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Appendix 1: Acute Lower Extremity Fracture Management in Chronic Spinal Cord Injury: 2022 Delphi Consensus Recommendations:

Methods, Materials and Background

To address this gap, with oversight from the Orthopaedic Trauma Association (OTA) and with funding provided by VA Health Services Research and Development (VA HSR&D), an expert panel was convened to develop a clinical practice guideline (CPG) for LE fracture management in persons with a chronic SCI. The initial activity included developing a set of key questions regarding LE fracture management. Questions were invited from national and international leaders in research and clinical care in SCI. The Patient, Intervention, Comparison, Outcomes (PICOS) formatted questions relative to the acute management of lower extremity fractures and the background (clinical context) that formed the basis for these recommendations and reported in the main manuscript. The guidelines consists of three sections related to fracture treatment: acute fracture treatment, the role of physical therapy, and management of fracture-related complications.

Key questions for the acute treatment section included:

1. Is the preferred primary (first) management operative or non-operative?
2. What are the optimal non-operative treatments?
3. What are the optimal operative treatments?

The key question for the rehabilitation section was:

1. What is the role of physical therapy in post-fracture rehabilitation?

The key question for the post fracture complications section was:

1. What are important considerations in prevention and management of post-fracture complications and fracture treatment failures?

These questions formed the basis of a literature search, findings of which were published as a systematic review (20). A multidisciplinary expert panel consisting of orthopedic surgeons physiatrists, physical therapists, health service and clinical researchers, an endocrinologist, a rheumatologist and a hematologist was convened. **Details on the expert panel and specific areas addressed by each panel member are included in the appendix 2.** Prior to the first in-person meeting, all conflicts of interest (COI), were identified. Updates to these COI occurred prior to the second meeting and again prior to publication. The guidelines were informed in part by the *AAOS Clinical Practice Guidelines and Systematic Review Methodology* (21). Information from the systematic review (20), semi-structured interviews of physical and occupational therapists (22), additional hand searches of the literature done by members of the expert panel to inform particular areas of knowledge gap and expert opinion by members of the task force, formed the basis for the recommendations. Panel members consulted with content experts when needed. Grading of Recommendations, Assessment, Development and Evaluations (GRADE) was used to determine the quality of evidence and the strength of the recommendations (23-25). An overall GRADE quality rating was applied to the evidence across outcomes, by taking the lowest quality of evidence from all of the outcomes (26). *A priori*, it was decided that the maximum grade that could be given for the quality of evidence was low if data were obtained only from the able-bodied population, with no reports available in persons with a SCI. Table 1 indicates the original GRADE scoring system (27) and Table 2 indicates how this original scale was applied to these guidelines using letters (A to D) to rank the quality of the evidence, and numbers (1 to 2) to rank the strength of these recommendations. For example, Grade 1C indicates a low quality of evidence and strong recommendations either for or against intervention, Grade ID indicates a very low quality of evidence and strong recommendations either for or against an intervention, and Grade 2D indicates a very low quality of evidence and weak recommendations either for or against an intervention.

Recommendations were voted on independently by all members of this expert panel using a survey format (Qualtrics). There were minor formatting changes suggested for four of the recommendations that were incorporated into the final recommendations. There was disagreement by one panel member on the recommendation concerning internal fixation for treatment of a femoral neck fracture (recommendation 1.5), specifically that there was not sufficient information to inform specific operative treatment of femoral neck fractures in persons with a SCI. An advisory panel consisting of three outside experts in care of persons with a SCI also independently reviewed the guidelines. This outside advisory panel included one endocrinologist (WB) and two orthopaedic surgeons (JB, GD). Suggestions from this expert outside advisory panel resulted in inclusion of information on exoskeleton use and foot fractures, and clinical considerations regarding these. Members of the OTA Evidence Based Quality Value and Safety (EBQVS) Committee reviewed and unanimously endorsed these guidelines. In addition, the OTA Board of Directors approved these guidelines.

These clinical practice guidelines, while based on what the panel considered the best available evidence, consisted largely of expert opinion, so future updates may be necessary. Moreover, many of the guidelines related to surgical procedures were informed by the literature and practice in the able-bodied population with LE long bone fractures due to a dearth of high-quality evidence in this area specific to persons with a SCI. It is recommended that future research studies address risks and benefits of operative vs. nonoperative treatment of acute lower extremity fractures and optimal operative and nonoperative treatment strategies for these fractures in persons with a SCI**. It is recognized that given the relatively few numbers of patients with a SCI, such studies would need to be multi-institutional and most likely international.**

Moreover, the critical importance of prevention of these fractures is recognized, and for a full discussion of the role of osteoporosis medications in the prevention of fractures in persons with a SCI, the reader is referred to the PVA Consortium for Spinal Cord Medicine Clinical Practice Guidelines: Bone Health and Osteoporosis Management in Persons with Spinal Cord Injury.

