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A Systematic Review of Therapeutic Interventions for Pressure Ulcers Following Spinal Cord Injury

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Abstract

Objective—To systematically review evidence on the prevention and treatment of pressure ulcers in those with a spinal cord injury.

Data Sources—For this evidence-based review, the following data sources were used: MEDLINE[®]/PubMed, CINAHL[®], EMBASE[®] and PsycINFO[®]

Study Selection—To be selected for inclusion in the current review, there had to have been an intervention, studies had to have 3 or more subjects, and 50% or more of the participating group had to have a spinal cord injury.

Data Extraction—Data extracted included study design, subject demographics, inclusion and exclusion criteria, study type, sample size, outcome measures used, and study results.

Data Synthesis—Articles selected for this review were organized into one of two categories: prevention or treatment. Within each broad category, several smaller ones were created and articles were grouped together according to the prevention (direct or indirect) or treatment intervention discussed.

Conclusions—Of the 26 articles selected for inclusion in the systematic review, 7 were randomized control trials that dealt with treatment for pressure ulcers, and there was one RCT on prevention. Despite the cost effectiveness of prevention, little research exists on preventative interventions, and what does exist mostly is Level 4 evidence. More research is needed for both prevention and treatment, but especially the former.

Keywords

Pressure ulcers; pressure sores; tetraplegia; paraplegia; treatment and prevention

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Introduction

Pressure ulcers are a serious, secondary complication of SCI that have the potential to “interfere with physical, psychological and social well being and to impact overall quality of life.” (p9)¹ Although preventable in most situations, pressure ulcers may disrupt rehabilitation, prevent individuals with SCI from working or attending school, and interfere with community reintegration.¹⁻⁴ When the pressure ulcer is severe, it can lead to further disability, decreases in mobility, loss of independence, the need for surgical interventions, and fatal infections.^{3,5}

Pressure ulcers have been defined as a lesion on any skin surface that results from pressure or pressure in combination with shear force and/or friction.⁵⁻⁸ The primary cause is felt to be externally applied pressure for a prolonged period of time over bony prominences, such as the sacrum and ischial tuberosities (IT). This leads to ischemia of overlying soft tissues, which ultimately can lead to necrosis.^{6,9,10} Moreover, DeLisa and Mikulic¹¹ have noted that “the visible ulcer represents only the tip of the iceberg or the apex of the lesion”(p210) and muscle is more sensitive than skin to ischemia caused by pressure.¹

Pressure ulcers are staged according to the degree of tissue damage observed. The staging system developed by the *National Pressure Ulcer Advisory Panel* (NPUAP) in 1989¹² and recently revised in 2007⁸ is widely used and supported.^{13,14} It consists of four stages which range in severity from stage I (which involves intact skin) to stage IV (full thickness tissue loss) (see Table 1). In community-dwelling individuals with SCI, 25% of pressure ulcers are classified as severe (stage III or IV).² Another type of pressure ulcer is suspected deep tissue injury. This injury looks like a bruise on intact skin, but may rapidly progress to involve deeper layers, despite treatment.^{2, 8}

Cost data on pressure ulcers in SCI populations are difficult to obtain.⁴ In a case study of a community dwelling client with paraplegia, Allen and Houghton⁴ demonstrated that the cost of three months of accelerated wound treatment to heal a stage III ulcer was \$27,632 Canadian, with approximately half the cost paid for by the patient. In the United States, for individuals with SCI, it has been estimated that the cost of care for pressure ulcers is about \$1.2–1.3 billion annually, whereas prevention would cost about one-tenth of this.^{15,16} Despite the attention given to preventative strategies by rehabilitation and public health professionals, pressure ulcers are common among individuals with a SCI.^{16,17} Annual incidence rates range from 20%–31% and prevalence rates from 10.2%–30%.^{11,16}

Prevention of pressure ulcers requires the recognition of significant risk factors, which effect either the intensity and duration of pressure or the tissue tolerance for pressure.¹⁸ Identified risk factors include: limitations in activity and mobility; injury completeness; moisture from bowel and/or bladder incontinence; lack of sensation; muscle atrophy; nutritional status; and being underweight.^{11,16,19}

Prevention of pressure ulcers begins at the time of injury and is a lifelong commitment for those living with SCI or their caregivers, requiring “understanding, cooperation and initiative”. (p341)²⁰ Typical prevention recommendations made during rehabilitation include: examining skin daily to allow for early detection; minimizing moisture and incontinence, and keeping skin clean and dry; having an individually-prescribed wheelchair with a pressure redistribution cushion and regular pressure relief; ensuring that all equipment is functioning properly; decreasing or stopping smoking, and limiting alcohol consumption; and eating a well-balanced, nutritionally-complete diet, which includes monitoring of weight to detect undesirable trends.^{1,21} Clark *et al.*²² suggested that, to promote sustainable outcomes, health care professionals must assist individuals with SCI to determine which preventative strategies are realistic for them to implement, based upon their

life circumstances, and must help to identify ways to integrate these preventative strategies into their daily schedule.

Given the significant personal and societal consequences of pressure ulcers, it is prudent to understand the existing evidence for prevention and treatment interventions, and to identify future directions for research on pressure ulcer management. Prevention and treatment interventions for pressure ulcers post-SCI will be examined in the following review article.

Methods

A systematic review of all relevant literature published from 1980 to 2007 was conducted using multiple databases (MEDLINE[®]/PubMed, CINAHL[®], EMBASE[®], PsycINFO[®]) and our standardized SCIRE methodology.²³ Search terms included: pressure ulcers (skin sores, decubitus ulcer, ischemic ulcer, bed sores or skin sores) paired with spinal cord injuries or tetraplegia or paraplegia or quadriplegia. Over 17,000 titles were reviewed for version 1 of the SCIRE project (<http://www.icord.org/SCIRE>). For the current review, 26 articles met inclusion criteria, consisting of English language interventional studies with a sample size of 3 or greater, and with at least half of the study population having a spinal cord injury.

A quality assessment was conducted for each article, using either the *PEDro*²⁴ assessment tool (for RCTs) using questions 2–10, or the *Downs and Black*²⁵ tool for nonrandomized studies. With the *PEDro* tool, the higher the score, the better the quality of the study, with the following cut-points used: 9–10 -excellent; 6–8 - good; 4–5 - fair; <4 - poor. The *Downs and Black* tool consists of 27 questions that evaluate the level of (1) reporting, (2) external validity, and (3) internal validity (both bias and confounding). It was modified slightly, due to ambiguity in the last question; thus the highest score any reviewed article could receive was 28, with a higher score indicating higher methodological quality.²⁵ Five levels of evidence, based upon a modified Sackett scale, were used to summarize the data²⁶ (see Table 2).

The results of the quality assessment and a brief study summary were tabulated for each study as follows: *PEDro* or *Downs and Black* score, study design, inclusion/exclusion criteria (when stated), a brief summary of intervention outcomes, and study results.

Direct versus Indirect Indicators of Prevention

It should be noted that outcome assessment for pressure ulcer prevention can be measured via either direct or indirect means. That is, the effectiveness of preventative interventions can be determined by direct indicators, like pressure ulcer incidence, or by indirect indicators, like ischial tuberosity (IT) pressure mapping or transcutaneous oxygen tension (P_{TCO_2}) levels.

Prevention of Pressure Ulcers

Electrical Stimulation

Electrical stimulation has been used since the 1960's to enhance the healing of various chronic wounds, including pressure ulcers in both able-bodied and spinal cord injured individuals.^{27–29} Given that the primary cause of pressure ulcers is felt to be externally-applied pressure over bony prominences like the ischial tuberosities,⁹ investigators have studied the role of electrical stimulation at reducing ischial pressures and redistributing seating interface pressures, both of which might assist with pressure ulcer prevention²⁹ (see Table 3).

Bogie and Triolo³⁰ studied changes in interface pressure distribution at the support/surface interface following 8 weeks of chronic neuromuscular electrical stimulation (NMES) delivered via an implanted neuroprosthesis. With long-term NMES, mean ischial regional interface pressure uniformly decreased post exercise assessment, $p < 0.01$.

Research also has shown that, with increasing interface pressures over bony prominences, regional blood flow is adversely affected.^{27,29} Electrical stimulation has been shown to change blood flow to skin and muscle. It is believed that, by increasing regional blood flow, tissue viability is enhanced, thereby assisting with pressure ulcer prevention^{9, 29–32} (see Table 4).

Mawson et al.³³ administered high-voltage pulsed galvanic stimulation (HVPGS) to 29 SCI subjects lying supine. Baseline transcutaneous oxygen tension (P_{TCO_2}) levels were compared to levels reached at the end of 30 minutes of HVPGS. The authors found that the P_{TCO_2} level at the end of stimulation was 66 ± 18 mmHg or 35% higher ($F = 39.42$, $p < 0.0001$).

