonstrated a nearly 1.5-fold higher risk of pulmonary embolism compared with controls. The discrepancy in the observed increased risk of thromboembolic events between the two studies is likely due, in part, to the fact that our study used a comorbidity-matched control group, who themselves likely have an elevated risk of thromboembolic events above the general population. Moreover, our findings describe a nationwide cohort representative of the average IIM patient undergoing THA, whereas the study by Antovic *et al*[8] did not evaluate the rates of VTE in a surgical cohort and instead compared VTE incidences between IIM patients and the general population. Conversely, bleeding and hematoma formation are also potential complications, with 0.41% of patients who undergo THA requiring surgical evacuation of a hematoma[18]. Interestingly, this study found that patients with IIM had a 42% lower incidence of hematoma compared with controls, which is in concordance with the hypercoagulable state these patients are in at baseline.

Based on the results of this study and studies involving other high-risk groups undergoing arthroplasty, it may be prudent to use more aggressive postoperative chemoprophylaxis in IIM patients undergoing THA as part of a multimodal approach

to overall VTE prophylaxis. Further research is necessary to better characterize the elevated VTE risk and commensurate prophylaxis regimen for IIM patients undergoing THA.

Patients with IIM have an elevated baseline risk of developing pulmonary disease, including pneumonia[5-7,19]. The lungs are the most commonly involved extra-muscular organs in IIM. Infectious pulmonary complications occur in 26% of IIM patients, with *Pseudomonas* and *Staphylococcus* being the most common causative organisms for pneumonia in these patients[19]. In the present study, we found that IIM patients demonstrated a nearly 1.5-fold higher risk of pneumonia compared with controls. It is unclear which, if any, IIM-associated risk factors (*e.g.*, dysphagia, leukopenia, hypoproteinemia, myopathy of thoracic musculature, concurrent immunosuppressive treatment) contributed to the development of pneumonia in our study population or what subtype of pneumonia each patient developed (*e.g.*, community-acquired, hospital-acquired, *etc.*)[19]. Further studies are necessary to better characterize pneumonia in this population, including elucidating the most common mechanisms (*e.g.*, aspiration, poor hand or equipment hygiene of staff, *etc.*) and whether more intensive therapy or precautions (*e.g.*, pulmonary hygiene, topical decontamination, vaccination, *etc.*) may be warranted.

With total annual Medicare reimbursements of approximately $20 billion and growing for arthroplasty, considerable efforts have been undertaken to reduce costs and limit spending[20]. In this study, we observed similar ninety-day reimbursements between IIM patients ($15530) and controls ($14480). On the one hand, the similarity in reimbursement is commensurate with the matched comorbidity profile of the two groups. On the other hand, given the higher number of complications observed in patients with IIM, it was surprising that we did not observe a corresponding higher reimbursement. With complications comes increased healthcare utilization, leading to increased costs and ultimately increased insurance reimbursements[20-22]. The Center for Medicare and Medicaid Services' Comprehensive Care for Joint Replacement (CJR) bundled payments program penalizes hospitals with higher-than-average reimbursements and rewards hospitals with lower-than-average reimbursements[21]. As a result, there is debate as to whether such bundling programs may incentivize hospitals and providers to treat patients who are more profitable (*e.g.*, fewer comorbidities, lower costs) while creating barriers to treatment for higher-risk populations[21]. Currently, the CJR program risk-stratifies patients undergoing lower extremity arthroplasty based on diagnosis related group codes, geographic region, and presence of a fracture; there is currently minimal risk adjustment for comorbidities [21]. The specific complications quantified in this study contribute to an overall more robust risk stratification for IIM patients undergoing THA. This may have the added benefit of aiding bundled payment negotiations, providing more equitable reimbursement, and ultimately improving access for certain higher-risk patients.

There are a number of limitations with this retrospective data review that must be considered. As with any large, national database, there is the potential for errors, omissions, inconsistencies, and/or variability in the data. When statistical analysis is performed on a large dataset, the establishment of statistically significant differences is likely. Unfortunately, clinically important differences in rates of complications are seldom defined, as they are often subjective. Thus, clinically important differences in rates of complications were not established in our methodology. The database includes no specific operative details (*e.g.*, operative time, anesthesia, intraoperative findings, prosthesis used, antibiotics used, postoperative protocol, *etc.*). Patients were not stratified based on length-of-stay in the hospital after surgery. Due to the nature of the database query in this study, there is the potential for retrospective bias. Using reimbursement data as a surrogate for costs introduces limitations to our analysis, given the convoluted payment models currently in place in the healthcare industry. In addition, reimbursement values captured in this study were not adjusted for inflation. Notwithstanding, these values represent reimbursements from the biggest payer in the country (Medicare) and thus allow for comparisons between studies[4]. This study included a majority of female patients and did not evaluate hemiarthroplasty, revision procedures, or the two remaining IIM groups (inclusion body myopathy and autoimmune necrotizing myopathy), which may limit the generalizability of our results. Lastly, numerous studies have reported consistent validity of the CCI as a prognostic factor for mortality and health costs, the CCI includes only a limited number of fields for diagnosis entry and does not account for the clinical severity of most of the included diagnoses[21,23]. Consequently, CCI may potentially underestimate the number and/or extent of comorbidities, which may limit the external validity of our results. In addition, and despite an identical mean CCI for both groups, the control group had a higher frequency of comorbid diabetes, pulmonary disease,

and peripheral vascular disease, which may have had a confounding effect on postoperative complications and/or reimbursements. Future studies are needed to prospectively follow these patients and their complications, yet the low prevalence of IIM makes this a difficult feat.

## CONCLUSION

Compared with patients in the general population with a matched comorbidity profile, patients with IIM who undergo primary THA are at an increased risk of potentially serious ninety-day complications (pneumonia and pulmonary embolism) and incur similar total costs following surgery. The results of this study may help improve patient selection for surgery and aid physicians in providing a more accurate, individualized risk-benefit assessment for IIM patients prior to surgery.

## ARTICLE HIGHLIGHTS

### *Research background*

There is a paucity of data evaluating patients with dermatomyositis (DM) and polymyositis (PM) undergoing total hip arthroplasty (THA).

### *Research motivation*

To compare and contrast the outcomes of patients undergoing THA with DM and PM *vs* a matched control without inflammatory arthropathies.

### *Research objectives*

To elucidate whether patients with DM and PM have increased risk of complications and greater 90-d costs when undergoing THA compared to controls.

### *Research methods*

A retrospective case control was performed based on the medicare data.

### *Research results*

Patients with DM and PM had increased rates of pneumonia [odds ratio (OR) 1.45, $P < 0.001$] and pulmonary embolism (OR 1.46, $P = 0.035$) and decreased hematoma risks (OR 0.58, $P = 0.00$). 90-d costs were on average $1411 greater for those with idiopathic inflammatory myopathies (IIM) yet not significantly different ($P = 0.034$).

### *Research conclusions*

Patients with IIM have an increased 90-d rate of pneumonia and pulmonary embolism concomitant with a decreased hematoma rate consistent with their pro-coagulatory state.

### *Research perspectives*

It is important to evaluate deep vein thrombose prophylaxis and respiratory status in those undergoing THA with DM or PM.

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ORIGINAL ARTICLE

Retrospective Cohort Study

# Outcome and revision rate of uncemented humeral head resurfacing: Mid-term follow-up study

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## Abstract

***BACKGROUND***

Glenohumeral osteoarthritis (OA) is a common cause of pain and disability affecting nearly a third of the world's population over 60 years of age. As in other joints, shoulder arthroplasty appears to be the most effective treatment. The implant design has evolved during time transitioning to shorter humeral stem lengths or even stemless components.

***AIM***

To evaluate the medium-term outcome and survival of a cementless humeral head resurfacing (HHR) in a group of patients affected with OA or avascular necrosis.

***METHODS***

This is a retrospective study of prospectively collected data using HHR in 23 patients (15 female and 8 male) after a 7.4 year follow-up. The collected data included clinical and radiographical evaluation. The Constant score, the visual analogue scale, and a clinical evaluation of range of motion were registered pre- and postoperatively. Fifteen patients affected with OA (2 cases of mild, 6 moderate, and 7 severe) and 10 with avascular necrosis (stage III according to Cruess classification) were enrolled. X-rays were evaluated to detect loosening signs, degenerative changes, and superior humeral head migration. Magnetic resonance preoperatively was also performed to assess the rotator cuff status. Tendon integrity was mandatory to implant the HHR.

***RESULTS***

In total, 19 patients (21 shoulders) completed the follow-up. Data on 4 shoulders,

**Data sharing statement:** Patients were not required to give informed consent to the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

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in 4 patients, were lost because of prosthesis failure. The global revision rate was 16%. A statistically significant improvement in the mean Constant score, visual analogue scale, and range of motion have been reported. No signs of loosening were registered, while in 12 cases a glenoid erosion was found. The osteophytes appeared 7 times on the humeral side and 12 on the glenoid. Superior humeral migration was recorded in only 1 case.

*CONCLUSION*

HHR remains a reasonable option in patients with an intact rotator cuff for the treatment of OA and avascular necrosis.

**Key Words:** Shoulder; Arthroplasty; Humeral head; Resurfacing; Glenoid erosion; Prosthesis failure



**Core Tip:** Shoulder arthroplasty is the most effective treatment of glenohumeral osteoarthritis. The medium-term outcome and survival of a cementless humeral head resurfacing was retrospectively evaluated in 23 patients affected with osteoarthritis or avascular necrosis after a 7.4 year follow-up. The global revision rate was 16%. A statistically significant improvement in the mean Constant score, visual analogue scale, and range of motion have been reported. No signs of loosening were registered, while in 12 cases a glenoid erosion was found. Humeral head resurfacing remains a reasonable option in patients with an intact rotator cuff for the treatment of osteoarthritis and avascular necrosis.

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## INTRODUCTION

Glenohumeral osteoarthritis (OA) is a common cause of pain and physical limitation, with an estimated prevalence between 4% and 26%[1], affecting nearly a third of the world's population over 60 years of age[2]. The choice of treatment of shoulder OA is often controversial, and it is related to the surgeon and based on the patient's age, severity of symptoms, level of activity, radiographic findings, and medical comorbidities[3]. Activity modification, physical therapy, and anti-inflammatory drugs are the major nonoperative treatment options. In case of failure (nonresponding) of this therapeutic approach and when the patients may not wish to progress directly to surgery, intra-articular injection with either corticosteroid or hyaluronic acid or platelet-reach plasma[4] represents a valid alternative. Finally, surgery may be considered. As in other joints affected by severe OA, different surgical procedures are available, being joint arthroplasty the most effective treatment[3].

Shoulder arthroplasty was introduced by Neer *et al*[5]; from that date prosthesis design has evolved during time to better reproduce and accommodate the individual shoulder anatomy and variability[3,6]. During this evolution, implants have transitioned to shorter humeral stem lengths or even stemless components. The latter has been introduced in 2004 by Copeland, who designed a cementless humeral head resurfacing (HHR) prosthesis for the treatment of glenohumeral OA[7], providing good clinical results[8]. Over time, the indications to implant a cementless HHR changed and extended to other shoulder pathologies, such as humeral head avascular necrosis (AVN), instability arthropathy, rheumatoid arthritis, post-traumatic arthropathy, and cuff tear arthropathy, with good functional results[8,9]. The rationale to implant a cementless HHR is to restore the patient's individual humeral head anatomy, characterized by articular retroversion, neck shaft angle, lateral offset, and center of rotation, and it is easier to remove, preserving the bone stock for a possible

future revision[8,10].

The main criticism referred to HHR is usually related to the incorrect sizing and orientation of the prosthesis, resulting in an oversizing of the joint. A deviation of the center of rotation higher than 5 mm has been shown to correlate to clinical failure of the implant[10]. HHR failure rate is among 6% and 37%[9,11,12]. A direct correlation between overstuffing and glenoid wear has been demonstrated, leading to prosthesis failure[13]. Moreover, an operative change of the lateral glenohumeral offset as a predictive factor for implant failure has been reported[14]. Among other causes for prosthesis failure, rotator cuff tear, painful stiffness without glenoid erosion, or infections were reported[14].

The aim of the present study was to evaluate the medium-term outcomes and survival of a specific cementless HHR in a group of patients operated by a single surgeon in a single center.

## MATERIALS AND METHODS

This is a report of prospectively collected data of 23 patients who have undergone cementless Aequalis HHR (Tornier, Warsaw, IN, United States) with a mean follow-up of 89 mo (range 44-131 mo).

All procedures involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with 1964 Helsinki Declaration and its later amendments. This study was reviewed and approved by the Ethics Committee/Scientific Council of the Istituto Chirurgico Ortopedico Traumatologico of Latina, Italy.

All participants gave informed written consent.

### *Subjects*

Between February 2009 and May 2014, 25 shoulders in 23 patients (15 females and 8 males; mean age: 67.2 years, min/max: 39-83 years) were surgically treated with the same type of cementless HHR performed by the same surgeon (CC) in a single center. The indications for surface replacement were primary OA (15 shoulders) and humeral head AVN (10 shoulders). The exclusion criteria were the presence of rotator cuff tears (partial or complete) and a damaged glenoid (evaluated with magnetic resonance).

### *Surgical technique*

All patients were operated under general anesthesia in the beach-chair position, by using the delto-pectoral approach. An L-shaped tenotomy of the subscapularis tendon was performed, followed by a capsular release for soft tissue balancing. The glenoid surface status was then assessed by retracting the humeral head. Once the humeral head was exposed, all osteophytes were carefully circumferentially removed. This step is critical because head sizing and head orientation are based off the anatomic neck. If the actual humeral head appeared to be in between sizes, the smaller size was selected. The humeral head was then reamed down to restore the original head height. The uncemented press-fit technique was the method of choice for fixing the resurfacing implant (Aequalis RH Tornier, Warsaw, IN, United States). Primary stability was achieved in all cases thanks to the presence of a tapered press-fit, tri-fin antirotational stem and a diamond-shaped macrotexture. In addition, all bone contacting surfaces were hydroxyapatite-coated.

In all cases, the long head biceps tenotomy was performed close to its glenoid attachment, followed by tenodesis in the bicipital groove. After implant reduction, the subscapularis was repaired in a tendon-to-tendon fashion using three to five nonabsorbable sutures. In no cases drains were placed in the shoulder.

The patient's arm was placed in a shoulder abduction pillow for 4 wk. Passive rehabilitation was started from day 2 with external rotation restricted to 0°. Patients were asked to support these movements actively. Free range of motion was allowed 6 wk after surgery.

### *Clinical study*

Clinical evaluation included pre- and postoperative administration of the Constant scale and the visual analogue scale. The active range of motion was evaluated in pre- and postoperative time, with particular attention to the forward elevation, abduction, and external rotation with the arm at the side.

### Radiological study

Pre- and postoperative radiographs were performed in two projections: A true antero-posterior view in neutral rotation and an axillary view. All radiographs were digitalized and scaled on the same size thanks to the software of Picture Archiving and Communication System monitor (General Electric, Chicago, IL, United States), available in the radiology department of our institute.

In the preoperative, the glenohumeral OA and humeral head AVN were radiologically classified according to Samilson and Prieto (mild: inferior humeral and/or glenoid exostosis < 3 mm in height; moderate: inferior humeral and/or glenoid exostosis measuring 3 mm to 7 mm, slight glenohumeral irregularity; severe: inferior humeral and/or glenoid exostosis measuring > 7 mm, glenohumeral joint narrowing and sclerosis) and Cruess (stage I: normal X-ray, changes on magnetic resonance; stage II: sclerosis, osteopenia; stage III: crescent sign indicating a subchondral fracture; stage IV: flattening and collapse; stage V: degenerative changes extend to glenoid).

Preoperative X-ray images revealed OA in 15 shoulders (2 cases of mild, 6 moderate, and 7 severe) and 10 shoulders affected by humeral head AVN (10 cases stage III).

During follow-up, the radiographic evaluation was useful to check signs of: (1) Loosening around the peg and in the eighth humeral zone. Probably loosening is intended as a radiolucent 2 mm wide line or greater around the implant without any change in position of the implant. Definite loosening was defined as a change in position of the implant over time; (2) Degenerative changes (*i.e.* glenoid erosion, humeral head or glenoidal osteophytes); and (3) Vertical humeral migration of the head intended as a superior migration of the prosthesis outside the center of the glenoid.

### Statistical analysis

The paired t-test was used to determine whether there was a significant difference between preoperative and postoperative Constant score, visual analogue scale, and range of motion obtained at the latest check-up at 7.4 years. A $P$ value of < 0.05 was considered to be statistically significant.

## RESULTS

In total, 19 patients (21 shoulders) completed the follow-up.

Data on 4 shoulders in 4 patients were lost because of prosthesis failure due to a rotator cuff tear after a traumatic accident (1 case) (Figure 1) and glenoid erosion (3 cases) (Figure 2) that required a revision surgery (Table 1). In all the revised cases the implant was removed without complications, leaving a sufficient bone stock for reimplantation (Figure 3)

The Constant score improved from the preoperative mean value of 31.1 (range 16-57) to the postoperative mean value of 74.9 (range 57-100) ($P$ < 0.001). In detail, an improvement of all the sections of the Constant score was registered from the preoperative to the postoperative latest evaluation and was statistically significant ($P$ < 0.001) except for the recovery of the strength ($P$ = 0.3).

The pretreatment visual analogue scale grading scale was 7.8 (range 5-10), while at the final follow-up decreased to 2.1 (range 0-5) ($P$ < 0.001).

An improvement in the clinical evaluation of the active range of motion was also registered. The mean flexion forward changed from 75° (range 30°-120°) in the preoperative to 111° (range 60°-160°) in the postoperative ($P$ = 0.06). The pre- and postoperative mean value of abduction were respectively 68° (range 30°-120°) and 104° (range 60°-160°) ($P$ < 0.001), while the mean external rotation value pre- and postoperative were respectively 30° (range 10°-50°) and 54° (range 30°-75°) ($P$ < 0.001) (Table 2).

No signs of loosening around the peg and in the eighth humeral zone[15] were detected at the latest follow-up. In 11 cases, a glenoidal erosion has been reported. In 3 patients, this condition was symptomatic, while in the remaining 8 it was not. In 12 cases the presence of inferior glenoidal osteophytes was registered, and in 7 cases humeral head osteophytes were registered. Only 1 case of superior humeral migration had been reported due to the traumatic rotator cuff tear (Figure 1).

The global revision rate was 16% at a mean follow-up of 7.4 years, and the survival rate was 84% (Figure 4).

**Table 1 Demographic data of patients who required revision**

| Patient | Sex | Age | Indication | Lifespan of the prosthesis | Failure cause | Revision |
|---|---|---|---|---|---|---|
| 1 | Male | 66 | Right OA | 65 mo (5.41 yr) | Glenoiditis | rTSA |
| 2 | Female | 78 | Right AVN | 44 mo (3.66 yr) | Traumatic RCT | rTSA |
| 3 | Female | 75 | Right AVN | 50 mo (4.16 yr) | Glenoiditis | rTSA |
| 4 | Male | 48 | Left AVN | 66 mo (5.50 yr) | Glenoiditis | TSA |

AVN: Avascular necrosis; OA: Osteoarthritis; RCT: Rotator cuff tear; rTSA: Reverse total shoulder arthroplasty.

**Table 2 Preoperative and 7.4 yr postoperative clinical finding**

| | Preoperative value (min-max) | Postoperative value (min-max) | *P* value |
|---|---|---|---|
| Pain | 3.20 (0-5) | 12.38 (10-15) | < 0.001 |
| Daily activity level | 7.96 (6-11) | 16.66 (12-20) | < 0.001 |
| ROM | 10.48 (2-17) | 35.47 (28-40) | < 0.001 |
| Strength | 9.44 (3-25) | 10.42 (4-25) | 0.3 |
| Constant score | 31.08 (16-57) | 74.95 (57-100) | < 0.001 |
| VAS | 2.88 (1-4) | 7.76 (5-10) | < 0.001 |
| Flexion forward | 74.80° (30°-120°) | 111.42° (60°-160°) | 0.06 |
| Abduction | 68.00° (30°-120°) | 104.28° (60°-160°) | < 0.001 |
| External rotation | 30.40° (10°-50°) | 54.04° (30°-75°) | < 0.001 |

ROM: Range of motion; VAS: Visual analog scale.

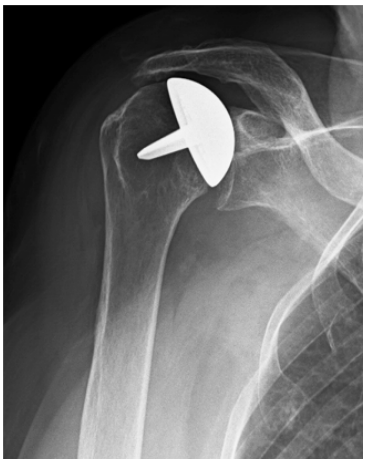

**Figure 1 Patient 2.** X-ray of a right shoulder anteroposterior view. Note the superior humeral head migration caused by a traumatic rotator cuff tear 3, 6 yr after surgery.

