



## **Group A- Subacute**

### **A. Lowback Strain**

1.     **Diagnosis – lowback strain**  
Age of patient- 88  
Sex- M  
Number of interventions- 4  
Other active interventions- manual stretching, mechanical traction, spinal stabilization  
Outcome – complete resolution of lowback pain
  
2.     **Diagnosis – lowback strain**  
Age of patient- 75  
Sex- M  
Other active interventions- manual stretching  
Number of interventions- 5  
Outcome – 80 % resolution of pain and increased ROM
  
3.     **Diagnosis –Lowback pain secondary to chronic Degenerative Lumbar Disc Disease**  
Age of patient- 62  
Sex- M  
Number of interventions- 3  
Other active interventions- manual stretching, mechanical traction  
Outcome – 70% resolution of pain and significant increase in ROM of lumbar spine
  
4.     **Diagnosis – Sub acute Lumbar Disc herniation**  
Age of patient- 41  
Sex- M  
Number of interventions- 5  
Other active interventions- mechanical traction  
Outcome – 100% short term 1-2 days resolution of pain, with overall 50% reduction of pain and increased tolerance to lumbar forward bending
  
5.     **Diagnosis – Sub acute lumbar disc herniation**  
Age of patient- 45  
Sex- M  
Number of interventions- 3  
Other active interventions- mechanical traction, manual stretching, spinal stabilization, active exercise  
Outcome – 90% resolution of pain in lowback, 100% resolution of pain in leg, return to work 1 week earlier than projected.
  
6.     **Diagnosis – Lowback strain secondary to lifting incident. Ligamentous strain- onset 5 months**  
Age of patient- 56  
Sex- Male  
Number of interventions- 6  
Other active interventions- physical therapy modalities, mobilization

Outcome – restoration of range of motion, relief of pain, increased strength, return to full activities of daily living

7.     **Diagnosis – Sub acute Lumbar Disc herniation**  
Age of patient- 41  
Sex- M  
Number of interventions- 5  
Other active interventions- mechanical traction  
Outcome – 100% short term 1-2 days resolution of pain, with overall 50% reduction of pain and increased tolerance to lumbar forward bending

## **B. Cervical /Thoracic strain-**

1.     **Diagnosis- Cervical/thoracic strain**  
Age of patient- 65  
Sex- Male  
Number of interventions- 5  
Other interventions- modalities  
Outcome- 80 % relief of pain, increased range of motion, postural realignment
2.     **Diagnosis – cervical/thoracic strain**  
Age of patient- 44  
Sex- Female  
Number of interventions- 4  
Other active interventions- modalities, joint mobilization, exercise  
Outcome – Complete resolution of pain and restoration of range of motion, return to work regular duty
3.     **Diagnosis – cervical/thoracic strain, cervical pain**  
Age of patient- 38  
Sex- Male  
Number of interventions- 4  
Other active interventions- cervical traction, physical therapy modalities, massages  
Outcome – resolution of cervical pain, increased thoracic range of motion
4.     **Diagnosis – cervical/thoracic, thoracic pain**  
Age of patient- 54  
Sex- Male  
Number of interventions- 3  
Other active interventions- physical therapy modalities, joint mobilization  
Outcome – resolution of thoracic pain and increased range of motion
5.     **Diagnosis – cervical/thoracic pain secondary to motor vehicle accident**  
Age of patient- 63  
Sex- male  
Number of interventions- 7  
Other active interventions- physical therapy modalities, cervical traction, exercise  
Outcome – resolution of thoracic pain, 80% resolution of cervical pain
6.     **Diagnosis – cervical/thoracic strain, thoracic pain and loss of range of motion**

- Age of patient- 41  
 Sex- Male  
 Number of interventions- 3  
 Other active interventions- physical therapy modalities, thoracic mobilization  
 Outcome – complete resolution of pain and restoration of range of motion,
7. Diagnosis – cervical/thoracic strain, thoracic pain  
 Age of patient- 55  
 Sex- female  
 Number of interventions- 5  
 Other active interventions- none  
 Outcome – resolution of pain, restoration of range of motion
9. Diagnosis – cervical/thoracic strain, thoracic/lumbar pain  
 Age of patient- 53  
 Sex- male  
 Number of interventions- 4  
 Other active interventions- physical therapy modalities, mobilization  
 Outcome – increased thoracic range of motion, pain and tenderness 30% reduction

### **C. Post-Surgical lumbar**

1. Diagnosis – Post Surgical lumbar laminectomy – (patient underwent second surgery due to complication and suffered a post-surgical infection - 6 months)  
 Age of patient- 44  
 Sex-F  
 Number of interventions- 3  
 Other active interventions- physical therapy modalities, active exercise, spinal stabilization  
 Outcome – 80% decrease in lumbar muscle pain to palpation and during active exercise, full restoration of lumbar forward bending following exercise on PR3000 without pain, 50% reduction in pain two days after intervention on PR3000, patient able to increase tolerance to work demands by 75%.
2. Diagnosis – Post Surgical Lumbar Laminectomy – 10 weeks  
 Age of patient- 53  
 Sex- M  
 Number of interventions- 5  
 Other active interventions- spinal stabilization, active exercise, manual stretching  
 Outcome – resolution of pain during forward bending, increased forward bending of the lumbar spine, decreased thoracic kyphosis, return to work with no pain and minimal restriction

### **D. Cervical pain secondary to postural dysfunction**

1. Diagnosis – Cervical pain secondary to mid thoracic dysfunction  
 Age of patient- 72  
 Sex- F  
 Number of interventions- 2

Other active interventions- no physical therapy treatment, home exercise  
Outcome – resolution of cervical pain