Bogie and Triolo³⁰ administered 8 weeks of neuromuscular electrical stimulation (NMES) to 8 subjects using gluteal electrodes. They then assessed unloaded gluteal tissue blood flow by measuring local transcutaneous oxygen levels (P_{TCO_2}). While the results did not achieve statistical significance, baseline mean unloaded tissue oxygen levels increased by 1–36% in 5/8 subjects.

Conclusions—There is limited Level 4 evidence that electrical stimulation decreases ischial pressures post SCI. There is Level 4 evidence that electrical stimulation may increase blood flow at sacral and gluteal areas post-SCI.

Pressure Relief Practices

Current clinical practice regarding pressure relief education is based upon the premise that the absence of regular pressure relief places the person with SCI at a higher risk for pressure ulcers.³ The techniques chosen for pressure relief depend upon the physical and cognitive status of the individual. When a manual weight shift cannot be performed, one alternative is a mechanical reclining or power tilt wheelchair. It has been suggested that pressure relief optimally should be performed every 15–30 minutes for 30–120 seconds, depending on the technique¹ (see Table 5).

A retrospective chart review of 46 SCI subjects seen in a seating clinic noted that approximately 2 minutes of pressure relief was required to raise transcutaneous oxygen tension (T_CPO_2) to unloaded levels for most subjects.³⁴ The required duration of pressure relief was more easily sustained by the subjects leaning forward or side to side, or having the wheelchair tipped back by $\geq 65^\circ$ compared to a vertical lift for pressure relief.

Henderson *et al.*³⁵ pressure mapped 10 SCI subjects at the ischial tuberosities and over a circumscribed area around the ischial tuberosities. Subjects were placed in 4 different positions: sitting upright at rest in a neutral position; tipped back 35° from vertical; tipped back 65° from vertical; and leaning forward as far as was comfortable. When the subjects were in a forward leaning and 65° tipped-back position, there was a statistically significant pressure reduction at the ischial tuberosities and over the circumscribed area (forward lean: 78% reduction at IT, 70% reduction over circumscribed area; 65° tipped back: 47% reduction at IT, 36% reduction over circumscribed area ($p < 0.05$)); this compared to a 27% reduction at the IT and to a 17% reduction over the circumscribed area ($p > 0.05$) in the 35° tipped-back position. The authors noted that, while the pressure reduction for the 65° tipped-back position was statistically significant, only 1 out of 10 subjects had a maximum point

pressure below 32 mmHg, considered the threshold for pressure ulcer formation, compared to 7 of 10 in the forward leaning position.

These findings suggest that a forward leaning position is the most effective pressure relief technique, if sustained for an appropriate time period. Leaning side to side, having the wheelchair tipped back by 65° or more, or doing a pressure relief lift for an appropriate length of time (i.e., 2 minutes) also were effective. The traditional pressure relief lift (15–30 sec) was ineffective at reducing tissue oxygen levels to unloaded levels.

Conclusions—There is Level 4 evidence to support the forward leaning position as the most effective method of pressure relief. There is Level 4 evidence that a 15–30 second vertical lift is not effective.

Wheelchair Cushion Selection

Wheelchair cushion selection is important when an individual with a SCI is prescribed a wheelchair. Bogie *et al.*⁹ noted that 47% of pressure ulcers occurred over the ischial tuberosities and sacrum and are, therefore, more likely to have been initiated while the patient was seated. When optimizing wheelchair cushion selection for an individual with a SCI, the degree of pressure reduction and redistribution³⁶ and temperature effects^{37, 38} along with individual patient characteristics - like paraplegia or tetraplegia, pressure relief abilities, transfer techniques and lifestyle - must be considered.^{36, 39} Seat cushioning can be made from various materials; it may be static or dynamic (typically accomplished with air bladders);^{36,39} and it may be incorporated into upright, powered tilt or reclined wheelchairs (see Table 6).

In the study conducted by Burns and Betz,⁴⁰ 3 wheelchair cushions were tested: dry flotation (ROHO High Profile), gel (Jay 2), and dynamic (ErgoDynamic), the last consisting of two air-filled bladders (H-bladder, IT- bladder). These were compared to each other under high pressure conditions (upright sitting or IT-bladder inflated) and low pressure conditions (seat tilted back 45° or H-bladder inflated). When analyzing the pressure placed on the ischial tuberosities, it was found that the pressure was higher during upright sitting than in the tilted back position for both the dry flotation and the gel cushion ($p < 0.001$), with the dry flotation cushion providing more pressure relief than the gel cushion during upright sitting (112 versus 128 mmHg, $p = 0.01$). Mean pressure with the IT-bladder-inflated cushion (157 mmHg) was greater than upright pressures for either the dry flotation or gel cushions (111 and 128 mmHg, respectively $p < 0.01$). Most importantly, ischial tuberosity pressure for the dynamic cushion during H-bladder inflation in an upright position was comparable to the pressure for the dry flotation cushion in a tilted back position (71 versus 74 mmHg, $p = 0.91$) and significantly less than the pressure obtained with the gel cushion (71 versus 86 mmHg, $p < 0.05$).

Brienza and Karg⁴¹ had twelve subjects with a SCI sit on 3 different surfaces (flat foam, initial contour, and final contour) while measuring interface pressures using a pressure-sensing pad. SCI subjects had greater depth values than elderly subjects with a SCI ($n = 30$), and the mean maximum depth of the final contour was deeper for the SCI group, suggesting that pressure distributions for the SCI group were more sensitive to support surface characteristics than for non-SCI elderly subjects.

Seymour and Lacefield³⁷ evaluated 8 cushions for pressure, temperature effects, and subjective factors influencing cushion purchase. While data indicated a wide variability in pressure measurements in individual subjects, the air-filled cushion had the best pressure readings. The alternating pressure and foam cushions had consistently higher temperature

readings across both groups, which could increase tissue susceptibility to pressure ulcer formation.^{37,38}

Garber³⁶ evaluated 7 cushions based upon the amount of pressure reduction achieved, and noted how frequently each cushion was prescribed to subjects with quadriplegia and paraplegia. The ROHO cushion produced the greatest pressure reduction in the majority of subjects (51%) and was prescribed more often for subjects with quadriplegia than with paraplegia (55% versus 45%).

Makhsous *et al.*,³⁹ in a case-control study, exposed subjects to two 1-hour protocols: alternate, where sitting posture was alternated dynamically every 10 minutes between normal (sitting upright with ischial support) and sitting upright with partially-removed ischial support and lumbar support (WO-BPS); and normal (normal posture plus pushups performed every 20 minutes). These investigators found that the anterior portion of the seat cushion had a larger contact area among those with tetraplegia compared to those in the other groups. It also was determined that those with a SCI had a larger contact area in the mid portion of the seat cushion. There were significant differences between the groups when looking at the average pressure over the whole seat ($p < 0.001$) and the total contact area on the seat cushion. With the WO-BPS posture, the average pressure for the tetraplegia group was higher than it was for the other groups ($p < 0.001$). Most importantly, the total contact area on the posterior portion of the cushion was less for the WO-BPS posture group. As well, peak interface pressure was lower for all groups, with the greatest decrease from normal posture seen in the tetraplegia group. The average pressure increased on the anterior and middle portion of the cushion in all groups.

The results of the above studies and the apparent inter-individual variation inherent in those with a SCI (e.g. paraplegia vs. tetraplegia) support the practice of specialized pressure mapping assessments to assist with individualized wheelchair cushion prescriptions. None of these studies included direct evidence of pressure ulcer prevention associated with a particular practice or cushion type. Objective findings - such as pressure mapping together with the clinical knowledge of the prescriber and the clients' subjective reports - need to be considered when prescribing a wheelchair seat cushion for an individual with a SCI, so as to minimize pressure ulcer risk factors.

Conclusions—There is Level 3 evidence that various cushions or seating systems (e.g., dynamic versus static) are associated with potentially beneficial reductions in seating interface pressure or pressure ulcer risk factors, like skin temperature.

Thickness of Lumbar Support

Shields and Cook⁴² discussed the role that spinal deformities, like kyphosis, may play in the formation of pressure ulcers in individuals with chronic SCI. In previous research on non-disabled subjects, they had demonstrated that the addition of lumbar support reduced highest seated buttock pressure ($>0.915 \text{ kg/cm}^2$) and was associated with a change in pelvic tilt. If those findings were to hold true in the SCI population, the authors noted that this could lead to ways to “*monitor seated postures for optimal pressure distribution*” (p.219)⁴² and augment electric wheelchair backrests by adding an automated lumbar support system, potentially providing a mechanism for continuous pressure shifts.

In the Shields and Cook⁴² study, 18 SCI and 18 able-bodied subjects were studied to test the effects of varying lumbar support thickness (0, 2.5, 5.0, 7.5 cm) on seated buttock pressures at the ischial tuberosities. Within the SCI group, a 2% decrease in mean highest seated buttock pressure ($>0.915 \text{ kg/cm}^2$) was seen with the 7.5 cm lumbar support compared to a 90% reduction within the able-bodied group. With the 5 cm and the 2.5 cm lumbar support,

there was an increase in mean high pressure of 13% and 12%, respectively, compared to reductions in the able-bodied group of 80% and 25%, respectively. Surprisingly, the findings showed that the addition of lumbar support to wheelchairs had minimal effect on reducing highest seated buttock pressure at the ischial tuberosities of subjects with chronic SCI ≥ 3 years (see Table 7).