## DISCUSSION

Even if during the years the indications to implant a cementless HHR changed and extended from OA to numerous shoulder pathologies[8,9], the authors' rationale to implant a cementless HHR was to restore the patient's individual humeral head anatomy, and two major aspects were considered crucial: (1) The integrity of the rotator cuff; and (2) A good bone stock to fix the implant.

The latter aspect may be a problem in AVN. This condition in fact is characterized by the death of cellular components of bone secondary to an interruption of the subchondral blood supply determining a deep bone distortion with abnormal

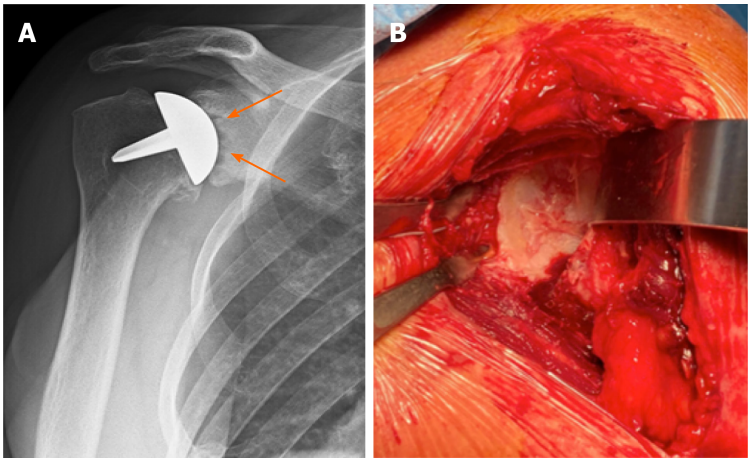


**Figure 2 Patient 3.** A: X-ray of the right shoulder. Anteroposterior view. An evident glenoid erosion (arrows) is detectable 5.5 yr after humeral head resurfacing; B: Revision surgery. Deltopectoral approach. After removal of the implant the glenoid surface damage was assessed by retracting the humerus.

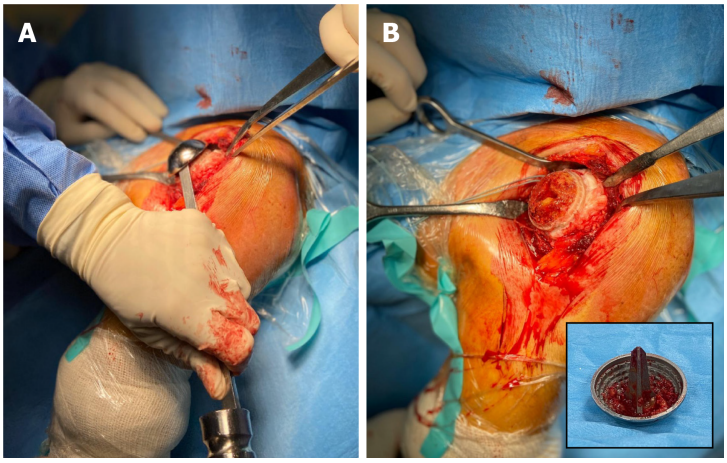


**Figure 3 Patient 4. Revision surgery, deltopectoral approach.** A: The removal of the implant; B: The humeral bone stock appears maintained after prosthesis removal (square).

architecture and for this reason may be considered not an absolute indication to implant a cementless HHR, especially in its late stages (IV and V according to Cruess).

According to the findings of the present study, the clinical and radiological results were good in a mean term follow-up of more than 7 years using the Aequalis HHR in the treatment of glenohumeral OA and humeral head AVN compared to similar data reported in the literature[9,11,14,16-19] (Figure 5).

In contrast, to our knowledge there exists only one paper reporting no failure at a long-term follow-up[20]. In that paper, the study population consisted of 14 young patients (aged 19-49 years) affected by juvenile idiopathic arthritis and treated with HHR with a 10.4 year follow-up period. The authors reported that only two shoulders required early arthroscopic subacromial decompression. This interesting study may have a limitation/bias in the age of its population because it was limited to young patients.

As underlined above, the use of HHR as the primary implant presents numerous advantages in all ages, but especially in younger patients. The cementless implant may preserve the bone stock, and this aspect could be useful during a future revision[7]. Moreover, HHR may be considered a valid alternative in the post-traumatic arthropathy to restore shoulder anatomy[7,14].

As already underlined in the literature and confirmed by this study, glenoid erosion is considered as the most important reported cause of prosthesis failure[14,16,17]. This complication could be caused by an incorrect assessment of the humeral head size and orientation, producing an overstuffing of the joint[10,21].

In the past, different attempts were suggested to limit glenoid erosion, and particular interest was given to the procedure employing a biological glenoid

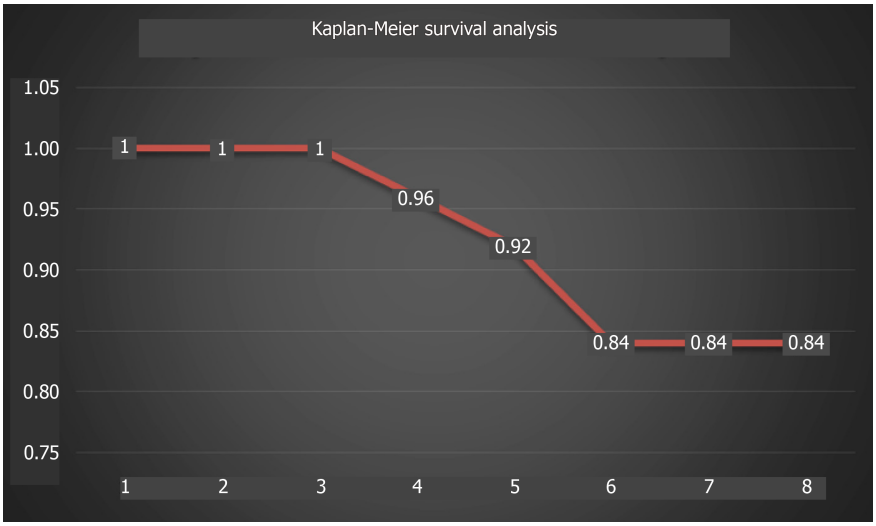


**Figure 4 Kaplan-Meier survival analysis.**

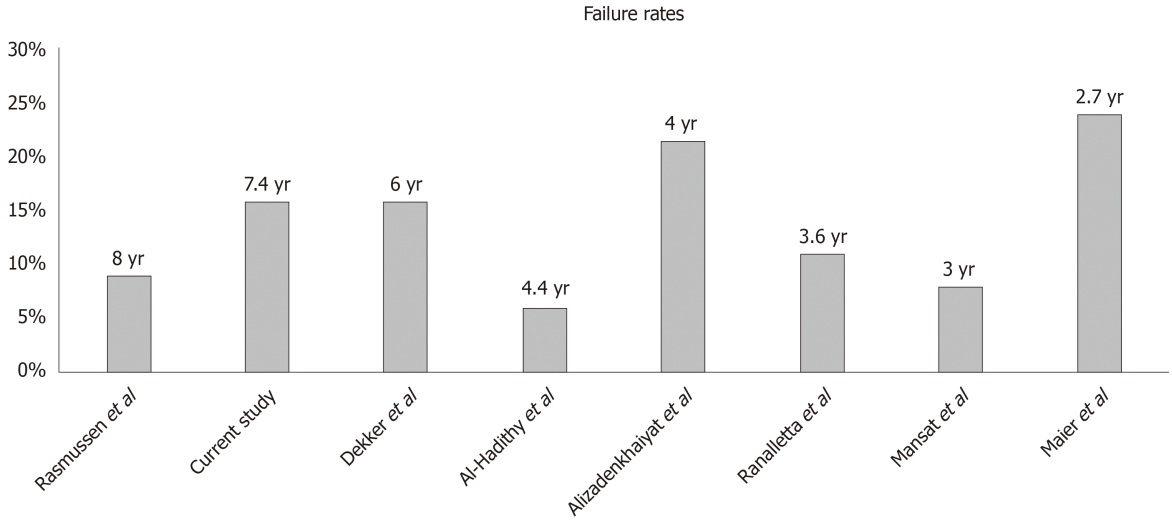


**Figure 5 Reported incidence of humeral head resurfacing failure rates in the literature compared with the current study.**

resurfacing[22-24]. After promising early results, all these attempts have failed. The reported long-term failure rate of the biological glenoid resurfacing was 56% using the anterior shoulder capsule even though the authors registered good clinical results after 5 years[22].

Also, the use of autograft Achilles tendon or allograft fascia lata for biological glenoid resurfacing was inconsistent. Elhassan *et al*[23] registered 10 cases of erosion in 13 patients (failure rate > 70%), so they do not recommend this kind of treatment. The same conclusion was drawn by Lollino *et al*[24] who proposed to resurface glenoid with the lateral meniscus. After a 2 year follow-up period, the authors reported a narrowing of the articular space, probably related to the meniscal reabsorption.

Taking into consideration the overall results of HHR, the weak part is to date the glenoid. This conclusion is apparently similar to the results of the traditional anatomical shoulder arthroplasty[25]. In fact, many studies have reported that the glenoid component loosening, and failure represented the most common long-term complication of total shoulder arthroplasty. This accounted for approximately 24% of all total shoulder arthroplasty complications[26], so that we have to conclude that the result of a shoulder replacement highly depends on the status of the glenoid, be it native or implanted. Unfortunately, this remains still true although glenoid component design, material, and surgical technique of implant including cement use have been rapidly changed and evolved during the last decades[25].

## CONCLUSION

HHR can be considered a good treatment option in OA and humeral head AVN in patients with an intact rotator cuff. This paper, even though is based on a small cohort of patients, shows a good outcome with a failure rate of 16% in a 7.4 year follow-up. No loosening or infection issues were encountered. The main problem of this prosthesis is the higher revision rate due to glenoid erosion, which is comparable to reported rates on total shoulder arthroplasty. Its advantage is bone preservation in the proximal humerus.

## ARTICLE HIGHLIGHTS

### *Research background*

Glenohumeral osteoarthritis and avascular necrosis are causes of shoulder pain and disability. Shoulder arthroplasty is the most effective treatment. The implant design has evolved during time transitioning to shorter humeral stem lengths or even stemless components.

### *Research motivation*

The rationale to implant a cementless humeral head resurfacing (HHR) is to restore the patient's individual humeral head anatomy, characterized by articular retroversion, neck shaft angle, lateral offset, and center of rotation, and it is easier to remove, preserving the bone stock for a possible future revision. The reported revision rate at a mid-term follow-up is not so high, so this could be an alternative to a total shoulder arthroplasty.

### *Research objectives*

Our aim is to evaluate the medium-term outcome and survival of a cementless HHR in a group of patients affected with osteoarthritis or avascular necrosis.

### *Research methods*

This is a report of prospectively collected data using HHR in 23 patients (15 female and 8 male) after a 7.4 year follow-up.

### *Research results*

The global revision rate was 16%. Data on 4 shoulders in 4 patients were lost because of prosthesis failure. Nineteen patients (21 shoulders) completed the follow-up. No signs of loosening were registered, while in 12 cases a glenoid erosion was found. The osteophytes appeared 7 times on the humeral side and 12 on the glenoid. Superior humeral migration was recorded in only one case.

### *Research conclusions*

The use of a cementless HHR in the treatment of osteoarthritis and early stage avascular necrosis could nowadays be consider a valid therapeutic option.

### *Research perspectives*

Further research based on well-designed studies with longer follow-up examination and with a bigger patient population need to be performed in order to elucidate the efficacy of cementless HHR.

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ORIGINAL ARTICLE

Retrospective Study

# Trends in leadership at orthopaedic surgery sports medicine fellowships

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## Abstract

### *BACKGROUND*

Fellowship directors (FDs) in sports medicine influence the future of trainees in the field of orthopaedics. Understanding the characteristics these leaders share must be brought into focus. For all current sports medicine FDs, our group analyzed their demographic background, institutional training, and academic experience.

### *AIM*

To serve as a framework for those aspiring to achieve this position in orthopaedics and also identify opportunities to improve the position.

### *METHODS*

Fellowship programs were identified using both the American Orthopaedic Society for Sports Medicine and the Arthroscopy Association of North America Sports Medicine Fellowship Directories. The demographic and educational background data for each FD was gathered *via* author review of current curriculum vitae (CVs). Any information that was unavailable on CV review was gathered from institutional biographies, Scopus Web of Science, and emailed questionnaires. To ensure the collection of as many data points as possible, fellowship program coordinators, orthopaedic department offices and FDs were directly contacted *via* phone if there was no response *via* email. Demographic information of interest included: Age, gender, ethnicity, residency/fellowship training, residency/fellowship graduation year, year hired by current institution,

time since training completion until FD appointment, length in FD role, status as a team physician and H-index.

*RESULTS*

Information was gathered for 82 FDs. Of these, 97.5% ($n$ = 80) of the leadership were male; 84.15% ($n$ = 69) were Caucasian, 7.32% ($n$ = 6) were Asian-American, 2.44% ($n$ = 2) were Hispanic and 2.44% ($n$ = 2) were African American, and 3.66% ($n$ = 3) were of another race or ethnicity. The mean age of current FDs was 56 years old (± 9.00 years), and the mean Scopus H-index was 23.49 (± 16.57). The mean calendar years for completion of residency and fellowship training were 1996 (± 15 years) and 1997 (± 9.51 years), respectively. The time since fellowship training completion until FD appointment was 9.77 years. 17.07% ($n$ = 14) of FDs currently work at the same institution where they completed residency training; 21.95% ($n$ = 18) of FDs work at the same institution where they completed fellowship training; and 6.10% ($n$ = 5) work at the same institution where they completed both residency and fellowship training. Additionally, 69.5% ($n$ = 57) are also team physicians at the professional and/or collegiate level. Of those that were found to currently serve as team physicians, 56.14% ($n$ = 32) of them worked with professional sports teams, 29.82% ($n$ = 17) with collegiate sports teams, and 14.04% ($n$ = 8) with both professional and collegiate sports teams. Seven residency programs produced the greatest number of future FDs, included programs produced at least three future FDs. Seven fellowship programs produced the greatest number of future FDs, included programs produced at least four future FDs. Eight FDs (9.75%) completed two fellowships and three FDs (3.66%) finished three fellowships. Three FDs (3.66%) did not graduate from any fellowship training program. The Scopus H-indices for FDs are displayed as ranges that include 1 to 15 (31.71%, $n$ = 26), 15 to 30 (34.15%, $n$ = 28), 30 to 45 (20.73%, $n$ = 17), 45 to 60 (6.10%, $n$ = 5) and 60 to 80 (3.66%, $n$ = 3). Specifically, the most impactful FD in research currently has a Scopus H-index value of 79. By comparison, the tenth most impactful FD in research had a Scopus H-index value of 43 (accessed December 1, 2019).

*CONCLUSION*

This study provides an overview of current sports medicine FDs within the United States and functions as a guide to direct initiatives to achieve diversity equality.

**Key Words:** Sports medicine fellowship; Medical education; Orthopaedic surgery; Orthopaedic fellowship; Orthopaedic leadership



**Core Tip:** This retrospective study provides an overview of current fellowship directors (FDs) within sports medicine in the United States. Currently, orthopaedics has lower percentages of females and minorities in leadership roles than many other specialties. Gender and racial diversity of these specialties should be a continued focus for improvement. Overall, the trends identified in this study serve as objective data on current FDs within sports medicine. These trends could function as a guide for individuals who strive to become academic leaders in sports medicine orthopaedics as well as direct initiatives to achieve diversity equality.

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## INTRODUCTION

In medicine, those in leadership roles share certain characteristics that are gained from their formal training and mentors. Specifically, the fellowship director (FD) is one that will be a significant influence on many aspiring leaders. Potential factors that help physicians reach leadership positions are the ability to influence peers, develop research and educate the next generation of physicians. Through academic training, societal and community involvement, and clinical experience, such individuals decisively develop a set of leadership skills. However, the objective standards that serve as a foundation for these leaders, and sets them apart from others, remains unclear. Furthermore, it seems that developing orthopaedic surgeons pursuing these leadership positions lack objective directions on how to achieve them.

Within orthopaedics, sports medicine FDs oversee decisions that have an effect on current and future trainees. An assessment of the shared attributes associated with these individuals that achieve professional accomplishment to this extent needs to be developed. This review evaluated objective information on the traits and attributes of these leaders. Particularly, this review identifies and examines the demographics, academic experience, and institutional training backgrounds of current sports medicine FDs in the United States. Overall, this study may serve as a guide for aspiring leaders on how to achieve leadership positions in orthopaedic sports medicine and identify opportunities to improve the FD position, specifically with regards to diversifying leaders' racial, gender, training, and research backgrounds.

## MATERIALS AND METHODS

### *Data collection*

The American Orthopaedic Society for Sports Medicine (AOSSM) and the Arthroscopy Association of North America Sports Medicine Fellowship Directories for 2019-2020 were queried in order to locate all sports medicine orthopaedic surgery fellowships in the United States. For each program, all listed FDs were included. The demographic and educational background data for each FD was gathered *via* author review of current curriculum vitae (CVs). Any information that was unavailable on CV review was gathered from institutional biographies, Scopus Web of Science, and emailed questionnaires sent to fellowship administrators. To ensure the collection of as many data points as possible, fellowship program coordinators, orthopaedic department offices and FD were directly contacted *via* phone if there was no response *via* email. The demographic information of interest included: Age, gender, race/ethnicity, former residency and fellowship training location, the year of residency and fellowship graduation, year hired by current institution, time since residency and fellowship completion until FD appointment, length in FD role, each individual's H-index and status as a team physician at either the professional or collegiate level. Team physician roles included in the study were 'team physician', 'head team physician' or 'assistant team physician'.

To obtain the individual H-index for each FD, the Scopus database (Elsevier BV, Waltham, MA, United States) was queried to access their research specific information. This database has a search engine feature that operates through an extensive repository of peer-reviewed scientific literature with a citation tracking component. Scopus was employed to retrieve the H-index for every FD in the study.

Pearson correlation coefficients were determined *via* Statistical Analytics System (9.4) software. Data was interpreted according to Mukaka's guide for correlation coefficients[1]. Values under 0.3, 0.3 to 0.5, 0.5 to 0.7, 0.7 to 0.9 and greater than 0.90 are indicative of negligible, low, moderate, high, and very high positive correlation respectively.

## RESULTS

Of 82 FDs were included in this study. The demographic information includes age, gender, race/ethnicity, and mean Scopus H-index. This information is summarized in Table 1.

Table 2 presents a detailed overview of educational, employment, and leadership progression of sports medicine FDs, including mean calendar years for completion of residency and fellowship training, mean duration from fellowship graduation until FD appointment, mean duration of employment for a FD at his/her current institution,

**Table 1 Demographics of sports medicine fellowship directors**

| Demographics | |
|---|---|
| Male | 80 (97.5%) |
| Female | 2 (2.5%) |
| Race/ethnicity | |
| Caucasian | 84.15% ($n$ = 69) |
| Asian-Americans | 7.32% ($n$ = 6) |
| Hispanic/Latinos | 2.44% ($n$ = 2) |
| African American | 2.44% ($n$ = 2) |
| Other | 3.66% ($n$ = 3) |
| Mean age, yr | 56 ± 9.00 ($n$ = 76) |
| Mean FD Scopus H-index | 23.49 ± 16.57 ($n$ = 81) |

FD: Fellowship director.

**Table 2 Education, employment, and leadership progression of sports medicine fellowship directors**

| Education and employment progression | mean ± SD |
|---|---|
| Mean calendar year of residency graduation | 1996 ± 15.00 ($n$ = 73) |
| Mean calendar year of fellowship graduation | 1997 ± 9.51 ($n$ = 73) |
| Mean duration from fellowship graduation to earning position of FD | 9.77 yr ± 7.33 ($n$ = 57) |
| Mean duration of employment at current institution | 18.20 yr ± 9.12 ($n$ = 65) |
| Mean duration that FD has held position as FD | 13.14 yr ± 9.54 ($n$ = 59) |
| Mean time from year of hire by current institution to year promoted to FD | 4.72 yr ± 7.93 ($n$ = 64) |
| **Institutional loyalty** | ***n* (%)** |
| FDs currently working at same institution as Residency training | 14 (17.07) |
| FDs currently working at same institution as Fellowship training | 18 (21.95) |
| FDs currently working at same institution as both Residency and Fellowship training | 5 (6.10) |
| **Correlation of research productivity** | ***r* (*P* value)** |
| Years as FD *vs* Scopus H-index | 0.29 (0.02) |
| Age *vs* Scopus H-index | 0.38 (0.001)[1] |

[1]Correlation is significant. FD: Fellowship director.

mean duration that an FD has held his/her current position, and the average time from initial hire until FD appointment. Table 2 also details the percentages of FDs who, at the time of the study, were working at the same institution where he/she completed their residency training, fellowship training, or both residency and fellowship training. Correlation of research productivity, which was measured in the form of Scopus H-indices, is included in Table 2.

Table 3 demonstrates FD team physician status. Furthermore, team physician status is categorized into professional and collegiate team physicians, as well as sport specific involvement.