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Background (Clinical Context): Choosing Operative or Non-operative Management

A general principal of open fracture care is that consultation with a surgeon is required (32). In the able-bodied population, the tibia is the most common site of open fractures (33) and a frequent site of fracture in persons with a SCI (8, 16, 34, 35). Reports from the able-bodied population of infections following open fractures have led to the consensus recommendation that open fractures necessitate debridement and fracture stabilization (36) and early soft tissue coverage (37). Historically, timing of debridement was recommended within six hours (36, 37).

However, a systematic review and other studies concluded that infection rates were associated with increasing grade of injury and not necessarily with timing of surgery (38). **All open fractures need an operative debridement. Open fractures can be classified as Type 1, 2, 3A, 3B or 3C fractures that provide communication and prognosis on the severity of the soft tissue injury and risk of complication. The level of contamination may also drive a different urgency for debridement and management. The ACS and OTA (29-31) have provided recommendations for management of open fractures for able-bodied patients, and these references are applicable to the same injuries in patients with a chronic SCI.**

In the able-bodied population, displaced LE fractures require surgical treatment (39). No studies have compared treatment strategies for displaced long bone LE fractures in persons with a SCI; however, displaced fractures leading to malalignment are problematic for this population. In non-ambulatory persons who use a wheelchair for mobility, it might not be necessary to have perfect anatomical alignment; however, maintaining limb-length symmetry and limiting pelvic obliquity might optimize seating and transfers and mitigate risk for subsequent skin breakdown (20). In ambulatory individuals, minimizing deformity is important for upright posture for stance (35).

Hip fracture is the most common LE long bone fracture site that is treated surgically in both able-bodied persons and persons with a SCI (40, 41). In the able-bodied population, non-operatively treated femoral neck fractures have high rates of nonunion and avascular necrosis (41), and prophylactic screw fixation is recommended even in non-displaced fractures (42). Early repair of these fractures is important, but definitions of early surgical repair are inconsistent, and range from 6 to 48 hours (43, 44). Delayed surgery is associated with higher morbidity (45) and mortality (46, 47). The AAOS recommends hip surgery be done within 48 hours of fracture (48).

Some, (49, 50) but not all, (51) studies suggest that fracture healing is accelerated in persons with a SCI. Surgeons should decide whether the fracture is likely to heal without surgery or whether malalignment problems might compromise the individual's functional abilities or health related quality of life.

The European League against Rheumatism (EULAR) and the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) guidelines state that appropriate treatment of fractures requires a balanced approach to operative vs. non-operative treatment, considering the individual patient's situation (52). This guideline points out that the most important goal for all persons with a fragility fracture is to regain the prior level of mobility and independence (52). The premorbid level of function, as well as the individual's desires for independence and function, are important considerations when deciding on management of LE long bone fractures in persons with a SCI (35, 40). Moreover, it is important to recognize that there may be substantial differences in bone health between individuals who can weight-bear and at least partially ambulate vs. those who are confined to a wheelchair (53), particularly when the injury is of long duration (54). Ultimately, it is critically important to consider patient preferences regarding fracture treatment strategies (operative vs. non-operative).

There are inherent risks with both operative and non-operative management of fractures in persons with a SCI. Osteoporosis is common in chronically injured individuals (55) and poor bone quality may be a risk for the long-term failure of osteointegration of implants and non-union (56). Prolonged immobilization also carries a risk of skin breakdown and pressure injuries

(57). Malalignment of fractures can result in poor sitting balance or limb alignment that challenges transfers or wheelchair sitting.

Traditionally, non-surgical approaches have been favored. Treatments range from circular or bivalved casts, padded or pillow splints, prefabricated immobilization devices, traction, external fixation, as well as benign neglect (35, 58-60). While studies are limited by small sample size, heterogeneity of persons and treatment strategies, and no studies directly compare non-operative management strategies, a recent systematic review reported that soft tissue complications were associated with rigid casting and traction (20). Favorable results of non-operative management were found with well-padded or soft splints (20). Non-operative treatment strategies for LE fractures in SCI should be targeted towards maximizing return to activity and prevention of secondary complications.

Recent studies indicate that surgical management of LE fractures in individuals with a SCI may be becoming more prevalent, with reports of favorable outcomes including preservation of function in activities of daily living and routine wheelchair use (10) as well as return to former employment and participation in wheelchair sports (17). Significantly better range of motion (ROM) has been noted in cohorts managed operatively compared to those managed non-operatively (10, 17). In active, non-ambulatory wheelchair-bound users, operative treatment of long bone fractures allows rapid return to activities (61). Furthermore, favorable outcomes in validated measures of quality of life and pain have been reported in operatively managed cohorts, however, these were not compared to non-operatively managed individuals (61).

