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REVIEW & ANALYSIS

# Spinal Cord Injury Rehabilitation

## State of the Science

**ABSTRACT**

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**Key Words:** Spinal Cord Injury, Rehabilitation Research, Outcomes

Spinal cord injury (SCI) is a low-incidence phenomenon (15–40 cases per million), resulting in about 11,000 new cases in the United States per year, and a prevalence near 250,000. Men sustain this injury about four times as often as women; age of onset is typically in the young 30s. As measured by the Model Systems database, over time, proportionately fewer whites have sustained SCIs, and more cervical injuries have occurred. Motor vehicle accidents, falls, violence, and sports have been the leading causes of SCI, respectively, over time, based on the Model Systems data, with a period of time in the 1990s in which violence superseded falls as the second-leading cause.[1] In very young children who sustain SCI, gender and injury characteristics are different from adults, becoming much more similar when onset is in adolescence.[2]

Research related to the epidemiology of SCI has largely been descriptive, with a focus on primary prevention.[3] This information is important for estimating the impact of SCI as measured by incidence, prevalence, survival, and characteristics of those who receive such injuries. Methodologies for capturing this information have varied widely from retrospective attempts to capture all cases of a particular etiology over a given time period[4,5] to prospective attempts to capture all cases in a geographic area.[6,7,8] Countries with centralized health care and record keeping have come the closest to population-based estimates of incidence and prevalence,[5,6] and several state-based registries in the United States have attempted to do the same.[4] The National Institute on Disability and Rehabilitation Research–funded SCI Model Systems of Care database, though not population-based, has been collecting epidemiologic data on a large sample of persons with SCI back to 1973, with enough of the funded systems being the same throughout that period that important trends have been identified.[9]

The neurologic injury with its resultant paralysis and loss of sensation is only one of a myriad of physical consequences of SCI. Thus, the care of persons with SCI is not limited to the treatment of the neurologic injury. Medical consequences as a result of altered neurologic input such as the development of respiratory failure or neurogenic bladder and resultant complications such as pneumonia and urinary tract infections affect most organ systems. In addition, the psychological impact of the injury is vast, and complications such as depression and anxiety are frequent. Rehabilitation has traditionally focused on maximizing the person's recovery from the injury and returning him or her to home as independently as possible. It has included such techniques as performing range of motion, strengthening weakened muscles, and retraining bladder and bowel functioning. However, once the milestone of returning home with a new SCI is crossed, the individual must conquer the barriers of societal reintegration with his or her altered body habitus.

The care and treatment of persons with SCIs has drastically improved, and we are now concerned with improving quality of life rather than merely extending survival. Despite this, many shortfalls are noted in the research supporting our past and current practices in the field of SCI. The purpose of this article is to develop an understanding of the level of evidence about practice patterns in the field of SCI and to make recommendations for where and how future research initiatives should be targeted.

## METHODS

We realized that performing a review of all topics related to the treatment and needs of persons with SCIs would be impossible; therefore, we limited our search to a series of medical and psychosocial topics deemed most crucial to promote the rehabilitation of persons with SCI. We chose to study pharmacologic and surgical treatment of the acute injury, followed by neurologic recovery and functional potential. Medical topics that were searched included respiratory, pneumonia, neurogenic bowel dysfunction, acute abdomen, gastric ulcer, gallstone, management of neurogenic bladder, urinary tract infection, bladder stone, bladder carcinoma, neurogenic sexual dysfunction, pressure sore, deep vein thrombosis, musculoskeletal complications, heterotopic ossification and osteoporosis, metabolic dysfunction, body composition, spasticity, and pain. Outcome measures were reviewed. In addition, we searched the terms rehabilitation therapies, exercise, body-weight–supported treadmill training, and electrical stimulation. Psychosocial topics included community integration, depression, substance abuse, anxiety, family and caregiver issues, coping effectiveness, and life satisfaction. We also searched vocational issues, assistive technology, and aging.

We performed searches using MEDLINE, PubMed, and Psych Lit in addition to performing secondary reviews and conferring with known experts in the fields. We also surveyed ongoing research. After group discussions with other Model Systems representatives, we chose to include in the evidence tables the level I and level II studies published in the English language (as per the American Academy of Neurology Guidelines) from Fall 1999–2004 with a sample size of ≥20 for both subjects and controls. For those areas in which limited recent research was available, we sought the most recent and meaningful articles published before 1999. In addition, we determined whether the article's focus was diagnostic, prognostic, or therapeutic. Published clinical practice guidelines were also reviewed. Because of the paucity of research in certain topics when level I or II evidence was not available, other level III and IV studies deemed important were reviewed and evaluated. If not specified in the text or tables as a level I, II, or III study, the reader can assume that the study reviewed was a level IV study. Based on this information, recommendations have been made for future directions in the field of SCI. Throughout the sections of this article, to the extent that various types of evidence were available for different topics, we have attempted to follow the pattern of discussion of diagnostic studies first followed by prognostic and therapeutic studies.

## CLINICAL PRACTICE AND INTERVENTIONS RELATED TO THE NEUROLOGIC INJURY

### Acute Management of Spinal Cord Injury

#### Pharmacologic Management

Much attention has been paid to the acute management of SCI and whether pharmacologic therapy is justified. The National Acute Spinal Cord Injury Study (NASCIS) trials,[10,11,12,13] all published before 1999, were the first to document a potential beneficial treatment for SCI and quickly led to methylprednisolone (MPSS) being known as a standard of care for acute SCI management. However, these results have been questioned due to the use of post hoc analyses,[14] inappropriate use of statistics,[15] and the potential harmful side effects of MPSS. Based on reviews of the literature,[16] the use of MPSS post-SCI has been deemed a recommendation for acute, nonpenetrating SCI within 8 hrs of trauma. It is not recommended for acute nonpenetrating SCI over 8 hrs postinjury or for penetrating SCI. It is recommended that acute patients with SCI who present within 3 to 8 hrs postinjury may reasonably be given 48 hrs as opposed to 24 hrs of therapy.

Other drugs that were evaluated as part of the NASCIS studies included naloxone, a nonspecific opioid receptor agonist, studied as part of NASCIS 2, and tirilazad, a member of the 21-aminosteroid family of antioxidants called lazaroids developed to prevent lipid peroxidation without activation of glucocorticoid receptors, studied in NASCIS 3. Although a subsequent analysis[17] of data showed that naloxone promoted significant neurologic recovery in subjects with incomplete injuries, it was originally touted as lacking efficacy. Furthermore, neurologic recovery with tirilazad was found to be comparable with that of MPSS for 24 hrs.

Two level II therapeutic trials were noted between 1999 and 2004. Monosialotetrahexosylganglioside GM1 sodium salt (Sygen)[18] is a naturally occurring compound that has previously been shown to have neuroprotective and regenerative effects. Subjects who participated in the multicenter clinical trial of Sygen all received MPSS as per the NASCIS 2 protocol, followed by either a 300-mg loading dose of Sygen followed by 100 mg/day for 56 days, a 600-mg loading dose of Sygen followed by 300 mg/day for 56 days, or placebo for a loading dose and subsequently for 56 days. A number of analyses were conducted. Significance was not achieved with the predefined primary efficacy analyses; however, various subgroups of subjects such as those with American Spinal Injury Association (ASIA) B injuries and those who did not have spinal surgery seemed to have earlier and greater recovery with Sygen. In a smaller, placebo-controlled study,[19] the use of nimodipine, a calcium channel blocker, was compared with MPSS alone, MPSS combined with nimodipine, and placebo alone. Although this study may not have been sufficiently powered to achieve significance, no differences in neurologic recovery were noted between the groups at 1 yr postinjury.

### *Conclusion*

Few clinical trials have targeted improved neurologic recovery post-SCI. It is clear that further research should and will continue to be performed to evaluate neuroprotective strategies post-SCI.

## Spinal Surgery

Surgical stabilization of acute spinal trauma is common; however, there is little agreement with respect to the usefulness of surgery in promoting neurologic recovery post-SCI. The exact timing of "early" *vs.* "late" surgery has not been defined, and the logic behind the choice of different times in various studies varies. Some authors define early surgery as up to 8 hrs postinjury, whereas others have used a 72-hr window. Although a number of meta-analyses have been performed evaluating various issues related to surgery, the studies that have been performed are primarily level III, with only one prospective, randomized level II study performed before our time frame and eight prospective, nonrandomized case series. All other studies were retrospective case series. Thus, the number of recommendations that can be made are small. There are level II data to show that surgery for acute SCIs can safely be performed. There are also level III data that support urgent decompression with bilateral facet dislocation or in incomplete SCI with a neurologic deterioration. Aside from these subcategories, however, the data only support the use of surgical decompression and stabilization as a practice option.

### *Conclusion*

In light of the large number of persons with SCIs who undergo surgery, this is an area in which future prospective, randomized studies are definitely warranted. These should determine whether there is a benefit of early or late surgery, when those time frames are, and whether surgery does promote neurologic recovery.

## Neurologic Recovery

It is important to be able to prognosticate the recovery of motor and sensory function in persons with SCIs so as to provide accurate information to patients and their families, to guide the patient's rehabilitation, and to determine if new treatment methods are effective. In addition, it is important to be able to prognosticate the recovery of voluntary bladder and bowel function and other autonomic functions. This area has been considered so important that clinical practice guidelines for Outcomes Following Traumatic Spinal Cord Injury were published in 1999.[20] However, as can be seen from the guidelines, the scientific evidence regarding prognosis for recovery of neurologic function post-SCI was primarily level V. Moreover, research in this area has primarily focused on the recovery of motor and sensory function and generally avoided the recovery of autonomic function. Multiple studies have shown that the prognosis for neurologic recovery after SCI is best predicted by the clinical neurologic examination using the International Standards for Neurological and Functional Classification of Spinal Cord Injury Patients.[21] The examination at 72 hrs postinjury has been determined to be superior to that at 24 hrs postinjury for determining recovery post-SCI.[22,23] Those subjects with incomplete injuries at the time of examination are well known to have a better prognosis for neurologic recovery than those with complete injuries.

Using the American Academy of Neurology criteria for rating of prognostic articles, we were able to find six level III studies and one level II study published between 1999 and 2004. Successive grades in both the Frankel and the ASIA impairment scale (AIS) have better prognosis for functional motor recovery.[24] A prospective multicenter study recently documented that subjects with incomplete injuries demonstrated a greater likelihood of improvement of neurologic function by one level than those subjects with complete injuries.[25] In another smaller prospective study, patients free from cervical fractures with central cord syndromes all demonstrated neurologic improvement, and the absence of magnetic resonance imaging findings of abnormal signal intensity in the spinal cord was considered a positive predictor for neurologic recovery.[26] One issue that remains unresolved with regard to documenting the remaining motor control of subjects with motor complete paralysis post-SCI is that of the subclinical discomplete[27] syndrome used to describe persons who are clinically paralyzed but show subclinical evidence of translesional motor connections. In a recent study[28] of 67 subjects with chronic AISA A or B SCI, surface electromyographic evidence of this discomplete state was found in 68% of AISA A subjects and 58% of AISA B subjects. How this finding relates to the potential for recovery induced by new therapies in subjects with acute and chronic SCI needs to be determined.