Figures 1 and 2 represent the most attended orthopaedic surgery residency and fellowship training programs, respectively. Figure 1 includes the orthopaedic surgery residency programs which trained at least 3 current FDs. Figure 2 includes the orthopaedic surgery fellowship programs which trained at least 4 current. Notably, 8 FDs (9.8%) completed two fellowships and 3 FDs (3.7%) finished three fellowships. Three FDs (3.7%) did not complete any formal orthopaedic surgery fellowship training.

**Table 3 Additional team physician roles of sports medicine fellowship directors, *n* (%)**

| Team physician roles | |
|---|---|
| **Fellowship directors' team physician status** | ***n* = 82** |
| Yes | 57 (69.51) |
| No | 25 (30.49) |
| **Professional *vs* collegiate** | ***n* = 57** |
| Professional | 32 (56.14) |
| Collegiate | 17 (29.82) |
| Both | 8 (14.04) |
| **Sport** | ***n* = 103** |
| University-wide Athletics | 26 (25.24) |
| Professional other | 23 (22.33) |
| Professional baseball | 20 (19.41) |
| Professional football | 16 (15.53) |
| Professional hockey | 8 (7.77) |
| Professional basketball | 7 (6.80) |
| Professional soccer | 3 (2.91) |

FD: Fellowship director.

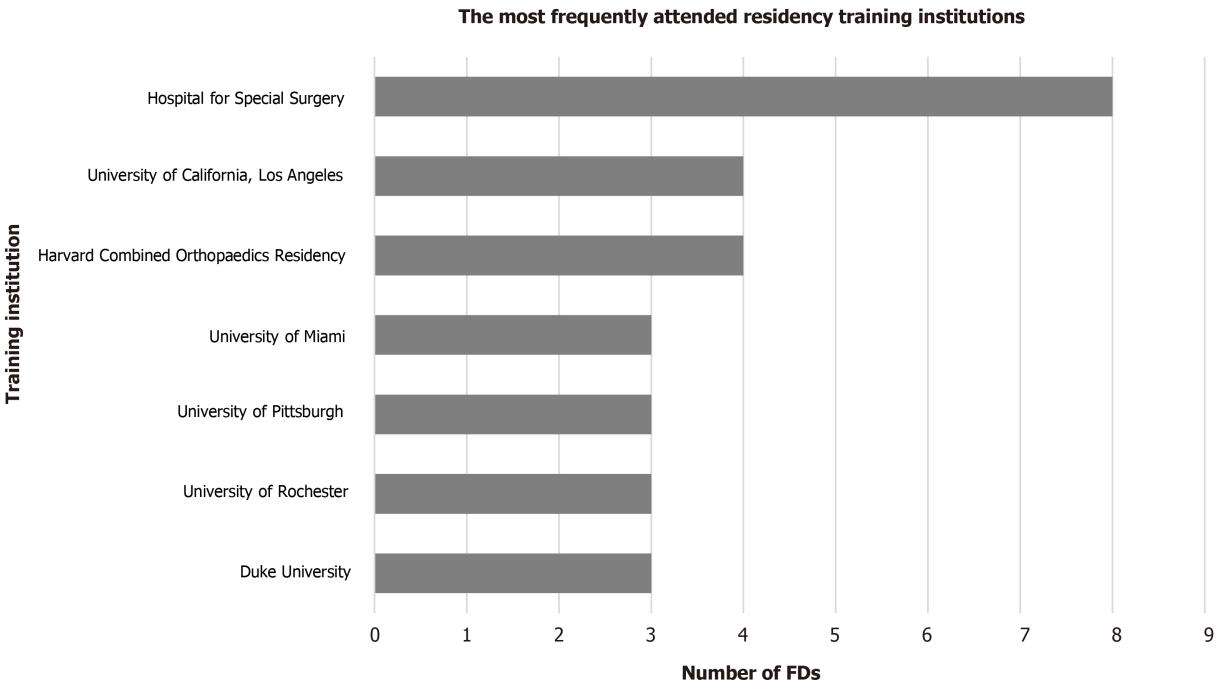


**Figure 1 A summary of the most attended residency training programs among current sports medicine fellowship directors.** Note: Residency programs at which at least 3 fellowship directors trained were included. FD: Fellowship director.

Figure 3 illustrates the distribution the Scopus H-indices for FDs in the form of ranges. In terms of Scopus H-indices, the ten most impactful sports medicine FDs in research had a Scopus H-index values between 43 and 79. (data retrieved December 1, 2019).

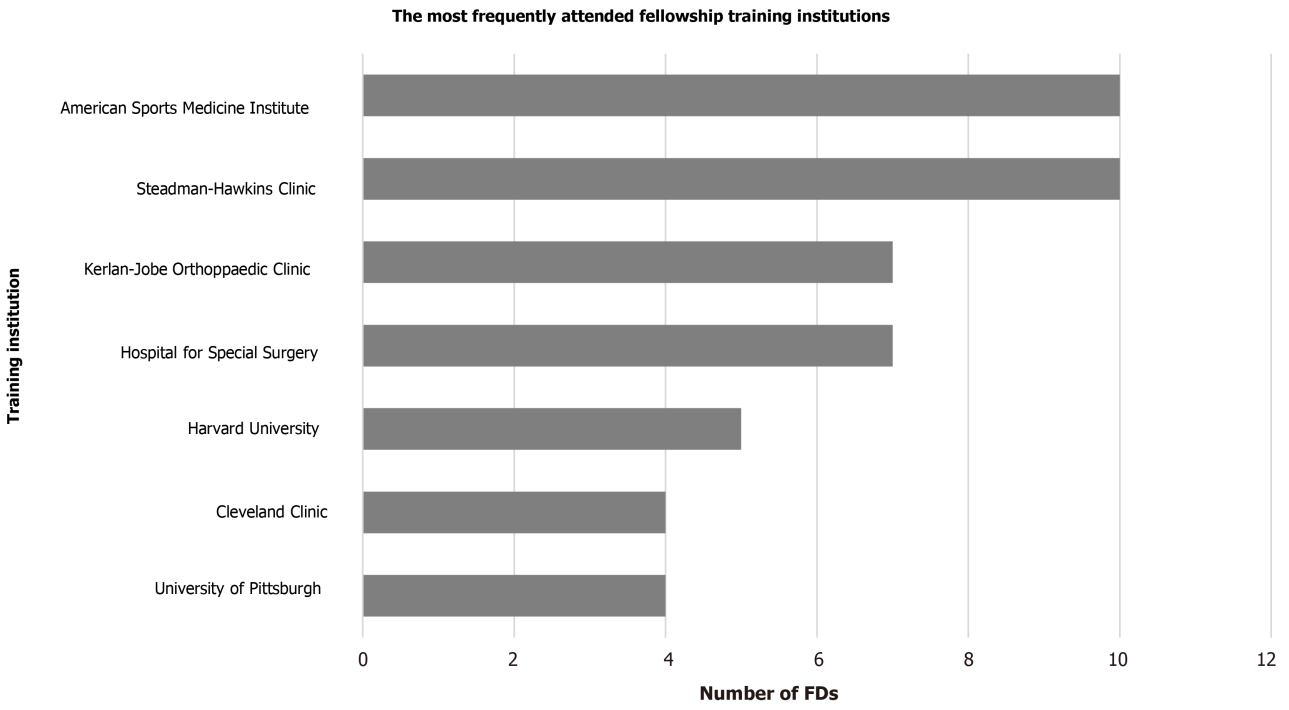


**Figure 2 A summary of the most attended fellowship training programs among Current sports medicine fellowship directors.** Note: Fellowship programs at which at least 4 fellowship directors trained were included. FD: Fellowship director.

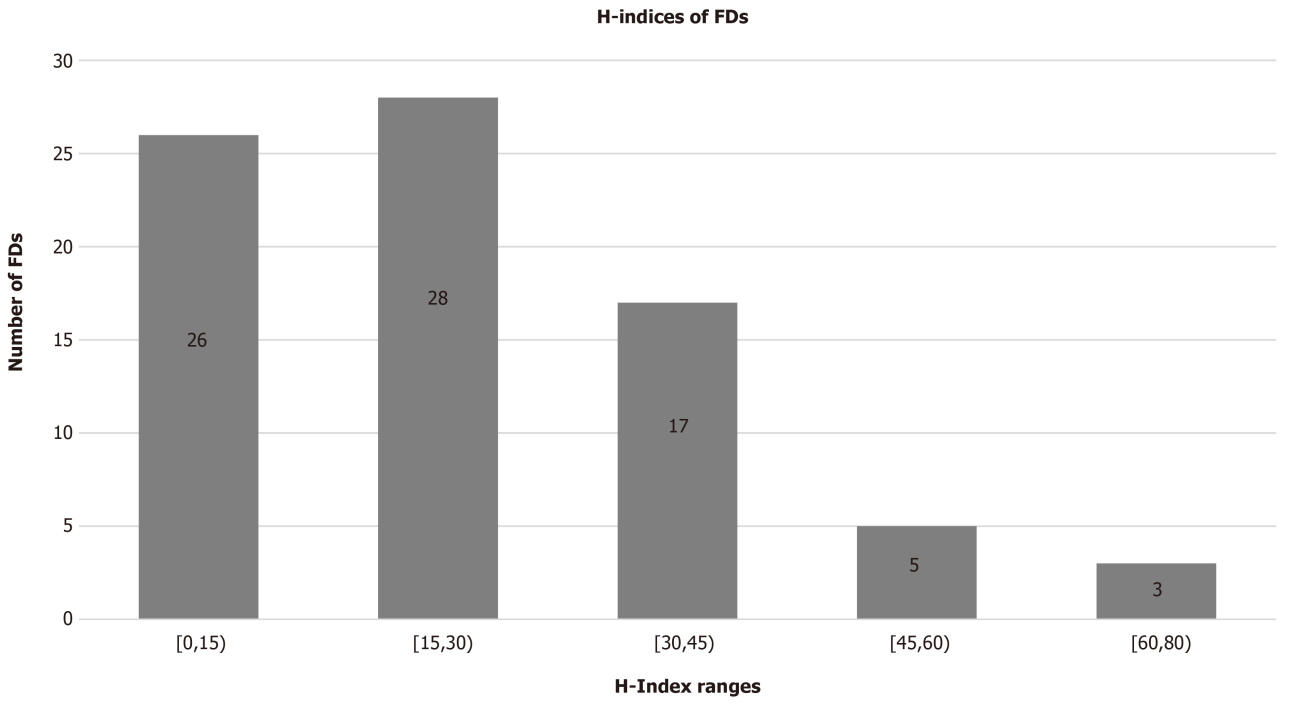


**Figure 3 A representation of the Scopus H-indices of all sports medicine fellowship directors.** Note: The Scopus H-index values are as of December 1, 2019. Interval notation is used. "[": Indicates that the range includes the adjacent numerical value; "(": Indicates that the range does not include the adjacent numerical value. FD: Fellowship director.

## DISCUSSION

Currently, literature documenting the necessary training and skill development of physician leaders in other surgical specialties is limited[2-5]. One study in the field of general surgery, discussed the relationship between past residents' rank lists to future academic career path[6]. Plastic surgery is another subspecialized field that has also evaluated leadership roles and trends in characteristics[7,8]. Previous studies in

orthopaedics have considered the pertinent motivating factors impacting the applicant selection process of residency and FDs, as well as the selection process of medical students and residents when considering orthopaedic surgery as a specialty[9-15]. In discussions on appropriate or discrepant representation of gender and cultural diversity, the leadership within orthopaedics has come into focus[16-19]. Two other studies have described demographic characteristics for spine fellowship leaders and adult reconstruction FDs which similarly noted FDs are more likely to have graduated from certain residency and fellowship programs[7,20]. As in this sports medicine cohort, the spine and adult reconstruction cohorts might attract applicants with a predilection to later seek academic leadership roles post-training[7,19,20].

Academic careers within medicine are founded upon clinical service, teaching, and research. Involvement and, naturally, productivity in research is a significant metric among those who achieve academic leadership positions. One study, by Cvetanovich *et al*[21] concluded that a higher cumulative h index correlated with higher academic rank among AOSSM sports medicine fellowship faculty[21]. Our analysis reveals a mean Scopus H-index of 23.49 (± 16.57) for sports medicine FDs which is considered high. Paralleled to these findings in research productivity, our results indicated that clinical experience is a crucial factor to sports medicine leadership appointment as the mean duration from fellowship graduation to FD appointment was 9.77 years (± 7.33 years). This data is similar to the results in the other orthopaedics FD demographic studies. Spine FDs' mean duration from fellowship graduation to FD appointment was 8.59 years, while, adult reconstruction FD's had a mean duration 9.55 years[7,20]. The average age of sports medicine FDs was 56 years-old. Compared to an average age 52.85 years and 52.60 years for spine and adult reconstruction FDs, respectively[7,20].

Based on our data, a select group of residency and fellowship training programs have a predilection for producing future sports medicine FDs. The residency program most commonly attended by current sports medicine FDs produced 8 current directors, while six other residency programs produced between 3 and 4 current FDs each. Interestingly, 8 FDs (9.75%) graduated from two fellowships and 3 FDs (3.66%) graduated from three fellowships. Unusually, 3 FDs (3.66%) did not undergo any post-residency training most likely because they completed their training before the 1990s.

In our study, we noted that 91.5% ($n$ = 76) of FDs were AOSSM members. While subspeciality society membership is not a requirement to be in an academic leadership role, the benefits of such societies can give orthopaedic surgeons more access to collaborative research, networking opportunities, team physician skills as well as committee leadership positions. These early leadership roles can develop the necessary skillset required to transition into a FD role later in one's career. AOSSM is a society with a mission to foster the development and growth of all those affiliated in the care of athletes, and through this affords an aspiring FD access to the annual meeting, scholarships, faculty resources, online education and recertification aid. These many facets of the society all likely contribute to the growth of these surgeons into academic leaders. Specifically, words from the presidential address at 43$^{rd}$ annual AOSSM meeting highlight these concepts well "AOSSM inspires all of us to participate in the organization, strive for excellence in the care of our patients, produce outstanding research, and share knowledge and educate ourselves."[22]

Among fellowship programs attended, two programs each produced 10 current sports medicine FDs, while the next five programs produced between 4 and 7 FDs each. Overall, the top seven fellowship programs produced 57.32% ($n$ = 47) of all the current sports medicine FDs. Interestingly, there was significant overlap in the training sites for both the sports and spine leadership training and show some overlap between sports and adult reconstruction[7,20]. This may indicate that attending specific fellowship training programs may correlate with future academic leadership possibilities. These programs potentially offer specific training curricula that foster the development of vital skills that translate well into leadership roles, perhaps through mentor style training between residents of different training levels and attendings alike. It is also likely that these institutions provide increased access to scholarly activity and have more research staff. This is supported by a study that included all faculty at United States adult reconstruction fellowship programs that indicated that most of the literature in adult reconstruction is generated from a small subset of academic institutions[23]. Thus, orthopaedic surgeons in-training interested in pursuing academic leadership positions may be more incentivized to select programs that promote orthopaedic surgery research. Program reputation and professional networks might serve as additional factors that could potentially play a role in the association of these specific programs with current FDs. These are just some possible explanations for our findings, however this is likely multifactorial. Nonetheless, our analysis supports the correlation that attending and graduating from specific training

programs has a predilection to produce future program directors.

Of the major professional sports in America, sports FDs most commonly served as team physicians in baseball, then football, followed by hockey, basketball and soccer. It was also more likely that FDs also served as team physicians for university-wide athletics and provide care for all affiliated sports teams. This is likely due to the collaborative care philosophy amongst the various team physicians part of an academic institution or because part of being the FD for an academic institution includes the responsibilities of treating all types of athletes in all types of sports.

While literature exists regarding the legality, responsibilities, ethics and financial aspects of being a team physician, currently, there is no literature describing how an orthopaedic surgeon becomes a team physician and if leadership within the field tends to influence team physician status[24-28]. Our results showed that 69.51% ($n$ = 57) of current sports medicine FDs also served as team physicians at the professional or collegiate level or both. It is possible that the percentage of FDs as team physicians is likely not the same as non-FD sports medicine surgeons. While having a leadership position, such as FD, potentially opens more opportunities for sports medicine physicians, it may also give them increased options to be involved as a team physician. This may be due to the similar leadership skills that are required as a FD and team physician. Alternatively, it may be that athletic teams, particularly at the more elite levels, desire to have surgeons with leadership roles caring for their organizations. Aspiring sports medicine physicians, therefore, may find that being a FD might possibly enhance their chances of becoming a team physician or vice versa. Therefore, a better understanding of these objective leadership qualities may enhance the likelihood of a sports medicine surgeon achieving either/both of those roles.

Our study indicates that there is a significant gender disparity in the FD role, as females were notably under-represented at only 2.5% ($n$ = 2) of all the current sports medicine FDs. This is actually a better representation that what was observed among adult reconstruction FDs, where no females were in an FD position at the time of the study[20]. As the healthcare profession advances, there has been a focus on the importance of overall diversity. Specifically, gender diversity has been addressed in several healthcare specialties with a broad range of findings[17,29]. Currently, orthopaedic surgery has one of the poorest ratios of female to male residents as compared to other specialties in medicine[17,29]. Although the total amount of orthopaedic surgery female residents has increased over the past 10 years, the corresponding percentage change is not as significant as other historically male-dominated specialties[29]. Moreover, certain orthopaedic subspecialties, such as sports medicine, continue to have decreased female involvement[29]. This may represent the inappropriate but historically prevalent perspective of the physicality of orthopaedics and sports medicine specifically. In addition, because of historical restrictions on females in male locker rooms, particularly at the most elite levels, gender inequality has existed in the team physician role. Most recently, the current leadership of the American Academy of Orthopaedic Surgeons, and more specifically the AOSSM, have identified this issue and have focused on achieving gender equality. This is evidenced by the recent female presidents of both of these organizations, the establishment of Diversity Committees within each societies' infrastructure and the creation of educational programs in their regional, national and international meetings focused on diversity equality. In a study by Ence *et al*[30] it was specifically reported that a lower median H-index was observed when comparing female orthopaedic surgeons to their male colleagues[30]. And yet, most certainly some of the most impactful and important research is created by female investigators. This could be a critical issue as our study shows research productivity is a key feature to achieving leadership roles. Furthermore, the previous gender barriers in the team physician role are being removed as all types and levels of sports teams have enlisted females as team physicians [31]. As gender disparity continues to be addressed in medicine, and more specifically orthopaedics, this study could be used to support those initiatives that seek to enlist female members, to provide female access to both mentorship and research, and to encourage female participation in all leadership roles.

Our study also considered racial and ethnic diversity, demonstrating that sports medicine leadership at the FD level also lacks underrepresented minorities. Among the sports medicine FDs in the study, only 7.32% ($n$ = 6) were Asian-Americans, 2.44% ($n$ = 2) were Hispanic/Latino, 2.44% ($n$ = 2) were African American and 3.66% ($n$ = 3) were of another race or ethnicity. One study from 1999[32] and another from 2004[33], reviewed the disparities in underrepresented minorities within the field of orthopaedics, and may have played a part in progressive changes that followed. Okike *et al*[34] described that total minority representation in orthopaedic surgery averaged 20.2% from the years 2001 to 2008, this included 11.7% Asians or Asian-Americans,

4.0% African Americans, and 3.8% Hispanics. Upon reviewing their data, the authors believed that this was an improvement compared to years prior with regards to representation of minorities among orthopaedic residents[34]. Adelani *et al*[35] subsequently illustrated a regression in minority representation. The number of programs *per* year with more than one underrepresented minority resident fell from 61 programs in 2002 to 53 programs in 2016 and reached as low as 31 programs in 2010. Likewise, the number of programs *per* year without a single underrepresented minority resident rose from 40 programs in 2002 to 60 programs in 2016 and reached 76 programs in 2011. In the end, the study called for a more detailed evaluation of program-level diversity and its impact on the recruitment of underrepresented minorities to orthopaedic surgery[35]. Our data identified a similar trend to those previously reported. As the orthopaedic community continues to adapt, a focus on diversity will remain pivotal to the advancement of any healthcare system that desires to appropriately represent the population it serves. Focusing on increasing the number of underrepresented minorities in leadership positions may be one way to begin to address these disparities.

This study does have several limitations. One limitation was the use of CV for data collection. Given that CV's are usually self-reported, there is an inherent potential bias with the possibility of reporting errors including duplication of events, failure to list appropriate research or leadership activities, and outdated information. Furthermore, this cross-sectional study design only provides information on sports FDs at a single point in time. Future studies may opt to complete a year-by-year comparison to understand the changes in the leadership over time. Lastly, a subset of sports medicine trained orthopaedic surgeons may have selected specific programs with academic career aspirations in mind with the understanding that certain training institutions tend to produce future FDs and leaders.

## CONCLUSION

This study provides an assessment of current FDs within sports medicine in the United States. Currently, the field of orthopaedics has lower percentages of females and minorities in leadership roles. Gender and racial diversity of these specialties should be a continued focus. Overall, the trends identified in this study serve as objective data on current FDs within sports medicine. These trends could function as a guide for individuals who strive to become academic leaders in sports medicine orthopaedics as well as direct initiatives to achieve diversity equality.

## ARTICLE HIGHLIGHTS

### *Research background*

Fellowship directors (FDs) in sports medicine influence the future of trainees in the field of orthopaedics. Understanding the characteristics these leaders share must be brought into focus. Currently, there is little research regarding the demographic landscape of these leaders.