The emergence of new therapies for rehabilitation, including robotic exoskeletons (62), weight supported treadmill training (63) and functional electrical stimulation therapy (64) make it imperative to consider how fracture treatment strategies may impact an individual’s ability to participate in current or *future* rehabilitation strategies. For example, joint contractures at the hip, knee or ankle joint (65), and/or the inability to attain adequate passive hip extension ROM and the ankle joint in neutral position (66-74), prohibit use of robotic exoskeletons. Joint contractures and decreased passive ROM are frequent sequelae following non-operative management of LE fractures (10) and would impact exoskeleton use (62). Specific skeletal requirements for safe and effective operation of these devices in the future are unknown; consideration for future use of these devices is an important factor to consider when choosing management strategies for LE fractures.

Background (Clinical Context): Role of Therapists in LE Fracture Management

The input of an interdisciplinary team is critically important in the care of individuals with a SCI who have sustained a LE fracture for which complications and individual differences (such as mobility status) must be considered. In the rehabilitation setting, PTs, OTs, and KTs work closely with physiatrists, rehabilitation nursing, case management, and social work to coordinate and provide for the often complex medical, rehabilitation, and social needs of SCI individuals. When someone with a SCI experiences a LE fracture, their medical status, function, and ability to access their home and community can be affected, requiring the input and expertise of many disciplines to be effectively addressed. The goal of fracture management is to assist the individual with SCI to return to their pre-fracture functional status. Therapists play an important role in this process (22).

Prolonged bedrest, which can be a consequence of LE fracture treatment, is associated with various complications including pressure injuries, deep vein thrombosis, pneumonia, exacerbation of disuse osteoporosis, and joint stiffness (8, 17, 75-78). Early mobilization and protected weight-bearing in post-fracture treatment have been shown to reduce these complications and allow restoration of full range of motion to affected joints in the general population (79). Therefore, early mobilization strategies are commonly employed as a part of rehabilitation after fractures (79). Knowledge concerning optimal management of fractures in persons with a SCI however, is quite limited. There are many aspects of patient function in addition to the medical history and fracture characteristics that should be considered when devising a treatment plan. These include transfers, mobility both in the home and the community, ability to adequately perform pressure relief for prevention of pressure injuries, and participation in vocation and avocation. In order to return to many of these activities, restoration of full or pre-injury range of motion of the affected limb may be an important consideration (17, 80, 81).

While non-operative management has historically been the prominent treatment strategy of LE fractures in SCI individuals, prolonged immobilization can increase the burden of supportive care (60, 82). For example, if a fracture is non-operatively managed with a knee immobilizer or pillow splint that requires full knee extension, an individual may no longer be able to access his/her home environment and may require extended hospitalization, placement in a nursing facility, or discharge to an alternate living setting. A retrospective review of persons with chronic SCI who sustained fractures revealed that over 80% were hospitalized with extended stays, primarily due to home inaccessibility or inadequate caregiver support in the home (83). In one large study of Veterans with a SCI, 4% had changed residence to nursing home or assisted living and an additional 4% required in-home healthcare at one-year post discharge from LE fractures (34). In appropriately selected persons, surgical intervention for fracture may help to mitigate the negative effects of LE fractures on function, quality of life, and caregiver burden. Sugi *et al*. reported that surgical management of LE fractures in non-ambulatory chronic SCI individuals resulted in improved pain scores and better quality of life

(61). As rigorous evidence to support selection criteria for surgical management of LE fractures in SCI persons is lacking, guidance from therapists regarding functional and quality of life considerations in individual persons with a SCI may be beneficial in decision-making regarding operative vs. non-operative treatment.

The approach to treating LE fractures in a patient with a SCI should avoid relying on assumptions about disability to inform medical necessity. Rather, as in the non-SCI population, an understanding of the patient's prior function, goals, and quality of life should be considered, and a model of shared decision-making with the patient should be employed. It is therefore valuable to involve therapists early and throughout the treatment course.

Background (Clinical Context): Failure of Non-operative Treatments

A Girdlestone procedure (femoral head ostectomy) or Castle procedure (resection of proximal femur at level of lesser trochanter) are most commonly performed as a salvage procedure in combination with soft tissue reconstruction in the management of osteomyelitis in the presence of infected or non-healing pressure injuries due to shortening of the femur after non-operative management of a proximal femur or femoral neck fracture (84).

Amputation of the limb is rarely the first choice in treatment of pressure injuries or infection related to a fracture in the individual with a SCI. Factors to be considered include level of amputation, soft tissue coverage required, nutritional status, vascular sufficiency, the extent of infected or involved bone, the effect of amputation level on sitting balance and the persons' desire to proceed with amputation. A resection/ amputation at the hip and pelvis level will often result in a hip disarticulation and the creation of a large dead space and soft tissue defect that can lead to challenges for soft tissue reconstruction and wound coverage. Additionally, pelvic osteomyelitis from pressure injuries frequently involves large portions of the pelvis (hip, ischium, and ilium) and a curative operative resection is not feasible. In these cases, a multidisciplinary team including infectious disease specialists, physiatrists, physical therapists, and orthopaedic and plastic surgeons will allow for consideration of the complex issues related to management and treatment of pelvic osteomyelitis (85). At times, fecal and/or urinary diversion may be necessary. Amputation is likely a more successful treatment option for lower leg pressure wounds if a below the knee level can be maintained. **However, amputation at even a below knee level can have an adverse effect upon wheelchair activities as the weight of the L.E.s serve a useful purpose in maintaining balance in the wheelchair when patients are using their upper extremities actively (86-89).**