2. Diagnosis – Cervical pain secondary to postural dysfunction, increased thoracic kyphosis  
Age of patient- 83  
Sex- female  
Number of interventions- 6  
Other active interventions- exercise, postural instruction  
Outcome – resolution of cervical pain and reduction of thoracic kyphosis

#### **E. Total hip replacement-**

1. Diagnosis – Total hip replacement, 10 weeks post-op  
Age of patient- 68  
Sex- M  
Number of interventions- 3  
Other active interventions- active exercise, manual stretching,  
Outcome – increased hip extension, adduction, internal and external rotation
2. Diagnosis – Total hip replacement, 12 weeks post-op  
Age of patient- 66  
Sex- male  
Number of interventions- 5  
Other active interventions- active exercise, range of motion, soft tissue mobilization  
Outcome – increased range of motion, internal and external rotation, adduction, extension

#### **F. Total knee replacement-**

1. Diagnosis – L Total knee replacement- loss of knee extension, posterior capsule restriction, hamstring length restrictions  
Age of patient- 74  
Sex- M  
Number of interventions- 3  
Other active interventions - manual stretching, active exercise,  
Outcome – restoration of knee extension, improved hamstring range of motion
2. Diagnosis – R Total knee replacement- loss of knee extension, posterior capsule restriction, hamstring length restrictions  
Age of patient- 72  
Sex- Male  
Number of interventions- 6  
Other active interventions- Total Knee replacement rehabilitation protocol  
Outcome – Restoration of full knee extension
3. Diagnosis – R Total knee replacement- loss of knee extension, posterior capsule restriction, hamstring length restrictions

Age of patient- 78  
Sex- Male  
Number of interventions- 3  
Other active interventions- Total Knee replacement rehabilitation protocol  
Outcome – Restoration of full knee extension

## **Group II – Chronic**

### **H. Mechanical Lowback Pain**

1. Diagnosis – Mechanical lowback pain, lumbar extension limitation  
Age of patient- 45  
Sex- M  
Number of interventions- 3  
Other active interventions- active exercise, spinal stabilization, manual stretching  
Outcome – increased hip extension, increased lumbar range of motion in lumbar extension, increased tolerance to all activities of daily living
2. Diagnosis – Degenerative lumbar disc disease, Postural Dysfunction with advanced osteoporosis,  
Age of patient- 84  
Sex- M  
Number of interventions- 3  
Other active interventions- manual stretching, mechanical lumbar traction, active exercise  
Outcome – 60% decrease in lumbar disc pain, improved postural alignment, increased hip extension, decreased thoracic kyphosis, followed by resistive exercise to postural muscles
3. Diagnosis – chronic Degenerative lumbar disc disease,  
Age of patient- 43  
Sex- F  
Number of interventions - 2  
Other active interventions- active exercise, manual stretching, spinal stabilization  
Outcome – acute increase in pain initially, followed by decreased thoracic kyphosis, pain reduction of 50%, increased tolerance to exercise
4. Diagnosis – Mechanical lowback pain due to auto accident, limitation of lumbar flexion  
Age of patient- 60  
Sex- F  
Number of interventions- 5  
Other active interventions - active exercise, spinal stabilization, mechanical traction  
Outcome – Complete resolution of lowback pain with improved tolerance to activities, restoration of range of motion,
5. Diagnosis – Mechanical lowback pain secondary to facet arthropathy, increased lumbar lordosis, tight hamstrings  
Age of patient- 67  
Sex- M  
Number of interventions- 4  
Other active interventions- active exercise, manual stretching, mechanical traction

Outcome – treatment in progress increased lumbar forward bending with decreased lumbar lordosis and pressure on the facet joints. 50% resolution of pain over a 2-day period, with overall increase in activities of daily living.

6.     Diagnosis – Mechanical lowback pain secondary to lumbar disc disease at L5 S1  
Age of patient- 45  
Sex- M  
Number of interventions- 2  
Other active interventions - mechanical traction, active exercise, spinal stabilization  
Outcome – treatment in progress, notes better relief of pain than passive mechanical traction to the lumbar spine. Relief for 2 days with return of symptoms.
7.     Diagnosis- Mechanical lowback pain secondary to lumbar strain, possible herniated disc disease  
Age of patient- 38  
Sex- Male  
Number of Interventions- 4  
Other active interventions- Home exercise  
Outcome- Complete relief of pain and increased lumbar flexion, increased hamstring flexibility
8.     Diagnosis- Lowback pain secondary to fall from height, compressive force  
Age of patient- 35  
Sex- Male  
Number of Interventions- 6  
Other active interventions- physical therapy for 5 months, 9 months ago  
Outcome- Complete resolution of local lowback pain, 70% reduction in leg pain and paresthesias, 80 % increase in range of motion of lumbar spine in all planes
9.     Diagnosis- Mechanical lowback pain, lumbar spondylosis  
Age of patient- 66  
Sex- Male  
Number of Interventions- 2  
Other active interventions- none  
Outcome- Increased range of motion, in all planes
10.    Diagnosis- Mechanical lowback pain secondary to lumbar spondylosis  
Age of patient- 71  
Sex- Male  
Number of Interventions- 5  
Other active interventions- Active resistive exercise program- independent  
Outcome- Relief of pain for two weeks, gradual increase to 30% of previous level

#### **I. Lowback pain secondary to loss of range of motion**

1.     Diagnosis- Lowback pain secondary to post-operative scar formation and decreased range of motion of the lumbar spine  
Age of patient- 51  
Sex- Female  
Number of Interventions- 3  
Other active interventions- physical therapy treatment and spinal exercise 1 year ago  
Outcome- 90% relief of pain, increased range of motion in all planes