### *Research motivation*

The current literature highlighted a lack of research specifically using objective data analyze sports medicine FDs. By adding to this gap in the literature, this study may promote future research towards understanding further the requirements and qualifications needed to hold a leadership position in orthopedic surgery.

### *Research objectives*

This study aimed to analyze the demographic background, institutional training, and academic experience for all current sports medicine FDs.

### *Research methods*

A national orthopedic surgery sports medicine fellowship program directory was used to incorporate all United States fellowships and their respective FDs. Demographic information of interest included: Age, gender, ethnicity, residency/fellowship training, residency/fellowship graduation year, year hired by current institution, time since training completion until FD appointment, length in FD role, status as a team

physician and H-index. This information was collected *via* online resources, emailed questionnaires, phone call and current curriculum vitae. Data was then complied and reviewed to evaluate for trends among sports medicine FDs. This is a novel research method for analyzing the current cohort of sports medicine FDs.

### Research results

Of 82 FDs were incorporated into the study, 97.5% of which were male. 84.15% identified as Caucasian, 7.32% as Asian-American, 2.44% as African American, and 2.44% as Hispanic, and 3.66% were of another race or ethnicity. The mean age of current FDs was 56 years old, and the mean Scopus H-index was 23.49. 45.12% completed their residency training, fellowship training or both at the same institution where they currently work. Additionally, 69.5% are also team physicians at the professional and/or collegiate level. Seven residency programs least three future FDs. While seven fellowship programs produced at least four future FDs. 9.75% of FDs completed two fellowships and 3.66% of FDs completed three fellowships. 3.66% of FDs did not graduate from any fellowship training program.

### Research conclusions

This study provides an overview of current sports medicine FDs within the United States and functions as a guide to direct initiatives to achieve diversity equality. This study may be referenced to help dictate efforts to address disparities in gender and racial equality in orthopedic surgery.

### Research perspectives

The direction of future research should focus on the progression of leaders in orthopedic surgery, evaluating the changes in demographic and academic backgrounds of leaders in subsequent years. Applying this methodology longitudinally may prove paramount in reaching the goals the field of orthopedic surgery aims to achieve.

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ORIGINAL ARTICLE

Prospective Study

# Has platelet-rich plasma any role in partial tears of the anterior cruciate ligament? Prospective comparative study

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## Abstract

### *BACKGROUND*

Partial tears of the anterior cruciate ligament (ACL) are frequent, and there is still considerable controversy surrounding their diagnosis, natural history and treatment.

### *AIM*

To examine patient-reported outcomes, physical examination and magnetic resonance imaging (MRI) findings of partial ACL tears treated with an intraarticular injection of platelet-rich plasma (PRP) compared to a control group.

### *METHODS*

From January 2015 to November 2017, consecutive patients from a single institution with partial ACL tears treated nonoperatively were prospectively evaluated. Partial tears were defined as a positive Lachman test with a clear endpoint, a negative pivot-shift and less than 3 mm of side-to-side difference using the KT1000 arthrometer. Patients in group 1 were treated with one intraarticular injection of PRP and specific physical therapy protocol. Control group consisted of patients treated only with physical therapy. Prospective analyzed data included physical examination, Tegner activity level and Lysholm and International Knee Documentation Committee scores. Baseline MRI findings and at 6 mo follow-up were reviewed. Failure was defined as those patients with clinical instability at follow-up that required a subsequent ACL reconstruction.

### *RESULTS*

A total of 40 patients where included, 21 treated with PRP injection with a mean follow-up of 25 mo [standard deviation (SD): 3.6] and 19 in the control group with a mean follow-up of 25 mo (SD: 5.68). Overall failure rate was 32.0% ($n$ = 13). No significant differences were observed between groups regarding subjective outcomes, return to sport and failure rate. MRI findings revealed an improvement in the ACL signal in half of the patients of both groups. However, we did not find

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a significant relationship between MRI findings and clinical outcomes.

*CONCLUSION*

Overall, 95.0% of patients returned to sports at a mean follow-up of 25 mo. Mean time to return to sports was 4 mo. Out of these patients, almost 30.0% in each group had a new episode of instability and required surgery at a median time of 5 mo in group 1 and 8 mo in group 2. The addition of PRP alone was not sufficient to enhance any of the outcome measures evaluated, including MRI images, clinical evaluation and failure rate.

**Key Words:** Anterior cruciate ligament; Partial tears; Platelet-rich plasma; Non-operative treatment



**Core Tip:** This was a prospective comparative study with 40 patients seeking to evaluate the effect of platelet-rich plasma on partial tears of the anterior cruciate ligament. Prospective analyzed data included physical examination, Tegner activity level and Lysholm and International Knee Documentation Committee scores. Baseline magnetic resonance imaging findings and at 6 mo follow-up were also reviewed.

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## INTRODUCTION

Partial tears account for 10% to 30% of all anterior cruciate ligament (ACL) tears[1,2]. There is still considerable controversy surrounding the diagnosis, natural history and treatment of this type of lesion[3,4]. Diverse criteria are often used to define a partial ACL tear. Magnetic resonance imaging (MRI) features include the estimation of the percentage of torn fibers, specific affected bundle (anteromedial or posterolateral) and location of the tear (proximal, middle third or distal). The physical examination is decisive in this type of lesion[1]. Finally, arthroscopy remains the gold standard for the diagnosis of macroscopic integrity of the intact bundle. Intraoperative findings of intact remnant ACL fibers from femur to tibia insertion points confirm the diagnosis[5-7].

Regarding natural history, complete ACL tears have low intrinsic healing capacity, which prevent restoring anatomy and function. However, there has been some disagreement concerning whether partial ACL tears could heal. Though favorable results have been reported with either nonoperative or surgical treatment (such as repair or augmentation) as well as with biological approaches, some authors reported progression to complete deficiency of the ACL and symptomatic knee laxity with conservative treatment[4,7-10].

Platelet-rich plasma (PRP) has received much attention in the last years as a biologic alternative for the treatment of sports-related injuries. Various growth factors and bioactive proteins from the a-granules contained in platelets can potentially enhance tissue healing[11-14]. PRP utilization in ligament injuries has grown remarkably[15-17]. Regarding specifically to ACL injuries, the focus has been mostly on biologic augmentation to improve graft healing after a reconstruction, and only a few studies aimed to improve healing of the native injured ACL[18-22].

The purpose of this study was to examine patient-reported outcomes, physical examination and MRI findings of partial ACL tears treated with an intraarticular injection of PRP compared to a control group.

## MATERIALS AND METHODS

### Patient population

Following Institutional Review Board approval, all patients who were diagnosed with a partial ACL tear and treated nonoperatively between January 2015 and November 2017 were retrospectively selected from a database of prospectively collected data. Figure 1 shows the algorithm used for the diagnosis and treatment of partial ACL tears. It consists of an adaptation of a previously published algorithm by Sonnery-Cottet *et al*[1]. We included patients with a positive Lachman's test with a firm endpoint, negative pivot shift, a side-to-side differential laxity less than 3 mm measured by arthrometer (KT-1000 knee arthrometer, MEDmetric Corp.) and MRI signs of partial ACL tear. Patients with a differential laxity between 3 and 5 mm without meniscal lesions and/or participation in high-risk sports were also included.

The exclusion criteria were as follows: patients younger than 18-years-old, patients with less than 6 mo follow-up, patients diagnosed after 1 mo of injury, previous ipsilateral ACL tear or reconstruction, confirmed or suspected contralateral ACL injury, diagnosis of concomitant ipsilateral posterior cruciate ligament, posterolateral corner or grade 3 medial collateral ligament injury and arthritis (International Knee Documentation Committee C or higher).

Nonoperative treatment consisted of one intra-articular injection of leukocyte reduced PRP during the first 4 wk after injury (within the inflammatory phase) and specific physical therapy protocol (group 1). However, not all patients were able to receive the PRP injection, mostly because medical insurance coverage or refusal from the patient to do so. These patients were considered the control group (group 2).

### Data collection and definitions

All medical care interventions are centrally registered in a computerized data repository, with only one electronic health record per person. After initial consultation and treatment, patients underwent clinical follow-up at 1, 3, 6 and 12 mo by the same observer. Variables analyzed included patient gender, age, Tegner activity Score both at time of injury and at time of final follow-up, return to sports (RTS) rate, time to RTS and subsequent surgeries. Subjective assessment included Lysholm and International Knee Documentation Committee scores.

Objective stability was tested at the time of injury and at 6 mo follow-up with a knee arthrometer test (KT-1000 knee arthrometer, MEDmetric Corp.), and the manual maximum difference between knees (in mm) was used for analysis of reported mean side-to-side differences. All patients were evaluated by a single orthopedic observer (JPZ-staff member/knee surgeon).

Baseline MRI findings and at 6 mo follow-up were reviewed. Images were analyzed according to a classification published by van Meer *et al*[23]. Nine features are used to assess the ACL on MRI: fiber continuity, signal intensity, slope of ACL with respect to the Blumensaat line, distance between the Blumensaat line and ACL, tension, thickness, clear boundaries, assessment of original insertions and assessment of intercondylar notch. A total score is determined by summing scores for these 9 features. A score of 10 is maximally abnormal for all features, whereas a score of 0 is normal for all features. Lesion localization was also determined (proximal, middle third and distal). All images were evaluated by a single orthopedic observer (JPZ) who was blinded to the treatment group.

Failure was defined as those patients with clinical instability at follow-up that required a subsequent ACL reconstruction.

### PRP preparation

On the basis of previously published reports on criteria that influence the composition or biological effect of PRP[24], we included the following information regarding PRP preparation. After harvesting 150 mL of blood, the extracted unit was doubled centrifuged in a Thermo Scientific Sorvall BP-16 Refrigerated Blood Bank Centrifuge. First, a light centrifugation for 4 min at 1400 rpm to separate the PRP from the globular mass was performed. The product obtained was separated into satellite bags without opening the circuit, guaranteeing the sterility of the process. Next, the PRP was centrifuged for 6 min at 3000 rpm to achieve a higher concentration of the product. At the end of the process, quality control was carried out on the product through an XT ROCHE hematological counter. It consists of volume, platelet count, white blood cell count and calculation of product concentration.

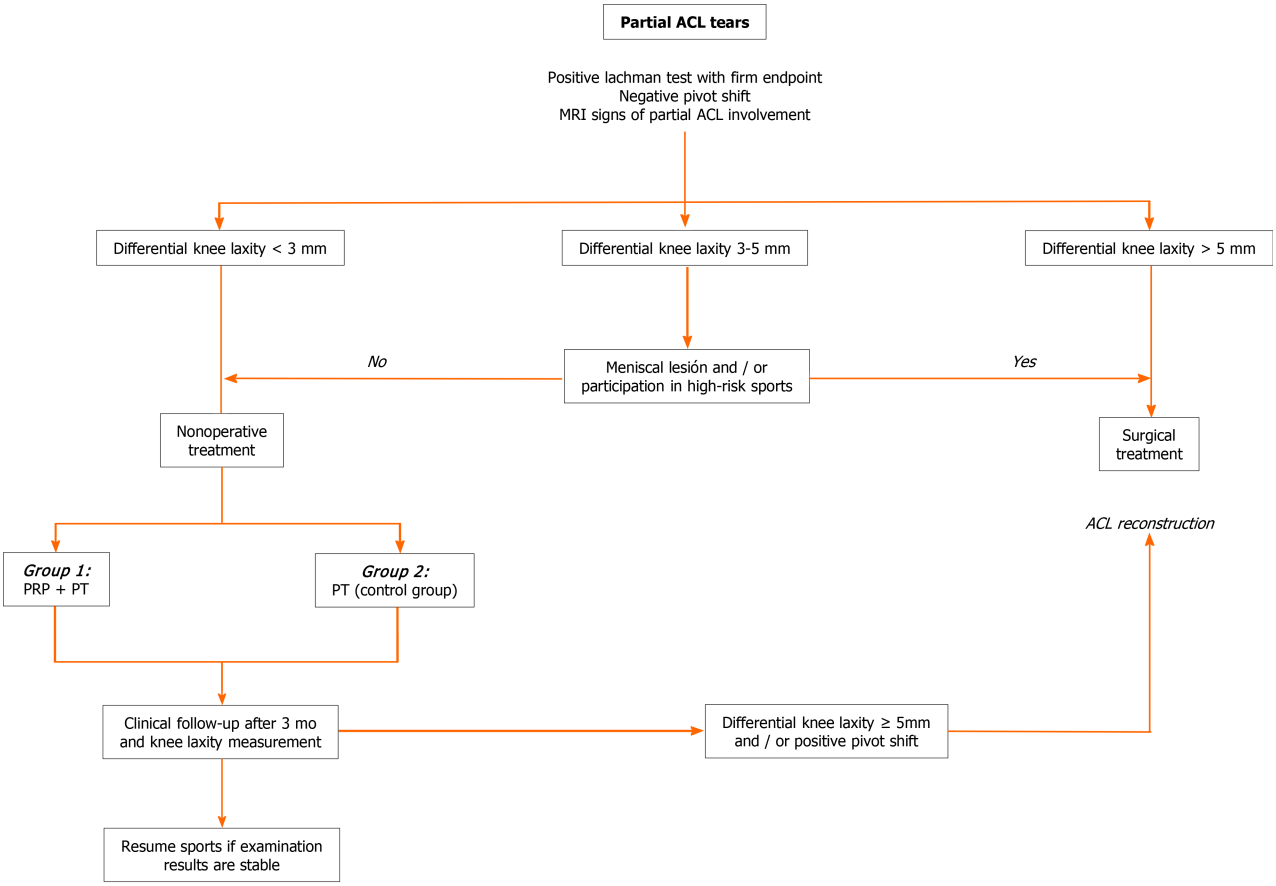


**Figure 1 Flow chart for partial anterior cruciate ligament tears.** Management algorithm used to select treatment for partial anterior cruciate ligament tears. ACL: Anterior cruciate ligament; MRI: Magnetic resonance imaging; PRP: Platelet-rich plasma; PT: Physical therapy.

### *Injection protocol*

Group 1 (PRP group) received a single intra-articular injection of PRP. A median of 8 mL (6-10) was injected. All injections were performed by one of the authors (Zicaro JP). Intra-articular injection aiming at the ACL was performed as a standard sterile procedure. A 25-gauge 3.0-inch needle was inserted through the skin in a similar localization as a medial portal, towards the ACL femoral insertion. No imaging was used as guidance. The median concentrations of platelets and white cells of the product are detailed in Table 1. After the procedure, full weight bearing, cryotherapy and daily life activities was allowed as tolerated. No post treatment bracing was administered. Physical therapy protocol began after 72 h of the injection.

### *Physical therapy protocol*

Even though not all patients performed the rehabilitation at the same center, both groups received the same rehabilitation protocol. The goals of the first 4 wk were to recover range of motion, prevent quadriceps inhibition and normalize proximal muscle strength. Nonimpact exercises such as bicycle or swimming were allowed during the first week. Linear impact and strengthening exercises began 6 wk after injection, with progression to multiplanar exercises between 8 to 10 wk. The goal was to return to their previous sport not before 3 to 4 mo after injection.

### *Statistical analyses*

Descriptive statistics including means, standard deviations (SDs), medians and quartile ranges were applied as appropriate to assess the available demographic, surgical, physical examination and patient-reported outcome data. Statistical hypothesis testing was performed using the Fisher exact test and Wilcoxon rank-sum test. Categorical data was performed using Chi square test. Analysis was performed with 95% confidence interval, and $P$ values < 0.05 were considered statistically significant. All statistical analyses were performed using STATA version 13.

**Table 1 Details of the baseline and platelet rich plasma platelets and white cells concentrations**

| | Initial platelet concentration | PRP | % |
|---|---|---|---|
| Platelets, median (IQR) | 264500 (247000-278000) | 1125500 (1088000-1340500) | 444 (407-519) |
| WC, median (IQR) | 5200 (4790-6480) | 600 (220-810) | 10 (3-15) |

IQR: Interquartile range; PRP: Platelet rich plasma; WC: White cells.

## RESULTS

A total of 40 patients where included. In total, 21 treated with PRP injection (group 1) with a mean follow-up of 25 mo (SD: 3.60) and 19 in the control group (group 2) with a mean follow-up of 25 mo (SD: 5.68). The overall median age was 26.0-years-old (IQR 22.5-35.0). Demographic data is shown in Table 2. The only statistically significant difference between groups was gender; no females were included in the control group ($P = 0.021$).

Results at final follow-up are shown in Table 3. One patient in each group (5.0%) was unable to RTS due to subjective instability. The other 95.0% in each group were able to return to their previous sports level. Overall mean RTS time was 4 mo (SD: 1.06), without significant differences between groups. We found no significant differences for subjective outcomes between groups.

Regarding objective stability, at 6 mo follow-up in group 1, 13 presented a decrease in the side-to-side difference, 7 remained with the same difference, and 1 had 2 mm more. In group 2, 9 had a decrease in the side-to-side difference, 9 remained with the same difference, and 1 had 1 mm more. None of the patients had a positive pivot shift at final follow-up.

According to van Meer *et al*[23], MRI classification for partial ACL tears at baseline for most patients were classified between 4 and 10 in both groups (Table 4). At 6 mo follow-up, more than 50.0% of patients in both groups where classified as 0 and 3, showing an improvement in the ACL MRI signal (Figure 2).

Overall failure rate was 32.0% ($n = 13$) with no significant differences between groups (Table 3). Five failures in group 1 where Tegner 7, one Tegner 8 and one Tegner 5. In group 2, four failures where Tegner 7 and two Tegner 6. We found no significant differences when analyzing the location of the lesion and failure in both groups. Two proximal (2/10) and five mid-substance (5/11) tears failed in group 1 ($P = 0.21$). Four proximal (4/12) and two mid-substance (2/7) tears failed in group 2 ($P = 0.83$).

## DISCUSSION

The present study evaluated the results of a series of patients with partial ACL tears treated nonoperatively. No significant differences were identified between patients treated or not with a single intraarticular injection of PRP. Overall, 32.0% failures were observed in both groups at a mean follow-up of 25 mo. The remaining 67.0% of patients were able to RTS in a mean of 4 mo.

A key factor in the treatment of partial ACL tears is a correct diagnosis. There has been some disagreement with regard to the definition of this lesion, and most of them are underdiagnosed. Some authors agree that physical examination cannot differentiate a partial ACL tear from an intact ACL[25,26]. On the other hand, MRI has a low level of accuracy for the diagnosis of partial ACL tears (25.0%-50.0%), mainly because of the significant overlap of the imaging findings between partial and complete tears, mucoid degeneration of the ACL and the initial post-traumatic hematoma[27]. Therefore, many surgeons rely on arthroscopy to define the extent of injury. A recently published study analyzed the correlation between preoperative clinical assessment and the arthroscopic examination in patients with ACL tears[26]. While evaluation under anesthesia demonstrated a high sensitivity for the detection of partial tears (100%), it was not necessarily specific (65.5%) and resulted in a high number of false positive partial tears. MRI, on the other hand, demonstrated a relatively high sensitivity (90.9%) and specificity (85.7%). The accuracy of MRI (86.3%) was also greater than that of evaluation under anesthesia (69.5%). These results suggested that MRI is 1.24 times more likely to result in correctly diagnosing a partial tear, which was a statistically significant finding.

**Table 2 Demographic data**

| | Group 1, *n* = 21 | Group 2, *n* = 19 | *P* value |
|---|---|---|---|
| Age in yr, median (IQR) | 25 (22-39) | 31 (26-34) | 0.54 |
| Male, *n* (%) | 15 (71.4) | 19 (100) | 0.02 |
| FU in mo, median (IQR) | 25 (18-36) | 25 (18-30) | 0.86 |
| MRI tear location: | | | |
| Proximal, *n* (%) | 10 (48) | 12 (63) | |
| Mid-substance, *n* (%) | 11 (52) | 7 (27) | |

FU: Follow-up; IQR: Inter quartile range; MRI: Magnetic resonance imaging; TAL: Tegner activity level.

**Table 3 Results at final follow-up**

| Baseline | Group 1, *n* = 21 | Group 2, *n* = 19 | *P* value |
|---|---|---|---|
| Lysholm score, median (IQR) | 69.5 (43.0-85.0) | 54.0 (41.0-77.0) | 0.41 |
| IKDC score, median (IQR) | 58.5 (44.0-60.0) | 58.0 (44.0-60.0) | 0.84 |
| TAL, mean ± SD | 6.90 ± 1.07 | 6.70 ± 1.18 | 0.65 |
| At final follow-up | | | |
| Lysholm score, median (IQR) | 80 (75-90) | 80 (73-86) | 0.53 |
| IKDC score, median (IQR) | 77 (71-89) | 71 (70-79) | 0.33 |
| TAL, mean ± SD | 6.70 ± 1.52 | 6.50 ± 1.61 | 0.7 |
| RTS rate, *n* (%) | 20 (95) | 18 (95) | 0.9 |
| Time to RTS in mo, mean ± SD | 3.8 ± 0.8 | 4.3 ± 1.2 | 0.09 |
| Failure rate, *n* (%) | 7 (33) | 6 (31) | 0.9 |

IKDC: International Knee Documentation Committee; IQR: inter quartile range; RTS: return to sports; SD: Standard deviation; TAL: Tegner activity level.