Background (Clinical Context): Compartment Syndrome

Compartment syndrome most frequently occurs after acute higher energy mechanisms of injury and may more often occur concurrently with the initial traumatic event that caused the SCI, rather than with a subsequent lower impact fracture. Improper application of a cast or splint used for immobilization may incur a risk of developing compartment syndrome (90). Following fracture, the diagnosis of compartment syndrome in patients with a SCI is difficult due to the loss of sensation which may eliminate important early diagnostic features including unrelenting pain, stretch pain, and loss of sensation. A high index of suspicion, and frequent physical examinations including monitoring for increased swelling and fullness in compartments are critically important. Laboratory studies including increased CPK/lactate and/or pressure measurements and treatments including fasciotomy if indicated, are appropriate. A missed compartment syndrome may be associated with rhabdomyolysis which can result in acute kidney injury or myonecrosis and fibrosis that may lead to

late contractures (91). The morbidity of surgical release (fasciotomy) which includes issues with wound healing and possible infection should be considered.

Background (Clinical Context): Post Fracture Heterotopic Ossification

Persons with a SCI are at risk for primary heterotopic ossification (HO) formation, particularly following severe and more proximal levels of SCI, even in the absence of fracture (92). Risk factors for HO following SCI identified in a recent systemic review and meta-analysis included male sex, smoking, AIS “A” injury, pneumonia, pressure injuries, urinary tract infections (UTI) and spasticity. Location of injury (cervical vs. non-cervical injury) and DVT were not associated with HO (93). However, the frequency of HO in persons with an established SCI, specifically after fracture, is not well defined. No ideal prophylaxis for prevention of HO exists for persons with a SCI or the able-bodied patient who sustains a fracture. As well described in a recent review of HO, all current prophylactic or treatment strategies have substantial shortcomings (94).

There is level 1 evidence that medications that affect the Cox pathway (rofecoxib and indomethacin) and PLIMF (pulsed low intensity electromagnetic field), reduce primary HO formation administered soon after SCI (95-98). Cox inhibitors may present challenges for use in clinical practice secondary to potential adverse gastrointestinal, renal and cardiovascular side effects. Although rofecoxib is no longer available another selective Cox-2 inhibitor, celecoxib, is available. Level 4 evidence exists for radiotherapy as prevention for HO formation (99, 100).

In a retrospective database study examining use of alendronate, a second-generation bisphosphonate for HO, including 291 persons with an acute SCI, HO developed in approximately 6% of the male persons. However, there was no significant difference in the odds of developing HO in the 135 persons receiving oral alendronate vs. the 174 who did not (101). For treatment of HO not related to fracture, Level 2 evidence exists for use of first generation bisphosphonates (etidronate) in stopping the progression of HO in SCI persons (102, 103). However, etidronate is not available in the U.S. and in many other places worldwide. There is no evidence for use of more potent second or third-generation bisphosphonates for primary treatment of HO. Relative to any bisphosphonate use, it should be noted that the treatment does not influence the deposition of bone matrix and only stops mineralization while the medication is administered. Once treatment is stopped, mineralization may occur. Side effects may be significant. Case series support surgical excision of ectopic bone in selected persons for seating, ROM and personal care (104, 105). Hip ROM has been studied after excision of primary HO. Post resection, bisphosphonates (etidronate and pamidronate) and radiotherapy reduced recurrence after resection in small case series (100, 106-108), but cannot be routinely recommended.

Background (Clinical Context): Prevention and Treatment of Fracture Nonunion

Risk factors associated with impairment of fracture healing include smoking, diabetes, advanced age and osteoporosis (109) which are conditions common in persons with a SCI (110).

In a small animal study modeling fracture healing following acute SCI, rat femur fracture callus formation was characterized by high porosity and low strength while the remaining long bone skeleton exhibited SCI related bone density loss characterized by increased RANK/RANKL (Receptor activator of nuclear factor kappa-B/ligand) driven osteoclastogenesis and decreased osteoblastic gene expression (111). The catabolic milieu of the SCI fracture may be affected by anabolic pharmacologic therapy. Parathyroid hormone (PTH) administered in pulsed dosing acts by normalizing extracellular calcium homeostasis and increasing osteoblast activity. Teriparatide, a synthetic hormone with PTH activity, is approved by the FDA for treatment of osteoporosis.