2.     **Diagnosis-** Lowback pain secondary to increased lumbar lordosis  
        **Age of patient-** 48  
        **Sex-** Male  
        **Number of Interventions-** 4  
        **Other active interventions-**None  
        **Outcome-** Increased range of motion in forward bending, 50% decrease in pain
  
3.     **Diagnosis-** Lowback pain secondary to increased lumbar lordosis  
        **Age of patient-** 63  
        **Sex-** Male  
        **Number of Interventions-** 3  
        **Other active interventions-** physical therapy modalities, lumbar traction  
        **Outcome-** 70% decrease in pain, Increased range of motion of lumbar spine
  
4.     **Diagnosis-** Lowback pain secondary to lumbosacral strain- loss of forward bending  
        **Age of patient-** 54  
        **Sex-** Male  
        **Number of Interventions-** 2  
        **Other active interventions-** physical therapy modalities, lumbar spine exercise  
        **Outcome-** complete resolution of pain, full range of motion of lumbar spine
  
5.     **Diagnosis-** Lowback pain due to loss of range of motion of lumbar spine  
        **Age of patient-** 59  
        **Sex-** male  
        **Number of Interventions-** 3  
        **Other active interventions-** physical therapy modalities, lumbar spine traction  
        **Outcome-** restoration of range of motion, 80% decrease in pain

**J. Increased Thoracic Kyphosis with Postural Dysfunction**

1.     **Diagnosis –** Postural dysfunction with advanced osteoporosis  
        **Age of patient-**82  
        **Sex-** F  
        **Number of interventions-** 5  
        **Other active interventions-** active exercise, manual stretching  
        **Outcome –** improved postural alignment, decreased thoracic kyphosis, increased hip extension, followed by resistive exercise to postural muscles
  
2.     **Diagnosis –** Postural Dysfunction with advanced osteoporotic thoracic kyphosis  
        **Age of patient-** 84  
        **Sex-** F  
        **Number of interventions-** 4  
        **Other active interventions-** active exercise, manual stretching, resistive exercise  
        **Outcome –** improved postural alignment, increased hip extension, followed by resistive exercise to postural muscles
  
3.     **Diagnosis –** Thoracic Kyphosis with Postural Dysfunction  
        **Age of patient-** 68

Sex- F  
Number of interventions- 3  
Other active interventions- none  
Outcome – improved postural alignment, decreased thoracic kyphosis, increased hip extension, followed by resistive exercise to postural muscles

4. Diagnosis – Postural Dysfunction, cervical pain  
Age of patient- 62  
Sex- M  
Number of interventions- 5  
Other active interventions- manual stretching, active exercise  
Outcome – complete resolution of pain, increased cervical range of motion, followed by resistive exercise to postural muscles, manual stretching to cervical thoracic junction
5. Diagnosis – Cervical pain related to postural dysfunction  
Age of patient- 48  
Sex- F  
Number of interventions- 4  
Other active interventions - mechanical traction, cervical thoracic mobilization, active exercise, cervical/thoracic manual therapy,  
Outcome – improved postural alignment, increased cervical range of motion, decreased thoracic kyphosis, resolution of pain, return to normal function
6. Diagnosis – Thoracic kyphosis, Postural Dysfunction, Degenerative lumbar disc disease  
Age of patient- 72  
Sex- F  
Number of interventions- 3  
Other active interventions- mechanical traction, active exercise, manual stretching, spinal stabilization  
Outcome – decreased thoracic kyphosis, decreased lumbar spine pain, treatment in progress.
7. Diagnosis – Increased thoracic Kyphosis with Mid thoracic arthritis  
Age of patient- 72  
Sex- F  
Number of interventions- 1  
Other active interventions - active exercise, manual stretching  
Outcome – increased pain and soreness, treatment discontinued
8. Diagnosis – Thoracic strain secondary to Increased thoracic kyphosis  
Age of patient- 76  
Sex- M  
Number of interventions- 2

Other active interventions - mechanical traction, active exercise, manual stretching

Outcome – significant increase in forward bending of the lumbar spine, patient had increased pain in side bending of lumbar spine, forward bending motion only.

9.     Diagnosis- Thoracic pain secondary to Increased thoracic kyphosis with lumbar spine spondylosis  
Age of patient- 71  
Sex- female  
Number of Interventions- 2  
Other active interventions- spinal exercise, lumbar spine traction  
Outcome- Increased lumbar spine pain
10.    Diagnosis- Thoracic pain secondary to Increased thoracic Kyphosis and postural dysfunction, osteoporosis  
Age of patient- 78  
Sex- female  
Number of Interventions- 5  
Other active interventions- independent exercise program  
Outcome- improved postural alignment
11.    Diagnosis- thoracic kyphosis, postural dysfunction, osteoporosis  
Age of patient- 80  
Sex- female  
Number of Interventions- 6  
Other active interventions- independent exercise program  
Outcome- improved postural alignment and decreased cervical/thoracic strain

#### **I . Postural dysfunction with Hip extension restriction**

1.     Diagnosis- Postural dysfunction with Hip extension restriction  
Age of patient- 72  
Sex- Male  
Number of Interventions- 2  
Other active interventions- Lowback pain treatment, physical therapy modalities, lumbar spine traction  
Outcome- Increased range of motion of hips in extension, abduction, internal rotation
2.     Diagnosis- Postural dysfunction with Hip extension restriction and lumbar spine spondylosis  
Age of patient- 77  
Sex- Male  
Number of Interventions- 4  
Other active interventions- physical therapy modalities, lumbar spine traction  
Outcome- Increased hip range of motion of hips in extension, abduction, internal rotation