**Table 4 Magnetic resonance image Van Meer classification at baseline and at 6 mo**

| | MRI Van Meer classification | | |
|---|---|---|---|
| | Group 1 | Group 2 | *P* value |
| Baseline MRI, mean ± SD | 6.1 ± 1.7 | 6.2 ± 2.4 | 0.97 |
| MRI at 6 mo follow-up, mean ± SD | 3.4 ± 2.9 | 3.6 ± 2.5 | 0.82 |

MRI: Magnetic resonance image; SD: Standard deviation.

Regarding nonsurgical management of partial ACL tears, Pujol *et al*[8] performed a systematic review and analyzed 12 articles where diagnosis was confirmed on arthroscopy, without ACL surgery. A total of 436 patients were followed up over the period 1976-1997 with a mean follow-up of 5.2 years (range 1.0-15.0). They found good short- and mid-term functional results, especially when patients limited their sports activities. The mean rate of revision ACL was 8.1% (0%-21.0%). RTS rate was 52.0% (21.0%-60.0%), lower than our findings, with 95.0% of patients returning to the same level. Noyes *et al*[7] reported a 38.0% progression to a complete rupture in a prospective evaluation of 32 patients with a partial ACL tear. Lehnert *et al*[28] reviewed a series of 39 partial ACL tears 5 years after injury and found that 56.0% had progressed to ACL deficiency. Finally, Fritschy *et al*[9] reported a rate of 42.0% in 43 patients. and Fruensgaard *et al*[29] reported 51.0% in a series of 41 patients. Although these results may be comparable to our overall 32.0% failure, these findings are to be viewed in the light of the indications for ACL surgery in vogue 30 years ago. It is

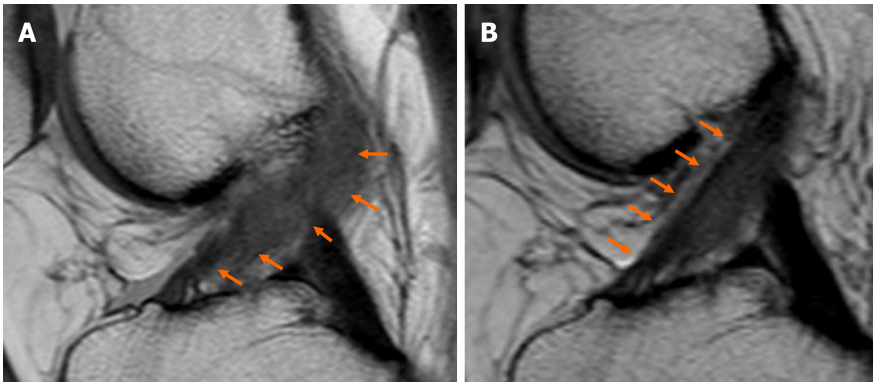


**Figure 2 Magnetic resonance images.** A: Baseline magnetic resonance imaging (MRI) showed widening of anterior cruciate ligament (ACL) fibers with continuity of fibers (orange arrows). Total score of 4 points according to Van Meer's classification; B: Six months after platelet-rich plasma injection, MRI showed an improvement in the signal intensity as well as tension of ACL fibers (orange arrows). Total score of 0 points according to Van Meer's classification (MRI sequence: sagittal proton density weighted turbo spin echo).

important to highlight that in some cases, side-to-side difference in KT-1000 arthrometric evaluation was greater, probably due to a lack of healing of ACL fibers, particularly cases when the anteromedial bundle was affected. Nevertheless, most of these patients were active in their sports practice.

The use of biologic agents, including growth factors, PRP, stem cells and biological scaffolds, has been the focus of current research in ACL repair and healing[3]. In a systematic review analyzing biologic agents for ACL healing, the large majority of articles (21 out of 23) were focused on their application during ACL reconstructive surgery, whereas only two trials, both case series, investigated their potential in partial ACL tears[19]. Centeno *et al*[30] published a prospective case series of 10 patients treated with percutaneous injection of autologous bone narrow nucleated cells, using fluoroscopic guidance. Patients were included if they had a grade 1, 2 or 3 ACL tear without greater than 1 cm retraction. Treatment protocol consisted of a preinjection of a hypertonic dextrose solution into the ACL followed by a reinjection of 2-3 mL of bone marrow cells, PRP and platelets 2-5 d after, using the same procedure. Seven of ten patients demonstrated improvement in MRI measures of ACL integrity at a mean follow-up of 3 mo. The lack of a control group and the multiple component of the protocol are the main shortcomings of their methods. On the other hand, Seijas *et al*[20] published a retrospective case series of 19 football players (Tegner 9-10) with a partial ACL tear treated with an arthroscopic intraligamentary application of PRP (leukocyte poor). All cases presented a complete rupture of the anteromedial bundle with an intact posterolateral bundle. RTS rate was 84%. Average RTS in 15 patients Tegner 9 was 16 wk and in 2 patients Tegner 10 was 12 wk. In our study, mean time to return to sport was 4 mo.

Regarding the use of MRI in partial ACL tears, we consider there is an important role in the diagnosis and follow-up. However, these results must not be considered in isolation. Although we thoroughly analyzed nine different imaging parameters, no significant correlation was found between laxity and MRI images. Neither association was identified between lesion localization and treatment failure. These findings might be due to the low number of patients.

The lack of standardization of PRP protocols has been published recently[24]. Chahla *et al*[24] analyzed 105 studies finding high inconsistences in the way PRP preparation was reported. The majority of studies did not provide sufficient information to allow the protocol to be reproduced, which also prevents comparison of the PRP products. Based on this review and following the proposed guidelines, we included in our study data regarding PRP preparation and composition of the PRP delivered.

It is plausible that a number of limitations may have influenced the results obtained. First, the sample size might be considered to be low. However, a sample size estimation was not possible due to the lack of studies published with the same treatment. Although a control group was established, this group was not randomized, which may raise the possibility of a selection bias. Another possible source of error related to the procedure. The injections were not guided by imaging, and patients underwent only one injection. Nevertheless, there is no standardization in terms of how much and how many PRP injections are required for better results.

## CONCLUSION

Our research provided further evidence about natural history of nonoperative management of partial ACL tears. Overall, 67% of patients with this type of lesion RTS in a mean of 4 mo without clinical instability either with or without an intra-articular PRP injection. The addition of PRP alone was not sufficient to enhance any of the outcome measures evaluated, including MRI images and clinical evaluation.

## ARTICLE HIGHLIGHTS

### *Research background*

Platelet-rich plasma (PRP) is being widely used in many orthopedic areas. The use of PRP has for "healing" purposes is still controversial in the field of partial ligamentous lesions.

### *Research motivation*

To our knowledge, there are no comparative series reported in the literature regarding the use of PRP for partial anterior cruciate ligament (ACL) tears.

### *Research objectives*

The aim was to prospectively compare the patient-reported outcomes, rerupture rate and magnetic resonance (MR) findings in patients with partial ACL tears treated with a single PRP intra-articular injection compared to a control group.

### *Research methods*

Patients who met the inclusion criteria for stable partial ACL tears were divided into two groups. One group received a single intra-articular leukocyte-poor PRP injection within the first 4 wk after the lesion. Both groups received the same rehabilitation protocol. Clinical objective outcomes (KT1000 arthrometric evaluation), subjective outcomes, time to return to sports, rerupture rate and MR findings were evaluated. PRP preparation data was detailed.

### *Research results*

Forty patients where included, 21 treated with PRP injection (group 1) (mean follow-up of 25 mo) and 19 in the control group (group 2) (mean follow-up of 25 mo). Overall, 95% of patients in each group returned to their previous sport at a mean time of 4 mo. After 6 mo follow-up, more than 50% of patients improved the ACL signal intensity in the MR. Overall failure rate was 32% ($n$ = 13) with no significant differences between groups.

### *Research conclusions*

A single PRP intra-articular injection was not sufficient to enhance any of the outcome measures evaluated, including MR images and clinical evaluation. Overall, 67% of patients returned to sports in a mean of 4 mo without clinical instability either with or without an intra-articular PRP injection.

### *Research perspectives*

Further rigorous and objective studies including more patients and different PRP preparations, such as less platelet concentrations or leukocyte-rich preparations, would be useful to determine the true efficacy of PRP for enhancing healing properties of partial ACL lesions.

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SYSTEMATIC REVIEWS

# Arthroereisis in juvenile flexible flatfoot: Which device should we implant? A systematic review of literature published in the last 5 years

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## Abstract

*BACKGROUND*

Flexible flatfoot (FFF) is a very common condition in children, characterized by the loss of the medial arch and by an increase in the support base with valgus of the hindfoot. Arthroereisis (AR) procedures are widely performed corrective surgeries and are classified as subtalar AR and calcaneo-stop (CS).

*AIM*

We investigated the literature published in the last 5 years with the aim of providing an update on the evidence related to AR treatment in FFF patients. We report the principal findings of subtalar AR and CS procedures concerning clinical and radiological outcomes and complication rates in the general population, young athletes, and obese people according to material device.

*METHODS*

Following the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses, a systematic review of studies published in the past 5 years and included the PubMed and Science Direct databases was performed on May 6, 2020. The research string used was (pediatric OR children OR Juvenile NOT adult) AND (flexible NOT rigid) AND (flat foot OR pes planus) AND (calcaneo-Stop OR arthroereisis OR subtalar extra-articular screw OR SESA OR subtalar arthroereisis OR endosinotarsal). The risk of bias assessment was performed using the Dutch checklist form for prognosis.

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**Country/Territory of origin:** Italy

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*RESULTS*

A total of 47 articles were found. Ultimately, after reading the full text and checking reference lists, we selected 17 articles that met the inclusion and exclusion criteria. A total of 1864 FFFs were identified. Eight studies concerned the subtalar AR (47.1%) and nine concerning CS (52.9%). The average age of patients at start of treatment was 11.8 years, the average follow-up of the studies was 71.9 mo (range 29.1-130). Globally, complications occurred in 153 of the 1864 FFF treated, with a rate of 8.2%.

*CONCLUSION*

Both AR procedures are valid surgical techniques for treating FFF. Surgeon experience, implant cost, and cosmetic correction are the most common considerations included in the orthopedic device decision-making process. In obese patients, the subtalar AR is not recommended. In adolescents who need to improve sports performance, the CS screw had better results compared with other implants.

**Key Words:** Pes planus; Arthroereisis; Treatment; Calcaneo-stop; Subtalar arthroereisis; Complication



**Core Tip:** Arthroereisis (AR) procedures are widely performed corrective surgeries for juvenile flexible flatfoot. The AR procedures include impact blocking devices and self-locking implants. Impact blocking devices include subtalar extra-articular calcaneo-stop (CS) screws that have a stem and a head and interfere with the talus. Self-locking implants (subtalar AR) are inserted in the sinus tarsi along its main axis. Surgeon experience, implant cost, and, cosmetic correction are the most common criteria included in the orthopedic decision-making process. Both AR procedures improved clinical and radiological parameters. Considering the complications, calcaneo-stop screws had a slightly better rate than subtalar AR.

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## INTRODUCTION

Flexible flatfoot (FFF) is a very common condition in children[1] characterized by loss of the medial arch and increases of both heel valgus and plantar pressure[1]. FFF is typically an asymptomatic condition, but pain may occur in the lower leg or medial level of the foot at the insertion point of the posterior tibial on the scaphoid, especially after intense exercise or long walks[2]. In some cases, early and easy fatigue can occur and are consider important symptoms[3]. Surgical treatment is indicated in symptomatic children over 8 years of age or not responsive to conservative treatment. Arthroereisis (AR) procedures are common corrective surgeries that are widely performed. AR was first introduced in 1946 by Chambers[4], who described the "abduction block," as a wedge-shaped bone block aimed to impact the anterior border of the posterior facet of the calcaneus and to limit excessive anterior displacement of the talus on the calcaneus and correct the deformity.

The first author to introduce the term "arthroereisis" was Lelièvre[5] in the early 70s to illustrate a temporary staple across the subtalar joint. In 1979, the Buruturan[6] impact blocking screw, which was inserted into the calcaneus using the sinus tarsi as the entry point, is the first description of a calcaneo-stop (CS) procedure. In 1992, Viladot[7] reported the success rate achieved by the first non-osseous sinus tarsi implant. The aim of implants is to correct the FFF deformity with preservation of foot function and limitation of excessive anterior displacement of the talus upon the

calcaneus[8]. Moreover, some authors[9,10] have hypothesized that CS could play a role in the activation of mechanoreceptors in the sinus tarsi, although it has not yet been supported by experimental evidence. Subtalar implants are classified by type as impact blocking devices, which include subtalar AR; and self-locking implants, which include CS screws[11]. Impact blocking devices have a stem that is fixed in the sinus tarsi vertically just anteriorly to the posterior subtalar surface and a head, that interferes with the talar lateral process, limiting its internal rotation. Self-locking implants are inserted in the sinus tarsi along its main axis, supporting the talar neck, avoiding contact between talar lateral process and sinus tarsi floor, and reducing talar adduction and plantar flexion.

The aim of the study was to review the literature of the last 5 years regarding the surgical treatment of juvenile FFF with a focus on the AR procedures and to report the principal subtalar AR and CS procedure findings concerning clinical and radiological outcomes and complication rate in general population, young athletes and obese population according to the device.

## MATERIALS AND METHODS

### Study design

A systematic review of studies published in the last 5 years. Clinical outcomes and radiological measurements, Athletes and Obese cohorts' outcomes, Complications, Materials of subtalar AR and CS were recorded.

### Search strategy

A systematic review of studies published in the last 5 years and indexed in PubMed and Science Direct was performed by an author (Vescio A) on May 6, 2020. The research string used was "(pediatric OR children OR Juvenile NOT adult) AND (flexible NOT rigid) AND (flat foot OR pes planus) AND (calcaneo-stop OR arthroereisis OR SESA OR subtalar arthroereisis OR s OR subtalar extra-articular screw)".

### Study selection and inclusion criteria

Eligible studies for this systematic review included FFF treatment and AR. The titles and abstracts were screened, using the following inclusion criteria: treatment consisted of AR with or without additional soft tissue procedures, operative treatment, or cast application, and a minimum average follow-up of 6 mo in patients between 7 and 17 years of age. Studies of patients with secondary, including syndromic and neurological FFF, nonoperative treatment or lateral column lengthening (LCL), or medializing calcaneal osteotomy duplicate publications, articles dealing with other topics, those with poor scientific methodology or without an accessible abstract were excluded. Reference lists were also hand-searched for further relevant studies. Systematic reviews, Meta-analyses, abstracts, case reports, conference presentations, editorials, and expert opinions were excluded.

### Data extraction and quality assessment

Two subtalar implant types were considered, impact blocking devices and self-locking implants[13]. The risk of bias assessment was performed independently by two authors (Vescio A and Amico M) using the Dutch checklist form for prognosis recommended by the Cochrane Collaboration[13]. Conflicts about data were resolved by consultation with a senior surgeon (Pavone V). Table 1 presents a risk of bias summary including checklist items with low risk (+), high risk (-), or unclear risk (?). The forms were compared and discussed for final consensus (Table 2).

### Evidence synthesis

For each included article, a standard data entry form was used to extract the number of patients, number of feet treated, affected side, sex, patient age when treated, type of procedure with or without additional surgeries, number of successes and failures, period of the study, and implant materials. We considered improvement of the medial arch, hindfoot valgus, radiological evaluation, pedobarographic measurements, and functional outcome as indicators of treatment success. The assessment included: (1) The American Orthopedic Foot and Ankle Society (AOFAS) Ankle–Hindfoot score; (2) The Oxford Ankle Foot Questionnaire for Children; (3) The Foot and Ankle Disability Index (FADI); (4) FADI Sport scores; (5) The Foot Function Index Questionnaire; (6) The self-reported Foot and Ankle Score; and (7) Visual Analogue Score. Major and

**Table 1 Study results**

| Ref. | Patients (mean age) | AR type | Assessment | Results | Complications | Limits |
|---|---|---|---|---|---|---|
| Ruiz-Picazo *et al*[8], 2019 | 16 (32 FFF), 9 yr (range: 7-11 yr). | Subtalar device. Titanium self-locking device. | OxAFQ-C pre- and postoperatively. | Postoperative results were positive, with statistical significance for the "school and play", "emotional", and "footwear" domains of the OxAFQ-C scale ($P < 0.05$) and no differences in the "physical" domain. | 4 (25%). 2 extrusion of the implant and 2 overcorrections. | Retrospective nature, no control group, sample size. lack of objectively measurable parameters. |
| Pavone *et al* [16], 2019 | 105 (174 FFF) (12.6 ± 1.3 yr), mean follow-up 67.5 ± 16.4 mo. | Calcaneo-stop. | BMI-for-age AOFAS, FADI, FADI Sport, and SF-36 at 1 and 3 yr. Variation of the angles measured on X-ray images. | AOFAS, FADI, FADI Sport, and SF-36 scores and radiological assessments improved significantly postoperatively ($P = 0.001$) and remained stable over time (1 yr: $P < 0.001$; 5 yr: $P < 0.001$) in all groups of patients. An increased persistence of pain and/or discomfort in obese patients than in normal weight patients ($P = 0.02$). | 20 (11.5%) patients. 1 screw loosening (0.6%); 14 transient pain and discomfort at the level of the surgical incision (8%), 2 contractures of the lateral peroneal muscles (1.15%); 3 superficial infections (1.7%). | Retrospective nature, no control group, sample size. lack of objectively measurable parameters. |
| Pavone *et al* [1], 2018 | 68 (136 FFF) 12.7 yr (9-15 yr), mean follow-up 57.6 mo. | Calcaneo-stop. | AOFAS, Yoo Score, FADI, FADI Sport, OxAFQ-C scores at 1 and 3 yr. variation of the angles measured on X-ray images. | AOFAS (F 2, 201 = 287.51; $P < 0.0001$), Yoo Score (F 2, 201= 2627.00; $P < 0.0001$), OxAFQ-C (F2201 = 210.60; $P < 0.0001$), FADI (F 2, 201 = 372.62; $P < 0.0001$) and FADI Sport (F 2, 201= 189.32; $P < 0.0001$). Radiological assessments improved ($P < 0.0001$). | 17 (12.5%); 5 pain at surgical scar (3.7%), 4 local symptoms at the incision (2.9%), 3 screw loosening (1.2%) and 4 superficial Infections (2.9%); 1 screw breakage (0.73). | Retrospective study. No control group. Mid-term follow-up. Lack of objectively measurable parameters. |
| Memeo *et al* [26], 2019 | 202 FFF, 13.6 yr (8-16 yr). Median follow-up was 130 mo (35-150 mo). | Calcaneo-stop. | Clinical evaluation, pain, and variation of the angles measured on X-ray images. | 92% Percutaneous lengthening of the Achilles tendon. Improvement of clinical outcome, restoration of the medial arch and the hind foot valgus in orthostasis. | 32 (15.8%): 23 (11.4%) incomplete correction; 9 (4.5%) screw breakages. | Retrospective study. No control group. Short-term follow-up. Lack of objectively measurable parameters. |
| Memeo *et al* [26], 2019 | 200 FFF, 12.8 yr (8 to 16 yr). Median follow-up 130 mo (35-150 mo). | Subtalar AR bioabsorbable device. | Clinical evaluation, pain, and variation of the angles measured on X-ray images. | 71% Percutaneous lengthening of the Achilles tendon. Improvement of clinical outcome, restoration of the medial arch and the hind foot valgus in orthostasis. | 25 (12.5%): 20 (10%) inflammatory process involving soft tissues around tarsal sinus; 5 (2.5%) device. removals and substitutes. | Retrospective study. No control group. Mid-term follow-up. Lack of objectively measurable parameters. |
| Megremis *et al*[18], 2019 | 14 (28 FFF), 10.71 ± 1.58 yr (range 8-14 yr). Mean follow-up duration of 35.14 ± 9.82 mo (19-60 mo). | Subtalar AR. | AOFAS pre- and postoperatively. | The mean postoperative AOFAS score was 88.851 (range 83-97) points ($P < 0.0001$). | No complication. | Retrospective study. No control group. Short-term follow-up. Lack of objectively measurable parameters. |
| Martinelli *et al*[14], 2018 | 49 (98 FFF) 10.7 yr (7-14 yr), mean follow-up 4.9 yr. | Subtalar AR. | CHQCF; OxAFQ pre- and postoperatively. Number of sessions per week. | The mean OxAFQ scores within the 'Emotional' ($P < 0.05$) and 'footwear' item ($P < 0.05$) (children), and in the 'school and play' ($P < 0.05$) and 'footwear' item for the parent scale. 44 (89%) parents were satisfied with the surgical procedure. | Three residual pain; 1 residual deformity, and one sport limitation. 3 subtalar implants removed because of pain at the sinus tarsi. | Retrospective nature; as some of the anthropological measures were not obtained before surgery. |
| Kubo *et al* [20], 2020 | Group A (5-8 yr): 6 (11 FFF) MA 7.4 ± 1.2 yr; Group B (9-12 yr): 33 (63 FFF) MA: 11.2 ± 1.0 yr; Group C (13-15 yr): 11 (21 FFF). MA 13.6 ± 0.7 yr. | Calcaneo-stop. | CP; lat. TCA; a.p. TCA, kite angle; NCI; Meary angle. Bony maturation. | Improvement of radiological assessment in each group ($P < 0.05$). Best deformity correction when surgery was conducted between 9 and 12 yr, with significant improvement in all measured parameters without secondary deterioration during FU. | No complications. | Retrospective study; no clinical scores. |