Conclusions—There is Level 3 evidence that adding lumbar support to the wheelchair of those with a chronic SCI has a negligible effect on reducing seated buttock pressures at the ischial tuberosities. As a consequence, it is unlikely to have a role in pressure ulcer prevention post-SCI.

Specialized Seating Clinics

Education regarding the prevention of pressure ulcers post-SCI includes an emphasis on taking personal responsibility for maintaining healthy skin through personal care, inspection of skin, pressure relief, and the correct use of prescribed equipment.⁸ The incorporation of seating clinics into both inpatient and outpatient rehabilitation programs has been shown to reduce the incidence of pressure ulcers and readmission rates due to pressure ulcers.⁴³ Seating clinics not only provide education; they also make recommendations for appropriate seating systems based upon interface pressures, thermography and assessments of tissue viability. Verbal and visual feedback are provided to the individual with a SCI, and active participation is encouraged^{34, 43, 44} (see Table 8).

Kennedy *et al.*⁴⁴ studied 50 individuals with a SCI participating in a comprehensive rehabilitation program. The individuals were divided into 3 groups (Group 1 (attendance at seating assessment clinic (SSA) prior to NAC 1); Group 2 (attended SSA between their first and second NAC; Group 3 (no attendance at SSA) to determine if attendance at SSA would improve skin management ability, as evidenced by lower ‘*to be achieved*’ scores on the skin subscale of the *Needs Assessment Checklist* (NAC). The NAC was administered within one month of mobilization (NAC 1) and on admission to the pre-discharge ward (NAC 2).⁴⁴ Optimal timing of attendance at the SSA also was studied. Results indicated significant differences between Group 1 and Group 3 at both NAC 1 ($p < 0.05$) and NAC 2 ($p < 0.01$) assessments. Skin management ‘*to be achieved*’ scores were significantly lower among individuals who attended SSA before their first NAC at both time points. Significant differences also were observed between ‘*to be achieved*’ scores at first and second NAC within all groups: Group 1 ($p < 0.0001$), Group 2 ($p < 0.01$) and Group 3 ($p < 0.01$).⁴⁴

Conclusions—There is Level 2 evidence showing that early attendance at specialized seating assessment clinics (SSA) increases the skin management abilities of individuals post-SCI. Attendance at SSA is an adjunct to the skin management abilities learned during a comprehensive rehabilitation program.

Education

Although education plays a significant role in the prevention of pressure ulcers, it has been found that little information is provided to patients that would assist them in reducing the number of pressure ulcers that develop⁴³ (see Table 9).

In an RCT conducted by Garber *et al.*,⁴⁵ while they were in hospital, those in the treatment group ($n=20$) were provided with four 1-hour sessions of structured education on the prevention and management of pressure ulcers. Information presented at the education sessions included information regarding nutrition, pressure redistribution surfaces for the bed and wheelchair, and pressure ulcer etiology. The control group ($n=21$) received only

standard education regarding preventative practices. After discharge, the groups were followed for 2 years.

Improvement on the pressure ulcer knowledge test was noted in both groups upon discharge from hospital; however, it was significantly different between the groups ($p < 0.03$), with those in the treatment group gaining more knowledge about preventing pressure ulcers. No significant differences were noted on the multidimensional *Health Locus of Control Scale* and the *Health Beliefs Questionnaire* between the two groups at discharge. Two years post treatment, it was noted that both groups had retained most of the knowledge they had been given during their hospitalization, but the level of knowledge retained by the control group was substantially below that of the treatment group: 60.8% versus 68% on the pressure ulcer knowledge test.⁴⁵

Conclusions—There is Level 2 evidence that providing enhanced pressure ulcer prevention education is effective at helping individuals with SCI gain and retain this knowledge. However, no evidence exists regarding whether or not this enhanced education results in a reduction in pressure ulcer formation.

Behavioral Contingencies

Jones *et al.*¹⁵ documented that “*despite what we know about pressure ulcers and methods of prevention, the problem persists. Little is known about why some patients do not establish and maintain the health behaviors necessary for optimal skin care and pressure ulcer prevention*” (p. 796).¹⁵ There is a subset of patients who experience recurrent pressure ulcers because of non-adherence to recommended prevention strategies. Patients with recurrent pressure ulcers may lack incentives to promote prevention behaviours.¹⁵ What is not known is whether rewarding positive preventative strategies reduces the severity or likelihood of a patient developing pressure ulcers.

Jones *et al.*¹⁵ conducted two small separate studies. The behavioral intervention in the first study ($n=6$) consisted of a health plan, clinic visits and financial rewards (50 dollars/visit as long as ulcer free), all of which were implemented at the same time. In the second study ($n=3$), a health plan and visits were implemented in phase one of the study; payments were added if a patient experienced new skin problems. Results from the first study revealed that average *Pressure Ulcer Scale for Healing (PUSH)* scores were lower by 10.5 points from baseline at the end of the intervention phase. No hospitalizations were required and, ultimately, costs during the intervention phase went from \$6263.00 (US) to \$235.00 (US). In the post-intervention phase, 3 subjects were able to maintain lower PUSH scores and 3 were not. In the second study, mean PUSH scores decreased from baseline by 8.3 points (visits only) and a further 3.1 points when payments were added. PUSH scores rose again in 2 out of 3 participants during the post-intervention phase. The mean number of hospitalizations dropped from 1.67 (baseline) to 0.33 (intervention and post-intervention) (See Table 10).

Conclusions—There is very limited Level 4 evidence to suggest that the introduction of behavioral contingencies is associated with a reduction in pressure ulcer severity and decreased health care costs.

Telerehabilitation and Pressure Ulcer Management

“*Telerehabilitation is the use of telecommunication technology to deliver rehabilitation services at a distance.*”(p264)⁴⁶ Impaired mobility and distance to specialized SCI centers often make follow-up care difficult for individuals with SCI.^{47,48} Telerehabilitation has the potential to deliver medical rehabilitation, nutritional and psychosocial elements of health

care at a distance, thereby facilitating continuity of care. Pressure ulcer management is one area in which telerehabilitation currently is being used⁴⁶ (see Table 11).

Vesmarovich *et al.*⁴⁶ described the use of telerehabilitation delivered via a videophone system that transmitted still images and audio to treat stage III/IV ulcers. While no statistical results were reported, 7 out of 12 ulcer sites healed. Phillips *et al.*,⁴⁹ using the same videophone system, divided SCI participants into 3 groups: information delivered by telephone; information delivered by video; and standard care. The video group had the highest number of identified and/or reported ulcers during the study. The annualized data for emergency room (ER) visits, hospitalizations and health care visits were similar for the video and telephone groups, and were tracked weekly. Hospitalizations and health care visits, tracked every 8 to 12 weeks, were less in the standard care group. Fifty-five percent of each of the 3 groups had no hospitalizations. Repeat emergency room visits and hospitalizations appeared to be driven by a small number of people; no significant differences were noted between the three study groups.⁴⁷

Conclusions—There is Level 4 evidence that telerehabilitation does not make a significant difference in the prevention and treatment of pressure ulcers post-SCI.

Treatment of Pressure Ulcers

Electrical Stimulation for Pressure Ulcer Healing

The therapeutic effects of electrical stimulation for wound healing has been well documented since the 1940's, especially for wounds not responding to standard forms of treatment.^{27,28,31} Despite the use of electrical stimulation to promote wound healing, there remains a lack of clear understanding as to how it works to facilitate tissue repair.³⁰

Some of the effects of electrical stimulation on wound healing include decreased healing time, increased collagen synthesis, increased wound tensile strength, increased rate of wound epithelialization, and enhanced bactericidal effects.²⁷ Electrical stimulation also has been shown to improve tissue perfusion and reduce edema formation, indirectly stimulating healing by improving oxygen delivery to tissue.⁵⁰ The literature shows high variability as to which type of electric current and application protocol is effective for a specific patient or ulcer type³¹ (see Table 12).

Griffin *et al.*⁵¹ showed the efficacy of high voltage pulsed direct current (HVPC) for the healing of pelvic pressure ulcers in subjects with SCI. When compared with a placebo group, the subjects treated with HVPC experienced a greater percentage reduction in wound surface area (WSA) at day 5 ($p=.03$), day 15 ($p=.05$) and day 20 ($p=.05$). Stefanovska *et al.*⁵² showed that the healing rate for wounds treated with low frequency pulsed current (AC) was significantly better than for groups treated with direct current or conventional treatment alone ($p=.003$). Baker²⁸ demonstrated that, for ulcers that responded to any form of electrical stimulation ('good responses'), asymmetric biphasic stimulation (group A) was most effective for enhanced wound healing. Wounds that already were exhibiting signs of healing in the control group, with the subsequent addition of either protocol A or B (symmetrical biphasic), experienced a greater healing rate ($43.3\% \pm 12.5\% \Delta/\text{week}$) versus the control period ($9.7\% \pm 3.4\% \Delta/\text{week}$). Adegoke and Badmos⁵³ found that the surface area of grade IV pelvic pressure ulcers treated with interrupted direct current (IDC) and nursing care decreased by 22.2% versus 2.6% with sham treatment. While there were differences in the type and duration of electric current applied in the 4 studies, all the studies demonstrated that, when used in conjunction with standard wound management, electrical stimulation can accelerate the healing rate of pressure ulcers in patients with SCI.