Other recent studies that have looked at neurologic recovery have been limited in that they have retrospectively reviewed longitudinal data collected as part of the Model Systems or for other studies. These level III studies have begun to look at the late effects of SCI[29] and the impact of sex[30] and etiology[24] on neurologic recovery, whereas other studies have considered the potential for marked recovery at various levels of injury[18] and the reasons for neurologic deterioration[31] postinjury.

### *Conclusion*

Based on the current literature, further prospective studies of the natural history of neurologic recovery for both motor and sensory function post-SCI and how these variables affect recovery are necessary. In addition, studies should address recovery of autonomic function. This information will be particularly relevant to effectively plan for clinical trials in SCI.

### Functional Potential

Determining the potential functional outcome of an individual post-SCI is an important part of the rehabilitation process. Functional outcomes are traditionally determined based on the level of SCI in conjunction with a review of the age, medical status, motivation, and family support of the patient. A number of tables have been developed to document the optimal functional potential of persons with SCIs. These have recently been reviewed in conjunction with an evidenced-based review of the literature on functional potential after SCI performed by the Spinal Cord Medicine Consortium.[20] Unfortunately reviews of the literature conducted by the Consortium reveal that the majority of studies are retrospective rather than prospective. In addition, potential recovery is generally determined by the FIM™ motor subscale, which is not optimal to assess the progress of SCI patients. Based on our criteria, we found eight level III studies addressing this topic. The issues of sex,[32] age,[33–36] and cause of injury[37,38] and their impact on function have been studied. Magnetic resonance imaging[39] has also been used to prognosticate functional recovery post-SCI. Overall, these studies have not found a significant difference between groups with respect to function; however, there is some suggestion that with older age there is a negative impact on functional potential.

### *Conclusion*

Further studies should be performed to document the optimal functional potential of persons with SCIs. Moreover, more sensitive outcome measures than the FIM™ instrument should be used to describe changes in functional status, and further research should be pursued to determine the impact of findings in using imaging on functional recovery.

## TREATMENT OF MEDICAL CONSEQUENCES AND COMPLICATIONS

A large part of rehabilitation from acute SCI involves the management of the effects of the injury on various organ systems. These include the optimal management of the injury on bladder and bowel function, optimizing respiratory function, preventing pressure ulcers and deep vein thrombosis, among other effects. In addition to managing these problems, patients and their families are educated about the impact of their SCI on organ system functioning and how to manage potential problems.

### Respiratory Function

Persons with SCIs at the level of T12 and above have a decrease in respiratory function. Impaired muscular function results in a decline in vital capacity and the ability to cough. Consequently, respiratory complications such as pneumonia are a major source of morbidity, and respiratory conditions are the number one cause of death post-SCI.[40] Despite this fact, only one level II and one level III therapeutic study and one level III prognostic study were found during our designated time period.

Traditional methods to improve pulmonary function after SCI include respiratory strengthening exercises and assistive coughing. These methods have not, however, been proven as efficacious in improving vital capacity above and beyond the natural recovery that occurs after SCI. Liaw et al.[41] documented the benefits of resistive inspiratory muscle training in patients with complete SCI; however, their sample size was limited and it is uncertain whether testing of pulmonary function was done in a blinded fashion.

### Ventilator Dependency

Secondary complications associated with the decline in respiratory capacity post-SCI include the development of ventilator dependency, especially in patients at the level of C4 and above and in those persons with vital capacities of <1 liter. Weaning of persons with SCIs from ventilators in SCI units is generally done with progressive T-piece trials and with rest on the ventilator between trials using assist–control mode. However, the optimal ventilator tidal volume settings to facilitate weaning of patients from ventilatory support has not been prospectively studied. A retrospective evaluation[42] demonstrated that persons with SCI ventilated with tidal volumes of ≥20 ml/kg body weight were able to wean from the ventilator substantially quicker than those who were ventilated with tidal volumes <20 ml/kg body weight. Furthermore, those patients who were weaned using large tidal volumes had substantially less atelectasis than those weaned using low tidal volumes. Nevertheless, in the acute hospital setting, weaning is generally performed using pressure-support ventilation, and when on assist–control mode, patients are ventilated using more traditional tidal volumes of 5–10 ml/kg.

### Pneumonia

Along with atelectasis, pneumonia is also a frequent problem for persons with both acute and chronic SCI. Treatment of community-acquired pneumonia was recently reviewed in a level III prognostic study in the Veterans Administration Healthcare system,[40] with the finding that most SCI patients with pneumonia are admitted for treatment and that the short-term mortality is comparable with community-acquired pneumonia in the general population.

### Conclusion

Although pulmonary consequences are the primary cause of death post-SCI, there is a paucity of current research. A multicenter, clinical trial to determine the optimal method to wean ventilator-dependent SCI patients is a priority for future research, as are studies addressing effective ways to improve overall pulmonary function and to prevent respiratory complications.

## Neurogenic Bowel Dysfunction

### General Care

Neurogenic bowel can result in incontinence, constipation, and a general decrease in quality of life post-SCI. A recent comparison of 467 SCI and 668 able-bodied age- and sex-matched control subjects revealed fecal incontinence was significantly higher in SCI persons than controls and that among SCI subjects was greater in those with complete *vs.* incomplete injuries.[43] Guidelines for neurogenic bowel management in adults with SCI[44] were developed in 1998. Unfortunately, there was an overall lack of high-level evidence in most topic areas; thus, the guidelines developed were primarily based on expert consensus. During our time frame, we found one level II prognostic study related to neurogenic bowel dysfunction, with three level III prognostic studies (of which two could also be considered diagnostic) and one level IV prognostic study related to gallstones.

It is generally accepted practice that SCI patients should be trained in a bowel program that takes into account the type of injury (upper motor neuron *vs.* lower motor neuron) affecting their bowel, their symptoms, and whether they have physical capability and support to perform a bowel program. Based on the patient's neurologic injury, a bowel management program is developed using an appropriate chemical or mechanical rectal stimulant for those with reflexive bowels and an appropriate manual evacuation technique with areflexive bowels. A sufficient fluid intake is recommended, along with proper diet and regular performance of the bowel program. Stool softeners and fiber are used when appropriate.

Gastrointestinal transit is delayed in subjects with SCI as compared with able-bodied control subjects.[45] Furthermore, the specific locations of segmental decreases in colonic transit time in respect to level of neurologic injury have recently been documented using radiopaque markers and radiographic examinations.[46] Cisapride, a prokinetic agent previously used to improve gastrointestinal transit time in SCI, has been discontinued.[47] Positive pilot data were also obtained that demonstrated potential efficacy and tolerability of prucalopride to improve transit time in patients with SCI.[48] Unfortunately, this drug was also discontinued. Thus, further testing of the newest prokinetic drug, tegaserod,[49] is warranted via a multicenter double-blind, placebo-controlled study.

### Complications

Little is known about the incidence of acute abdomen in SCI and the optimal treatment of this unfortunate occurrence. No studies were found in the past 5 yrs on this topic or with regard to management of gastric ulcers after SCI. Little is also known about the effects of colostomy for long-term impact of neurogenic bowel and whether the impact on timing of bowel care and quality of life in persons with SCI justifies this procedure. Consortium Guidelines indicate a decision for colostomy or ileostomy should be based on "the results of specialized screening procedures and the individual's expectation" but that "a permanent stoma is the best option." Although a recent retrospective study revealed a decrease in bowel care time from 10.3 hrs/wk to 1.9 hrs with a colostomy,[50] prospective controlled data are still necessary to determine the risk and benefits of this procedure.

### Gallstones

Gallstones have been known to occur in almost one third of patients with SCIs,[51–53] which is a 3- to 6-time greater risk than that seen in age- and sex-matched controls.[54] Whether the presentation of symptomatic gallstones is similar to that of the able-bodied person is uncertain, as is the recommended treatment of asymptomatic stones. Moonka et al.[52,54,55] performed a number of level III studies in the veteran population using routine abdominal screening ultrasonography. They noted a prevalence of 31% for gallstones, with an annual rate of cholecystectomy of 6.3%. SCI subjects with stones were noted to have typical right upper quadrant and epigastric pain similar to able-bodied controls, and vague abdominal symptoms were not indicative of gallstones.[56] Regardless of level of injury, the presentation of gallbladder disease was not more advanced than that in neurologically intact patients. The weakness of these studies is that they were retrospective and performed in a veteran population; however, the findings regarding symptoms and treatment for gallbladder disease are probably relevant to a nonveteran SCI population.

### Conclusion

Few prospective studies are available to support practice patterns for management of neurogenic bowel dysfunction. Further research should include double-blind, placebo-controlled studies of methods to optimize bowel function. In addition, optimal methods for diagnosing and treating complications such as gastric ulcers and the acute abdomen should be researched.

## Neurogenic Bladder

### General Care

A neurogenic bladder is an anticipated consequence of most SCIs. Over the past few years, the treatment of neurogenic bladder has improved such that the mortality from renal disease post-SCI has been exceeded by that of pulmonary disease. The management of a neurogenic bladder involves the use of physical examination and urodynamic testing to determine the type of injury affecting the bladder and the pressure profiles present in the bladder. Then patients are "bladder trained," a process which describes the physical and medical manipulation of the pressure profiles in the bladder to facilitate storage of urine or increased voiding.

In our time frame, we located eight level II, three level III, and four level IV notable studies related to neurogenic bladder dysfunction. Avoidance of high detrusor pressures is one of the caveats in maintenance of bladder function post-SCI. Level II evidence supports the use of tamsulosin[57] as a means to decrease maximal urethral pressure and the use of intravesical capsaicin and resiniferatoxin[58] for the treatment of detrusor hyperreflexia. Level IV evidence supports the efficacy of botulinum toxin A[59] for the treatment of detrusor hyperreflexia and the use of an endoprosthesis for detrusor sphincter dyssynergia.[60] It is notable that these level IV studies used pre-urodynamic and posturodynamic outcome measures rather than control groups due to the invasive nature of these procedures, and this underscores the difficulties of performing clinical research.

Regardless of the prescribed method of bladder emptying that individuals with SCI use at discharge from rehabilitation, they often change their bladder-emptying method over time. In a retrospective study of 235 SCI individuals at a mean of 24.1 yrs postinjury,[61] the use of clean intermittent catheterization increased from 22% at initial discharge to 36%, suprapubic tapping decreased from 57% to 31%, and the use of Crede increased from 5% to 19%. A higher portion of patients continued with their bladder management method when they were using clean intermittent catheterization.

### Urinary Tract Infections

Urinary tract infections (UTIs) are a common complication post-SCI, and much research has targeted their prevention. Level II evidence[62] supports the use of an educational program to decrease the number of bacterial colony counts in persons with SCI. Two level II studies[63,64] showed no benefit of the use of cranberry extract in reducing UTIs. Level II evidence supports the use of ofloxacin over trimethoprim sulfamethoxale[65] in hospitalized persons with SCI and symptomatic UTI. Interestingly, level III evidence supports the use of bacterial interference in preventing UTI[66,67] and noted this could develop into a safe, effective means of preventing symptomatic UTIs.