No studies are published that address fracture healing augmented by PTH-based therapies in persons with a SCI. However, literature in pre-clinical and clinical settings supports PTH as an approach to improving fracture healing. PTH has demonstrated improved fracture healing and increased fracture callus volume in animal models of unimpaired fracture healing, as well as impaired fracture models of aging, estrogen deficiency, and malnutrition (112). In a randomized controlled trial in post-menopausal fracture persons, low dose teriparatide improved time to radiographic distal radius fracture healing versus placebo from 9.1 weeks to 7.4 weeks (113). In a non-randomized observational cohort, 32 persons with an established nonunion of various osseous sites were treated with teriparatide an average of 24 months after fracture (114). The authors attributed the high frequency (95%) of progress to healing within 2-6 months after PTH treatment to the drug intervention (114). However, teriparatide is not FDA approved for treatment of fracture nonunion and insurance companies may not pay for this indication.

Low Intensity Pulsed Ultrasound (LIPUS) has been used in acute fractures and nonunions. Fracture healing requires reduction of the fracture gap, stabilization of the fracture, with restoration of bone perfusion (115). Not all patients heal uneventfully. Some patients do not heal even when the environment for bone union is optimal. In spite of challenges faced by persons with risk factors for nonunion such as smoking and diabetes, some clinical and pre-clinical evidence suggests that LIPUS may decrease the incidence of nonunion. Animal studies provide data on how LIPUS improves fracture healing in diabetes. Diabetic rats have lower levels of VEGF and less neovascularization in fracture

callus than non-diabetic rats (116). Diabetic rat fractures treated with LIPUS increase VEGF production and neovascularization, to levels similar to nondiabetic rats (115, 116).

In a n rat study on the use of LIPUS for fracture healing in osteoporosis, a 26-30% increase in callus was found between rats treated with and without LIPUS. Xrays also showed of fracture gap was eliminated 2 weeks earlier in the LIPUS rats than the controls (117). LIPUS increased expression of 5 genes for type I collagen, BMP-2, angiogenesis-related Vascular Endothelial Growth Factor (VEGF), and for the remodeling gene RANKL. All of these genes are thought to improve fracture healing(117).

Clinical data that indicates LIPUS has a positive effect on fracture healing was published in a meta-analysis by Lou et al. of 12 studies that included 1,099 fresh fractures in persons without a SCI. All studies showed a reduced time for fracture healing with LIPUS. (95% CI –1.13, –0.17). A subgroup analysis of LIPUS vs. conservative management showed that LIPUS significantly reduced the time to healing compared to conservative fracture management by a standard mean difference of –1.08 (95% CI –1.82, –0.34) (118). Another meta-analysis of 24 studies on the use of LIPUS in acute fractures concluded: "LIPUS treatment effectively reduces the time to radiographic fracture union, but this does not directly result in a beneficial effect of accelerated functional recovery or the prevention of delayed union or nonunion" (119). An ongoing trial to assess effect of LIPUS on preventing nonunion in at risk persons is currently registered at clinicaltrials.gov (120). The U.S. FDA and the United Kingdom National Institute for Health and Care Excellence (NICE) have both approved the use of ultrasound for use in nonunion and delayed union (121). The FDA has approved use of LIPUS for acute fractures, but the United Kingdom has not.

A few studies have addressed incidence rates and risk factors for fracture nonunion in persons with a SCI (15, 122). In one report, following fracture, more than half of persons with a SCI of one year or more in duration suffered fracture-related complication, with fracture nonunion/delayed healing accounting for 25% of all the reported complications (15). Others have reported that fracture nonunion rates in persons with a SCI approximate 16.0% of all fractures (122). Fracture location (proximal femur compared with tibia), fracture classification [OTA B vs. A] and fracture management [conservative (nonsurgical) treatment compared with operative management] were risk factors for fracture nonunion in persons with a SCI identified in a case series from Germany (122). Persons with a fracture nonunion often have continued pain, are unable to work, and may require additional surgical intervention.

Fracture malunions are fractures that have healed but with inadequate positioning and as such, are not necessarily indicative of a fundamental problem in bone biology. Fracture malunions of the lower extremity with malalignment may be of concern, particularly if they interfere with transferring or with optimal seating as pressure injuries might occur. Operative correction of the deformity with realignment and restoration of normal anatomy has resulted in improved functional outcomes (123).

Background (Clinical Context): Venous Thromboembolism (VTE) Prophylaxis

We consider persons with chronic SCI who develop a major lower extremity fracture to be at increased risk for VTE. As a key component in a comprehensive fracture management program, we believe that anticoagulant thromboprophylaxis should be provided routinely at least during admission for the fracture and rehabilitation care with a consideration given for post-discharge thromboprophylaxis in selected persons. We believe that a similar consideration be given to persons who are not admitted. The options include subcutaneous low molecular weight heparin (LMWH), including enoxaparin, dalteparin or tinzaparin, or a direct oral anticoagulant (DOAC), including rivaroxaban, apixaban, edoxaban, or dabigatran.