3. **Diagnosis- Postural dysfunction with Hip extension restriction, Increased thoracic kyphosis**  
**Age of patient- 69**  
**Sex- female**  
**Number of Interventions- 2**  
**Other active interventions- independent exercise program**  
**Outcome- Increased range of motion of hips in extension, abduction, internal rotation**
  
4. **Diagnosis- Postural dysfunction with Hip extension restriction, thoracic kyphosis**  
**Age of patient- 67**  
**Sex- female**  
**Number of Interventions- 3**  
**Other active interventions- independent exercise program**  
**Outcome- Increased range of motion of hips in extension, abduction, internal rotation**
  
5. **Diagnosis – Hip arthrosis, loss of hip extension, internal and external range of motion, thoracic Kyphosis, osteoporosis**  
**Age of patient- 75**  
**Sex- female**  
**Number of interventions- 4**  
**Other active interventions- manual stretching, active exercise,**  
**Outcome – Increased range of motion of hips in extension, abduction, internal rotation**
  
6. **Diagnosis – Postural Dysfunction with Hip arthrosis, loss of hip extension, abduction, internal rotation**  
**Age of patient- 77**  
**Sex- M**  
**Number of interventions- 5**  
**Other active interventions- active exercise, manual stretching**  
**Outcome – increased hip extension, increase in hip strength, 50 % reduction in pain**
  
7. **Diagnosis – Hip arthrosis, loss of range of motion of the hip, lumbar spine pain**  
**Age of patient- 59**  
**Sex- Male**  
**Number of interventions- 3**  
**Other active interventions- active exercise, manual stretching**  
**Outcome – restoration of range of motion, pain decreased by 20 %, patient had advanced arthritis.**
  
8. **Diagnosis- Postural Dysfunction with Hip arthrosis, loss of hip extension, abduction, internal rotation**  
**Age of patient- 87**  
**Sex- Female**  
**Number of interventions- 3**

Other active interventions- physical therapy modalities, lumbar spine traction  
Outcome- Increased range of motion of hips in extension, abduction, internal rotation

9. Diagnosis- Postural Dysfunction with Hip arthrosis, loss of hip extension, abduction, internal rotation

Age of patient- 77

Sex- Female

Number of interventions- 2

Other active interventions- lumbar spine physical therapy

Outcome- Increased pain and tenderness in right hip

**Specific Indications for Marketing the PR 3000 Device  
And  
Discussion of How the Data Collected Demonstrates  
The Effectiveness of the Claimed Indications**

**Specific Indications for Marketing the PR 3000**

I. Lowback Pain

- A. Mechanical lowback pain – secondary to injury
- B. Mechanical lowback pain – chronic pain with loss of range of motion
- C. Sacroiliac pain- secondary to strain/sprain
- D. Post surgical – four to six weeks post-operative
- E. Lowback strain – three to four weeks post-injury
- F. Chronic Lowback pain –
  - i. Secondary to spondylosis
  - ii. Secondary to post-surgical restrictions
- G. F. Herniated disc without referred pain into lower extremity
- H. G. Herniated disc with referred pain below hip/gluteal region

II. Postural Dysfunction

- A. Thoracic Kyphosis with extension restriction
- B. Lumbar spine lordosis – forward flexion restriction
- C. Hip extension restriction secondary to tight hip flexor muscles
- D. Cervical Pain related to Postural Dysfunction

III. Orthopedic

- A. Total hip replacement-
- B. Total knee replacement-

## **Discussion of How the Data Collected Demonstrates The Effectiveness of the Claimed Indications**

### **I. Lowback Pain**

#### **A. Mechanical lowback pain – secondary to injury**

Treatment Procedure –

1. Patient placed in a standing position that allows forward bending of the lumbar spine, with stabilization straps across the upper thighs and approximate level of the anterior superior iliac spine.
2. Patient was asked to perform an active forward bending movement, at which time pain during the motion was assessed.
3. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.
4. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
5. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
6. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the forward bending movement.
7. An exercise-restraining strap attached to a rubber resistance band was placed around the patient's chest and the patient instructed to move into the resistance to facilitate the trunk muscles and resistively exercise the trunk within a pain free and limited range of motion.
8. The patient was then repositioned in the opposite direction with the stabilization straps placed around the hips at the level of the greater trochanters and the lower lumbar spine, level determined by symptoms, flexibility and pain. Same precautions of questioning the patient regarding pain during setup and movement, was completed prior to proceeding to the next step.
9. A third, exercise restraining strap placed around the mid to upper thoracic region, tightened to limited the range of motion of the lumbar spine in a backward bending position.
10. The patient was asked to move into the resisted, limited range of motion to facilitate the lumbar extensor muscles, in a pain free range of motion.
11. The patient was asked to do ten repetitions of the movement into backward bending of the lumbar spine and rotation of the lumbar spine.
12. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition, other contributing factors such as hypertension, cardiopulmonary history and medications, were taken into consideration.

### **Discussion-**

Mechanical lowback pain is often associated with loss of range of motion secondary to healing of strained myofascial tissues. The healing and immobilization of the lowback during the initial stages of healing result in a fibrosis of supporting ligaments, joint capsule and fascial connective tissue, which in turn causes a shortening of the muscles, during end range of motion movements such as forward bending. It is well documented in the literature, Janda, V., et al, that shortened myofascial tissues frequently become painful during movement and often times as rest.

The PR 3000 has shown to be an effective method of safely stretching these fibrotic, restricted tissues. The stabilization of the hips and pelvis allows the patient to selectively stretch these tissues while in a stabilized position. The reaction to the movement due to the stabilization of the straps around pelvic and hips causes the lumbar spine extensor muscles to move independently of the stabilizing muscles of the hips.