Conclusions—There is Level I evidence from 2 RCTs to support the use of electrical stimulation to accelerate the healing rate of stage III/IV pressure ulcers, when combined with standard wound management.

Laser Treatment for Pressure Ulcer Healing

The *Consortium for Spinal Cord Medicine*¹ reviewed the literature on adjunct wound therapies, including laser treatments, and did not identify enough supporting evidence to recommend laser for the treatment of pressure ulcers in individuals with SCI. The two studies presented in this article support the conclusion of the consortium (see Table 13).

Taly *et al.*⁵⁴ studied 35 subjects (64 ulcers) using multi-wavelength light therapy compared to ‘standard’ wound care alone. Overall, no significant differences were found between the two groups with regard to the number of ulcers healed or the time required for ulcers to heal.

Nussbaum *et al.*⁵⁵ studied 16 patients and compared standard wound care alone to standard care combined with either laser or Ultrasound/Ultraviolet C (US/UVC). In this study, laser treatment combined with standard wound care had the least effect on wound healing when compared to either standard care or US/UVC. A significant difference was found between the US/UVC and the laser group, with the US/UVC treatment producing the greater effect on wound healing.

Conclusions—There is Level 1 evidence (from two RCTs) to suggest that laser treatment has no added benefit in pressure ulcer healing post-SCI over standard wound care alone.

Ultrasound/Ultraviolet C for Pressure Ulcer Healing

Houghton and Campbell⁵⁰ note that both ultrasound (US) and ultraviolet light C (UVC) have been used in the treatment of chronic wounds. Ultrasound acts mainly at the “inflammatory stage of the wound healing cascade to stimulate the release of chemical mediators of cells which in turn produces changes in the amount and strength or integrity of the scar tissue.” (p464)⁵⁰ The bactericidal effects of UVC suggest that it is best used for the treatment of chronic, infected wounds, wherein there is an excess of surface bacteria or where bacteria have become resistant to antibiotic therapy. The authors go on to say that there is research to support the positive effects of these two treatments for chronic wounds. In contrast, the *Consortium of Spinal Cord Medicine*¹ found minimal data specific to the use of US or UVC to treat pressure ulcers in SCI.

In one small RCT (n=16), Nussbaum *et al.*⁵⁵ demonstrated that, when compared to standard wound care alone or laser combined with standard wound care, ultrasound/ultraviolet C (US/UVC) plus standard wound care generated a greater effect on wound healing over a shorter period of time. As US and UVC were alternated over 5 days and provided in combination to a single treatment group, however, conclusions cannot be drawn as to the individual effects of either US or UVC (see Table 14).

Conclusions—There is Level 1 evidence, from 1 small RCT, to suggest that combining US/UVC with standard wound care decreases the wound healing time of pressure ulcers post-SCI, but no evidence exists to clarify whether UVC or US, used alone, exert any beneficial effect.

Effects of Non-Thermal Pulsed Electromagnetic Energy Treatment

Keast *et al.*, while updating best practice recommendations for the prevention and treatment of pressure ulcers, recommend considering electromagnetic fields as one adjunct modality for stimulating closure of chronic non-healing pressure ulcers (see Table 15).

Salzberg⁵⁶ evaluated the effects of non-thermal pulsed electromagnetic energy (PEE) for the healing of stage II/III ulcers in patients with SCI, assessing effects in stage II ulcers and stage III ulcers separately. In those with stage II ulcers (n=10), a greater proportion of ulcers healed (84%) after 1 week of active treatment versus a sham treatment (40%; p=.01). For complete healing, the treatment group healed in a median of 13 days versus 31.5 days among controls (p<.001). Given that there were a larger number of ulcers with size > 60cm² in the sham group, the data were reanalyzed and the results obtained were consistent with the initial findings; again, treated patients with stage II ulcers experienced a greater proportion of lesions healed at one week (p=.002) and the number of days to being fully healed was less (p=.007). In those with stage III ulcers, healing also was associated with PEE treatment: 3/5 healed within an average of 43 days; while 0/5 healed in the sham group. Ulcer area decreased 70.6% with active treatment versus 20.7% with the sham treatment.⁵⁶

Conclusions—There is Level I evidence from one RCT to support the efficacy of pulsed electromagnetic energy to accelerate the healing of stage II and III pressure ulcers post-SCI.

Anabolic Steroid Agents

Impaired nutritional status and decreased nutritional intake are significantly associated with the development and healing of pressure ulcers.¹ The use of anabolic steroids and increased protein intake have been associated with promoting anabolism, weight gain and, in turn, wound closure in burn patients.⁵⁷ Since a “*hypermetabolic, potentially catabolic state also is associated with pressure ulcers,*” (p 140)⁵⁸ the use of an anabolic steroid agent may also promote closure of non-healing, pressure ulcers in the SCI population.

In a case series of nine subjects with stage III or IV pressure ulcers, Spungen *et al.*⁵⁸ demonstrated complete healing in 8/9 subjects 3–12 months after administration of 20mg oxandrolone. Given the small size of this case series, further research is needed to determine the role of anabolic steroid agents (oxandrolone) for the promotion of healing of stage III and IV pressure ulcers post-SCI (see Table 16).

Conclusions—There is very limited Level 4 evidence to support the use of anabolic steroid agents (oxandrolone) to promote the healing of stage III and IV pressure ulcers post-SCI.

Effectiveness of Dressings

Due to the estimated costs associated with pressure ulcers and their treatment, various dressing types used with the SCI population have been investigated including hydrogel⁶³ and hydrocolloid dressings⁶³ (see Table 17).

Hollisaz *et al.*,⁵⁹ in a RCT involving 83 subjects, found that those in the hydrocolloid dressing (HD) group (n=28) seemed to have the greatest level of healing, compared to those in the phenytoin cream (PC) group (n=28) or simple dressing (SD) group (n=27). This could be seen when looking at both stage I and stage II ulcers. Those in the HD group healed faster than those in the other two groups; however, for stage II ulcers, there was no difference in healing between the HD and PC groups. When looking at the area of injury, gluteal ulcers also healed more completely in the HD group than in the other two, whereas the healing of sacral ulcers did not differ between the 3 groups.

Kaya *et al.*⁶⁰ compared the effectiveness of applying an occlusive hydrogel type dressing to a povidone-iodine soaked gauze dressing. Although those using the hydrogel dressing experienced a somewhat higher rate of healing, no statistically significant differences were

noted between the two groups The 21 subjects in the treatment group did have significantly more wounds heal than did the 13 controls ($p < 0.04$).

Conclusions—There is Level 1 evidence from a single RCT that an occlusive hydrocolloid dressing is effective at increasing the rate of healing of stage I and II pressure ulcers. There is Level 2 evidence from another single, small RCT that occlusive hydrogel-type dressings heal more pressure ulcers than conservative treatment.

Maggot Therapy

Maggot therapy, also called *maggot debridement therapy* (MDT), is a treatment for wound healing that has been practiced for several centuries; however, with the development of various antibiotics, this therapy began to lose its popularity following World War II. More fashionably called *myiasis* or *bio-surgery*, MDT utilizes specially bred larvae of the *Lucilia sericata* species. *Lucilia sericata* larvae do not damage healthy dermis or subcutaneous tissue, but can destroy healthy epithelium; thus, epithelium protection is mandatory with MDT. Maggots assist with the debridement of wounds by secreting digestive enzymes which dissolve necrotic tissue; these enzymes also contain antibacterial substances which assist with disinfecting wounds.^{61,62} Maggot therapy is associated with an increase in wound granulation tissue and with debridement and disinfection, and is felt to accelerate wound healing (see Table 18).^{61,62}

In one non-RCT conducted by Sherman *et al.*,⁶³ 8 of 20 patients diagnosed with pressure ulcers (level III or IV) were treated with maggot therapy. All 8 patients underwent 3 weeks of conventional treatment, followed by maggot therapy. All necrotic wounds were debrided within one week of maggot treatment and wound healing was faster among the 8 who had received maggot therapy than in the 12 who had not.

Conclusions—There is Level 2 evidence from one study to support the use of maggot therapy as an adjunctive therapy for non-healing pressure ulcers post-SCI.