### Other Complications

Other complications of neurogenic bladder include the development of renal stones and a higher incidence of bladder cancer post-SCI. The incidence of renal stones was recently noted to be unchanged over the past 25 yrs[68] and found to be approximately 3% in a new cohort of subjects with SCI, with an incidence going up to approximately

7% within 10 yrs of injury. Furthermore, once a person has a kidney stone, level II evidence documents that 34% develop a second stone within 5 yrs.[69] Bladder cancer was recently shown to have a standardized morbidity ratio in the SCI population of 25.4 as compared with the general population.[70] Level III[70] and level IV[71] evidence supports the sole use of indwelling catheters as a risk factor for bladder cancer. The 5-yr mortality from bladder cancer in SCI was 38%.[70] To more effectively screen for bladder cancer, a new method to detect bladder cancer through analysis of urine for BLCA-4 was tested. A prospective study[72] established a normal cutoff point for BLCA in the urine and showed that 19% of SCI patients had a higher level than normal, despite the lack of bladder cancer. Thus, it will be important to continue to follow these patients to see if this could be an early marker for the development of bladder cancer.

### Conclusion

A number of studies have recently addressed prophylaxis against symptomatic UTI after SCI. Prospective controlled studies evaluating the efficacy of new therapies to manage neurogenic bladder are warranted. Moreover, determination of the natural history of neurogenic bladder function as it relates to remaining neurologic function postinjury is needed.

## Neurogenic Sexual Function

### Natural History

Spinal cord injuries result in predictable effects on sexual responses. This is an area in which recent research has been relatively plentiful, and overall we noted two level I studies, eight level II, and one level III. There is level II evidence that a loss of psychogenic erection correlates with sympathetic denervation, and loss of somatic and parasympathetic reflex activity correlate with the loss of reflex erection.[73] In women, there is level I evidence that the ability to achieve psychogenic lubrication is related to the degree of preservation of sensation in the T11-L2 dermatomes and that reflex lubrication is maintained in women with upper motor neuron injury affecting the sacral segments.[74] There is also level II evidence that the ability to achieve orgasm is maintained in women post-SCI, provided they have an intact sacral reflex arc.

### Treatment of Sexual Dysfunction

Treatment of sexual dysfunction has been revolutionized since the development of oral therapies for erectile dysfunction. Previous therapies included penile prostheses, intracavernosal injection of vasoactive agents,[75] the use of intraurethral alprostadil[76] and the use of vacuum erection devices. These have largely been replaced by pharmacologic therapies as first-line agents to treat erectile dysfunction after SCI. Level I[77] and level II[78] evidence exist to document the benefits of the use of sildenafil to treat erectile dysfunction post-SCI. Level II evidence has also noted slightly lowered blood pressure in men with SCIs above T6 after taking sildenafil.[79,80] The use of new phosphodiesterase inhibitor tadalafil may have some advantages over sildenafil,[81] primarily due to a longer half-life. Treatment of female sexual dysfunction after SCI has also recently been explored. Three level II studies were recently published. One[82] revealed beneficial effects of sildenafil on subjective sexual arousal along with an acceptable safety profile, and another[83] documented potentially beneficial effects of anxiety-provoking stimulation. Finally, potentially beneficial effects of false-feedback on sexual arousal were noted in the subset of women with significantly impaired sympathetic input to their genitals.[84]

### Male Fertility

The study of reproductive health after SCI has focused on male infertility and the elicitation of ejaculation, primarily through the use of electroejaculation[85] or penile vibratory stimulation.[86] Predictors of successful ejaculation through vibratory stimulation have been studied,[87] and 80% of subjects who had both a bulbocavernosus reflex and hip flexor response ejaculated with penile vibratory stimulation, whereas only 8% of patients negative for both reflexes ejaculated. Although optimal parameters for vibration have been suggested,[88] it has been noted that repeated ejaculation in men with SCI does not change typically poor semen quality.[89]

### Female Reproductive Health

Women's reproductive health has received little attention as compared with that of men. A multicenter outpatient questionnaire study was recently performed[90] to document the unique reproductive health conditions, complications, and behaviors of women with SCIs. In 472 women, similar gynecologic problems were found preinjury and postinjury, with the exception of increased UTIs and vaginal yeast infections postinjury. Women with SCI were less likely to have routine mammograms, and although there were similar numbers of hysterectomies both preinjury and postinjury, the reasons were significantly different. Almost 14% of women with SCI became pregnant postinjury. Menopause after injury was reported by 14.6% of women.

## Conclusion

Further research pertaining to neurogenic sexual function should address better methods to treat other components of male sexual dysfunction such as orgasmic dysfunction as opposed to the previous isolated focus on return of erectile function. Moreover, research should continue to target optimizing the sexual and reproductive issues of women with SCIs. Dissolution of barriers to mammography and routine gynecologic care should be pursued. Finally, any therapeutic effects associated with routine sexual activity should be explored.

## Pressure Ulcers

Pressure ulcers are a serious and common consequence of SCI. The prevalence of pressure sores has been described as 33% in a community-based sample,[91] and the 1998 incidence was noted as 34% in patients admitted to model SCI systems within 1 day of injury when one considered the time period through their discharge from rehabilitation.[92] Having a complete cervical injury has been noted to be associated with a higher prevalence of pressure sores,[93] and age, injury duration, sex, marital status, education, activity, mobility, and comorbidities have been associated with increasing risk from pressure sores; however, findings are inconsistent. Pressure ulcers were noted to least likely occur in persons with normal weight who have returned to their work and family roles and who do not have a history of substance or tobacco use, suicide, or incarceration.[94]

Pressure ulcer prevention and treatment[95] has recently been reviewed via the Consortium for Spinal Cord Medicine Clinical Practice Guidelines. Unfortunately, despite the fact that the cost of pressure ulcers has been estimated as $1.335 billion per year,[96] there were no level I, II, or III studies related to pressure sores that met our review criteria; thus, this discussion is primarily based on the clinical practice guidelines. Pressure sores are graded from I to IV based on their severity. A standard in treating pressure ulcers is to determine their location and appropriately relieve pressure from the area. Other standards of care include instituting pressure relief as soon as emergency medical care and spinal stabilization allow, turning every 2 hrs in bed during the beginning of rehabilitation, avoiding direct positioning on the trochanters while in bed, and performing weight shifts while in the wheelchair. Shearing forces should be minimized, and appropriate seating and cushioning should be provided. When manual pressure relief is not possible, a power weight-shift system is appropriate. Patient education is generally considered paramount in emphasizing the need to prevent pressure sore development. There is level I evidence[97] for the use of air-suspension beds to prevent pressure ulcers; however, the use of these beds is not practical for chronic SCI.

Treatment of pressure ulcers should be instituted as soon as possible. To determine appropriate therapies and document their efficacy, the existing pressure ulcer must be described in detail, including the anatomical location, size, stage, whether there is necrosis, exudates/odor, undermining, infection, the appearance of the wound margins, and surrounding tissue.[91] The wound should be removed from the offending pressure source, and appropriate debridement and cleansing should be ordered. Dressings should be used that keep the ulcer bed moist and the surrounding tissue dry. Wound cavities should be packed enough to be effective but not too tightly so as to prevent granulation at the base of the wound.[93] A variety of dressings are available for treatment of wounds and should be selected based on the clinical appearance of the wound. Electrical stimulation is the sole therapy for which level I evidence is present to support its efficacy in promoting closure of stage III or IV wounds in SCI in conjunction with standard wound care,[98–100] and surgical closure is an appropriate option in patients with nonhealing pressure ulcers.

## Conclusion

As pressure ulcers are common, costly, but often easy-to-treat, the lack of overall level I evidence to support treatment paradigms is surprising. Multicenter clinical trials to determine the most effective means to treat pressure sores after SCI are clearly overdue.

## Thrombophlebitis

Thrombophlebitis is a common complication of SCI that occurs in conjunction with the paralysis of the injury. Thrombophlebitis is the cause of pulmonary embolism after SCI and can also be a cause of untimely death. Due to this potentially lethal complication, the second edition of Clinical Practice Guidelines for thromboembolism prevention was published in 1999.[101] The clinical practice guidelines noted nine studies with a total of 419 subjects that documented a 40% rate of objectively diagnosed deep vein thrombosis (DVT) in patients with acute SCI. Based on consensus opinion and the literature at the time, the guidelines recommended first determining the level of risk for DVT based on whether SCI patients are motor complete or incomplete or motor complete with other risks such as lower limb fracture, previous thrombosis, cancer, heart failure, obesity, or age of >70 yrs. The guidelines recommended the use of compression hose or pneumatic devices for the first 2 wks after SCI, with anticoagulant prophylaxis with either low molecular weight heparin or adjusted-dose unfractionated heparin within 72 hrs after SCI, provided there are no contraindications. Recommendations are that prophylaxis be continued for 8 wks in patients with uncomplicated motor complete injury and, in patients with complications, that prophylaxis continue for 12 wks or until rehabilitation discharge.

A recent retrospective review of 243 persons with acute SCI,[102] all of whom had objective testing, revealed 51 subjects had DVT and eight died. The highest likelihood for DVT was in persons >35 yrs of age who had cancer. Obesity was also a risk factor. Women between 36 and 58 without cancer and men with flaccid paralysis were also noted to be at high risk. In our time period, there were two level II and one level three therapeutic studies addressing prophylaxis against DVT. Two studies[103,104] of prophylaxis compared the use of unfractionated heparin or enoxaparin combined with pneumatic compression during the first 2 wks postinjury and alone for the next 6 wks. No significant differences were found in the efficacy or the complications associated with either treatment. Another study looked at the incidence of thromboembolism in acute SCI patients *vs.* other trauma patients and found that the subgroup of patients with SCI and long bone fractures were significantly more likely to incur a DVT. They noted that routine use of prophylactic Greenfield filters does not seem warranted as a preventative measure against pulmonary thromboembolism post-SCI; however, those patients with long bone fractures and SCI, those with DVT formation despite prophylactic anticoagulation, and patients with contraindications to anticoagulation may be appropriate candidates for prophylactic caval filters.[105]

### Conclusion

Future prospective studies should be designed to evaluate the adherence to and efficacy of the clinical practice guidelines in preventing DVT. Optimal methods for treatment of DVT should be determined.

## Musculoskeletal Effects of SCI

### Heterotopic Ossification

Heterotopic ossification is a frequent complication post-SCI that is generally diagnosed between 1 and 6 mos postinjury but most commonly at 2 mos postinjury.[106] Two level II therapeutic studies showed successful prevention of heterotopic ossification through the use of indomethacin[107] and rofecoxib.[108] Both studies showed a significant decrease in the development of heterotopic ossification post–acute SCI; however, although statistical significance was achieved, the studies were limited by a small $n$ and the use of the clinical presence of heterotopic ossification as a primary screening measure. Moreover, rofecoxib has recently been taken off of the market.

Once heterotopic ossification forms, the usual treatment involves the use of etidronate sodium and/or indomethacin and can also include radiotherapy and surgical resection.[109] However, surgical resection involves significant risks and thus is generally only undertaken in the presence of complications such as joint immobility or pressure sores as a result of the ossification.