The ability to isolate the lumbar tissue without the influence of the stabilizing muscles of the hips, such as the gluteus maximus and medius, which are neurologically facilitated when the lumbar multifidus muscles are active (Hodges 2000). This allows the tissues to be selectively stretched and/or exercised without the extraneous forces transmitted through the pelvis into the lumbar spine.

## **B. Mechanical lowback pain – chronic pain with loss of range of motion**

### **Treatment Procedure –**

1. Primary goals- increase pain free range of motion in all planes, restore patient confidence in movement activities, and increase strength of trunk and spine muscles.
2. Patient placed in a standing position that allows forward bending of the lumbar spine, with stabilization straps across the upper thighs and approximate level of the anterior superior iliac spine.
3. Patient was asked to perform an active forward bending movement, at which time pain during the motion was assessed.
4. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.
5. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
6. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
7. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the forward bending movement.
8. An exercise-restraining strap attached to a rubber resistance band was placed around the patient's chest and the patient instructed to move into the resistance to facilitate the trunk muscles and resistively exercise the trunk within a pain free and limited range of motion.
9. The patient was then repositioned in the opposite direction with the stabilization straps placed around the hips at the level of the greater trochanters and the lower lumbar spine, level determined by symptoms, flexibility and pain. Same precautions of questioning the patient regarding pain during setup and movement, was completed prior to proceeding to the next step.
10. A third, exercise restraining strap placed around the mid to upper thoracic region, tightened to limited the range of motion of the lumbar spine in a backward bending position.
11. The patient was asked to move into the resisted, limited range of motion to facilitate the lumbar extensor muscles, in a pain free range of motion.
12. The patient was asked to do ten repetitions of the movement into backward bending of the lumbar spine and rotation of the lumbar spine.
13. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition, other contributing factors such as hypertension, cardiopulmonary history and medications, were taken into consideration.
14. Patient released from the device, active movements assessed.

## **Discussion –**

As outlined above, the fibrosis that occurs following the acute injury to the myofascia of the lumbar spine will continue to be a cause of pain in the chronic lowback pain patient. When muscle become shortened or restricted due to injury, strength of the muscles is decreased causing an imbalance of the interaction of the anterior trunk muscles and the supporting muscles of the hips. This imbalance has shown to be a cause of pain and restricted movement, (Punjabi, 1992; Sahrman 2002); additionally it has been shown that the chronic painful motion causes atrophy of the multifidii muscles, (Hodges, etal. 2000). The ability to selectively stretch the muscles with a stabilized spine and pelvis into a pain free motion has shown to be extremely effective in this type of patient.

### **C. Sacroiliac pain- secondary to strain/sprain**

#### **Treatment Procedure –**

1. Primary goals, increase in forward bending, reduce soft tissue restrictions, reduce pelvic asymmetries and reduce pain during all movements.
2. Patient placed in a standing position that allows forward bending of the lumbar spine, with stabilization straps across the upper thighs and approximate level of the anterior superior iliac spine.
3. Patient was asked to perform an active forward bending movement, at which time pain during the motion was assessed.
4. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.
5. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
6. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
7. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the forward bending movement.
8. An exercise-restraining strap attached to a rubber resistance band was placed around the patient's chest and the patient instructed to move into the resistance to facilitate the trunk muscles and resistively exercise the trunk within a pain free and limited range of motion.
9. The patient was then repositioned in the opposite direction with the stabilization straps placed around the hips at the level of the greater trochanters and the lower lumbar spine, level determined by symptoms, flexibility and pain. Same precautions of questioning the patient regarding pain during setup and movement, was completed prior to proceeding to the next step.
10. A third, exercise restraining strap placed around the mid to upper thoracic region, tightened to limited the range of motion of the lumbar spine in a backward bending position.
11. The patient was asked to move into the resisted, limited range of motion to facilitate the lumbar extensor muscles, in a pain free range of motion.
12. The patient was asked to do ten repetitions of the movement into backward bending of the lumbar spine and rotation of the lumbar spine.
13. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition,

- other contributing factors such as hypertension, cardiopulmonary history and medications, where taken into consideration.
14. Active movements into the hip restraining strap where performed five times with each hip into an extension movement. Pain assessment performed.
  15. Patient released from device and sacroiliac joint movement and position assessed.

### **Discussion-**

The sacroiliac joint has long known to be a source of pain secondary to myofascial strain and associated injuries of the lumbar spine (Jackson, 1996). The pelvic girdle asymmetries are often overlooked by the medical examination and unless specifically trained to exam and treatment this complex region, the clinician and/or physician will presume the origin of pain is the lumbar spine, or pain from the inguinal area, resulting in delay in proper care and unnecessary, expensive diagnostic treatment.

The PR3000 has shown to be very effective in reducing sacroiliac pain when the cause is myofascial strain. The resulting fibrosis of the myofascia will cause shortening of the ligaments and connective tissue with muscle imbalances of the hip and multifidii muscles. This leads to extraneous forces acting on the sacroiliac joints, resulting in positional joint asymmetries, dysfunction and pain.

The PR 3000 is able to very selectively stabilize and reduce the positional sacroiliac dysfunction and stretch the restricted tissues that are responsible for the muscle imbalances. Often, no other treatment is needed to reduce the sacroiliac joint positional faults and dysfunctions.