Summary

Numerous authors cited in this article have spoken to the fact that pressure ulcers, though largely preventable, remain a common, potentially serious lifelong secondary complication of SCI. Pressure ulcers have the potential to impact overall quality of life, and to disrupt rehabilitation, vocational and educational pursuits and community reintegration,^{1-3,15} Pressure ulcers lead to increased hospital readmission rates with longer lengths of stay. While pressure ulcer prevention is more cost effective than treatment, pressure ulcers continue to be a major issue.^{15,30}

Many of the prevention studies reviewed suffered from very small sample sizes. Most of the evidence supporting the interventions was only Level 4; and, for two of the interventions, there was no supporting evidence at all. More rigorous research is needed in all areas of pressure ulcer prevention post-SCI to determine effective interventions, so that evidence-based conclusions may guide education and practice.

Eleven articles were found that studied treatment interventions post SCI. While there was a small number of articles and generally small sample sizes, there was Level 1 evidence to support electrical stimulation, US/UVC and pulsed electromagnetic energy as adjunctive therapies to standard wound management. There also was Level 1 evidence to support the use of an occlusive hydrocolloid dressing for healing stage I and II pressure ulcers. Interventions that are well supported by evidence need to be incorporated into treatment

plans for individuals with SCI who have non-healing pressure ulcers. Nonetheless, more research needs to be done assessing treatment interventions.

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Table 1

Stages of Pressure Ulcers

Stage	Descriptions
Suspected Deep Tissue Injury	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage underlying soft tissue from pressure and/or shear force. The area may be preceded by tissue that is firm, mushy, boggy, warmer or cooler, when compared to adjacent tissue.
Stage 1	Intact skin with non-blanchable redness of localized area, usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.
Stage 2	Partial Thickness loss of dermis presenting as a shallow open ulcer with a red/pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.
Stage 3	Full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon or muscles are not exposed. Slough may be present, but does not obscure the depth of tissue loss. May include undermining and tunneling.
Stage 4	Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present in some parts of the wound bed. Often includes undermining and tunneling.
Unstageable	Full thickness tissue loss in which the base of ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

National Pressure Ulcer Advisory Panel (NPUAP)⁸

Table 2

Levels of evidence

Level 1	RCTS with a PEDro score ≥ 6
Level 2	RCTS with a PEDro score < 6 , Cohort and Non-RCTS
Level 3	Case-Control studies
Level 4	Pre-Post or Post interventions and Case series,
Level 5	Case reports, Clinical Consensus or Observational studies

Straus *et al.*, 2000²⁶

Table 3

Electrical Stimulation

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Bogie & Triolo, 2003 ³⁰ USA D&B=13	Inclusion: Low cervical or thoracic level SCI (C6-T12); more than 6 months post-injury; skeletal and cognitive maturity; upper motor neuron injury; ASIA impairment scale score: for low cervical/high thoracic injuries (C6-T4): A, B, or C to mid to low thoracic injuries (T4-T12): A or B. Exclusion: Cardiac arrhythmia or pacemaker-fitted; acute orthopedic problems; acute medical complications; frequent urinary tract infections; current open pressure sores; immunodeficiency; acute chronic psychological problems or chemical dependency; seizure disorder; pregnancy.	Pre-Post: Recruited 7 males and 1 female who ranged in age from 27 to 47 and had ASIA scores ranging from 56 to 113.4. All 8 SCI patients participated in an exercise regimen which included 3 different stimulation patterns. The duration of exercise was varied over the 8-wk training period as the muscles became conditioned.	Interface pressure	1 Overall, with chronic neuromuscular electrical stimulation (NMES), mean interface pressure showed no significant differences between baseline and post exercise levels. 2 Mean ischial region interface pressure had a uniform tendency to decrease post exercise assessment, $p < .01$.

D&B = Downs and Black quality assessment scale score²⁵

Table 4

Effects of Electrical Stimulation on Regional Blood Flow

Author/Year/Country PEDr/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Bogie & Triolo, 2003 ³⁰ USA D&B=13	Inclusion: Low cervical or thoracic level SCI (C6-T12); more than 6 months post injury; skeletal and cognitive maturity; upper motor neuron injury; ASIA impairment scale: low cervical/high thoracic injuries (C6-T4): A, B, or C to mid to low thoracic injuries (T4-T12): A or B. Exclusion: Cardiac arrhythmia or pacemaker- fitted; acute orthopedic problems; acute medical complications; frequent urinary tract infections; current open pressure sores; immunodeficiency; acute chronic psychological problems or chemical dependency; seizure disorder; pregnancy.	Pre-Post: Recruited 7 males and 1 female who ranged in age from 27 to 47 and had ASIA scores ranging from 56 to 113.4. All 8 SCI patients were included in the following study. Electrical stimulation was delivered via an implanted neuroprosthesis, which included gluteal electrodes. 8 weeks of conditioning exercises followed.	Transcutaneous Oxygen levels (P _{TC} O ₂).	1 Baseline mean unloaded tissue oxygen levels increased by 1–36% at post exercise assessment for 5/8 subjects. 1 Differences between baseline and post exercise tissue oxygen levels were not statistically significant.
Mawson et al., 1993 ³³ USA D&B=10	Inclusion: Inclusion criteria not specified; however, those selected ranged in age from 18–57 years. Ulcer sites were as follows: sacral n=7, heel n=2, other n=1. Ulcer grade ranged from 1–4. Exclusion: Not specified.	Case Series: 29 SCI patients lying on egg crate mattresses were included in the study. Sensor was applied to the skin at approximately the second sacral segment along the midline, using a two-sided airtight seal. 2 electrodes and conductive sponges, measuring 4 cm in diameter, were used to administer electrical stimulation.	P _{TC} O ₂ .	1 Experiment 1: Subsequent experiments were performed using 75 volts, as no additional effect on transcutaneous oxygen tension (P _{TC} O ₂) was seen when 100 volts were used. 2 Experiment 3: No change in P _{TC} O ₂ with simulated high-voltage pulsed galvanic stimulation (HVPGS). 3 Experiment 4: No significant differences were observed (p=0.66 in all comparisons) when experiment 2 and 4 results were compared. 4 Experiment 4: Compared to final baseline P _{TC} O ₂ reading (mean ± SD) of 49±21mmHg, the level reached at the 30min period of HVPGS was 66±18 mmHg -- 35% higher (p<0.00001). 5 The level fell slightly following the first 15 minutes post stimulation (p<0.00001).

D&B = Downs and Black quality assessment scale score²⁵

Table 5

Pressure Relief Practices

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Coggrave & Rose, 2003 ³⁴ UK D&B=14	Inclusion: No specific inclusion criteria were documented; however, patients selected were 13 females and 33 males who ranged in age from 20 to 83 years. No other details provided. Exclusion: Not specified.	Case Series: 46 SCI patients in a retrospective chart review.	Effect of pressure relief on T _c PO ₂ .	<ol style="list-style-type: none"> 1 Mean duration of pressure relief required to raise tissue oxygen to unloaded levels was 1 min 51 sec (range 42 secs- 3½ min). 2 Leaning forward with elbows, or chest on knees, leaning from side to side or tilting back in wheelchair to ≥ 65° all were effective for pressure relief to unloaded (raising T_cPO₂ levels) and were more easily sustained for most individuals than a pressure lift. 3 Resulted in a change in practice at the seating clinic.
Henderson et al., 1994 ³⁵ USA D&B=12	Inclusion: Specific inclusion criteria not provided; however, individuals were from 22 to 67 years old, 9 were male and 1 was female. No further details provided. Exclusion: Not specified.	Case Series: 10 SCI subjects sat upright in a wheelchair in the neutral position; tipped backward at 35° & 65° assisted to lean forward (>45° from wheelchair backrest). Pressures were measured at ischial tuberosity (IT) (point pressure) and over a circumscribed area around the IT.	Pressure levels.	<ol style="list-style-type: none"> 1 Average pressure in the resting seated position was 189mmHg for point pressure area and 114mmHg for the circumscribed area. 2 When patients were in the 65° backward tipped position, there was a 47% reduction in maximum point pressure and a 36% reduction in circumscribed area pressure. (p<0.05). 3 In the leaning forward position, there was a 78% reduction in maximum point pressure and a 70% reduction in circumscribed area (p<0.05).