### Osteoporosis

Osteoporosis is also a known consequence of SCI. We were able to find two level I, three level II, and three level III prognostic studies related to osteoporosis but no intervention studies. A level II study[110] recently documented a significant decrease in radial bone density at 6 mos postinjury and both radial and ulnar bone density by 12 mos post-SCI in tetraplegics but not paraplegics. Furthermore, tibial trabecular bone mineral density was significantly decreased in all SCI subjects at 6 mos and 1 yr post-SCI. A recent level I analysis[111] showed that completeness of injury followed by body mass index were the most likely variables to predict bone loss at the knee leading to pathologic fractures. Moreover, the patterns of regional bone loss in women[112] include the greatest loss of density at the knee, followed by the hip, and complete preservation of bone mineral density at the spine.

### Conclusion

In conclusion, most research pertaining to the musculoskeletal consequences of SCI has focused on the treatment of heterotopic ossification and determining prognostic factors related to the occurrence of osteoporosis. Although significant information is available relating to prognosis of osteoporosis, double-blind, placebo-controlled trials are warranted to study prevention and treatment of osteoporosis after SCI. Furthermore, further studies are needed in relation to the occurrence of musculoskeletal consequences of SCI such as shoulder pain, carpal tunnel syndrome, and other overuse syndromes.

## Metabolic Consequences and Body Composition

### Metabolic Consequences

A number of metabolic consequences have been identified after SCI. As compared with the general population, persons with SCI have been shown to be more likely to have oral carbohydrate intolerance,[113] insulin resistance,[114] elevated low-density lipoprotein cholesterol,[115] and reduced high-density lipoprotein cholesterol.[116] We were able to find three level I and two level II prognostic studies related to metabolic consequences along with one level III intervention study. Level I evidence documents that SCI individuals with the greatest neurologic deficits have an increased risk of developing disorders of carbohydrate metabolism, men with SCI are more insulin resistant than women, and glucose tolerance seems to be independent of the effects of ethnicity.[117] Level I evidence indicates that in white and Latino men, but not in women or African Americans, immobilization subsequent to SCI seems associated with lower high-density lipoprotein cholesterol levels than in controls.[118] Level III evidence supports the use of a dietary intervention to reduce total cholesterol and low-density lipoprotein cholesterol in persons with SCI and elevated cholesterol.[119]

### Body Composition

Body composition in individuals with SCIs differs from that of the able-bodied. There is level I[120] evidence that men with SCI are 13% ± 1% fatter per unit of body mass index (kg/m$^2$) than an age-, height-, and ethnicity-matched able-bodied control population and level II[121] evidence documenting that as compared with able-bodied men with similar body mass indexes, body fat percentage was 9.4% greater in the SCI group.

### Conclusion

In light of the triad of altered body composition, glucose metabolism, and lipoprotein profiles, it is not surprising that there is a significant risk of cardiovascular disease in persons with SCIs. Over the time period 1973–1998, out of 1,543 deaths occurring in persons followed through the SCI Model Systems program, 18.8% of deaths were attributable to cardiac causes.[122] Further research is warranted to determine effective interventions to treat the negative metabolic and body composition effects of SCI. In addition, the efficacy of wellness programs in improving metabolic profiles and decreasing cardiovascular morbidity and mortality should be studied.

## Spasticity

Spasticity is a well-known consequence of upper motor neuron injury and can be as disabling to an individual with SCI as the injury itself. The first-line treatment of spasticity has traditionally been with oral therapies including baclofen, tizanidine, Dantrium, and Valium. However, each of these medications has known side effects and limited efficacy; thus, more invasive treatments have begun to be used, including botulinum toxin injections and neurosurgical procedures. Peripheral neurosurgical ablative procedures include rhizotomy and peripheral neurectomy. Central ablative procedures include cordectomy, myelotomy, and stereotactic procedures. Nonablative procedures include peripheral nerve or motor point blocks, the implantation of cerebellar or spinal stimulators, and the implantation of subdural catheters for relief of spasticity.[123] Despite the significant functional problems associated with spasticity and the expense and difficulty with treatments, we were unable to find any level I or II intervention studies during our time frame.

### Evaluation of Spasticity

Part of the difficulty in evaluating treatments for spasticity is the reality that spasticity changes with the time of day, whether a person has received range-of-motion exercise, whether the person has other acute medical problems or other conditions, and the weather. The Ashworth scale,[124] originally intended for use in multiple sclerosis, is part of a recommended triad for evaluations including spasm frequency and self-report. The Ashworth scale is reported to be used most commonly clinically post-SCI[125]; however, more exact outcome measures are needed. A recent study evaluating spasticity post-SCI included visual analog scales[126] and the Modified Ashworth Scale[127] as methods of documentation of spasticity. The latter study also documented significant fluctuation of the spasticity of cervical SCI subjects during the day as compared with thoracic-injured subjects. Findings confirmed that passive movement immediately decreased spasticity ratings in thoracic patients. Visual analog scale ratings correlated significantly with Modified Ashworth Scale ratings.

Other methods to document spasticity have included more quantitative analysis such as the use of isokinetic dynamometry[128] using maximum torque values and the sum of torque amplitudes. A positive correlation was noted between these values and Ashworth scores. However, even with such quantitative analysis, variability with different positions has been noted,[129] underscoring the importance of exact descriptions of test positions and procedures in research reports. Brain motor control assessment[125] using surface electromyography recordings has also been used to document degree of spasticity. In a study of 97 subjects with SCI[125] and varying levels of motor dysfunction, the analyses of averages of surface electromyography for a limb were able to document a significant difference for scores between those with Ashworth of 0 *vs.* 2 and 3 and 1 *vs.* 2 and 3 but not between 0 and 1.

## Conclusion

Spasticity is an area in which our ability to assess treatment in a laboratory may be excellent, but our clinical outcome measures are still in their infancy. In light of this fact, new therapies should have their efficacy documented in a laboratory-based setting before advancement into clinical trials. The development of a validated outcome measure to assess spasticity via self-report and clinical examination is necessary not only for the development of more effective therapies to treat spasticity but also to assess the effects on spasticity of therapies for promoting neurologic recovery.

## Pain

There is a substantial literature that has accumulated over the years documenting a significant prevalence of pain in persons with SCI.[130] Prevalence figures range from 65% to 79% for community-based samples,[131,132,133] with one third of those reporting severe pain. Age, sex, completeness of lesion, pathogenesis, and duration of injury have been examined cross-sectionally as risk factors for the development of chronic pain with inconsistent results across studies.[134,135] Chronic pain has been identified as having a negative influence on quality of life.[136–138] Although considerable attention has been given to neuropathic pain at and below the level of injury, increasing attention is being paid to upper limb pain and to ways to minimize it.[139,140]

One of the shortcomings of pain research is the failure to distinguish subtypes of SCI pain. Recently there have been a number of attempts to remedy this problem by the development of classification schemes[130]; however, there is no consensus. Reports have just recently started appearing in the literature demonstrating different time courses, levels of severity, implications for quality of life, and underlying pathology for different subtypes of SCI pain.[141–143] The International Association for the Study of Pain has recently proposed a classification scheme in the hope that it will be adopted world-wide,[144] but this has not occurred to date. Performance of reliability and validity studies for pain classification schemes, a necessary precursor for widespread acceptance, is imperative so that the subtypes of pain can be evaluated and treated appropriately. Our search, however, revealed no level I studies and only one level II study[145]supporting the validity of proposed SCI pain diagnostic schemes.

Several studies of prognostic outcomes derived from longitudinal sampling were recently published. Persons with recent-onset SCI were recently studied for 5 yrs in a level III study.[138] Neuropathic pain tended to persist over time, whereas musculoskeletal and visceral pain did not predict future pain. In a level II study using case-control methodology,[146] persons developing pain interference from one year to the next reported decreased life satisfaction and decreased physical and mental health, whereas those reporting decreased pain interference over that same period reported improvements in those measures. In another level II[142] study, demographic, injury-related, and radiographic variables were predictive of increased shoulder pain and range-of-motion problems over a 3-yr period. Furthermore, these problems were related to functional limitations, disability, and perceived health.

Much of the literature concerning treatment of SCI pain has been characterized by clinical reports and uncontrolled case series.[147] However, level I and II controlled trials for particular subtypes of pain have begun to emerge. Gabapentin has been proven efficacious for the treatment of neuropathic pain in two small, randomized, controlled trials (level I and II, respectively).[148,149] Intravenous ketamine was shown to significantly reduce neuropathic pain in a level II trial,[150] as did the intrathecal combination of morphine and clonidine (level II),[152] and oral lamotrigine (level II).[153] Amitriptyline did not prove efficacious for pain across all of the subtypes of SCI pain combined nor did the authors find a differential effect for the specific subtypes of pain for which their samples were large enough to examine (level I).[154] Exercise has been shown to reduce pain in a small level II, randomized, controlled trial in which subtypes of pain were not reported[155] and in a level II trial of stretching and exercise for shoulder pain in long-term wheelchair users.[151] Controlled trials of implanted spinal cord stimulation are lacking, and reported results from clinical series are not encouraging.[157] Dorsal root entry zone microsurgical ablative approaches have been reported in clinical reports as highly successful, primarily for selected cases of neuropathic pain.[158,159] Cognitive-behavioral interventions have not been subjected to controlled trials for their effectiveness in this population.[160] A large number of other modalities are in use,[161] and alternative medicine approaches such as acupuncture have been described in clinical series as helpful.[162] A level II study of the treatment of shoulder pain demonstrated the effectiveness of both acupuncture and Trager treatments.[156]

## Conclusion

Given the significant negative impact of pain on quality of life, continued efforts to demonstrate efficacious treatments are needed. Specifically, research is needed to validate and support the adoption of a standardized classification scheme with accompanying diagnostic procedures and criteria. Level I multicenter, randomized trials of interventions are also needed to reduce the severity and impact of the different subtypes of SCI pain. Such trials could include both primary prevention and treatment of acute and chronic pain.

### Outcome Measures

Outcome measures to address function post-SCI are in a state of dynamic change. Despite the fact that they do not fit into evidence guidelines, we thought it important to review the recent literature and document ongoing initiatives. The International Standards for the Classification of SCI remain the gold standard for the documentation of neurologic function post-SCI.[163] However, newer techniques such as quantitative sensory testing[164] have been assessed to see whether they could be used as an improvement over the testing of sensory function via the International Standards. The voluntary response index was also recently recommended[165] as a means for objective interpretation of surface electromyographic responses obtained after SCI. The voluntary response index consists of one numeric value derived from the magnitude of muscle activity recorded during a specific voluntary task and another numeric value (called the similarity index) from the surface electromyographic distribution across recorded areas during the same task. Although this instrument needs further validation, having a more sensitive method to quantify recovery of neurologic function would be of great benefit in order to develop methodology to study SCI.

The FIM™ motor score remains the most commonly used and studied scale to address the functional recovery of persons with SCIs. However, use of the FIM™ instrument in isolation is inadequate to describe function post-SCI. Therefore, the Walking Index for Spinal Cord Injury (WISCI)[166] and revision (WISCI II)[167] were recently developed as measures to quantify ambulatory function. To address other functional capacities, the Spinal Cord Independence Measure[168] was recently validated, and a short form of the Quadriplegia Index of Function[169] was developed. In addition to monitoring the recovery of motor and sensory function and functional recovery, documentation of the recovery of bladder, bowel, and sexual function is also important. However, there is a notable absence of a single scale to address autonomic function. A group involving the international collaboration of the International Spinal Cord Society and the American Spinal Injury Association is currently in the process of developing such a measure.