| | | | | | | |
|---|---|---|---|---|---|---|
| Indino *et al* [28], 2020 | 56 (112 FFF), 9-14 yr (MA 15.5 ± 1.2 yr), mean follow-up 40.1 ± 23.6 mo. | Subtalar AR. | AOFAS, SEFAS, SF-12. | AOFAS 97.3 ± 4.5, SEFAS 47.2 ± 1.5, SF-12.MCS 51.1 ± 8.8, SF-12.PCS 55.6 ± 9.1, Clinical scores were not correlated with the foot radiographic parameters at follow-up period. | No complications. | No preoperative clinical or functional scores. |
| Hsieh *et al* [15], 2019 | 102 (204 FFF) MA 9.1 ± 0.2 yr). | Subtalar AR. | CP; lat. TCA; a.p. TCA, kite angle; NCI; Meary angle. | 22 cases of bilateral extrusion in the overweight group (39%) *vs* 13 cases bilateral extrusion in the low body weight group (23%) ($P$ = 0.0004). The inter-observer correlation was 0.95. Improvement of radiological assessment at 3 mo postoperative follow-up ($P$ < 0.05). | 19%. | Retrospective nature, no control group, sample size. lack of objectively measurable parameters. No BMI loss evaluation surgical outcomes. |
| Hagen *et al* [32], 2019 | 7 (13 FFF), MA 12.43 ± 1.27 yr. | Calcaneo-stop. | Pedobarographic measurements before surgery, 3, 14, 28 d after. | The ground force increased significantly in lateral foot areas ($P$ < 0.001) and decreased in medial areas ($P$ < 0.001). | 1 minor soreness. | Sample size, short follow-up. |
| Hagen *et al* [31], 2020 | 14 (27 FFF), MA 12.4 ± 1.4 yr. | Calcaneo-stop. | Heel angle, rearfoot angle, leg axis angle, step length, and walking speed, pre- and postoperatively. | Heel valgus (F 1, 24 = 110.465, $P$ < 0.001); Dynamic heel angles *vs* static heel angles (F 1, 24 = 38.498, $P$ < 0.001). Correlation between heel angle and rearfoot angle (static: r = 0.647, $P$ < 0.001; dynamic: r = 0.640, $P$ = 0.001). Dynamic rearfoot angle *vs* static rearfoot angle (F 1, 24 = 166.55, $P$ < 0.001). | No complications. | Small size. No clinical assessment. |
| Giannini *et al*[21], 2017 | 44 (88 FFF). MA 11.7 yr (8-14 yr). | Bioabsorbable Calcaneo-stop. | Patient satisfaction; Meary angle; talocalcaneal angle. | 33 excellent, 9 good outcome, and 2 poor clinical. Meary's, talocalcaneal angle had improved ($P$ < 0.001). | 2 breakages. | Retrospective nature, no control group, sample size. lack of objectively measurable parameters. |
| Faldini *et al* [24], 2018 | 173 (283 FFF), MA 11.2 yr. MF 49.5 mo. | Bioabsorbable Calcaneo-stop. | FFI, SEFAS. | FFI score 4; SEFAS score 47.2, well into the normal range. No statistically significant differences between males and females ($P$ value > 0.05). | 3 implant breakages, 1 persistent pain secondary to a local inflammatory response. | No radiological assessment. No control group. |
| Caravaggi *et al*[33], 2018 | 13 (26 FFF), MA 11.3 ± 1.6 yr, MF 1 yr (12.5 ± 3.7 mo). | Endo-orthotic implant and Calcaneo-stop. | A 10-point VAS, Kinematic and kinetic analysis during normal walking, radiological parameters. | All radiological parameters and VAS were significantly improved at 1-yr follow-up ($P$ < 0.001). No significant differences were detected in spatiotemporal and ground-reaction-force parameters between pre-op evaluation and control in either implant groups. | No complications. | Multisegment foot protocol. Small size. No clinical assessment. |
| Bernasconi *et al*[27], 2020 | 31 (62 FFF), MA 10.5 ± 1.6 yr, MF 62 ± 15 mo. | Subtalar AR. | ROM; AOFAS; VAS-FA, radiological parameters. | Improvement clinical score and radiological parameters except talonavicular coverage angle ($P$ = 0.49) and calcaneo-fifth metatarsal angle ($P$ = 0.53). Improvement of dorso-plantar view. No loss of correction was found after removal of the implant. | 17 (24%) sinus tarsi syndromes. | Retrospective nature, no control group, sample size. lack of objectively measurable parameters. |
| Elmarghany *et al*[38], 2020 | 42 (84 FFF); MA 9.92 ± 2.2 yr; range (7-15 yr). MF 29.1 mo. | Calcaneo-stop. | AOFAS; radiological parameters. | Improvement clinical score and radiological parameters ( $P$ value < 0.000). | 3 minor complications, 1 (0.02%) under correction. 1 sunken screw. 1 synovits around screw. | Retrospective nature, No control group, sample size. lack of objectively measurable parameters. |

AOFAS: American Orthopedic Foot and Ankle Society; AR: Arthroereisis; FADI: Foot and Ankle Disability Index; FFF: Flexible flatfoot; FFI: Foot Function Index Questionnaire; MA: Mean age; MF: Mean follow-up; OxAFQ-C: Oxford Ankle Foot Questionnaire for Children; ROM: Range of motion; SEFAS: Self-

reported Foot and Ankle Score; VAS: Visual Analogue score.

minor complications included screw device loosening, transient pain and discomfort at the level of the surgical incision, contracture of the lateral peroneal muscles, and superficial infection.

## RESULTS

### Study selection

A total of 47 articles were retrieved, 34 duplicate publications were excluded, and after the first screening following the previously described selection criteria, 22 were eligible for full-text evaluation. After full-text evaluation, and reference list checking, we selected 17 articles for inclusion (Table 1). The Preferred Reporting Items for Systematic Reviews and Meta-Anal (PRISMA)[12] flowchart of selection and screening is shown in Figure 1. A total of 1864 FFFs were treated In the 17 studies. Eight (762 FFFs) evaluated subtalar AR (47.1%) and nine (1102 FFFs) evaluated CS devices (52.9%). At start of treatment, the average age of patients was 11.8 years, the average follow-up was 71.9 mo (range 29.1-130), and complications occurred in 153 of the 1864 FFF treated, a rate of 8.2% (Table 1).

### Clinical outcomes and radiological measurements

Eight studies evaluated subtalar AR in a total of 762 FFFs. The average age of patients at the start of treatment was 11.6 years (range 7 to 16 years) and the average follow-up of the studies was 68.9 mo. Every study reported statistically significant differences between pre- and postoperative assessments of pain, clinical scores, or parent and patient satisfaction ($P$ values of 0.001 to 0.05). Radiological measurements showed improvement in every trial ($P$ values of 0.001 to 0.05).

Nine articles evaluated CS in a total of 1102 FFFs. The average age of patients at the start of treatment was 12.0 years (range 7 to 17 years) and the average follow-up of the studies was 70.9 mo. As with subtalar AR Every study reported statistically significant differences between pre- and postoperative assessments of pain, clinical scores, or parent and patient satisfaction ($P$ values of 0.001 to 0.05). Radiological measurements showed improvement in every trial ($P$ values of 0.001 to 0.05). The clinical and radiological characteristics are summarized in Table 1.

### Athlete and obese patient outcomes

Two articles investigated sport activities in FFF patients. In Martinelli *et al*[14]'s, 49 patients (98 FFFs) underwent to clinical and radiological evaluation after subtalar AR implant. Despite improvements in the emotional, school and play, and footwear ($P < 0.05$) items of the OxAFQ, the authors did not find any increase sport ability ($P > 0.05$). On the other hand, Pavone *et al*[1]. evaluated 68 CS-treated FFFs and reported improvement of sport activity levels, with patients recovering sports activity within 3 mo of surgery and without limitation in the execution of preferred activities (FADI Sport pre- *vs* postoperative scores $P < 0.005$).

Two studies included obese patients. Hsieh *et al*[15] evaluated 102 (204 FFFs) subtalar AR-treated patients. The study outcome was radiological assessment at 3 mo postoperative follow-up. Significatively differences in implant bilateral extrusion (39% *vs* 23%) were seen in overweight and normal weight patients, respectively, $P = 0.0004$). Obese patients treated with CS procedure reported a persistence of foot pain (AOFAS pain domain $P < 0.05$) at 1 year after the surgery compared with normal weight and overweight subjects[16].

### Complications

Complications occurred in 74 of the 762 FFFs treated with subtalar AR 9.7% and 79 of 1102 FFFs treated with CS (7.2%). The complications in subtalar AR patients included tarsi pain in 40 patients, and under- or overcorrection in four patients. The complications in CS patients included incomplete correction of the deformity in 24 and transient pain or discomfort at the incision site in 20 patients.

### Materials

Fourteen studies evaluated nonabsorbable implants, seven were CS studies, and seven

**Table 2 Risk of bias of the included studies**

| Ref. | Dutch checklist form for prognosis | | | | |
|---|---|---|---|---|---|
| | No participant selection took place | Groups are comparable regarding age | Validated measuring system used | Independent (blind) determination of outcomes | Clear description of groups available |
| Ruiz-Picazo *et al* [8], 2019 | + | - | + | ? | + |
| Pavone *et al*[16], 2019 | + | + | + | - | + |
| Pavone *et al*[1], 2018 | + | + | + | - | + |
| Memeo *et al*[26], 2019 | + | + | + | ? | + |
| Megremis *et al* [18], 2019 | + | - | + | - | + |
| Martinelli *et al* [14], 2018 | + | ? | + | ? | + |
| Kubo *et al*[20], 2020 | + | + | + | ? | + |
| Indino *et al*[28], 2020 | + | - | + | ? | + |
| Hsieh *et al*[15], 2019 | + | + | + | - | + |
| Hagen *et al*[32], 2019 | + | + | + | ? | + |
| Hagen *et al*[31], 2020 | + | + | + | ? | + |
| Giannini *et al* [21], 2017 | + | + | + | ? | + |
| Faldini *et al*[24], 2018 | + | + | + | - | + |
| Caravaggi *et al* [33], 2018 | + | + | + | - | + |
| Bernasconi *et al* [27], 2020 | + | + | + | ? | + |
| Elmarghany *et al* [38], 2020 | + | + | + | - | + |

+: Low risk; -: High risk; ?: Unclear.

were subtalar AR studies. Four investigated bioabsorbable implants, three CS screws and one subtalar AR).

## DISCUSSION

AR procedures were found to simple, reliable, and minimally invasive interventions for the treatment of pediatric FFF, allowing the alignment of the talus and calcaneus and restoring a proper foot arch. Both implants improved clinical and radiological outcomes. Despite pain persistence for 1 year following CS treatment, subtalar self-locking is not recommended for obese patients. At the same time, an increase of sport activities was reported after CS implants but no differences were noted after subtalar implant procedures. Complications were reported in 153 of the 1864 FFFs that were treated. To the best of our knowledge, this is the first article investigating the outcomes of AR-treated patients reported in the past 5 years and analyzing CS procedures for impact blocking devices and subtalar AR self-locking implant results separately, including the technique-associated complications in specific populations.

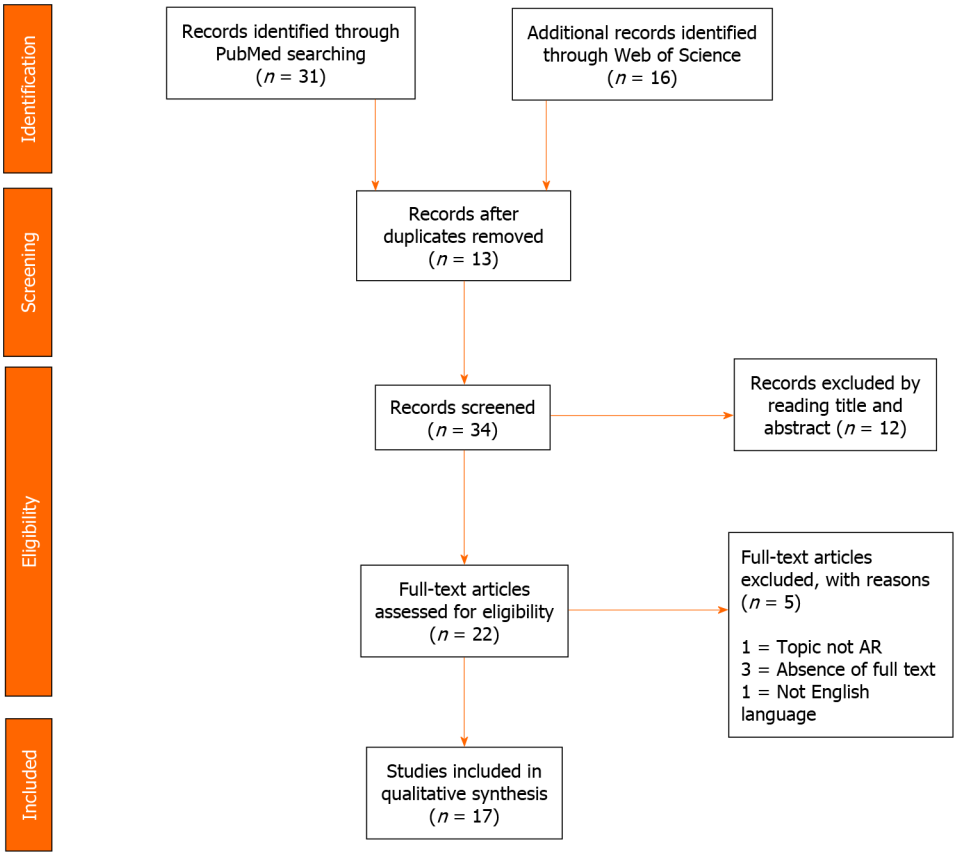


**Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart of the systematic literature review.** AR: Arthroereisis.

The juvenile and adult surgical indications were not completely defined, and a common consensus was not present among orthopedic surgeons. The principal intervention parameters were age, symptoms including pain while walking or standing, postural fatigue, or cramping sensation in the foot or arch. Night cramps, lower back or knee pain, or sedentary preference may also be reasons for patients to seek medical intervention[16-28]. In juvenile FFFs the most median age at treatment is 8 to 14 years of age, but only when the pain is persistent after conservative treatment[19]. Kubo *et al*[20], considering bone maturation stage, found that the best deformity correction was achieved when surgically was performed between 9 and 12 years of age, without secondary deterioration during follow-up.

Every study included in this systematic review reported significative improvements of clinical and radiological assessments. Unfortunately, few articles[24,29,30], comparing the self-locking and impact blocking devices, were published in the last 5 years. The articles did not clearly report the exact indication for the implant choice or if the procedures were all performed by the same surgeon. Nevertheless, subtalar AR and CS techniques were found to be similar. Hagen *et al*[31,32] described an increased ground force in lateral foot areas, a decrease in medial areas, and a correlation between heel angle and rearfoot angle. On the other hand, in Caravaggi *et al*[33] did not find significant differences in spatiotemporal and ground-reaction-force between preoperative evaluation and postoperative control achieved in either implant group.

The findings related to the return to sport activities after AR implant differed. Patients who underwent CS had improved levels of sport activities without any notable limitation in physical activity[16]. No enhancement of sport activities was found in a subtalar AR study[14]. Pavone *et al*[16] hypothesized better body awareness, removal of the impact of minor deformity on function, less FFF-related embarrassment, and the possibility of socializing through sport could have influenced the emotional involvement of CS-treated patients in social interactions. Emotional status was improved in patients with subtalar self-locking devices, but improvement of sport activities was not seen.

Obesity has long been considered a contraindication to AR implant because of excessive stress on the implant[20]. Two studies aimed to investigate the functional and radiological outcomes in overweight and obese patients. Pavone *et al*[16] reported

improvement of clinical and radiological assessments following treatment with CS procedures, even in heavy subjects, despite the persistence of pain for 1 year, compared to nonobese children. The discomfort could be related to the overload of foot structures[16], increased foot pressure with higher peak pressure, and peak force under the midfoot and metatarsal regions[25] during walking and inactivity, which delay the resolution of symptoms in obese children. On the other hand, Hsieh *et al*[15] noted that subtalar self-blocking implants in overweight patients had an increased possibility of implant extrusion, especially while walking.

Furthermore, a high percentage of satisfaction (78.5% *vs* 96.4%)[34] with AR procedures, lower risk and complication rates were reported when compared with other procedures. Suh *et al*[34] reported complication rates of 3.5% to 45% of minor complications in more than 50% of LCL studies. They also reported a 30% rate difference in complications between silicone, polyethylene, staple, titanium, bioresorbable, and stainless steel "old-type" AR implants (45%) and "recent-type" implants (15.4%). In this review, the overall complication rate was 8.2%; 7.2% with CS devices and 9.7% with subtalar AR. Differences in the potential for complications are related to the CS technique or subtalar self-locking devices[35].

As sinus tarsi pain is the most common complication (54.0%) associated with subtalar self-locking devices[35], with a total of 40 cases (5.2%). It has hypothesized that extrusion and over- or under correction occur because of the difficulty of finding the correct dimension of the implant. Under correction can result from a small device that cannot fully correct excessive subtalar joint eversion, and allow a few degrees of remaining eversion. On the other hand, if the chosen implant size is too large, the subtalar joint motion could be limited, thus resulting in pain or extrusion caused by weight bearing activities. The most frequent complication of CS procedures was the incomplete correction of the deformity (24 cases, 2.2%), transient pain, or discomfort at the incision site (20 patients, 1.8%).

Regarding surgery, no consensus is present about the indications for bioabsorbable, nonabsorbable, or a combination of implant materials[17]. Fourteen studies evaluated nonabsorbable implants (seven CS and 7 subtalar AR studies) and four (three CS[20,24,25], and one subtalar AR[26]) evaluated bioabsorbable implants. Both AR categories were found to result in improvement of clinical and radiological outcome measurements. Major advantages of the use of bioabsorbable implants include decreased interference during magnetic resonance imaging and avoidance of a second surgical procedure for hardware removal. Disadvantages and possible complications include screw breakage, inflammatory and foreign body reactions, cyst formation, and local bone lysis[29]. In the bioabsorbable implants studies, below-knee boot and crutch gait assistance were needed immediately after surgery for weight bearing or partial weight bearing to prevent implant breakage. Aggressive walking or athletic activities were not allowed. Fourteen of the 419 implanted bioabsorbable devices (3.3%) were broken compared with the only CS screw breakage in 683 nonabsorbable implanted devices. Polymer chemical structure, processing conditions and storage history, implant molecular weight, crystallinity, and size are common reasons of premature poly-(L-lactide) degradation. Cellular responses may include mild and temporary inflammatory reactions[23]. Despite implant rupture, the patients had good self-reported results, comparable to the other patients, even after having the implant removed[24,25]. A few months were not considered sufficient to promote complete correction of the deformity[9]. On the other hand, a second surgery was often necessary to remove nonabsorbable implants. In the AOFAS 2015 web-based survey[30], one-third of the participants who performed subtalar AR had decided to abandon the procedure because of the failure rate and the need for implant removal. Many participants who were dissatisfied by the AR practiced in the United States. Some authors believe that abandonment might be related to problems with health insurance payments[11].

Surgeon experience, implant costs, and cosmetic correction are the most common considerations in the orthopedic decision-making process. The CS procedure is less expensive surgery, compared with any of the other implants[16,17]. Moreover, Ortiz *et al*[19] noted that, in selected patients, tarsal canal implants produced better cosmetic corrections compared with the CS technique.

Few high-quality studies AR studies have been published. To the best of our knowledge, two systematic reviews and one meta-analysis were previously published. Baryeh *et al*[36] reported partially conclusive data supporting the subtalar AR as an adjunct treatment, but the analysis was limited to adult acquired flatfoot. Suh *et al*[34] performed a comparison between AR and the LCL procedures and concluded that LCL achieved more radiographic corrections and more improvements in the AOFAS score than the AR. Complications were more common in the LCL group than in the AR group, and the reoperation rates in the two groups were similar. As reported in a

recent European Pediatric Orthopedic Society flatfoot survey[3], the procedure indications are different. At the same time, the survey included dated findings regarding AR complications and first AR devices. A meta-analysis by Hsieh *et al*[37] in 2020 did not find a superiority between subtalar AR and CS procedures according to the clinical score, but endosinotarsal devices showed a better improvement in Meary's angle than exosinotarsal screws. Despite the remarkable conclusion, some concerns were present, for example, the authors chose the AOFAS score for the clinical assessment and Meary's angle for the radiological evaluation. Neither measurement is specific for juvenile FFF, moreover in the few studies included in the meta-analysis, the assessments were not the primary study outcomes and were supplemented with other measurements. In addition differences in study design made group comparability difficult in some cases.