D&B = Downs and Black quality assessment scale score²⁵

Table 6

Wheelchair Cushion Selection

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Burns and Betz, 1999 ⁴⁰ USA D&B=17	Inclusion: ASIA A or B tetraplegia; use of power tilt-in-space wheelchair; 18 or older. Those selected ranged in age from 24 to 65 years. All injuries were cervical (C4 to C6) and all were 0.5 to 31 yrs post injury. Exclusion: Current skin breakdown; history of surgical resection to any portion of the femur; hip flexion passive ROM < 90°	Non-RCT: 3 wheelchair cushions were tested: dry flotation, gel & dynamic (ErgoDynamic). The dynamic cushion was composed of two air bladders, which alternated test cushion, between inflation and deflation. One bladder was shaped like the letter 'H' (H-bladder) with the longer portions under the femurs. The other bladder (IT-bladder) filled the remainder of the cushion and supported the ischial tuberosities (IT). Subjects (n=16) had their regular cushions removed and replaced with one of the test cushions.	Interface pressure at ischial tuberosities (IT) was assessed with Clinseal seating interface pressure sensor placed on the	1 IT pressure for the dry flotation cushion in a tilted position was similar to that for the H-bladder in an upright position (74 vs. 71 mmHg, p=0.91) whereas the gel cushion had significantly higher IT pressure in the tilted position (86 mmHg, p<0.05). 2 Pressure was significantly higher in the upright position than in the tilted position for both the dry flotation and the gel cushion (p<0.001) and for IT bladder (157 ± 45) vs. H bladder inflation (71 ± 30, p<0.001) with the dynamic cushion. 3 In upright sitting position, the dry flotation cushion showed lower pressures than the gel cushion (111 vs. 128 mmHg, p<0.01), whereas the IT bladder (157 mmHg) had greater pressure than both (p<0.001).
Brienza & Karg, 1998 ⁴¹ USA D&B=14	Inclusion: Inclusion criteria not specified; however, all individuals were between the ages of 21 and 52 years, and had a BMI of 17 to 32.3 kg/m ² . Exclusion: Not specified.	Case series: 12 individuals assessed on 3 different surfaces (flat foam, or initial contour and a final optimized foam contour) with the force sensing array (FAS) pad between the cushion and buttocks. Compared SCI to seniors group.	Tissue stiffness, deformation (depth), interface pressure, BMI.	1 Depth values for the SCI group were greater for the final vs. the initial contour from 37.9 ± 6.5 mm to 52.5 ± 11.5 mm (p<0.001), as was the case for the elderly group (p<0.001). 2 The mean max depth of the final contour was deeper for the SCI group than for seniors (p=0.016). 3 Mean pressure values for initial and final cushions were significantly less than for flat cushions (p=0.006, p=0.003, respectively), but not for the initial vs. final cushions (p=0.80) 4 In general, mean and peak pressures were greater for the SCI subjects than for elderly subjects. 5 BMI was significantly related to peak and mean pressure values.
Seymour et al., 1985 ³⁷ USA D&B=13	Inclusion: Specific inclusion criteria not stated; however, the age range of the group was 16–35 years, the weight of the group ranged from 40.6–72.5kg. No other details provided. Exclusion: Not specified	Case-Control: 20 subjects (10 SCI patients & 10 able-bodied controls) participated in the study. 7 commercially-available cushions and 1 experimental cushion were evaluated for each subject.	Temperature and pressure effects (pressure evaluation pad) were assessed for each cushion. Subjects were asked to rate each cushion as to appearance, handling, and suitability for purchase.	1 Greatest pressure was seen under the soft tissue areas of most subjects, with no significant differences between cases and controls 2 Temperatures were lowest for gel, water and air cushions and highest for alternating pressure and foam cushions. 3 SCI group—Greatest pressure (GP) under a bony area occurred most often with the Spenco cushion (90.10 ± 8.75); controls- corresponding GP occurred most often with the Tri-pad (89.20 ± 11.40), indicating that these cushions did not compare favorably to others. 4 There was wide variability in pressure measurements in individual subjects (SD=12.21 mmHg). 5 Appearance (83%) and handling (73%) were related to purchase decisions
Garber, 1985 ³⁶ USA D&B=8	Inclusion: Inclusion criteria not specified; however, there were 207 males and 44 females. No other details provided. Exclusion: Not specified	Case Series: 251 SCI participants were selected for inclusion. An assessment of pressure distribution for 7 cushions was undertaken.	Seated pressure distribution using a pressure evaluation pad (PEP).	1 The air-filled cushion (ROHO, which was 1 of 2 used) produced the greatest pressure reduction in 51% of the subjects. 2 A foam cushion (the stainless comfy hard cushion) was effective for only 18% of the subjects, even though it was the second most frequently prescribed cushion.

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Makhsous et al., 2007 ³⁹ USA D&B=18	Inclusion: For those in the paraplegic group (T4 or lower) - able to independently do pushups for pressure relief. For the able bodied - no history of neuromuscular disorders. Overall, 45 males and 15 females participated. Exclusion: degenerative disorder of the spine; history of injury of or surgery to the pelvis, hip joint, or thigh; hip contractures; severe pain, spasms or psychological concerns preventing proper cooperation.	Case-Control : 60 subjects (40 cases - 20 paraplegic, 20 tetraplegic - and 20 controls) were exposed to two 1-hour protocols: alternate (sitting posture was dynamically alternated every 10 min between normal and partially removed ischial support (WO-BPS) postures; normal (normal posture plus pushups) performed by subjects themselves or using a hooyer lift every 20 minutes.	Interface pressure at the back rest and seat, assessed using a pressure mapping device.	3 More quadriplegic subjects received the ROHOs than paraplegic subjects (55% vs. 45%) while more paraplegic subjects were prescribed the Jay cushion - a combination of foam and flotation materials (19% vs. 7%). 1 Normal Posture: The anterior portion of the seat cushion had a larger contact area for those with tetraplegia compared to those in the other two groups. Those with a SCI had a larger contact area in the middle portion of the seat cushion. 2 At the posterior portion of the seat where ischial tuberosities are usually positioned, average pressure was highest for paraplegic group (88.9 ± 4.2 mmHg). 3 When looking at the total contact area on the seat cushion in the WO-BPS posture position, average pressure for the tetraplegia group was higher than it was for the other two groups ($p<0.001$). 4 Overall, the total contact area on the posterior portion of the cushion was less for all groups, as was peak interface pressure and average pressure, with the greatest decrease seen in the tetraplegia group ($p<0.001$). 5 Average push-up time \pm standard error (i.e., time of pressure relief) was 49.0 ± 2.8 sec for paraplegics.

D&B = Downs and Black quality assessment scale score²⁵

Thickness of Lumbar Support

Table 7

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Shields & Cook, 1992 ⁴² D&B=19	<p>Inclusion: ≥ 3 years post-SCI injury; complete motor deficit below the lesion level; Controls included 7 males and 11 females, ranging in age from 21 to 52 years. Cases ranged in age from 21 to 38 years, with 13 males and 5 females.</p> <p>Exclusion: No pressure sores; no spinal stabilization of the lumbar spine; no severe spinal scoliosis.</p>	<p>Case-Control: All 36 SCI participants were seated onto a pressure-sensing transducer incorporated into an adjustable chair. The output was calibrated so that eight pressure intervals were displayed.</p>	<p>Pressure distribution.</p>	<p>1 Significantly reduced pressures were seen with greater thickness of lumbar supports (2.5–7.5 cm) for controls, but not for those with SCI ($p<0.0001$).</p> <p>2 The highest-pressure areas were greater for SCI group ($p<0.05$) than controls for all lumbar support conditions.</p> <p>3 The mean area of lowest pressure for all support conditions was significantly less for SCI groups than controls.</p> <p>4 SCI group had significantly lower pelvifemoral angles than controls in all lumbar support conditions ($p<0.05$).</p>

D&B = Downs and Black quality assessment scale score²⁵

Table 8

Specialized Seating Clinics

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Kennedy et al., 2003 ⁴⁴ UK D&B=18	<p>Inclusion: All who participated had one or more pressure ulcers. Those who participated ranged in age from 16 to 74 years; 37 were male and 13 female. Individuals were either paraplegic or tetraplegic. Participants were divided into 3 groups: Group 1–30 who attended a seating assessment before their first NAC assessment, Group 2–11 who attended SSA between their first and second NACs, and Group 3–9 who did not receive SSA because of their methicillin resistant staphylococcus aureus status. Exclusion: Not specified.</p>	<p>Cohort: 50 individuals with a SCI participated. Postural assessment took place while the individual adopted their usual posture in the wheelchair. Physical alignment was documented and correct positioning of adjustable parts of the chair was checked. Any abnormal posture then was checked for correct alignment; set-up of the seating was adjusted, as required.</p>	<p>Skin management subscale of the <i>Needs Assessment Checklist (NAC)</i> to assess skin management rehab.</p>	<p>1 Significant differences were identified between Groups 1 & 3 for both NAC 1 (p<0.05) and NAC 2 (p<0.01).</p> <p>2 Skin management <i>'to be achieved'</i> scores were significantly lower for patients who had attended specialized seating assessment clinic (SSA) before their first NAC at both time points.</p> <p>3 Significant differences also were observed between the skin management <i>'to be achieved'</i> scores at the first & second NAC within all groups: Group 1 (p<0.0001), Group 2 (p<0.01) & Group 3 (p<0.01)</p>