With regard to outcome measures used in psychosocial, epidemiologic, and technology-related SCI research, there is such a diversity of measures used that comparing outcomes across studies is problematic. Two unresolved issues characterize this literature: whether SCI-specific as opposed to generic measures are needed and the extent to which generic measures are "biased" or lack validity when used with persons who have SCI. With well-validated generic measures, comparisons of outcomes can occur across different samples; however, some generic measures do not capture all relevant domains for persons with SCI. Moreover, specific item content can be irrelevant or misleading (e.g., sleep disturbance can reflect many medical phenomena other than depression). Ongoing efforts are directed toward developing SCI-specific measures of perceived needs,[170,171] quality of life,[172] and activity.[173] On the other hand, there are also ongoing efforts to validate the use of generic measures of various constructs with the SCI population in areas such as vocational rehabilitation intervention effectiveness,[174] environmental factors,[175] participation,[176] depression,[177] quality of life,[178,179] and receptivity to assistive technology.[180,181]

### Conclusion

Research is needed to determine the most sensitive yet practical outcome measures to be used to document both remaining functional and neurological status post-SCI. Research on the psychosocial aspects of SCI would be enhanced by funded efforts to identify, develop, or validate a set of instruments across the most important domains that could be proposed as the standard set of instruments for researchers to adopt in this area.

## REHABILITATION

### Exercise Therapies

Traditionally, management of the person with SCI involves the determination of the person's level of injury and functional capacity and then the generation of a problem list and prescription for therapies, with an overall goal of having the patient achieve his or her maximum functional potential. Based on this evaluation, various therapies including muscle strengthening, range of motion, transfer training, gait training, and activities of daily living training are pursued, generally through a team approach. The person is also prescribed and trained in the use of various pieces of equipment, including wheelchairs, transfer boards, and splints. Although the benefits of inpatient interdisciplinary rehabilitation after SCI are intuitively obvious, there have been few evidence-based analyses of the efficacies of specific exercise therapies. We were only able to find one level II study meeting our criteria; thus, we did not construct a separate table. This study compared the central cardiovascular responses of 20 complete thoracic SCI subjects to those of 20 able-bodied subjects during arm-crank exercise.[182] Despite significantly greater values of heart rate at rest and during matched absolute workloads compared with able-bodied subjects, cardiac output was lower in SCI subjects at both periods in time.

One area that has recently received significant attention is the use of body-weight–supported treadmill training. It is notable though that during our time period, none of the studies met levels I–III evidence criteria. This therapy has shown the ability to induce a locomotor pattern even in patients with complete paraplegia in conjunction with increases in leg extensor electromyographic responses.[183] Level IV evidence supports the use of body-weight–supported treadmill training combined with electrical stimulation in patients with acute[184] SCI and its use in subjects with incomplete SCI for ≥1 yr postinjury.[185] However, neither of these studies had control groups, and the final results of more recent multicenter studies were not yet published at the time of this review. More recently, a robotic orthosis has been used for performance of treadmill training[186] and has been made commercially available as the Lokomat[187] in the United States (Hokoma, Chicago, IL). Whether this device will prove cost-effective and beneficial as compared with conventional therapies targeting the improvement of gait post-SCI needs to be tested.

## Conclusion

As the foundation of rehabilitation involves exercise, it is surprising that so little evidence is available to support its use. Substantial research is needed to document the benefits of exercise interventions post-SCI. Issues that also need to be determined are the optimal methods for strengthening muscles, range of motion, gait, activities of daily living, and transfer training. In addition, the relative merits of endurance *vs.* strength training should be determined. Due to the impact of body composition, age, concomitant medical problems, and our limited knowledge of the natural history of recovery post-SCI, this research will need to be performed through well-designed multicenter trials. Moreover, because these therapies are costly and have traditionally been billed for despite lack of proven efficacy, consensus should be sought on an ethical way to finance this research.

## Electrical Stimulation

The use of electrical stimulation in persons with SCIs has been developed for both therapeutic and functional purposes. Although a significant amount of work has been published in this area, most of it has been in demonstration studies. Thus, traditional evidence levels often do not apply, and we have not constructed a table on this topic, as there was not any level I or II evidence. Therapeutic uses for electrical stimulation after SCI have included its use for prevention of DVT,[188] prevention of pressure ulcers,[189] and for the exercise of muscles post-SCI.[190] Documented benefits of the use of electrical stimulation for exercise post-SCI include increases in strength in paralyzed muscles,[191] increased muscle mass,[192] and improved muscle endurance for lower limb muscles.[193] Increased high-density lipoprotein levels[194] and improved insulin sensitivity[195] have been documented through the use of a lower limb electrical stimulation exercise program. With chronic use, the use of electrical stimulation has also been shown to potentially have a positive effect on bone density.[196] A recent controlled study tested 14 SCI subjects and controls who underwent isokinetic stimulation of the left quadriceps 1 hr daily, 5 days/wk for 24 wks. Although the initial bone density of the SCI subjects was lower than that of the controls, after training, 30% of the bone lost in the distal femur and proximal tibia was regained as compared with controls. These findings were associated with increased strength.[197] Another recent study examined 90 male paraplegics who performed isokinetic exercise through electrical stimulation to the quadriceps[198] to determine the optimal training protocol for exercise. Training for 3 days/wk for 30 mins/day with 6 secs of rest and 6 secs of exercise proved the optimal protocol.

### Functional Electrical Stimulation for Walking

Functional electrical stimulation (FES) has been used in a very limited fashion to allow individuals with SCI to stand and walk. In a recent postal survey in individuals with SCI in the UK, 4,840 questionnaires were mailed and 1,122 completed surveys were received.[199] Two percent of subjects had used FES for walking, whereas 13% had used some kind of orthosis. Of those who had used FES for walking, >50% had no functional walking ability, whereas most orthotic users had some independent walking ability. Another study compared three groups: 1) FES to the common peroneal nerve through a single channel stimulator, 2) this same stimulator combined with a hinged ankle-foot orthosis, and 3) the use of a hinged ankle-foot orthosis alone with baseline readings with respect to walking.[200] In 19 persons with incomplete SCI, gait speed was shown to increase with FES and with the use of a hinged ankle-foot orthosis as compared with baseline; however, the greatest increase in gait speed and endurance occurred with the combined ankle-foot orthosis and FES condition. Foot clearance was shown to improve with FES but not the orthosis. Those subjects with increases in gait speed from FES had weaker hip flexors, knee flexors, and ankle dorsiflexors than those who did not benefit from FES.

Surface, percutaneous, and implanted electrodes have been used as means of multichannel stimulation to produce standing and walking. With the availability of a commercial FES gait system, various groups have reported on its effects. Active standing through the use of the Parastep-1[201] (Altimed, Fresno, CA) was shown to result in significantly greater values of $\dot{V}O_2$ than performance of passive standing. In another report,[202] 15 patients were able to complete training and ambulate independently with a walker. The mean consecutive walking distance was 52.8 m, and the mean speed was 0.15 m/sec. Follow-up was 40 mos, and only five patients continued to use the system primarily for exercise. The authors concluded that this approach has limited practical usefulness for mobility in daily life but should be considered a resource for persons with SCIs. The use of the Case Western Reserve University/Veterans Affairs implanted standing neuroprosthesis was evaluated in 11 subjects with SCIs[203] who had used the device for >1 yr. Nine subjects continued to use the device regularly for standing or exercising. The system was considered safe, reliable, and easy to use, and all subjects expressed a willingness to repeat the surgery and rehabilitation to achieve the same outcome.

## Upper Limb FES

Another use of FES has been to promote improved function in the upper limbs. An implanted neuroprosthesis that allowed C5 or C6 tetraplegic individuals to restore the ability to grasp, hold, and release objects was developed[204] and eventually became commercially available as the FREEHAND System (NeuroControl, Valley View, OH). In an international multicenter cohort trial of this system,[205] 51 tetraplegic adults underwent concurrent tendon transfer surgery and implantation of the system in which electric stimulation of the grasping muscles of one arm were controlled by using contralateral shoulder movements. With >3 yrs of follow-up, pinch force was significantly greater with the prosthesis in all subjects and grasp-release abilities were improved in 49. Activities of daily living improved in 49 of 49 tested patients, and regular home use was reported in >90% of subjects. In a postal survey[206] of 34 individuals with C5 or C6 tetraplegia who received the prosthesis, 87% reported they were very satisfied with the device, 87% reported improvements in activities of daily living, 81% reported improved independence, and 88% reported a positive impact on their lives. A total of 15 participants used the device daily, whereas five individuals did not use the device at all. Another method of use of FES for the upper limbs was reported through the use of the "Bionic Glove,"[207] an external device that uses three channels of electrical stimulation to stimulate finger flexors, extensors, and thumb flexors, with a control signal coming from a wrist-position transducer. In 12 persons with SCIs at C5-C7 who had used the device for ≥6 mos,[208] daily use of the glove was shown to increase the subject's power grasp and range of movements. The authors recommended that the best candidates for use of the device are complete C6-7 tetraplegics with a FIM™ score between 25 and 50 and a Quadriplegia Index of Function between 0 and 13 and who are motivated to become independent. Another use of electrical stimulation for improved upper limb function is restoration of elbow extension through triceps stimulation. In 11 arms of persons with SCIs who received a triceps electrode as an addition to a hand-grasp neuroprosthesis,[209] triceps stimulation provided a significantly stronger elbow extension moment than a posterior deltoid to triceps tendon transfer. The elbow extension moment generated through simultaneous activation of the tendon transfer and triceps electrode was always greater than either method used alone. Addition of elbow extension to the neuroprosthesis resulted in a decreased amount of time required to acquire an object while reaching and significantly increased the ability to successfully reach and move an object.

## Other Uses

Other uses for FES include inspiratory muscle pacing and implantable stimulation to control bladder function. In individuals with high tetraplegia but preserved phrenic nerve function, electrical stimulation of these nerves can be used to restore respiratory function.[210] This procedure has generally been performed via thoracotomy; however, most recently laparoscopic placement of electrodes into the intramuscular portion of the diaphragm has been piloted,[211] and it is hoped that intramuscular pacing can provide similar results to conventional phrenic nerve pacing. An externally controlled implantable neuroprosthesis is available (VOCARE Bladder System, NeuroControl) for management of the neurogenic bladder and bowel.[212] A multicenter trial evaluated the safety and efficacy of this device 3, 6, and 12 mos postimplantation in 23 patients with SCI. At 1-yr follow-up, 18 of 21 patients were able to urinate >200 ml and 15 had postvoid volumes <50 ml. UTI, reflex incontinence, catheter use, anticholinergic drug use, and autonomic dysreflexia were substantially reduced, and 15 of 17 patients also reported reduction in the time spent in bowel management. One problem with this technique is that device placement is usually performed in conjunction with a sacral rhizotomy that generally leads to the loss of reflex ejaculation and erection in men. In addition, it has been hypothesized that this procedure could abolish the ability to achieve orgasm post-SCI.[74]

### Conclusion

As can be seen from the above discussion, the use of electrical stimulation continues to show great potential for both therapeutic and functional purposes post-SCI. Performance of research in this area is, however, costly and difficult because of its potentially invasive nature and the difficulties associated with blinding of subjects to this type of therapy. Whereas great progress has been made in this field, reports are generally uncontrolled case series. In conclusion, further research targeting randomized controlled trials of noninvasive means of stimulation is needed as a means of assessing the utility of electrical stimulation over standard orthoses. In light of the push toward curative therapies, the development of less-destructive techniques for internal stimulation and the development of consensus on the means to best test them in randomized controlled trials is also warranted. Moreover, if this research is truly to be performed in a randomized fashion, the ethics of subjects paying for the surgical procedures should be discussed.