Contraindications to use of anticoagulant-based thromboprophylaxis include high risk for bleeding or platelet count less than 30 x 10^9/L. Persons who have had heparin-induced thrombocytopenia (HIT) in the past should not receive LMWH unless this has specifically been supported by a hematologist or thrombosis specialist.

Although we recommend LMWH or a DOAC as the preferred thromboprophylaxis options, there may be situations in which warfarin or aspirin (ASA) are acceptable options.

It is well-established that persons with acute SCI have the highest risk of VTE among hospitalized persons, and that they warrant routine, "aggressive" thromboprophylaxis (124-127). The risk of VTE declines after the acute and rehabilitation phases of SCI although the risk remains greater than age-matched controls without SCI indefinitely (128-133). Among a cohort of 94 persons with a SCI the incidence of VTE in the first 3 months was 34/100 patient-years and 0.3/100 patient-years thereafter (134). The rates of VTE in 12,584 SCI persons at 3 months, 6 months and 12 months after injury were reported to be 34%, 1.1% and 0.4%, respectively (132). The reasons for a persistent thrombosis risk in persons with a SCI include:

- Venous stasis related to chronic immobilization
- Reduced venous outflow secondary to compression of the common femoral veins associated with prolonged sitting in a wheelchair
- Decreased endogenous t-PA release from the venous endothelium

- Leg injuries that are not appreciated by persons who have sensory deficits
- Increased inflammatory stress (135-139)
- Platelet dysfunction
- Novel circulating antibody that specifically blocks the high-affinity prostacyclin platelet receptors (140)
- Elevated thrombin generation and platelet-derived growth factor release (141)
- Impaired insulin-induced nitric oxide production (142)

Able-bodied persons with fractures of the lower extremity have repeatedly been shown to have increased risk of VTE (143). In a systematic review of persons with acute leg immobilization, DVT was found in 21% of the 416 persons with fractures, in 15% of the 429 persons with plaster casts, and in 26% of the 350 persons who had surgical repair (143). In the same review, LMWH was shown to reduce proximal DVT by 61% and symptomatic VTE by 91% compared with no prophylaxis. A randomized trial comparing enoxaparin with rivaroxaban as thromboprophylaxis in 3,604 persons following non-major lower extremity orthopaedic surgery, showed a 75% reduction in the risk of symptomatic VTE with rivaroxaban versus enoxaparin and no difference in bleeding (144). In persons with major pelvic trauma, femoral fractures or those hospitalized with other leg fractures, anticoagulant thromboprophylaxis is usually given while in hospital (including rehabilitation). Although post-discharge prophylaxis is commonly used for 10-28 days in persons with hip fracture, thromboprophylaxis after hospital care for persons with isolated lower extremity fractures is controversial (145, 146).

Few studies have reported VTE risks in persons with chronic SCI who develop a leg fracture, although SCI is a risk factor for VTE in persons with leg fractures (145). Among 1,027 men enrolled in the Veterans Affairs Spinal Cord Dysfunction Registry who developed lower extremity fractures at least 2 years after the SCI, the risk of thromboembolic events was increased compared with a propensity-matched SCI group without fractures (147). The excessive VTE risk decreased over time from the fracture: hazard ratio 2.6 (95% CI 1.1-6.3) at 1 month, 1.2 (95% CI 0.5-2.7) at 6 months, and 1.1 (95% CI 0.4-3.0) at 1 year.

We are not aware of any clinical trials or practice guidelines that specifically address thromboprophylaxis options in persons with chronic SCI who develop an acute lower extremity fracture. However, these persons likely have a higher risk of VTE than persons without SCI who have similar injuries. The 2016 Consortium for Spinal Cord Medicine guidelines “recommend that persons with chronic SCI who are hospitalized for medical illnesses or surgical procedures receive thromboprophylaxis during the period of increased risk” (124). Routine anticoagulant thromboprophylaxis options include LMWH or a DOAC. LMWH has been well-studied in numerous patient groups, including those having major orthopaedic surgery, are recovering from major trauma or have an acute medical illness (148, 149). DOACs have also been well-studied in orthopaedic surgery and as post-discharge prophylaxis in medical persons (150-153). The advantages of DOACs are their demonstrated greater efficacy in clinical trials and in clinical practice, oral route, and reduced cost compared with LMWH (144, 154, 155).

There is major uncertainty about the optimal duration of thromboprophylaxis in persons with a SCI who have leg fractures. Based on studies in persons who have undergone hip or knee replacement or high risk lower extremity fracture fixation, it is reasonable that thromboprophylaxis continue for at least 2 to 4 weeks after fracture (156).

Background (Clinical Context): Pain Management Post Fracture

Pain following fracture is very important to recognize and treat in persons with a SCI as these persons, regardless of their spinal cord injury level and extent, may experience pain following fracture (160). A LE long bone fracture can be a potent stimulus for nociceptive pain among persons with SCI, an independent source of neuropathic pain and/or a source of neuropathic pain exacerbation. At or below level neuropathic pain is a complex phenomenon after SCI; many persons experience pain exacerbations as they age and with changes in their health status.