D&B = Downs and Black quality assessment scale score²⁵

Table 9

Education

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Garber et al., 2002 ⁴⁵ USA Pedro=5	<p>Inclusion: Those with a SCI, regardless of age, ethnicity, level of function or independence. The average age of subjects was 53 years, and the average time since injury was 17 years. Injuries ranged from cervical to lumbar level.</p> <p>Exclusion: Cognitive impairment (not able to understand the consent form or the educational material).</p>	<p>RCT: 41 individuals participated in the study, 39 had a SCI and 2 had MS. Those in the treatment group received 4 1-hr sessions of structured education on the prevention and management of PU. After discharge, subjects were followed for 2yrs. The control group also was followed, but no information (other than standard education) was given regarding preventative practices.</p>	<p>Demographic and Health Information Questionnaire; Pressure Ulcer Knowledge Test; Multidimensional Health Locus of Control Scale; Health Beliefs Questionnaire.</p>	<p>1 An improvement in the pressure ulcer knowledge test was noted for both groups upon discharge from hospital, but it was significantly different between the groups ($p<0.03$). Those in the treatment group gained more knowledge about preventing PU.</p> <p>2 No significant inter-group differences were noted on the Multidimensional Health Locus of Control scale or the Health Beliefs Questionnaire at discharge</p> <p>3 AT 2 years post treatment, although both groups retained the knowledge the level of knowledge retained in the control group was substantially below that of the treatment group, 60.8% vs 68% on the Pressure Ulcer Knowledge Test.</p>

PEDro = Physiotherapy Evidence Database rating scale score²⁴

Table 10

Behavioral Contingencies

Author/Year/Country PEDr/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Jones et al., 2003 ¹⁵ USA D&B=1	Inclusion: Traumatic SCI; adults; history of repeated episodes of treatment for severe pressure ulcers; paraplegia. . Those included had one or more pressure ulcer. Exclusion: Not specified.	Pre-Post: two studies were conducted. In Study #1, 6 SCI patients participated; in Study #2, 3 participated. Study 1-Behavioral Intervention: 3 primary components-health plan, clinic visits and financial rewards. Study 2-Behavioral intervention: 2 treatment components were implemented (Health plan and visits) during the initial phase. Phase 2 began after the patient began to experience skin problems (included visits plus payment)	Severity of pressure sores were recorded at each phase; Ulcer severity-classified using Pressure Ulcer Scale for Healing (PUSH) tool.	Study 1: 1 Average PUSH decreased from baseline by an average of 10.5 points per participant (range 5.4–19.2). 2 6 participants were hospitalized (not during the intervention) a total of 16 times during baseline for treatment of pressure ulcers. 3 No hospitalizations were noted during the intervention phase. Compared to the baseline phase, the average monthly cost of care decreased from \$6262.00/participant to \$235.00 (US) Study 2: 1 Mean PUSH scores decreased from baseline by 8.3 pts (visits only) and a further 3.1 pts (visits plus payments phase). 2 Mean number of hospitalizations decreased from 1.67(baseline) to 0.33 (intervention and post-intervention phase).

D&B = Downs and Black quality assessment scale score²⁵

Table 11

Telerehabilitation and Pressure Ulcer Management

Author/Year/Country PEDr ^o /D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Phillips et al., 1999 ⁴⁹ USA D&B=12	Inclusion: All who participated had one or more pressure ulcers. Individuals ranged in age from 18 to 58 years. There were 9 males and 2 females. Level of injury ranged from C5 to L12. Exclusion: Not specified.	Case-Control: 37 SCI patients were asked to participate. Video-conferencing was used to assist patients in treating and monitoring pressure ulcers. Subjects were divided into 3 groups (telephone, video and standard care).	Number of pressure ulcers, emergency room (ER) visits, hospitalizations, and doctor visits annually; employment rate.	<p>1 Overall, it was found that the video group reported the largest number of ulcers, followed by the standard care group and the telephone group.</p> <p>2 The standard care group reported the lowest number of ER visits, hospitalizations, and health care provider visits.</p> <p>3 The numbers of visits were similar for the other two groups.</p> <p>4 55% of each group had no hospitalizations during the study period. It also was noted that 26% of the subjects had returned to work by 6 months after injury.</p>
Vesnarovich et al., 1999 ⁴⁶ USA D&B=10	Inclusion: Specific inclusion criteria not recorded. Participants were male, between the ages 38 and 78 and had either a cervical or thoracic spine injury. Exclusion: Not specified.	Case Series: 8 individuals participated. The outpatient nurse, using the Picasso Still Image Videophone, conducted weekly tele-rehabilitation visits. Subjects and family members received 30 min of education; equipment was sent home with subjects. Interviews were conducted to determine level of satisfaction	Development of pressure ulcers.	<p>1 Subjects were seen approx 7 times (range: 1–18 visits).</p> <p>2 7 of 12 wound sites healed completely; 2- needed surgery.</p> <p>3 Subjects and family were highly satisfied.</p>

D&B = Downs and Black quality assessment scale score²⁻⁵

Table 12

Electrical Stimulation for Pressure Ulcer Healing

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Griffin et al., 1991 ⁵¹ USA PEDro=7	Inclusion: Patients were male; had complete or incomplete SCI, with a pelvic pressure ulcer; classified between grades II and IV. Exclusion: Severe cardiac disease, cardiac arrhythmia or uncontrolled autonomic dysreflexia or used a pacemaker.	RCT: 20 SCI patients with pelvic (sacral/coccygeal or gluteal/ischial) ulcers received high voltage pulsed direct current (HVPC) or sham HVPC for one hour daily for 20 consecutive days. All patients received equivalent dressing changes. Wounds were mechanically debrided as necessary. 'Efforts' were made to relieve pressure, but this was not described.	Pressure Ulcer Status.	1 Percentage reduction in the wound surface area (WSA) exhibited by the HVPC group was greater than sham treatment group at day 5 ($p=0.03$), day 15 ($p=0.05$) and day 20 ($p=0.05$)
Adegoke & Badmos, 2001 ⁵² Nigeria PEDro=6	Inclusion: All ulcers were grade IV, and located in the pelvic region; Age from 21 to 60 years; either quadriplegic or paraplegic; ulcers located in the greater trochanter or sacral region. Exclusion: Non- smokers; otherwise not specified.	RCT: 7 SCI patients underwent stimulation with interrupted direct current (IDC) and nursing care or sham IDC and nursing care; 3–45 minute treatments once weekly for 4 weeks.	Surface area of pressure ulcers.	1 Surface area of pressure ulcers of IDC group decreased by 22.2% versus 2.6% in sham IDC group. 2 Most of the decrease in surface area occurred during the first two weeks of the study (IDC group 13.3 ± 14.1 , % change 15.8; sham IDC group 15.1 ± 3.6 , % change 1.9)
Baker et al., 1996 ²⁸ USA PEDro=4	Inclusion: One or more pressure ulcers. Age 17 to 76 years. SCI; 66 males and 14 females. Injuries either cervical, thoracic, or lumbar Exclusion: Not specified	RCT: Stimulation of A (asymmetric biphasic), vs. B (symmetric biphasic) vs. Microcurrent (MC) group (originally thought to incorporate stimulation below effective level) became the 3 rd treatment group when some early therapeutic effect was noted). All remained on their stimulation protocols until their ulcers healed, the Physician intervened or subject withdrew from study. Control Group C received sham for 4 wks, then were entered into either A or B stimulation protocol. Electrical stimulation treatment for all subjects consisted of 1.5 hrs of stimulation 5 days/wk.	Pressure ulcer status	1 No statistical differences were noted between the initial or discharge ulcer areas or in the mean healing rates among the four treatment groups— A(Asymmetric biphasic), B(Symmetric biphasic), MC(Microcurrent), C(Control) 2 Comparing the descriptive data by classifying them as good or poor healing responses failed to identify any statistically significant differences between these 2 groups. 3 When looking at the good response group, the group A protocol was more effective than either the MC or C protocols ($p<0.05$). No significant differences were found between protocol B and the other treatments. 4 Those in the control group who had wounds healed by either protocol A or B experienced a healing rate greater ($43.3\% \pm 12.5\% \Delta/\text{week}$) than during the control period ($9.7\% \pm 3.4\% \Delta/\text{week}$).

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Stefanovska et al., 1993 ³² Slovenia D&B=14	Inclusion: No specific inclusion criteria cited; however, all who participated were spinal cord injured and had one or more pressure ulcers. Exclusion: Not specified.	Prospective controlled trial: 150 SCI patients participated. Currents were applied across wounds by a pair of self-adhesive skin electrodes. Low density (DC) group (N=18) treated with low-density direct currents (600µA) for two hours daily. AC group (N = 82) treated with low frequency pulsed currents for two hours daily. CO group (N=50) received 'conventional' treatment (not described) for the first month.	Pressure Ulcer Status.	1 The healing rate for the AC group (N = 42) was significantly better than the other two groups: DC (N=12), CO (N=34) p=0.003, after excluding those with very deep, superficial, or long-term wounds.