## COMMUNITY INTEGRATION

Successful community integration is an end goal of the rehabilitation process. It is a multifactorial construct that reflects the extent to which a person's preferred level of social and physical involvement in the community is achieved. Given its inherent subjective core, some authors have used qualitative research methodology to explore correlates of successful community integration or participation.[213] Other quantitative efforts have been largely descriptive or cross-sectional, with the exception of a level II prognostic study we were able to identify, which revealed that only 9% and 29% of the variance in social integration and the ability to get out of the house and into the community, respectively, are explained by demographic and neurologic variables.[214] Other work suggests that community integration is better explained by such factors as education level, employment, income, functional independence, and health status than by demographics or neurologic variables.[215] A level II prognostic study suggested that for a population averaging 20 yrs postinjury, community integration declines over time, with a corresponding decline in satisfaction with life.[216] Recently, researchers have examined environmental factors as they facilitate or inhibit community integration.[217–219] Qualitative investigations[216] have supported the importance of the physical environment and attitudinal barriers for community integration, but quantitative approaches have found positive but less robust relationships between environmental factors and societal participation.[217,218] Availability of independent living services was not associated with better community integration outcomes, but this study was not a true randomized controlled trial.[220]

### Conclusion

The lack of level I or II intervention attempts in this area is striking but not surprising; interventions would likely have to be community based; such "remote" intervention studies are difficult logistically. However, with the advent of relevant technology (e.g., tele-health) and the availability of existing statewide networks with whom partnerships could be established (e.g., vocational rehabilitation, public health nursing, independent living centers), creative interventions could be formulated (see Forchheimer and Tate[220] for an example). With shortened rehabilitation lengths of stay, such attempts to link and enhance continuity between acute and longer-term care resources could be demonstrably helpful with regard to community integration.

## PSYCHOSOCIAL ISSUES

In a report for the American Association of Spinal Cord Injury Psychologists and Social Workers in 1997 reviewing the status of psychosocial research for persons with SCI,[221] the authors concluded that there was evidence for psychosocial interventions being "somewhat effective." Effect sizes were found to be small to medium but with clinical relevance. The authors also noted the preponderance of correlational research in this area and the lack of true intervention trials. In the following sections, the reader will note a maturing of this promising body of work in terms of research rigor, but with considerable room for further development.

### Depression

Recent published estimates of the prevalence of depression in persons with SCI vary as a function of measures used, how depression was defined, and years postinjury, among other factors. Studies suggest significant rates of depressive syndromes in this group of individuals, with estimates ranging from 16% to 30%.[222–224] Of note is a Canadian population-based level I prognostic study[225] in which all persons from Alberta who sustained an SCI for the 2-yr period between April 1992 and March 1994 were followed over 6 yrs postinjury. Cases were paired with able-bodied controls matched for age, sex, and region of residence. International Classification of Diseases-9 definitions for depression were used. The authors found that 27.5% of persons with SCI were treated for depression during the follow-up interval compared with 10.8% of controls. An attempt in the United States to assess depressive symptoms in persons with SCI using a community-based sampling framework yielded an estimate of 31%, scoring above the cutoff on a widely used measure of depressive symptoms.[226] Based on the more limiting category of probable major depression, 11.4% of 849 persons from the Model Systems[227] met criteria for that diagnosis 1 yr postinjury.

A number of studies have identified risk and protective factors for depression, but other than the level I prognostic study described above,[225] these have been based on cross-sectional designs; hence, they do not meet criteria for prognostic studies reviewed in detail in this article. High levels of wheelchair sports,[228] and higher quality social support,[229] have been associated with lower depression scores. Diagnosed posttraumatic stress syndrome has also been associated with a higher risk for depressive reactions.[230] Finally, a number of authors have demonstrated that coping style can affect outcomes such as depression.[231] All of these risk and protective factors could be or have been developed as interventions.

There have been few controlled trials for the treatment of depression for persons with SCI. No controlled trials of antidepressants for this group of individuals were noted, although several noncontrolled trials before the 1999 to present time period did suggest efficacy.[232] In a recent randomized controlled trial of Elavil for pain in SCI,[233] depression was assessed before and after administration in the study arm. No impact on depression was noted; however, doses were typically lower than would be used for depression. Thus, although this study was classified as a level I trial for pain (see earlier discussion), it was not considered an adequate trial of the efficacy of Elavil for depression. Consistent with the risk factor research reviewed above, two recent level III studies[234,235] have been reported suggesting that cognitive-behavioral coping-focused psychotherapy either in groups or individually may help ameliorate depressive symptoms. Although both used control groups, they were not true randomized treatment designs. In a small randomized controlled level III study, a group of persons who received massage demonstrated lower posttreatment depression scores than controls who were randomized to an exercise group.[236] Finally, in a small randomized controlled level III trial of the benefits of physical exercise, participants randomized to the exercise group showed improved depression scores after 9 mos of twice-weekly exercise compared with controls who were provided bimonthly education classes.[237]

### Conclusion

Given the high prevalence of major depression in community-dwelling individuals with SCI, funding is needed to pursue level I intervention trials through medical, psychological, environmental, or physical (e.g., exercise) modalities. As is the case for most other topics, however, multisite studies are likely needed to ensure adequate sample sizes.

## Substance Abuse

Substance abuse has been well documented as both a preinjury and postinjury problem for persons with SCI. In one university-based SCI treatment center, 96% of a consecutive admission sample of 26 newly injured individuals reported preinjury alcohol use, with 57% assessed as heavy drinkers.[238] In a mixed consecutive sample of persons with traumatic brain injury, SCI, or both admitted to a level I trauma center, 17.9% of the sample were characterized as persons who would meet criteria for current alcohol dependence, 21.1% were characterized by heavy alcohol use but with less evidence of physical dependence and fewer negative consequences, and 14.7% characterized by high levels of lifetime alcohol-related problems, but little current alcohol consumption.[239] Alcohol has also been demonstrated through statewide injury surveillance systems to be a risk factor in the accidents that cause SCI.[240] The converse, however, may not be true; SCI was not a risk factor in alcohol use patterns for identical twins who sustained an SCI compared with their non-SCI twin.[241] It has also been well demonstrated in both current[242] and previous work that there is a high recidivism rate in this population, although not always to the extent of preinjury use.

Substance use history has been examined as a risk factor in three level II prognostic studies. In a consecutive sample of 87 newly injured persons with SCI admitted to a university medical center, 53% presented with positive screens: 44% alcohol only, 30% drug only, 26% both. Rehabilitation outcomes were the same for those with positive and negative screens, however.[243] Alcohol use postinjury has also been associated with a higher risk for post-SCI injuries,[244] pressure sores (level II),[245] pain, and diminished quality of life.[246] Problem drinking before injury has also been demonstrated in a level II study to be a risk factor for longer initial rehabilitation and lower FIM™ efficiency scores pertaining to SCI and substance abuse.[247]

There were no treatment studies identified in the recent literature. There are recent treatment approaches such as motivational interviewing that are being evaluated for efficacy in related populations. A recent randomized, controlled, prospective trial of a brief intervention with 366 patients at a level I trauma center who screened positive for alcohol at admission, suggested a marked positive impact on drinking and injuries requiring hospitalization over 12 mos compared with controls.[248]

### Conclusion

In summary, given the well-documented recidivism rate in this population and the relationship between substance abuse and secondary complications, research is needed to determine the most efficacious methods, both during acute and follow-up care, to prevent a return to substance abuse after discharge from initial hospitalization.

## Anxiety Disorders

There has been less research emphasis on anxiety disorders in the SCI population, with relatively few intervention trials. The clinical literature[249] has highlighted the need to screen for anxiety disorders based on the cause of SCI (recollection of the trauma) and the experiences that can occur postinjury, ranging from the physical sequelae of SCI to the uncertainties of community, family, vocational, and avocational re-integration.

Base rates for anxiety disorders in non-SCI community samples are relatively low: 1–2% for panic disorder (1-yr prevalence), 3% for generalized anxiety (1-yr prevalence), and 1–14% for posttraumatic disorder.[250] Recent estimates of the prevalence of anxiety disorders in the SCI population are typically higher than that, although there is considerable variability.[251] Virtually all of these estimates are not community- or population-based estimates, however, but are hospital or clinic convenience samples. Fourteen percent of 85 SCI subjects were noted to have high levels of anxiety 6–24 wks postinjury.[252]

In a longitudinal study of a sample of persons with SCI from acute rehabilitation through discharge into the community out to 2 yrs postinjury, scores were above a cutoff on a state anxiety measure ranging from 10% to 60%, with scores increasing up to the point of initial discharge from rehabilitation.[223] In contrast, in a study of 33 persons with SCI and 33 able-bodied controls,[253] no differences were found on a self-report anxiety measure, but there were indications of higher anxiety using the Rorschach, a projective test.

In a presumably more at risk population of veterans many years post-SCI, a study using a screening instrument found that 40% of subjects scored above a cutoff for any anxiety disorder, with 9% at risk for generalized anxiety, 24% for panic attack, and 21% for posttraumatic stress disorder (PTSD).[222] In another sample of veterans with SCI,[254] 11% were noted to have a current diagnosis of PTSD and a lifetime rate of 28%. In a pediatric sample of children with SCI averaging 5.9 yrs postinjury, 25.4% met DSM-IV criteria for a current diagnosis of PTSD.[255]

More focus has occurred in the recent literature regarding risk and protective factors for PTSD than other anxiety disorders for persons with SCI, but these are typically cross- sectional studies in design; hence, they do not meet criteria for inclusion in our prognostic tables. War theater exposure before onset of SCI increased the risk of a current PTSD diagnosis in veterans compared with their peers who had not been exposed to combat.[256] The availability of social support from friends and a higher level of education have been correlated with a lower risk of a current PTSD diagnosis,[256] whereas another study noted a relationship between anxiety about death and the presence of PTSD.[257] High levels of participation in sports activity were found to be related to lower levels of anxiety after SCI.[228]

Few controlled trials exist for the treatment of anxiety for persons with SCI. A recent level III study[235] reported that cognitive-behavioral coping-focused psychotherapy provided in groups, compared with outcomes from historical controls, may help ameliorate anxiety symptoms. In a small, randomized, level III, controlled trial of the benefits of massage, participants assigned to the massage condition showed greater reductions in anxiety scores after 5 wks of treatment than did controls who were assigned to range of motion and strengthening exercises.[236]

### Conclusion

In conclusion, effective pharmacologic and behavioral treatments for anxiety disorders exist, but there is a virtual absence of evidence for their application to persons with SCI. Future research should include controlled trials of these interventions.