The OTA has published guidelines regarding pain management post-fracture including acute pain management considerations and tapering of pain medications which are applicable to persons with a SCI with major and minor fractures (159). However, frequent comorbid medical conditions among persons living with SCI including neuropathic pain, HO, VTE, mood disorders or poor coping may influence pain management considerations. Further information on pain management for persons with a chronic SCI is provided by the CanPain CPG (157), which was restricted to the SCI literature. This restriction in article inclusion, limited the volume of evidence available for synthesis but allowed for consideration of issues unique to persons with a SCI.

Autonomic dysreflexia (AD), uniquely occurs in persons with a neurological injury level at or above T6 and is a serious and sometimes emergent situation characterized by increases in systolic blood pressure of 30 mm Hg or greater, reflex bradycardia and diaphoresis. Pain (nociceptive input) is a leading cause of AD. Therefore, adequate pain management, even in the insensate patient (as discussed below), is a key consideration for preventing and treating AD in those at risk. For a full discussion of the relevance of AD to skeletal health, the reader is referred to the PVA Consortium for Spinal Cord Medicine Clinical Practice Guidelines: Bone Health and Osteoporosis Management in Persons with Spinal Cord Injury.

Pain assessment is a moral and legal obligation both for physicians caring for persons in outpatient and inpatient settings. Analgesic therapy should always be carried out in a stepwise approach to the patient. Although systemic analgesia is the mainstay of post-fracture pain management, evidence is trending toward multimodal pain control, supplementation with regional anesthesia, and minimizing narcotic use (161). In support of a multimodal pain approach rather than reliance on opioids alone, one study of male Veterans with chronic SCI taking high doses of opioids were reported to have twice the propensity to commit suicide (162) and a 5-year increased risk of death post-fracture (163). Moreover, for older persons and those with cognitive impairment, the use of aggressive pain control may be limited by the desire to reduce the risk of delirium (164). In the acute postoperative period, the goals of adequate pain control are intended to allow for early mobilization and to minimize the complications of immobility or delirium by minimizing narcotic use (161).

Persons with SCI are often subjected to polypharmacy (defined as being prescribed at least five medications concomitantly) and prescribed medications from multiple high-risk classes (e.g. analgesic-narcotics, anticonvulsant, antidepressant, and muscle relaxants), as well as multiple medications within each class (e.g. multiple analgesic-narcotics) (165). Clark and colleagues examined the risk of pain medication misuse (PMM) in 1,619 adults with traumatic SCI of at least one year's duration. They identified a cutoff score ≥30 measured using the Pain Medication Questionnaire (PMQ) for persons who reported at least one painful condition and use of prescription pain medication (166). PMM occurs in approximately one in four persons taking prescription analgesics and is highest among young adults, those with low education, and higher use of pain medications.

Administration of fascia-iliaca compartment blocks (FICB) and multi-model pain management preoperatively may decrease and delay analgesic consumption, reduce the amount of time required to administer preoperative spinal anesthesia, and provide superior pain control during movement compared with opioids in the general population (161, 167). Based on the limited data available, regional nerve blocks provide superior pain relief compared with opioids, and opioids provide superior pain relief compared to Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) (168). These observations may well be relevant to persons with a SCI and a fracture.

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Appendix

Supplementary Table 1. Members of Expert Panel with Areas of Expertise

[1]Names	Area of Expertise
Robert Adler, MD	Endocrinologist responsible for reaching bone mineral density tests in spinal cord injured patients; involved in multiple studies of methods to assess and improve bone and muscle function in persons with SCI
Jaimo Ahn, MD, PhD	Orthopaedic trauma surgeon who clinically cares for patients with a SCI individually with acute and chronic fractures and acute and chronic infections as well as programmatically through the University of Michigan Spinal Cord Injury Clinical Quality Board and SCI Advisory Council
Laura Carbone, MD, MS	Board Certified internist, rheumatologist, hospice and palliative care physician and epidemiologist involved in multiple studies of sublesional osteoporosis and fracture treatments and complications in patients with a SCI
Tomas Cervinka, PT, PhD	Licensed physiotherapist in Finland since 2020 working at the neurological rehabilitation ward of Central Finland Central Hospital which currently supports over 50 in ward rehabilitation care/rehabilitation plan re-assessment/outpatient visits for individuals living with spinal cord injury/disease per annum, including a fracture prevention program.
Catherine Craven, MD, MSc	Board certified specialist in physical medicine and rehabilitation and Medical Director of Canada’s largest freestanding spinal cord injury rehabilitation hospital, Fellow of the American Spinal Injury Association and the Canadian Academy of health Sciences
William Geerts, MD	Chair of the Prevention of Venous Thromboembolism guideline for the American College of Chest Physicians (CHEST guidelines) for 10 years (1999-2008) Principal member and author of the Consortium for Spinal Cord Medicine guidelines on VTE in spinal cord injury (1999, 2016)
Joseph Hsu, MD	Orthopaedic Trauma surgeon with experience in fracture management in this population. Also with experience in clinical practice guidelines to include pain management.
Donna Huang, MD	Board certified PM&R and SCI physician. Staff physician at Michael E. DeBakey VA Medical Center. Cares for patients with a SCI with a broad range of secondary complications of SCI, including fractures