D&B = Downs and Black quality assessment scale score²⁵

PEDro = Physiotherapy Evidence Database rating scale score²⁴

Table 13

Laser Treatment for Pressure Ulcer Healing

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Taly et al., 2004 ⁵⁴ India PEDro=10	Inclusion: Patients with SC disorders, admitted to the rehabilitation ward with pressure ulcers or who developed ulcers during their stay in the ward. Pressure ulcers at stage 2, 3, or 4 were included. Ages from 8 to 65 years; 27 males, 8 females. Exclusion: Stage 1 ulcer; non-blanching erythema of intact skin; photo-sensitivity; ulcers from other causes; necrotic tissue in ulcers that would interfere with the application of laser; flask-shaped ulcers that cannot be exposed to laser; pressure ulcers with underlying osteomyelitis; pressure ulcers requiring surgical intervention at first assessment.	RCT: 35 SCI patients with 64 ulcers. Experimental group received multi-wavelength light therapy (gallium-aluminum arsenide laser source) in addition to conventional treatment. For controls, the light therapy source was held over the ulcer after switching off the beam. 14 treatments were given, 1 every other day, 3 X weekly. Treatments ended once the ulcer had healed or after the 14 treatment exposures.	Number of ulcers that healed.	1 Overall, no significant differences were found between the control and treatment groups. In controls, 14 ulcers healed completely compared to 18 in the treatment group (p<0.80) 2 The mean time taken to heal was 2.5 ± 2.1 weeks in the treatment group and 1.8 ± 2.1 in controls (p<0.33). 3 Multi-wavelength light therapy reduced the time taken by a small subgroup (N=4) of stage three and four ulcers to reach stage two, 2.3 ± 0.5 weeks; control group (N=5) 4.3 ± 1.5 weeks. (t=2.62, p=.047)
Nussbaum et al., 1994 ⁵⁵ Canada PEDro=6	Inclusion: SCI + ≥ 1 skin ulcer. Ages: 15 – 61 years. 16 males and 2 females. Pressure ulcers were located in the cervical, thoracic or lumbar regions of the body. Exclusion: Not specified.	RCT: Originally 20 individuals began the study, but only 16 completed it.	Pressure ulcer status.	1 US/UVC and laser treatment with US/UVC showing greater effect on wound healing than laser or control. Mean percentage of change per week in ulcer size (±1 SD) from day 0 to complete healing for controls (32.4%), US/UVC (53.5%), and laser (23.7%). 2 Several subjects experienced deterioration, with ulcers increasing in size: (laser=3, 62–167% change; control =1, 58% change; US/UVC=1, 1% change). All ulcers healed by the end of the study; the last ulcer to heal in laser group healed by week 20 vs. week 6 with US/UVC.

PEDro = Physiotherapy Evidence Database rating scale score²⁴

Table 14

Ultrasound/Ultraviolet C for Pressure Ulcer Healing

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Nussbaum et al., 1994 ⁵⁵ Canada PEDro=6	<p>Inclusion: SCI + ≥ 1 skin ulcer. Ages: 15 – 61 years. 16 males and 2 females. Pressure ulcers were located in the cervical, thoracic or lumbar regions of the body. Exclusion: Not specified.</p>	<p>RCT: Originally 20 SCI individuals began the study, but only 16 completed it.</p>	<p>Pressure ulcer status.</p>	<p>1 US/UVC and laser treatment with US/UVC exerted greater effect on wound healing than laser or control. Mean percentage of change per week in ulcer size (± 1 SD) from day 0 to complete healing for controls (32.4%), US/UVC (53.5%), and laser (23.7%).</p> <p>2 Several subjects experienced deterioration, with ulcers increasing in size: (laser=3, 62–167% change; control=1, 58% change; US/UVC=1, 1% change). All ulcers healed by the end of the study; the last ulcer to heal in laser group healed by week 20 vs. week 6 with US/UVC.</p>

PEDro = Physiotherapy Evidence Database rating scale score²⁴

Table 15

Non-Thermal Pulsed Electromagnetic Energy

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Salzberg 1995 ⁵⁶ USA PEDro=8	Inclusion: All who participated had one or more pressure ulcers. Ages 24–69 years. Exclusion: More than one ulcer; recent ulcer surgery; fitted with a cardiac pacemaker; co- morbid disease; active cellulitis; sepsis; terminally ill or end stage disease; total joint replacement; Stage I or IV ulcers.	RCT: 30 SCI patients were selected to participate, and subclassified into Stage II vs. Stage III ulcers. Active treatment consisted of non-thermal pulsed high frequency, high peak power, electromagnetic energy (PEE) delivered through a treatment head placed in light contact with the wound site and tuned to resonance in the area of the wound. Treatment was non-invasive and delivered through wound dressings for 30 minutes, twice daily for 12 weeks or until healed. The control group received 12 weeks of sham treatment.	Pressure Ulcer Status.	1 Stage II group: active treatment (N=10), sham (N=10). After 1 week, active treatment healed a greater percentage of ulcers (84%) than sham (40%, p=.01) and the median size of ulcer also was smaller at one week (2.7 vs. 16.5 cm ² , p=.015). 2 Complete healing with active treatment occurred in a median of 13 days vs. 31.5 days with sham (p<.001). 3 Given that there were more large ulcers (>60cm ²) in the sham group, data were reanalyzed for 15 subjects with ulcers < 60cm ² , with similar results. 4 Stage III group: With active treatment 3/5 healed over an average of 43 days. 0/5 healed with sham. Ulcer area decreased by an average of 70.6% vs. 20.7%, respectively

PEDro = Physiotherapy Evidence Database rating scale score²⁴

Table 16

Anabolic Steroid Agents

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Spungen et al., 2001 ⁵⁸ USA D&B=15	Inclusion: One of the following: a self-reported or documented healing pressure ulcer (PU) that had existed for more than 2 mo; or a full-thickness PU that extended through fascia into muscle, tendon or bone. Exclusion: Not specified	Case Series: 9 SCI patients with stage III/IV PU were treated with 20mg oxandrolone daily and 20g of glutamine dissolved in orange juice. PU care and support services remained unchanged.	Not specified.	1. With oxandrolone and glutamine treatment, 8/9 subjects completely healed, the majority within 3–6 months. 2 subjects required 12 months of treatment for complete healing.

D&B = Downs and Black quality assessment scale score²⁵

Table 17

The Effectiveness of Dressings Post-SCI

Author/Year/Country PEDro/D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Hollisaz et al., 2004 ⁵⁹ Iran PEDro=7	Inclusion: Paraplegia caused by a SCI; all past soldiers in the Iran/Iraq war; Stage I or II pressure ulcers, smooth ulcer area so an adhesive dressing could be used. Exclusion: Addiction; heavy smoking (>20 cigarettes/day or >10 packs per year); concomitant chronic disease.	RCT: 83 individuals (with 91 PU) with a SCI were randomly assigned to one of three groups: (1) SD: simple dressing; (2) HD: hydrocolloid dressing (3) PC: adhesive + phenyntoin cream. Dressings were changed twice daily for SD; daily for PC; and twice weekly for HD.	Healing status of the ulcer.	<p>1 Overall, those with HD seemed to have the greatest level of healing (74% vs. 40% with PC and 27% with SD; $p<0.01$ and <0.005, respectively).</p> <p>2 Complete healing of stage I ulcers also was significantly greater in the HD group than in the other two ($p<0.05$).</p> <p>3 For stage II ulcers, those in the HD-treated ulcers healed better than SD-treated ulcers, but no better than PC-treated ulcers.</p> <p>4 Gluteal ulcers also healed more completely with HD than with either of the other two dressing.</p> <p>5 Complete healing of sacral ulcers did not differ between the 3 groups.</p>
Kaya et al., 2005 ^{60,61} Turkey PEDro=4	Inclusion: SCI; otherwise, no specific inclusion criteria cited. 24 males and 3 females; ages: 16–56. Pressure ulcers stages I to III. No further details provided. Exclusion: Not specified.	RCT: In total, 27 subjects with 40 PU were randomly allocated to either: Active treatment group (n=15 with 25 ulcers) - received an occlusive hydrogel type dressing, changed every 4 days unless the area became contaminated. Control group (n=12 with 24 ulcers) - received povidone-iodine soaked gauze applied to the area, with dressing changed daily to avoid contamination	Rate of healing (cm ² / day).	<p>1 There was no difference in the healing rates between the two groups.</p> <p>2 Those in the treatment group had more wounds (n=21) heal than those in the control group (n=13), $p<0.04$.</p>

PEDro = Physiotherapy Evidence Database rating scale score²⁴

Table 18

The Effectiveness Maggot Therapy

Author/Year/Country D&B Score	Eligibility Criteria	Study Design and Methods	Outcome Measures	Results
Sherman et al., 1995 ⁶³ USA D&B=9	Inclusion: SCI; quadriplegia or paraplegia; pressure ulcer stage III or IV. Ages ranged from 44 to 68 years. Both males and females, and 7 were paraplegics Exclusion: Not specified	Non-RCT: Overall, 20 SCI patients were recruited; but only 8 individuals were allocated to treatment group. Treatment group underwent conventional therapy for 3–4 weeks followed by the placing of maggots (covered with porous sterile dressings) which were left in place for 48–72 hr cycles. Between cycles of maggot therapy, the group received either sodium hypochlorite, normal saline or wet-to-dry gauze dressings every 8 hrs. Controls received traditional treatment.	Healing of the pressure ulcer, size of wound area.	1 Noted change in surface area during maggot therapy (ulcer surface area decreased by approximately 22% per week p<0.001 during therapy). 2 No complications or infection were noted as a result of treatment

D&B = Downs and Black quality assessment scale score²⁴