## Family Issues: Caregiving, Parenting, Marital Stability

Increasingly, in recent years, the requirements for providing physical care to persons with SCI have fallen on family members. We are beginning to explore and understand this important but complex area in terms of its positive and negative impact on the person who is providing care and in terms of the particular mix of individual, cultural, social, and environmental characteristics that help explain short- and long-term physical and emotional outcomes for those individuals. The importance of social support for the person with SCI, often provided principally by family members, is also increasingly well recognized.

### Marriage

With the profound effects of SCIs, impacts are expected on family issues with regard to marriage and divorce in the SCI population. Authors have generally found marginally higher divorce rates for persons who are married at the time of injury compared with national norms, with the greatest risk for divorce the first year postinjury.[258] Postinjury marriages have generally been found to be more stable than preinjury ones.[258] Being married may lead to improved quality-of-life outcomes. Putzke et al.[259] matched 53 single and married individuals with SCI on education, race, sex, lesion level, pathogenesis, and hospitalizations during the previous year. Married individuals reported higher quality of life and greater levels of participation than their single counterparts.

### Caregivers

Caregivers of persons with SCI have been shown to have declines in self-reported quality of life over time[260] and cross-sectionally when compared with matched, able-bodied controls.[261] Individual differences within caregivers in terms of how they cope with distress are important. A negative problem orientation among caregivers has been associated with poorer health, greater depression, lower social functioning, and lower vitality[262] and, in a level II prognostic study, a greater rate of developing psychological and health problems over the first year postinjury.[263] In a level II prognostic study, caregivers with a tendency to problem-solve carelessly and impulsively were associated with lower acceptance of disability in the person for whom they provide care and with the development of pressure sores 1 yr postinjury in that person.[264]

### Parenting

Parenting a child with SCI can be associated with elevated distress levels, even several years postinjury. In contrast, there is no evidence that SCI itself results in poorer outcomes for children raised by those individuals. In a cross-sectional study, 31 children raised by a parent with SCI were compared across a variety of dimensions with a matched group of children raised by an able-bodied parent. No differences were noted on any of the several adjustment measures utilized.[265]

### Conclusion

Family caregivers, whether providing care for a child, spouse, parent, or relative, may not experience caregiving as stressful; indeed, for some it may provide a sense of purpose. However, controlled research is needed for ways to identify caregivers in the community who are significantly distressed and to demonstrate ways of ameliorating that distress. The physical and emotional well-being of the person with SCI who is the recipient of that care should be secondary outcomes of those intervention studies.

## Mediating Factors in Individual Coping/Adjusting

### Spirituality

Experience suggests that the sudden onset of SCI can be either a test of spirituality, potentially weakening personal belief systems, or a source of comfort and confirmation of those belief systems. However, we are not far along in the development of psychometrically sound ways of assessing spirituality,[266,267] and empirical attempts to study the relationship between spirituality and coping/adjusting have been generally cross-sectional and not prognostic.[268] The importance of social support in the coping/adjusting process is also widely accepted. There has been some progress in developing psychometrically sound ways of assessing different types of social support such as emotion-oriented, problem-oriented,[269] esteem, informational, and tangible support,[270,271] and also negatively experienced support.[269] However, we were unable to find any therapeutic or prognostic studies in these areas.

### Recreation

Much of the recent literature on the effectiveness of recreation therapy on participation for persons with SCI is descriptive in nature[272–277] or poorly controlled,[278] so cause and effect cannot be inferred. Recent attempts to develop and evaluate a theoretic, predictive model of the impact of leisure on adjusting,[279] and to enhance motivation in therapy tasks by modifying traditional exercise activities to recreational ones,[280,281] provide encouragement that more empirically sound evaluations of the impact of recreation and recreation services can be forthcoming.

### Environment

The importance of understanding the limiting or facilitating impact of the environment in terms of adjusting and participation has received appropriate recent attention, with significant theoretic models addressing not only main effects but the importance of the interaction between individual characteristics and the environment.[282,283] Most environmental facilitators have been shown to be social, whereas the main obstacles are physical. Moreover, the extent to which environment influences individuals varies, among other factors, as a function of age, sex, and level of injury.[282] Other studies have identified level of education[284] and transportation[285,286] as barriers to employment and participation. Use of a wheelchair seems to improve participation in some instances, but in a complex interaction between personal and environmental characteristics.[287] Others have struggled with ways to measure and assess the impact of community structure or cohesion in terms of facilitating or limiting participation.[288] All of these studies have used cross-sectional methodology and, hence, did not meet the criteria used here for systematic review.

### Conclusion

Prognostic studies are needed that utilize well-validated measures of the environment. Therapeutic studies in this area are likely to be complex and ambitious undertakings, focused on the impact of policy change or measured changes in the environment on participation. Conceivably, individuals could be taught advocacy/political activism skills to cause environmental change, with concomitant assessment of the impact of that achievement on participation. Policy changes aimed at improving participation have likely done so, but not often within a scientific context so that the impact can be measured.

## Individual Differences

A recent study exploring the prevalence of personality disorders in the SCI population did not find a higher prevalence in this group compared with matched medical controls.[289] However, personality characteristics have been associated with subsequent additional injuries post-SCI.[290] In two level II prognostic studies,[295,299] social problem solving orientation and coping abilities were predictive of a variety of psychological and physical outcomes at one and 2 yrs postinjury. Coexisting cognitive dysfunction, be that from concomitant traumatic brain injury, previous head injury, prolonged substance abuse, or others, has been frequently overlooked[291] or has been associated with negative outcomes.[292,293] However, prognostic as opposed to cross-sectional descriptive studies are lacking, and no treatment studies (e.g., cognitive remediation) were identified.

One of the more fruitful lines of investigation in recent years has been the adoption of cognitive-behavioral formulations of coping, which have well-developed models, accompanying measures, and importantly, lend themselves to intervention.[294] Two level III studies, both of which used historic controls, and both of which adopted a stress and coping training intervention,[295] reported fewer hospital readmissions, higher self-reported adjustment after 2 yrs,[296] and lower levels of anxiety and depression after 6 wks.[297] Other positive constructs of recent interest in the SCI adjustment literature include hope[300–302] and purpose in life,[303] although prognostic studies and attempts to instill hope or purpose in life, and to examine subsequent outcomes, are lacking. Still others have attempted to delineate positive outcomes as a function of SCI[304] rather than measuring negative ones like depression and anxiety. One level III randomized controlled trial[305] of the effectiveness of a “wellness” intervention demonstrated some positive benefits in terms of short-term health outcomes.

### Conclusion

Prognostic research is needed here rather than the cross-sectional descriptive work that has characterized psychosocial research in SCI over many years. The thrust of this body of work should be in identifying and measuring enduring individual differences that significantly predict outcomes at a future time. Tied to this should be an emphasis on individual differences that are capable of modification, such as coping style and education, rather than more immutable characteristics of a person. In addition, the interaction between individual differences and environmental barriers/facilitators needs further exploration. Controlled interventions should be applied to subgroups with identified deficits or needs, rather than across the board to a convenience sample; not everyone, for example, needs coping effectiveness training. Multicenter trials will be needed to attain adequate sample sizes for such targeted interventions.

## Quality of Life

Quality of life has emerged as an increasingly important research endpoint in recent years. However, it is a subjective construct that has proven elusive in terms of the development of any standardized system, accepted across research groups, for its assessment.[306,307] Some have argued that given its inherent subjectivity, qualitative research methods are warranted.[308] Others have argued that although qualitative methods might be appropriate for early exploratory work, they are difficult to replicate, and more objective methods are needed. Accordingly, a variety of standardized quality-of-life scales have been used across studies.

There is a substantial literature in which quality of life (or similar terms) is an outcome. The bulk of this literature, however, is descriptive in methodology, chiefly using interview or survey methods cross-sectionally to identify correlates of quality of life.[308–325] Because these studies are not predictive, they do not meet criteria for detailed review here, but they remain important contributions in pointing out potential areas to develop interventions to improve quality of life such as increasing community mobility,[320] decreasing pain,[312] improving bowel and bladder control,[314] improving marital stability,[310] and increasing access to physical activity.[321]

Quality of life has been used as a secondary outcome in intervention trials in which the primary outcomes were more proximal to the intervention. It has been demonstrated in a level I double-blind randomized trial, for example, that aspects of quality of life were improved via treatment of erectile dysfunction, where the primary outcomes were measures of sexual performance and satisfaction.[326] Similarly, in a level III therapeutic study, exercise training as administered via a randomized controlled trial resulted in improvements in quality of life along with the primary endpoints of strength and stamina.[327] When quality of life is the primary endpoint, studies have more frequently been prognostic in nature rather than interventions designed to improve quality of life.[328–334] Several of these studies did meet criteria for inclusion in the evidence tables as level I or II prognostic studies.[329,332–334]

### Conclusion

Future research should concentrate on developing or identifying a well-validated, psychometrically sound set of methods for assessing quality of life post-SCI, with their advantages and disadvantages clearly spelled out. Until/unless there is some uniformity of measurement of this important construct across studies, this particular aspect of the SCI literature will be troubled by ambiguity.

## EMPLOYMENT

Most recent studies of employment post- SCI indicate that fewer people are employed after injury than was the case preinjury, with some studies showing that gap to be relatively narrow[335] and others indicating a much wider disparity.[336,337] It has been well demonstrated that increasing time postinjury is associated with increasing rates of return to employment,[335] with one estimate of 6.3 yrs to the first full-time employment.[335] A number of factors have been associated with return to employment, including whether the individual held a professional occupation before injury or was able to return to his or her previous job.[335] Other factors associated with return to employment have included sex, the level of physical exertion required, Barthel Index, education level, age postinjury,[336] and race.[337] Psychological variables including locus of control, and work attitudes have also been associated with return to work.[338] Individuals injured as children who grow into employment age are less likely to be engaged in paid employment than comparable able-bodied peers,[339] and education, community mobility, functional independence, and decreased medical complications have been associated with their success in employment.[340] Factors external to the individual have also been associated with return to employment, including availability of transportation, access difficulties, and perceived workplace discrimination.[341] However, for those able to overcome these barriers and return to employment, even part-time, benefits have been noted, including increased satisfaction with life and with social integration and decreased levels of depressive symptoms.[342] Similar benefits have been noted for volunteer activities.[343]

Most research in this area is cross-sectional. Two longitudinal, prognostic studies were identified. In a level I study,[344] variables derived at injury were used to predict employment at follow-up years 1, 2, 5, 10, 15, or 20 yrs postinjury. Being white, younger at injury, having lived more years post-SCI, having a less severe injury, and being better educated were predictive of being employed. In another level III prognostic study, positive expectations about returning to work assessed during initial rehabilitation were associated with later return to work.[345] Our searches did not turn up any controlled intervention trials and located only one description of early outcomes of an uncontrolled intervention to increase employment outcomes.[346]

### Conclusion

Low return-to-work rates postinjury have been adequately demonstrated over the years, along with descriptive studies identifying correlates of those who do and do not return to work. What is needed are controlled studies of attempts to encourage a return to employment with adequate follow-up to discern long-term work maintenance rates and to demonstrate the positive personal impact (or lack thereof) of a return to work.