The strength of this study is the reporting of the most important evidence published in the last 5 years. Major limitations include great heterogeneity of the outcome assessments and the lack of high-profile studies. We extensively searched and identified all relevant investigations of FFF treated with AR devices. Therefore, risk of bias assessment had moderate overall risk of influencing our analysis. Statistical analysis was not performed. Variations in clinical and radiological scores were reported in the selected studies. Often more than one measurement was performed in order to evaluate different disease features. Moreover, no FFF-specific scores or X-ray lines were developed, and randomized clinical trials are missing and few were case-control studies. In our opinion, the analysis of partial or not high-quality study data could be misleading.

## CONCLUSION

In conclusion, despite both AR procedures being valid surgical techniques for the treatment of FFF, surgeon experience, implant cost, and cosmetic correction are the most common considerations in the orthopedic decision-making process and AR choice. In obese patients, subtalar ARs are not recommended. In adolescents who need to improve sports performance, CS screws had a slightly lower rate of complications than subtalar self-locking implants.

## ARTICLE HIGHLIGHTS

### *Research background*

Flexible flatfoot (FFF) is a common disorder during childhood. When symptoms of early and easy fatigue during walking or pain are present, treatment is mandatory. Arthoereisis (AR) is frequently used for surgical management. Two device types were described, subtalar AR and calcaneo-stop (CS).

### *Research motivation*

No common consensus or AR among orthopedic surgeons is present.

### *Research objectives*

The aim of the study was to report the clinical and radiological outcomes after subtalar AR and CS procedures, including the results in obese and athlete populations, and the technique-related complications. Moreover, the intent was to include the more recent findings of the material devices.

### *Research methods*

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used to perform a systematic review of English-language articles published of the last 5 years.

### *Research results*

Seventeen articles were included in the study after the initial screening and the risk of bias assessment. A total of 1864 FFFs were identified. Eight studies evaluated subtalar AR and nine evaluated CS (52.9%). At the start of treatment, the average age of patients was 11.8 years and the average study follow-up was 71.9 mo.

### *Research conclusions*

Both AR procedures are valid surgical techniques for FFF treatment, surgeon experience, implant cost, and cosmetic correction were the most common considerations in the orthopedic decision-making process and AR choice. In obese patients, the subtalar AR is not recommended. In adolescents who need to improve sports performance, the CS screw had better results compared with other implants. In adolescents who need to improve sports performance, CS screws had a slightly lower rate of complications than subtalar self-locking implants.

### *Research perspectives*

High-quality randomized clinical trials are needed.

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CASE REPORT

# Nuances of oblique lumbar interbody fusion at L5-S1: Three case reports

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## Abstract

### *BACKGROUND*

Oblique lumbar interbody fusion is a mini-open retroperitoneal approach that uses a wide corridor between the left psoas muscle and the aorta above L5. This approach avoids the limitations of lateral lumbar interbody fusion, is considered less invasive than anterior lumbar interbody fusion, and is similarly effective for indirect decompression and improving lordosis while maintaining a low complication profile. Including L5-S1, when required, adds to these advantages, as this allows single-position surgery. However, variations in vascular anatomy can affect the ease of access to the L5-S1 disc. The nuances of three different oblique anterolateral techniques to access L5-S1 for interbody fusion, namely, left-sided intra-bifurcation, left-sided pre-psoas, and right-sided pre-psoas approaches, are illustrated using three representative case studies.

### *CASE SUMMARY*

Cases of three patients who underwent multilevel oblique lumbar interbody fusion including L5-S1, using one of the three different techniques, are described. All patients presented with symptomatic degenerative lumbar pathology and failed conservative management prior to surgery. The anatomical considerations that affected the decisions to utilize each approach are discussed. The pros and cons of each approach are also discussed. A parasagittal *facet line* objectively assesses the relationship between the left common iliac vein and the L5-S1 disc and assists in choosing the approach to L5-S1.

### *CONCLUSION*

Oblique retroperitoneal access to L5-S1 in the lateral decubitus position is possible through three different approaches. The choice of approach to L5-S1 may be individualized based on a patient's vascular anatomy using preoperative imaging. While most surgeons will rely on their experience and comfort level in choosing the approach, this article elucidates the nuances of each technique.

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**Core Tip:** Oblique lumbar interbody fusion (OLIF) provides safe retroperitoneal access to nearly all lumbar levels, including L5-S1, thus, allowing single-position surgery. L5-S1 OLIF access may be attempted through three alternative approaches — left intra-bifurcation, left pre-psoas and right pre-psoas approaches — the choice of which can be customized according to the patient's vascular anatomy.

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## INTRODUCTION

Oblique pre-psoas retroperitoneal access to the lumbar spine through a mini-open technique has recently gained popularity. The oblique trajectory avoids the iliac crest and lower ribs, which are impediments to lateral lumbar interbody fusion (LLIF)[1]. Staying outside the psoas reduces the risk of lumbar plexus injuries[2,3], and allows complete muscle relaxation as neuromonitoring is not considered essential for this approach[4,5]. Moreover, a wide anatomic corridor between the left psoas and aorta allows easy access to all lumbar spinal levels above L5[6], often without the need for any vascular retraction or ligation[7].

Isolated L5-S1 pathologies can be approached through the anterior lumbar interbody fusion (ALIF) technique in the supine position, taking advantage of the wide corridor between the bifurcated common iliac vessels. However, the ALIF approach requires ligation of the left iliolumbar vein (ILV) and transposition of the great vessels to reach the levels above L5[8]. In contrast, oblique lumbar interbody fusion (OLIF), or anterior to psoas (ATP) approach, performed with the patient in the lateral decubitus position, can address multiple lumbar levels, including L5-S1, with a relatively favorable complication profile[4,9]. The lateral decubitus position takes advantage of gravity-assisted retraction of the peritoneal sac, theoretically reducing the risk of postoperative ileus[10]. OLIF/ATP involves a mini-open muscle-splitting approach through the abdominal oblique and transverse muscles[11], which may be less traumatic than a midline ALIF approach through the anterior rectus muscle-sheath complex[12].

Oblique access to L5-S1 is not as straightforward as that for levels above L5. Variations in vascular anatomy create unique situations for which approaches may need to be customized. Oblique anterolateral approaches to L5-S1 have been described in previous studies as staying lateral to[4,13], or approaching between the bifurcated common iliac vessels[7] (Figure 1A and B). These variations of technique have been found to be safe and feasible in individual studies. However, these studies have not provided adequate guidance regarding the choice of approach. Careful assessment of the vascular anatomy is critical as vascular injuries range from 0.3%-4.3%, especially when L5-S1 is included[4,7,12]. Three representative case studies are presented to describe how the three previously described variations of approaches can be potentially customized based on a patient's anatomy.

All patients in the case studies were operated on in a single institution by a single spine surgeon with assistance from an access surgeon. Imaging and chart review were retrospectively performed. All patients presented with degenerative lumbar pathology and underwent nonsurgical treatment for a minimum of 6-12 wk before being considered for surgical intervention. After careful consideration, each patient elected to proceed with surgery and provided written informed consent.

In the preoperative magnetic resonance imaging (MRI), the location of the left common iliac vein (CIV) in relation to the L5-S1 disc was carefully assessed. We have previously described an imaginary parasagittal line drawn from the medial border of

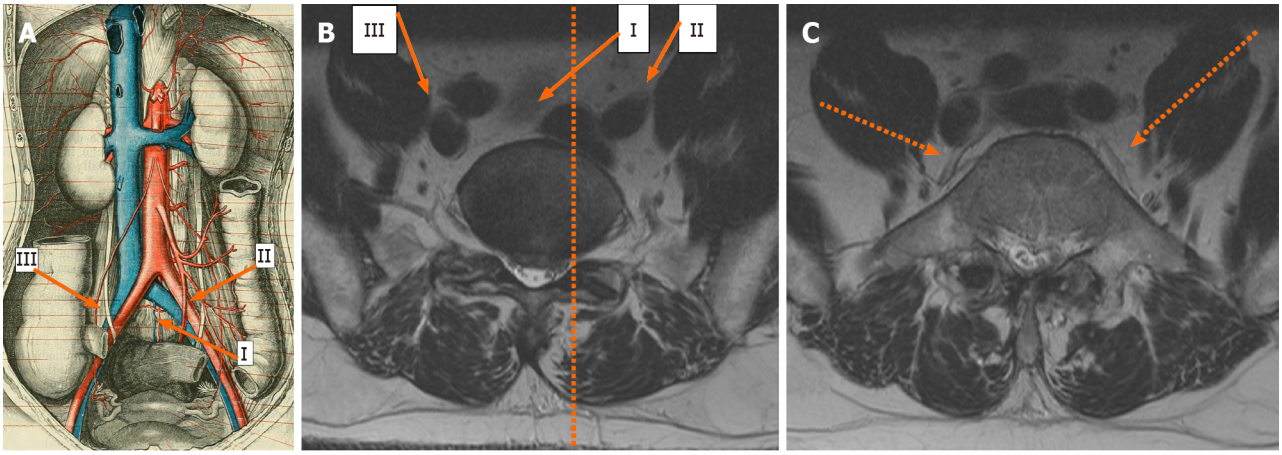


**Figure 1 Vascular anatomy as depicted through an illustration showing the frontal aspect (A), and that depicted through magnetic resonance imaging axial sections (B, C).** Image B shows magnetic resonance imaging (MRI) axial section through the L5-S1 disc, and the *facet line* (dotted line) running anteroposteriorly through the medial border of the left L5-S1 facet joint cutting through the left common iliac vein. The three oblique approaches to L5-S1; namely the left intra-bifurcation (i), the left pre-psoas (ii), and the right pre-psoas (iii) are shown in A and B. Image C shows an MRI axial section through mid-L5 vertebral body and shows the left and right ilio-lumbar veins (dotted arrows).

the left L5-S1 facet joint on the MRI axial section through the L5-S1 disc (the *facet line*) [13] and traced anteriorly to assess its relationship with the left CIV (Figure 1B). MRI axial images through the L5 vertebral body were also carefully evaluated to identify L5 segmental veins or ILV on either side[4] (Figure 1C). Computed tomography was not routinely performed to assess fusion.

### *Surgical techniques*

**Left intra-bifurcation approach:** The left intra-bifurcation approach has been described by Woods *et al*[7] and others[1,13-15] and is a modification of the supine ALIF technique. This is performed with the patient in the right lateral decubitus position. Lateral fluoroscopy is performed to mark all target spinal levels on the skin (Figure 2). An oblique 5-6 cm incision in the left lower quadrant of the abdomen is marked 2 fingerbreadths anterior to the anterior iliac crest and extending inferior enough to reach the plane of the sacral slope.

A muscle-splitting approach through the external oblique, internal oblique, and transversus abdominis muscles is performed, and the retroperitoneal space is entered. Blunt dissection is performed to reach the left psoas muscle. The peritoneal sac is then retracted further medially and inferiorly to reach the medial aspect of the left common iliac vessels. Careful blunt dissection is performed to identify the anterior annulus of the L5-S1 disc, which is confirmed with fluoroscopy. The median sacral vessels are identified and ligated (Figure 3A). Blunt dissection may be required to mildly elevate and retract the left CIV laterally to further widen the *intra-bifurcation interval*. Discectomy and endplate preparation is then performed at L5-S1. Double-bent curettes may be needed to adequately reach the posterior portion of the L5 inferior endplate (Figure 3B). An ALIF cage (width: 32-40 mm; height: 12-20 mm; depth: 24-32 mm; lordosis: 14-20°) packed with bone graft is inserted through an oblique inserter under image guidance. The anteroposterior (AP) fluoroscopy confirms the midline position of the cage. A screw with a washer or a plate is usually placed to cover the cage to prevent dislodgement.

**Left pre-psoas approach:** The left pre-psoas approach has been described by Tannoury *et al*[4] and others[13,16,17], and is an inferior continuation of the pre-psoas OLIF approach to levels above L5. As above, the patient is positioned in the right lateral decubitus position and spinal levels marked on the skin. A 4-5 cm incision is marked along the skin lines about 2 fingerbreadths anterior to the iliac crest, approximately mid-way between the target levels (Figure 2). A muscle-splitting approach through all abdominal wall layers is then performed to reach the retroperitoneal space. The left psoas muscle is identified and the pre-psoas interval is developed and extended inferiorly. The left CIV is identified. The left ILV is often identified inferior to the L4-5 disc, with psoas retraction (Figure 3A). Ligation of this left ILV may be required to allow anteromedial mobilization of the left CIV. This exposes the lateral annulus of the L5-S1 disc. Discectomy and endplate preparation is then performed using specialized

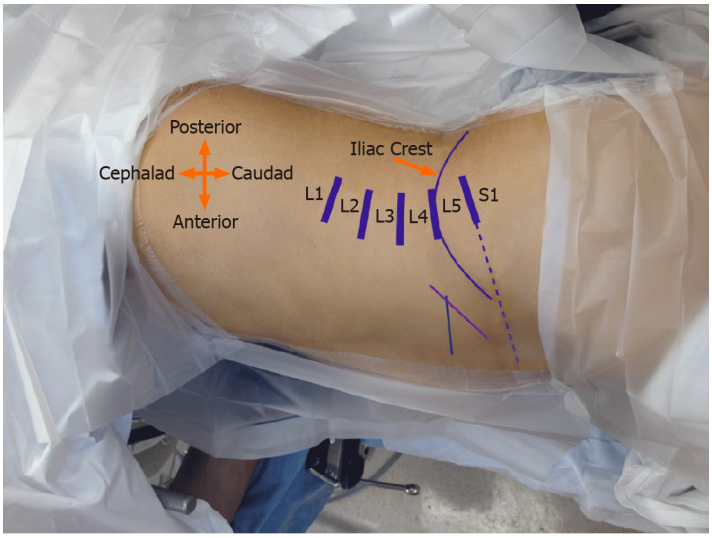


**Figure 2 Clinical photograph of a patient in the right lateral decubitus position with superimposed skin markings.** Disc levels from L1 to S1 are marked. L5-S1 disc marking is extended anteriorly (dotted line) to guide the incision. A longer oblique line (purple) somewhat parallel to the anterior iliac crest marks the suggested incision for a left intra-bifurcation approach for L3-S1 oblique lumbar interbody fusion (OLIF). The shorter transverse line (green) is the suggested incision (along skin lines) for a left pre-psoas approach for L3-S1 OLIF.

instruments that are bent in two planes (Figure 3C and D). An LLIF cage (width: 45-55 mm; height: 10-16 mm; depth: 18-22 mm; lordosis: 6-18°) packed with bone graft is inserted through a lateral inserter under image guidance. Fluoroscopy confirms the coronal position of the cage.

**Right pre-psoas approach:** The right pre-psoas approach is performed from the right side with the patient in the left lateral decubitus position and has been described by Tannoury *et al*[4] and others[13]. A transverse incision along the skin lines is made, as above. The procedure is similar to the aforementioned left pre-psoas approach in terms of muscle splitting, entering the retroperitoneal space, and retracting the peritoneal sac anteromedially. The right psoas and IVC are identified, and an interval is created between them. This interval is then traced inferiorly along the right CIV. The right L5 segmental vein, when present, is identified, ligated, and divided (Figure 4A). Next, the right CIV is carefully retracted anteromedially to expose the lateral annulus of the L5-S1 disc. Discectomy, endplate preparation, and placement of an LLIF cage is then performed using bent instruments (Figure 4B), similar to the left pre-psoas approach. While this approach has been found to be safe and feasible by previous studies[4,13], extensive experience and comfort level is required to work alongside the IVC.

## CASE PRESENTATION

### *Chief complaints*

Low back pain.

### *History of present illness*

**Case 1:** A 58-year-old man [body mass index (BMI): 34 kg/m$^2$] presented with longstanding back and leg pain refractory to conservative treatment.

**Case 2:** A 69-year-old man (BMI: 31 kg/m$^2$) presented with longstanding back and leg pain refractory to conservative treatment.

**Case 3:** A 72-year-old man (BMI: 23 kg/m$^2$) presented with longstanding back and leg pain refractory to conservative treatment.

### *History of past illness*

Case 1 had undergone prior laminotomy surgery. Case 2 and Case 3 did not have any relevant past illness.

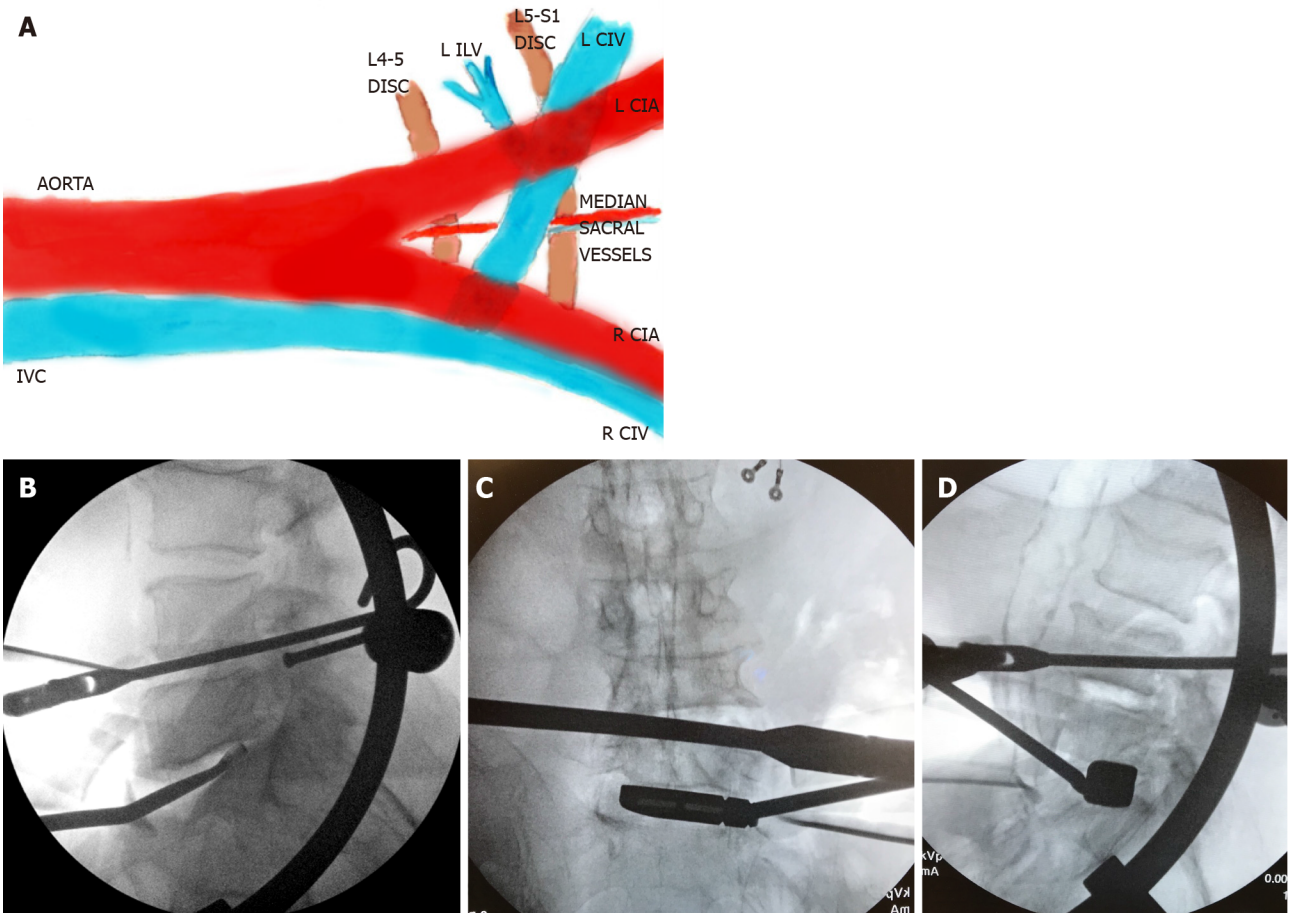


**Figure 3 Illustration showing left-sided oblique anterolateral approaches (A), and intraoperative fluoroscopy images (B-D).** Image A shows the median sacral vessels that are often encountered in the left intra-bifurcation approach, and the left ilio-lumbar vein (ILV), which may need ligation in a left pre-psoas approach. Image B shows a lateral fluoroscopy image with a double-bent curette which may be helpful in preparing the portions of the L5 inferior endplate that may not be under direct visualization. Images C and D show intraoperative anteroposterior and lateral fluoroscopy images during a left pre-psoas approach with specialized trial instrument bent in two planes. IVC: Inferior vena cava; CIV: Common iliac vein; CIA: Common iliac artery; ILV: Ilio-lumbar vein; R: Right; L: Left.

### *Personal and family history*

None of the 3 patients had any relevant positive personal and family history.

### *Physical examination*

All 3 patients had examination findings consistent with Lumbar degenerative disc disease and stenosis. No neurologic deficit was noted. Case 2, in addition, showed findings consistent with a severe lumbar dextroscoliosis.

### *Laboratory examinations*

None of the 3 patients had any significant laboratory examination findings.

### *Imaging examinations*

**Case 1:** He was found to have L3-S1 degenerative disc disease and stenosis (Figure 5). A careful review of all the available imaging revealed a wide intra-bifurcation interval between the left and right common iliac vessels in the axial section through the L5-S1 disc. There was an identifiable fat plane between the left CIV and the L5-S1 disc. The medial edge of the left CIV was lateral to the *facet line* (Figure 5B).