Madhav A Karunakar, MD	Over 20 years' experience as an Orthopaedic traumatologist treating a large number of patients with a SCI and LE fractures. Published on treatment of femur fractures in patients with a SCI
B. Jenny Kiratli, PhD	Over 35 years' experience conducting clinical research on individuals with SCI with a focus on musculoskeletal response to paralysis, fracture risk and DXA assessment.
Peter C Krause, MD	Orthopedic trauma surgeon working for twenty years at a major urban Level 1 trauma center. Managed many extremity fractures in patients with a SCI
Leslie Morse, DO	Board certified specialist in physical medicine and rehabilitation and Head of the Department of Rehabilitation Medicine at the University of Minnesota School of Medicine with over 20 years of clinical trial experience in SCI-induced osteoporosis. Task Force Chair for the International Society of Clinical Densitometry SCI-specific position statements.
Gudrun E. Mirick Mueller, MD	Orthopaedic traumatologist at an urban level one trauma center for 10 years. Responsible for the care of acute and subacute fractures of SCI patients, both operative and non-operatively.
Arvind D Nana, MD, MBA	Orthopaedic traumatologist, working for entire career in level one trauma centers responsible for the management of a significant number of lower extremity fractures in patients with SCI. For several years, was on the Spinal Cord Injury Team at a level one trauma center
William Obremskey, MD, MPH	28 years as an orthopedic surgeon at level 3, level 2 and 20 years at a level 1 hospital, caring for 3-10 patients a year with SCI lower extremity fracture.
Elaine Rogers, PT	Worked exclusively in SCI physical therapy for the past 25 years at VA Puget Sound Health Care System, Seattle WA. Holds an Assistive Technology Practitioners (ATP) certification from RESNA since 2007. Serves as the physical therapy resource for fracture management, therapy mentoring/training and local policy development for lower extremity fracture management strategies served as an active board member, Governance board member, Treasurer and conference planning member of the Academy of Spinal Cord Injury Professionals (ASCIP) since 2009 and an active member of the Therapy Leadership Counsel in SCI since 2003 to its merger into ASCIP in 2009).

Jessica Rivera, MD, PhD	Orthopaedic surgeon with >10 years' experience caring for orthopaedic trauma patients and performing fracture fixation. Practice environments include Level 1 trauma centers, military treatment facilities and Veterans Affairs facilities serving military, Veteran, and civilian trauma patients which include SCI patients. Additionally I have > 10 years' experience researching disability outcomes following military injuries, including SCI.
Clay A Spitler, MD	Orthopaedic surgeon at a busy level 1 trauma center serving a broad population including a significant number of SCI patients. Center is physically attached to a nationally recognized spinal cord injury rehabilitation center and provides coordination of care for fractures with PM&R physicians.
Frances Weaver, PhD	Research Director, SCI Quality Enhancement Research Initiative (14 yrs.) Methodology Editor, Journal of Spinal Cord Medicine

[1]In alphabetical order

Supplementary Table 2. Delegation of Responsibility for Literature Reviews and Recommendations for each Section of CPG

1. Overview of consideration of Fracture Issues in Patients with a SCI	• Cathy Craven* • Frances Weaver	• Jaimo Ahn*
2. Functional, Positional, and Mobility Considerations	• Frances Weaver* • Tomas Cervinka • Jenny Kiratli • Elaine Rogers	• Peter Krause*
3. Non-operative treatments for Fracture	• Donna Huang* • Tomas Cervinka • Elaine Rogers	• Jaimo Ahn* • Arvind Nana
4. Operative treatments for Fracture	• Leslie Morse* • Donna Huang	• Clay Spitler* • Jaimo Ahn

			• Peter Krause • Hsu, JR
5. Post Fracture Considerations			
	a. Augmentation of Fracture Healing(Fracture Nonunion)	• Robert Adler • Laura Carbone*	• William Obremskey* • Jessica Rivera
	b. Complications with Fracture Healing	• Leslie Morse*	• William Obremskey*
	c. Compartment Syndrome	B. Jenny Kiratli*	• Madhav Karunakar* • Jaimo • Ahn
	d. Thrombosis	• William Geerts*	• Gudrun Mirick Mueller*
	e. Heterotopic Ossification	• Robert Adler*	• Jessica Rivera* Madhav Karunakar

*Refers to the non-orthopedic and orthopedic leads for each section.

Drs. Carbone and Obremskey reviewed literature and all recommendations for each section