## ASSISTIVE TECHNOLOGY

Most studies reviewed in this area did not fit well conceptually into the classification rubric used for this review. Much of the literature over the past 5 yrs related to assistive technology documents technological advancements in equipment design, particularly wheelchair design and interfaces. Subjective[347] and objective[348] evaluations of new equipment are provided by persons with SCI.[349] The most rigorous evaluations use both objective and subjective data from both users and experienced staff in comparisons of new technology *vs.* more typical technology.[350,351] The use of independent, experienced observers to evaluate the effectiveness of technology helps somewhat with the obvious methodological problem of the impossibility of "blinding" the assessor. Cost-effectiveness evaluations are not prominent.

### Wheelchairs

New wheelchair designs have improved mobility across a variety of terrains,[350,351] and new, innovative interfaces, including head[348] and brainwave interfaces,[352,353] provide promise for increased mobility, community access, and environmental control[354] for persons with very high tetraplegia. Power-assist designs, filling a gap between fully manual and fully powered designs, have been developed, and their proper place in the wheelchair prescription process is being evaluated.[355] Considerable recent attention has been given to the role of improvements in the biomechanics of wheelchair designs in the preservation of upper limb function after SCI (see Consortium for Spinal Cord Medicine[356] for a through evidence-based review). Laboratory-based investigations of the impact of different wheelchair designs[357–359] and their interaction with individual differences and neurological level of SCI provide promise for optimizing efficiency of wheelchair propulsion,[360,361] at the same time minimizing the development of upper limb pain and dysfunction over time. In a level II prognostic study[362] using a combination of subjective and objective measures and subjects as their own controls, a pushrim-activated power assisted wheelchair was shown to have considerable energy demand advantages over the participants' own wheelchairs. Others have been exploring the biomechanics of push-up maneuvers[363,364,365]; these studies are the necessary precursor to intervention trials. Another important area of investigation is the assessment of equipment reliability and durability. Objective data in this arena could have important policy implications—for example, providing guidelines to funding agencies as to what normal lifetime expectancy would be for certain types of equipment. In a level II prognostic study of this type, the durability of three different types of manual wheelchairs was objectively demonstrated.[366] More work is needed in wheelchair design and evaluation because persons with SCI have listed the wheelchair itself as the most important factor limiting their social participation, above physical impairment and the environment.[367]

### Other Assistive Devices

Work has also been reported on applications of telemedicine for the remote management of complications.[368] Access to the Internet is generally reported to be lower for persons with a disability compared with the able-bodied population, but for those who do have access, positive benefits may accrue, particularly with regard to information gain and knowledge about access to services.[369] Finally, access to technology remains problematic based on subjective reports from persons with SCI[370] and may be particularly problematic for socioeconomically disadvantaged individuals.[371]

### Conclusion

Ongoing attention to objective evaluation of evolving technology is needed, along with cost-benefit analyses of such technology and longer-term evaluations of its utility and resilience in day-to-day community use.

## AGING

Most of the work identified in this area was cross-sectional or descriptive, with one prognostic and no therapeutic studies identified. Aging has become an important research focus in recent years, in part because acute and postacute medical care has improved, and people who sustain SCIs are living much longer. Aging is not an outcome or an independent variable but a marker for the passage of time and the cumulative impact of physical, psychosocial, and environmental events and experiences. Research has been focused on discovering trends that might help alert the clinician as to high-risk outcomes that are likely to occur as the result both of chronologic age and years postinjury. Many studies in this area are cross-sectional, with a few notable attempts to gather long-term longitudinal information.[372–374]

### Secondary Conditions

Secondary conditions such as kidney stones and musculoskeletal conditions like fractures[372] have been associated with increasing years postinjury. Depressive symptoms, including probable major depression, may also vary with years postinjury, although in a curvilinear fashion: those with the most recent ($<5$ yrs) and the greatest number of years ($\geq 26$ yrs) postinjury demonstrate the highest depression symptomatology.[375] There is some evidence based on qualitative research,[376] and as summarized in reviews,[377] that women have unique concerns and needs as a function of aging with SCI, including concerns about osteoporosis, bladder incontinence and UTIs, dependency, and financial security. Increasingly, physical medicine and rehabilitation physicians are assuming both primary care and geriatric care roles in managing these aging related concerns across the lifespan.[378] Interestingly, chronologic age in contrast to years postinjury has not been highly predictive of a variety of outcome domains across measures of functional independence, activity, and participation.[379,380]

There have been some attempts to examine prognostic factors related to aging in non–cross-sectional designs, but the predictive power of such studies in some cases is limited by the retrospective nature of the data gathered[381,382] or cross-sectional analyses of longitudinal data bases.[383–385] Such studies have been valuable nonetheless in demonstrating concerns about fatigue,[383] decreasing expectations for life satisfaction and independence with aging,[382] and marked sex differences in complications and concerns.[381] In one level II prognostic study[386] examining a large cohort of persons with SCI injured ≥20 yrs at study entry, measures of stress and depression at entry did not predict stress and depression 3, 6, or 9 yrs later, but perceived quality of life at entry did predict later stress and depression.

### Conclusion

Longitudinal, prospective risk factor studies, though difficult, time consuming, and costly to complete, are warranted to provide the best evidence for early identification of markers for later problems, thereby making possible the design and execution of prevention studies.

## CURRENT STATUS AND FUTURE RECOMMENDATIONS

### Systems of Care

Persons with SCIs have been treated in specialized centers since World War II in England through the National Health Service and in the United States through the Veterans Administration. The goal of establishing these centers was to improve the medical and rehabilitative care of persons with this costly disability. The SCI Model Systems program was started in 1970 with the funding of the Good Samaritan Hospital in Phoenix by the then Rehabilitation Services Administration. Twenty-seven centers in various institutions in the United States have been designated Model Systems since that time. These systems were conceptualized as places where superior clinical care could be given, education provided regarding SCI and its prevention, and lifetime management and research could be conducted, primarily through the development of a longitudinal database and the performance of collaborative studies among the centers. These systems continue to be funded through the National Institute of Disability and Rehabilitation Research.

### Rehabilitation Services

Over the years, a number of forces have acted to affect how and where SCI rehabilitation services are provided. Reimbursement patterns have led to dramatically shortened inpatient lengths of stay and a shift to greater outpatient service delivery. Reimbursement policies also encouraged the proliferation of rehabilitation units, with the result that SCI care began being provided in many more locations than primarily large, tertiary care centers.

### Research

Much of the early research emphasis for the field has been on the care and prevention of secondary conditions, both medical and psychosocial, with the goal of improving community participation and quality of life. Such efforts have led to improvements in survival, reductions in morbidity, a greater understanding of the process of adjusting, and an appreciation of the factors involved in living many years with such an injury. Recent theoretical and applied work has highlighted the importance of measuring and ultimately trying to affect the barriers imposed by the natural and built environment in terms of community participation.

Over the past 10 yrs, largely due to the SCI and resultant efforts of the late Christopher Reeve, there has been a burgeoning international interest in research aimed at diminishing the neurologic injury after SCI. New partnerships have formed between basic scientists and clinical researchers, and the schism between these two disciplines has lessened. There are a number of ongoing studies evaluating the efficacy of various pharmacologic and cellular therapies for the treatment of the neurologic consequences associated with acute and chronic SCI. These include pharmacologic studies with minocycline, HP184, and fampridine. In addition, cellular therapies such as the use of autologous incubated macrophages are in phase II studies for the treatment of acute SCI in the United States, and other therapies, such as the transplantation of olfactory ensheathing glia in patients as little as 6 mos post-SCI, are being tested in other parts of the world. At the same time, there are international attempts to bring together basic science and clinical researchers to develop standard protocols for clinical trials post-SCI. Unfortunately, efforts to overcome the challenge of translational research post-SCI still require more coordination. Within these groups of international investigators, there is a need to add more representation from the field of Physical Medicine and Rehabilitation, whose clinicians and researchers have the most experience pertaining to the functioning of persons with chronic SCIs.

### Recommendations for Research Development

Within each review section above, we have delineated proposed areas for needed research in diagnostic, prognostic, and/or therapeutic studies. Rather than repeat that information here, we add these comments intended to address broader issues that cut across specific topics. Many of the topics we reviewed were not amenable for classification according to the evidence-based criteria. Less than 20% of the literature reviewed here met criteria for class I or II studies. Inadequate sample sizes and attrition limit the impact of many studies. Many SCI centers do not have enough persons with new-onset SCI moving through their systems alone to mount adequately powered trials. Adequate funding is needed, therefore, to generate much needed multicenter trials.

Given the current and probable future absence in the United States of mechanisms for determining true population-based estimates of incidence and prevalence, longitudinal epidemiologic work like that of the Model Systems program and of other researchers will continue to be important to inform policy makers about the impact of SCI, its causes, its basic outcomes, and changes in those parameters over time. Effective SCI registries with demonstrated ability to capture all cases of SCI occurring in a region over a specific time frame would need to be funded and in place to assess changes in policy that might affect either the incidence of SCI (such as changes in highway safety regulations, improvements in sports equipment/rules) or the prevalence of SCI (such as improvements in healthcare procedures).

Despite the excitement with respect to cure and the optimism regarding the development of therapies to improve neurologic function after SCI, a number of areas continue to require significant research to optimize the lives of persons with SCI. A better understanding of the natural history of SCI is imperative, as is the development of outcome measures, to effectively describe its physiologic, psychosocial, and functional consequences. Improved management of secondary complications of SCI continues to remain a priority. Moreover, an evidence-based understanding of the benefits of rehabilitation is long overdue. The optimal use of electrical stimulation, robotics, and other assistive technologies in improving the quality of lives of persons with SCI needs to be defined, as does determining the best methods for fully integrating persons with SCI into society. At present, there are few multicenter, large clinical trials related to treatment and prevention of secondary complications of SCI, with the notable exception of a Veterans Administration cooperative study that will be evaluating the efficacy of oxandrolone as an augmentative therapy in the treatment of pressure sores.

Because of the inherent difficulties, small potential sample size, and expenses associated with performance of research in persons with SCIs, it is paramount that funded research topics target the highest priority areas. Requests for proposals for major funding programs (not pilot studies) should require designs capable of attaining level I evidence in chosen topic areas. This may require expansion of the traditional Model Systems or Veterans Administration study population to include select community-based partners as has been required to complete industry-sponsored studies in a timely fashion. In addition, collaboration with other federal agencies, industry, professional organizations, and consumer groups is imperative. With its rich history of system development, maintenance of a longitudinal database, documented accomplishments, and superior quality of its clinicians and investigators, the SCI Model Systems are well poised to serve as a catalyst to facilitate and focus future clinical research in the field of SCI. Areas to be addressed should be those that are most meaningful in terms of outcomes: both in terms of decreasing the morbidity that occurs in association with SCI and in terms of the psychosocial and physical needs of individuals affected by SCIs and their families.

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