**Case 2:** He was found to have severe lumbar dextroscoliosis, sagittal imbalance, and multilevel stenosis (Figure 6). An MRI axial cut at the L5-S1 disc showed the left CIV in the midline with no obvious fat plane underneath it (Figure 6D).

**Case 3:** He was found to have L3-S1 degenerative disc disease with central & foraminal stenosis. L3-S1 OLIF with posterior PPSI was recommended. A thorough evaluation of preoperative imaging was performed (Figure 7). As seen on the L5-S1 disc axial MRI cut, the medial wall of the left CIV was medial to the *facet line*

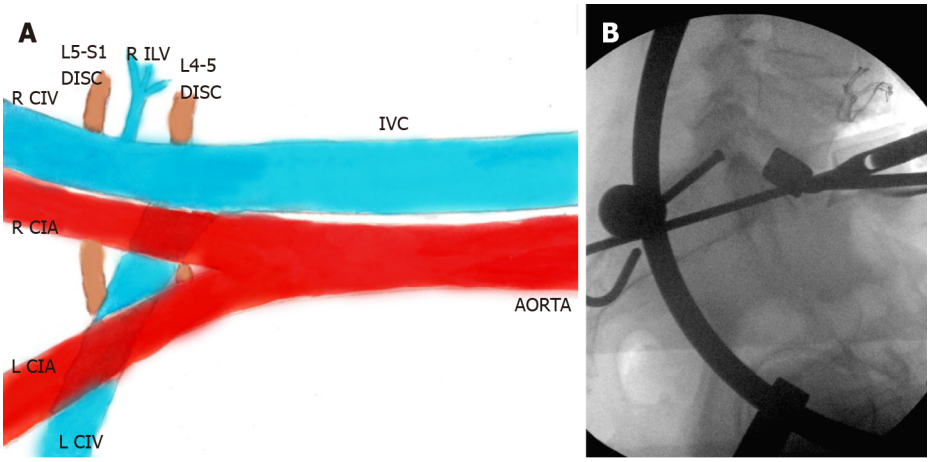


**Figure 4 Illustration showing right-sided oblique anterolateral approach (A), and a lateral fluoroscopy image (B) during a right pre-psoas approach.** The right ilio-lumbar vein (ILV) is longer in length and smaller in caliber (A) when compared to the left ILV (Figure 3A). Also note that the right common iliac vein (CIV) is visible throughout in the right pre-psoas approach, unlike the left CIV, which for the most part, is covered by the accompanying left common iliac artery. Image B again identifies specialized trial instrument bent in two planes (similar to Figure 3C and D). IVC: Inferior vena cava; CIV: Common iliac vein; CIA: Common iliac artery; ILV: Ilio-lumbar vein; R: Right; L: Left.

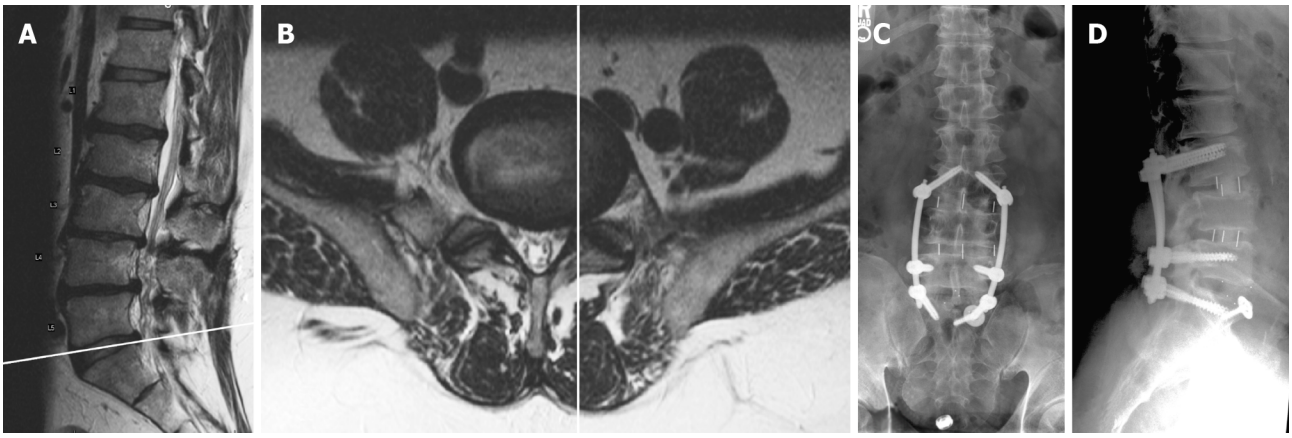


**Figure 5 Preoperative magnetic resonance imaging sagittal (A) and axial (B) images and postoperative anteroposterior (C) and lateral (D) upright radiographs for Case 1.** Image A shows the scout line corresponding to the axial image B. The anteroposterior *facet line* through the medial border of the left L5-S1 facet joint runs medial to the medial border of the left CIV (B). CIV: Common iliac vein.

(Figure 7B). The fat plane was not well-visualized between the left CIV and L5-S1 disc, but a small fat plane was identifiable between the right CIV and L5-S1 disc.

## FINAL DIAGNOSIS

**Case 1:** L3-S1 degenerative disc disease and stenosis.

**Case 2:** Severe lumbar dextroscoliosis, sagittal imbalance, and multilevel stenosis.

**Case 3:** L3-S1 degenerative disc disease and stenosis.

## TREATMENT

**Case 1:** L3-S1 OLIF with posterior percutaneous pedicle screw instrumentation (PPSI) was recommended. L5-S1 was approached through the left intra-bifurcation approach, and L3-4 and L4-5 through the left pre-psoas interval, all through the same incision. Minimal retraction and careful protection of the left common iliac vessels was required. Median sacral vessels were ligated. Posterior percutaneous pedicle screw

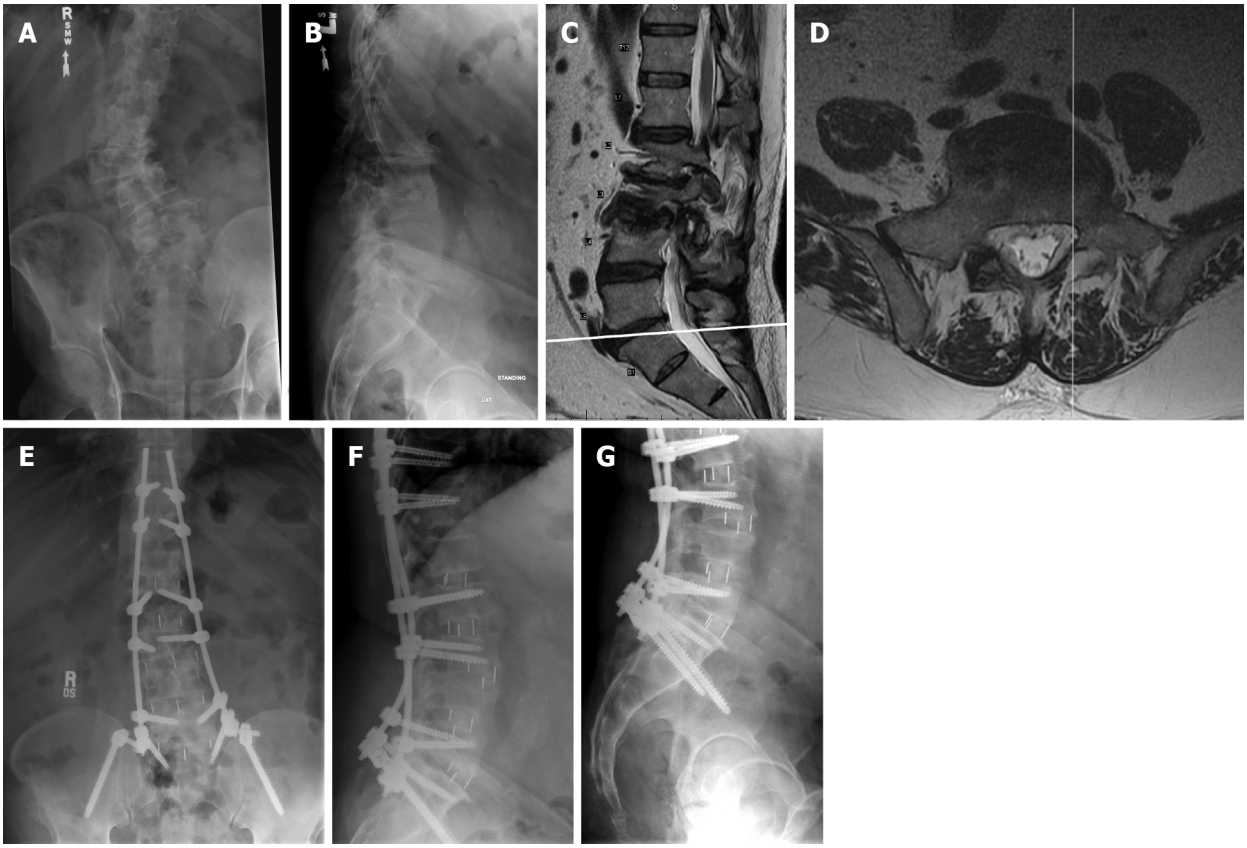


**Figure 6 Preoperative upright anteroposterior (A) and lateral (B) radiographs, preoperative magnetic resonance imaging sagittal (C) and axial (D) images, and postoperative anteroposterior (E) and lateral (F, G) upright radiographs for Case 2.** Image C shows the scout line corresponding to the axial image D. The left common iliac vein is in the midline medial to the anteroposterior *facet line* (D). CIV: Common iliac vein.

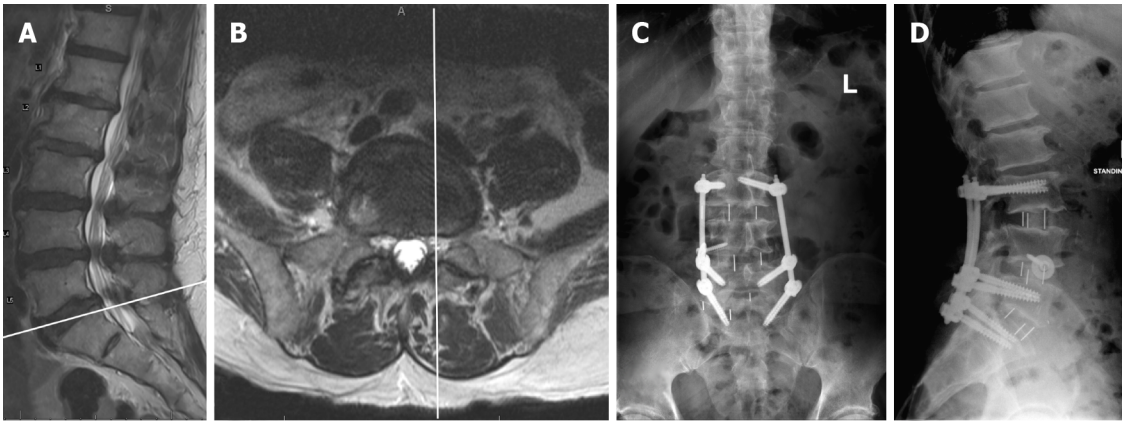


**Figure 7 Preoperative magnetic resonance imaging sagittal (A) and axial (B) images and postoperative (C) anteroposterior and (D) lateral upright radiographs for Case 3.** Image A shows the scout line corresponding to the axial image B. The anteroposterior *facet line* through the medial border of the left L5-S1 facet joint runs lateral to the medial border of the left common iliac vein (CIV) (B). The fat plane is better visualized under the right CIV than under the left CIV (B). CIV: Common iliac vein.

instrumentation was performed in the prone position in the same operative setting. Neuromonitoring was not utilized. Operative time was 358 minutes, and intraoperative blood loss was 100 mL. No vascular injuries and no perioperative blood transfusions were required.

**Case 2:** Staged L1-S1 OLIF followed by posterior T11-S1 PPSI and iliac fixation on the next day was recommended. A left-sided pre-psoas approach was performed. During the exposure of L5-S1, minimal retraction of the left common iliac artery and no retraction of the CIV were required. The left ILV was not identified and did not interfere with exposure. A single skin incision provided access to 5 spinal segments

from L1-S1, taking advantage of the scoliotic concavity on the left side. The patient underwent posterior instrumentation the next day, as planned. Neuromonitoring was used during the second stage only. Operative times for the two stages was 262 min and 294 min, and intra-operative blood loss was 500 mL and 250 mL, respectively. A minor vascular injury in the form of segmental bleed was encountered while exposing the L2-3 disc anterolaterally, which was controlled with ligation. No perioperative blood transfusions were required.

**Case 3:** L3-S1 OLIF with posterior PPSI was recommended. A right-sided pre-psoas approach was performed with the patient in the left lateral decubitus position. While accessing L5-S1, an L5 segmental vein was encountered, which was ligated with vascular clips and divided. Posterior PPSI was performed with the patient in the prone position at L3-S1 in the same operative setting. Neuromonitoring was not used. Operative time was 278 min, and intra-operative blood loss was 100 mL.

## OUTCOME AND FOLLOW-UP

**Case 1:** The patient recovered well and was discharged home on postoperative day 2. Transient left groin pain was reported but resolved by the 2-wk follow-up. No other approach-related complications were observed. The patient reported excellent clinical improvement at his one year follow up visit. No subsidence or pseudarthrosis was seen.

**Case 2:** Excellent recovery was seen postoperatively, and the patient was discharged to a rehabilitation facility on day 6. He showed no approach-related complications. The patient reported excellent clinical improvement and radiographic maintenance of alignment at his two year follow up visit. No subsidence, pseudarthrosis, hardware failure, or proximal junctional issues were seen.

**Case 3:** The patient recovered well and was discharged home on postoperative day 2. There were no approach-related complications reported. The patient reported excellent clinical improvement at his one year follow up visit. No subsidence or pseudarthrosis was seen.

## DISCUSSION

Lumbar interbody fusion techniques *via* anterior approaches (ALIF, OLIF, and LLIF) provide opportunities for indirect decompression[18] and better correction of lordosis than posterior techniques[19]. Among these approaches, OLIF/ATP shows the greatest versatility, allowing exposure of nearly all lumbar levels from T12-S1[4], and provides distinct advantages over other anterior and posterior approaches with favorable complication profiles[9,10]. Neuromonitoring is not considered essential[4,5,18] as the psoas muscle cushions the lumbar plexus during retraction. Intraoperative muscle relaxation can be employed with favorable effects on abdominal wall musculature compliance, psoas retractability[20], and intra-abdominal pressure.

### *Potential complications*

Complication rates in OLIF/ATP approaches have been reported between 7.2% and 48.3% in different studies[4,21-23]. The incidence of certain complications may be higher when L5-S1 is included in the OLIF/ATP procedure[7,13,23]. This is especially true for vascular injuries, which can be catastrophic and potentially fatal. In a series of 940 patients, Tannoury *et al*[4] found vascular injuries in 0.3%. They approached L5-S1 *via* the left or right pre-psoas approaches. Woods *et al*[7] reported a 2.9% incidence of vascular injuries in their series of 137 patients. This incidence went up to 4.3% when L5-S1 was included in the approach. They used the intra-bifurcation approach to L5-S1. Our previously published series did not show any differences in incidence of vascular injuries between the three approaches to L5-S1[13]. Approach-related complications like ileus, ipsilateral groin pain, anterior thigh numbness or pain, incisional hernia, or pseudohernia have also been reported with the OLIF/ATP approach[4,7,12,23]. Subsidence may be seen more often with the OLIF approach compared to other anterior approaches for interbody fusion, according to Woods *et al* [7].

### Pros and cons of each approach

The intra-bifurcation left-sided approach is a modification of an ALIF approach to L5-S1, which most spine surgeons are accustomed to. It utilizes an oblique trajectory through an anterolaterally placed incision with the insertion of an ALIF cage. This approach allows broad access to the anterior aspect of L5-S1, which permits near-complete resection of the anterior longitudinal ligament (ALL). Thus, better correction of lordosis can be achieved by utilizing a hyper-lordotic cage. This extensive ALL release may prompt the surgeon to place a plate or washer that covers the cage, to prevent the cage from dislodging anteriorly.

The intra-bifurcation approach may require careful retraction and mobilization of a flat left CIV that may be covering the left half of the L5-S1 disc[24] (Figure 3A). While this approach is similar to the supine ALIF approach, there is a higher likelihood of needing retraction or mobilization of the left CIV than the latter due to the left-sided oblique trajectory. This increases the risk of vascular injury as the medial aspect of the left CIV is often flat and stretched over the anterior osteophytes of the L5-S1 disc[13]. Additionally, in patients with a large sacral slope, a longer oblique incision extending far inferiorly may be required to align with the plane of the L5-S1 disc (Figure 2). In such instances, preparation of the L5 inferior endplate may be blind, requiring extensive help from fluoroscopy[15] (Figure 3B). Such blind endplate preparations might be common to all oblique approaches to L5-S1 and may be a reason for subsidence seen in some patients. Furthermore, due to the lower incision for L5-S1, separate incisions may be required to reach upper lumbar levels in multilevel surgeries. Midline orientation may also be challenging in the initial cases[7], because of the oblique trajectory of this approach. Lastly, the superior hypogastric sympathetic plexus, which lies anterior to the L5-S1 disc may still be at risk of injury with this approach.

The left and right pre-psoas approaches are an inferior continuation of the pre-psoas approach for levels above L5. Although the common iliac vessels are especially close to the psoas at L5-S1, this interval may be widened by retraction of the psoas and careful mobilization of the CIV, as needed. Being able to put a laterally-placed LLIF cage at L5-S1 reduces the need for longer skin incisions to align with the L5-S1 plane.

The left and right prepsoas approaches may be challenging in patients with large bulky psoas muscles. These approaches require specialized bent intruments and preparation of the L5 inferior endplate is often blind (Figure 3C, D and 4B). A blunt release of the contralateral annulus, which is common for OLIF or LLIF techniques at levels above L5, may not be advisable for the L5-S1 Level because of more laterally located contralateral common iliac vessels that may inadvertently get injured. ALL release is often not possible, however, a blunt ALL rupture may be achievable.

The right prepsoas approach may be useful in patients that may have a favorable indication to approach multiple levels from the right side; for example, in patients with a scoliotic concavity to the right, in those with prior left-sided abdominal surgeries with anticipated scarring, or in those with vascular anomalies[25]. This approach may also be used if the access surgeon believes that L5-S1 can be reached with greater safety than the other approaches[4]. However, this approach needs significant experience as the IVC and right CIV are approached head-on, and the prepsoas interval is much narrower at all levels on the right side.

### How to choose the approach

Most patients could possibly undergo L5-S1 OLIF through more than one of the approaches described above. The choice should depend on the access surgeon's comfort level and experience. However, the anatomic relationship of the left CIV to the L5-S1 disc may also be an important consideration. A wide anterior interval between the left and right CIVs, and a more lateral position of the left CIV (Patient 1) may favor an intra-bifurcation approach[13,26]. Although other methods of assessing the relative position of the left CIV to the L5-S1 disc are available[26], the *facet line* may be an easy, quick method[13]. If the medial border of the left CIV is medial to this *facet line* without a distinct fat plane underneath, the intra-bifurcation approach may be challenging, and a pre-psoas approach may be considered (Cases 2, 3). In such cases, the authors personally prefer a right-sided pre-psoas approach for the following reasons. The right CIV is somewhat vertical and is visible throughout its course in a right-sided approach, while the left CIV takes a more horizontal oblique course and is often hidden underneath its accompanying artery in left-sided approaches[24] (Figure 3A and 4A). In the authors' experience, the more vertical right CIV is far more predictable in its course and easier to retract medially due to its rounded lateral edge, unlike the oblique and flat left CIV (Figure 7B). Moreover, according to Tannoury *et al*

[4], the right ILV tends to be longer in length and smaller in caliber than the left ILV. The right ILV is hence easier to ligate and divide. Careful assessment of MRI axial images through the L5 vertebral body, may help identify L5 segmental veins or ILV on either side[4] (Figure 1C).

The left pre-psoas approach may be beneficial in anatomy as in Patient 2, where the bifurcation is at a relatively lower vertebral level, such that the left CIV may not need any retraction or mobilization. The left pre-psoas approach can also be potentially used as an intraoperative bailout when an intra-bifurcation approach is unsuccessful due to difficulty retracting the left CIV laterally[13]. However, the right prepsoas approach has to be chosen prior to surgery and cannot be used as an intraoperative bailout.

## CONCLUSION

Altogether, L5-S1 can be exposed *via* an oblique approach using three different techniques, the choice of which may be customized according to a patient's anatomy. A significant learning curve may be involved, and experience with identifying and ligating venous structures through mini-open exposures is required to safely perform these procedures. The availability of an experienced access surgeon is critical and may be essential for such exposures. While the right-sided pre-psoas approach has been shown to be safe and feasible in some studies, we strongly recommend gaining adequate experience before adopting this technique. In early cases and in patients with challenging vascular anatomy, posterior alternatives may be considered.

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