### **D. Post surgical – four to six weeks post-operative**

### **E. Lowback strain – three to four weeks post-injury**

### **Treatment Procedure –**

1. The primary goal of treatment is to initiate pain free movement, remodel this scar, facilitate the trunk and multifidii muscles, and build patient confidence in movement activities.
2. Patient placed in a standing position that allows forward bending of the lumbar spine, with stabilization straps across the upper thighs and approximate level of the anterior superior iliac spine.
3. Patient was asked to perform an active forward bending movement, at which time pain during the motion was assessed.
4. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.
5. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
6. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
7. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the forward bending movement.
8. An exercise-restraining strap attached to a rubber resistance band was placed around the patient's chest and the patient instructed to move into the resistance to facilitate the trunk muscles and resistively exercise the trunk within a pain free and limited range of motion.
9. The patient was then repositioned in the opposite direction with the stabilization straps placed around the hips at the level of the greater trochanters and the lower lumbar spine, level determined by symptoms, flexibility and pain. Same precautions of questioning

the patient regarding pain during setup and movement, was completed prior to proceeding to the next step.

10. A third, exercise restraining strap placed around the mid to upper thoracic region, tightened to limited the range of motion of the lumbar spine in a backward bending position.
11. The patient was asked to move into the resisted, limited range of motion to facilitate the lumbar extensor muscles, in a pain free range of motion.
12. The patient was asked to do ten repetitions of the movement into backward bending of the lumbar spine and rotation of the lumbar spine.
13. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition, other contributing factors such as hypertension, cardiopulmonary history and medications, were taken into consideration.
14. Date of surgery and/or date of injury, residual pain, nature of surgery, soft tissue soreness, taken into serious consideration as to number of repetitions and sets.

### **Discussion-**

Post Surgical and lowback strain, early injury- will be discussed together as they present similar conditions of healing and treatment. As outlined previously, the fibrosis, which accompanies healing of injured tissues is similar with these two diagnoses. Proper remodeling of the scar of the post surgical patient and the injured myofascia of the strain patient is essential to reducing the post healing pain and restoration of range of motion of the lumbar spine.

Again, the ability to selectively isolated and stabilize the lumbar spine during active exercise and motion. The ability to stretch and exercise under strict, controlled conditions promotes confidence in the patient's ability to move safely, thus reducing rehabilitation time.

### **F. Chronic Lowback pain –**

- 1. Secondary to spondylosis**
- 2. Secondary to post-surgical restrictions**

### **Treatment Procedure –**

1. Primary goals- increase pain free range of motion in all planes, restore patient confidence in movement activities, and increase strength of trunk and spine muscles.
2. Patient placed in a standing position that allows forward bending of the lumbar spine, with stabilization straps across the upper thighs and approximate level of the anterior superior iliac spine.
3. Patient was asked to perform an active forward bending movement, at which time pain during the motion was assessed.
4. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.
5. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
6. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
7. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the forward bending movement.
8. An exercise-restraining strap attached to a rubber resistance band was placed around the patient's chest and the patient instructed to move into the resistance to facilitate

the trunk muscles and resistively exercise the trunk within a pain free and limited range of motion.

9. The patient was then repositioned in the opposite direction with the stabilization straps placed around the hips at the level of the greater trochanters and the lower lumbar spine, level determined by symptoms, flexibility and pain. Same precautions of questioning the patient regarding pain during setup and movement, was completed prior to proceeding to the next step.
10. A third, exercise restraining strap placed around the mid to upper thoracic region, tightened to limited the range of motion of the lumbar spine in a backward bending position.
11. The patient was asked to move into the resisted, limited range of motion to facilitate the lumbar extensor muscles, in a pain free range of motion.
12. The patient was asked to do ten repetitions of the movement into backward bending of the lumbar spine and rotation of the lumbar spine.
13. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition, other contributing factors such as hypertension, cardiopulmonary history and medications, were taken into consideration.
14. Patient released from the device, active movements assessed.

### **Discussion –**

The chronic lowback pain secondary to spondylosis and post surgical, has offered the medical profession the greatest challenge and the most expense to the third party insurer. The PR 3000 offers the patient a safe, conservative method to increase the range of motion, increase the strength and functional abilities. The selective isolation of the lumbar spine offers a conservative method for stretching and strengthening in a standing, functional position with safety and renewed confidence of the patient's ability to move without pain.

The ability to stabilize the lumbar spine and pelvis while allowing the patient to move into previously painful range of motion, without pain has a dramatic effect on the psychological component of chronic pain. The patient can now be trained and exercised in a variety of functional activities with renewed confidence that the pain of movement is eliminated or greatly reduced.

F. Herniated disc without referred pain into lower extremity

G. Herniated disc with referred pain below hip/gluteal region

### **Treatment Procedure –**

1. Primary goals- decrease and centralize pain, increase pain free range of motion in all planes, restore patient confidence in movement activities, and increase strength of trunk and spine muscles.
2. Patient placed in a standing position that allows forward bending of the lumbar spine, with stabilization straps across the upper thighs and approximate level of the anterior superior iliac spine.
3. Note: Patient was asked to perform an active forward bending movement, at which time pain during the motion was assessed. If pain increased the patient was repositioned as noted in Step 10, then movement reassessed.
4. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.

5. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
6. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
7. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the forward bending movement.
8. An exercise-restraining strap attached to a rubber resistance band was placed around the patient's chest and the patient instructed to move into the resistance to facilitate the trunk muscles and resistively exercise the trunk within a pain free and limited range of motion.
9. Note: If the pain was increased in backward bending the following steps were not performed.
10. The patient was then repositioned in the opposite direction with the stabilization straps placed around the hips at the level of the greater trochanters and the lower lumbar spine, level determined by symptoms, flexibility and pain. Same precautions of questioning the patient regarding pain during setup and movement, was completed prior to proceeding to the next step.
11. A third, exercise restraining strap placed around the mid to upper thoracic region, tightened to limited the range of motion of the lumbar spine in a backward bending position.
12. The patient was asked to move into the resisted, limited range of motion to facilitate the lumbar extensor muscles, in a pain free range of motion.
13. The patient was asked to do ten repetitions of the movement into backward bending of the lumbar spine and rotation of the lumbar spine.
14. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition, other contributing factors such as hypertension, cardiopulmonary history and medications, where taken into consideration.
15. Patient released from the device, active movements assessed.

## **Postural Dysfunction**

### **A. Thoracic Kyphosis with extension restriction**

#### **E. Lumbar spine lordosis – forward flexion restriction**

#### **F. Hip extension restriction secondary to tight hip flexor muscles**

## **Treatment Procedure –**

1. Primary goals- decreased thoracic kyphosis, lumbar lordosis and hip extension movement restrictions often associated with postural dysfunction.
2. Note: Cervical conditions are a consistent component of the Postural Dysfunction pattern, however, they are not treated on the PR 3000 at this time. The clinician treats the cervical pain and restrictions associated with this condition separately. Manual therapy and manipulative techniques are applied in a supine position, with adjunct use of physical therapy modalities and procedures deemed appropriate by the therapist.
3. Patient placed in a standing position that allows forward bending of the lumbar spine, with stabilization straps across the upper thighs and approximate level of the anterior superior iliac spine.
4. Patient was asked to perform an active forward bending movement, at which time pain during the motion was assessed.
5. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.

6. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
7. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
8. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the forward bending movement.
9. An exercise-restraining strap attached to a rubber resistance band was placed around the patient's chest and the patient instructed to move into the resistance to facilitate the trunk muscles and resistively exercise the trunk within a pain free and limited range of motion.
10. The patient was then repositioned in the opposite direction with the stabilization straps placed around the hips at the level of the greater trochanters and the lower lumbar spine, level determined by symptoms, flexibility and pain. Same precautions of questioning the patient regarding pain during setup and movement, was completed prior to proceeding to the next step.
11. A third, exercise restraining strap placed around the mid to upper thoracic region, tightened to limited the range of motion of the lumbar spine in a backward bending position. The clinician may apply assisted manual stretching or selective manual therapy techniques to the affected thoracic segments above the stabilization strap.
12. The patient was asked to move into the resisted, limited range of motion to facilitate the lumbar extensor muscles, in a pain free range of motion.
13. The patient was asked to do ten repetitions of the movement into backward bending of the lumbar spine and rotation of the lumbar spine.
14. The clinician instructs the patient to perform five to ten hip extension movements with each leg to increase hip extension movement. Following the active movements, the clinician can assist the patient into internal rotation and adduction movements to increase range of motion in multiple planes.
15. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition, other contributing factors such as hypertension, cardiopulmonary history and medications, where taken into consideration.
16. Patient released from the device, active movements assessed.
17. Patient placed in a supine position for manual stretching of the cervical and upper thoracic spine into axial extension.
18. Patient guided and instructed in muscle reeducation and strengthening of the posterior scapular, posterior cervical, lumbar extensors and hip extensor/abductor muscles.

## **Discussion-**

The patient with Postural Dysfunction often exhibits four common characteristics and dysfunctions. The symptoms will often vary according to a number of factors, which include and are not limited to:

- Age
  - Body type
  - Activity level such as frequency of exercise
  - Physical condition
  - Underlying pathology or other medical conditions
  - Medications

The four most common characteristics and areas of motion restriction seen in the Medicare-aged patient are:

- Increased cervical lordosis, restricted range of motion and associated pain
- Increased thoracic kyphosis, restricted range of motion
- Increased lumbar lordosis range of motion and associated lowback pain
- Restricted hip motion with associated lowback pain

These Postural Dysfunctions and movement restrictions are treated with the above outlined PR 3000 treatment protocol and exercise to selective postural muscles, that have become stretch weakened (Janda, 1992; Sahrmann, 2000) or hypertonic due to fibrotic shortening. The patient is also given a home exercise device and program to exercise and retrain these tissues during the days they do not come to therapy.

### **III. Orthopedic**

#### **1. Total hip replacement-**

##### **Treatment Procedure –**

1. Primary goals- Increase range of motion of the operative and non-operative hip into extension, internal rotation and abduction. Facilitate the gluteal muscles, strengthen the gluteal muscles in a standing position, inhibit the hip flexors, and stretch the anterior/medial joint structure.
2. Note: The accepted total hip replacement protocol was followed.
3. Patient placed in a standing position, facing the stabilizing pad, so the hips and pelvis are stabilized. The stabilization straps across the sacrum, above the greater trochanter to allowing motion through the axis of the hip joint.
4. Patient was asked to flex the knee and place the foot on a platform directly behind with the toe of the shoe resting on the platform. Assistance as needed to flex the knee safely without unnecessary effort.
5. Patient was asked to perform a hip extension movement into the stabilizing strap and extend the knee as much as possible.
6. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.
7. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
8. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
9. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the hip extension movement.
10. The patient was assisted in internal rotation of the hip with knee flexion. The physical therapist holding the foot in the air and guiding the motion in the direction of tissue resistance. Patient is being constantly monitored for pain or discomfort, five to ten repetitions of the movement.
11. The patient was assisted in internal rotation and abduction, five to ten repetitions of the movement.
12. The clinician instructs the patient to perform five to ten hip extension movements with each leg to increase hip extension movement. Following the active movements, the clinician can assist the patient into internal rotation and adduction movements to increase range of motion in multiple planes.

13. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition, other contributing factors such as hypertension, cardiopulmonary history and medications, where taken into consideration.
14. Patient released from the device, active and passive movements assessed.

### **Discussion-**

Treatment of the total hip patient with the PR 3000, offers the therapist an additional modality for achieving the goals as outlined. The ability to isolate and exercise the hip muscles while in a standing position has shown to shorten the rehabilitation time.

### **B. Total knee replacement-**

#### **Treatment Procedure –**

2. Primary goals- Increase range of motion of the operative knee into flexion and the hip into internal rotation and abduction. Facilitate the hamstrings muscles, strengthen the hamstring muscles, gluteal muscles, strengthen the gluteal muscles in a standing position, inhibit the hip flexors, and stretch the quadriceps muscles.
3. Note: The accepted total knee replacement protocol was followed.
4. Patient placed in a standing position, facing the stabilizing pad, so the hips and pelvis are stabilized. The stabilization straps across the sacrum, above the greater trochanter to allowing motion through the axis of the hip joint.
5. Patient was asked to flex the knee as much as possible and place the foot on a platform directly behind with the toe of the shoe resting on the platform. Assistance as needed to flex the knee safely without unnecessary effort.
6. Patient was asked to perform a hip extension movement into the stabilizing strap and extend the knee as much as possible.
7. The stabilizing straps were adjusted for tightness and position if the patient responded that the movement caused pain.
8. The movement reassessed, then if pain persisted, readjustment of the stabilizing straps.
9. If movement was still painful, the patient was judged not to be an appropriate candidate for treatment.
10. If the movement was pain free, the patient was instructed to perform up to ten repetitions of the hip extension with knee extension movement.
11. The patient was assisted in internal rotation and abduction, five to ten repetitions of the movement.
12. The clinician instructs the patient to perform five to ten hip extensions with emphasis on knee flexion movements with each leg to increase knee flexion range of motion.
13. The number of sets of repetitive movements was determined on an individual basis, factors of age, diagnosis, severity of pain, chronicity, range of motion, over all condition, other contributing factors such as hypertension, cardiopulmonary history and medications, where taken into consideration.
14. Patient released from the device, active and passive movements assessed.

## **Discussion-**

As an addition to the accepted total knee protocol, the patient is able to achieve range of motion of the operative knee in shorter period of time, thereby, decreasing the rehabilitation period.

## **Discussion Summary-**

The above listed diagnosis were evaluated and treated as outlined. In some cases the Pelvic Restrainer was the only treatment for the condition or range of motion restriction. In the cases annotated, other traditional and medically accepted treatment regimens preceded the use of the Pelvic Restrainer.

While the long-term follow-up (one year or more) has not been documented in these cases, in the short term (two months) an informal survey demonstrated the majority of patients continue to report the benefit of reduced pain and increased range of motion.

## **Benefit of the Pelvic Restrainer interventions:**

- Retained range of motion.
- Resolution or reduction of the pain complaints.
- Improved functional capacity to activities of daily living.
- Reduction of pain medication.
- Allows the clinician to selectively increase range of motion, exercise a spinal segment or region.
- Increase patient confidence in movements and activities of daily living.
- Allow the clinician to integrate manual therapy and joint manipulation techniques very selectively to the area of restriction.
- Reduction of rehabilitation time.

This device presents the clinician with a new approach to treating spinal disorders that has not been previously proposed. There are two aspects of the device that are new:

1. The selective compression and stabilization of the hips and pelvic girdle by the lateral straps,
2. The vertical loading of the pelvis and spine in a standing position while performing active and resistive pain free movements.

The lower strap stabilizes the hip joint and the upper strap crosses the iliac crests of the ilium resulting in complete stabilization of the hips and pelvic girdle. No movement of the pelvic girdle occurs during active and resisted movements.

Several neuromuscular mechanisms appear be facilitated that have not previously been used in the treatment of the spinal disorders.

- First, the stabilization of the hips and pelvis appear to negate or inhibit the hip stabilization muscles that work on the hip joints and the pelvic girdle. This allows the spinal muscles, the erector spinae and the multifidus to work

independently during active and resisted movements while on the PR 3000. It appears that there may be an interrelationship of the hip stabilizers and the spinal muscles during painful movement. When the hips and pelvic girdle are stabilized the spinal muscles can now function independently and the vertical loading of the spine changes due to the pelvic compression. The stabilization of the hips appears to inhibit the hip flexor muscles in addition, thus reducing an anterior muscle force and release of tension on the spine.

- Second, it appears that the compression of the vertical joints of the pelvic girdle; the paired posterior sacroiliac joints and the anterior symphysis pubis, increases the proprioception of the joints that may decreased or masked by pain of the lowback. In addition when the lumbosacral pain is reduced, the multifidus muscles are facilitated.
- Third, with relief of pain, and stabilization of the support system of the spine, the trunk musculature can be easily isolated and exercised in a functional, standing position. This method reduces the need for prolonged prone and supine exercise positions, both of which are non-functional positions, thus accelerating the progress of the patient safely and effectively.

The stabilization of the hips and pelvis allow for selective exercise of the trunk muscles. When performed in a standing position, the muscles work in a more functional position, allowing for a more rapid, and safe acceleration of the rehabilitation process, thereby reducing the time and costs of rehabilitation services.

From a safety standpoint, the patient is quickly selected for continued intervention. If the painful motion cannot be reduced very significantly and or completely eliminated, then the patient intervention is immediately terminated. This provides a significant safeguard to utilization and reduction of liability to injury from use of the device.

HJ Ferrante PT, OCS  
(Electronic signature)