The Chiropractic Report

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Professional Notes

RIO 2016 – Chiropractic at the Olympics

Following LONDON 2012 and now RIO 2016 it is clear that sports chiropractic services have finally arrived to stay at the Olympics.

One reason is demand from athletes and coaches. They rely on sports chiropractors in training and competition at home, and want these services at the Olympic Games when it counts most.

Another reason is the greater development and international organization of the specialty of sports chiropractic, in postgraduate education and practice, and led by the International Federation of Sports Chiropractic (FICS) and

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Chiropractic Boot Camp for LSS

An Impressive New Management Program

A Introduction

LUMBAR SPINAL STENOSIS (LSS), age-related, degenerative narrowing of the central and lateral spinal canals that often leads to compression and ischemia of the spinal nerves, produces the clinical condition of neurogenic claudication.

This syndrome features unilateral or bilateral buttock and lower extremity pain, heaviness, numbness, tingling or weakness brought on by walking or standing – because this further narrows the canal space for the spinal nerves and their blood supply. Symptoms are relieved by sitting and bending forward.

Accordingly, limited walking ability is the dominant functional problem for those with neurogenic claudication due to LSS. How significant is this?

• People with LSS have greater walking limitations that those with knee or hip osteoarthritis, and greater functional limitations than those with congestive heart failure or chronic obstructive lung disease.[1]

• Inability to walk leads to a sedentary lifestyle and the progressive decline in physical and mental health status which that brings

• Neurogenic claudication due to LSS is already a leading cause of pain and disability for persons over age 65, and its prevalence and economic burden are growing exponentially with the aging population. Today 25% of the population in Japan is over age 65 and about 12 million people suffer from this condition. By 2030, 73 million people in the US will be over 65 and an estimated 30% or them or 22 million are projected to have symptomatic DLSS.[2]

2. The world is looking for a remedy. Although LSS is the most common reason for spine surgery in persons older than 65[3], surgery has not been proven effective and has a high rate of adverse events. Relatively few LSS patients are candidates for and receive surgery[4]. The great majority receive forms of non-surgical care, such as spinal injections and bracing. However the effectiveness of these remains unknown also.[5]

Answering the challenge for a safe and effective non-surgical management strategy is Canadian chiropractic clinician and researcher Dr Carlo Ammendolia (*pictured below*) with his new *Boot Camp Program for Lumbar Spinal Stenosis.* On this:

• The program has been developed by him and colleagues over the past 8 years at Mount Sinai Hospital in Toronto, Ontario.

• It provides a 6-week multimodal program combining patient education, exercises and manual treatments, with the goal of achieving self-management through providing patients with the knowledge, skills, self-confidence and physical capacity to manage their symptoms and maximize function on their own.

• A retrospective study of results for 49 consecutive and eligible patients at Dr Ammendolia's Mount Sinai Hospital Chiropractic Spine Clinic over 3 years (January 2010 to April 2013) provided encouraging preliminary evidence of effectiveness – clinically important and statistically significant improvements

on all outcomes, and no adverse events.[1] This study, published in JMPT in 2015, was an award-winning ACCRAC (Association of Chiropractic Colleges Research Agenda Conference) research paper.

• The protocol for his follow-up randomized, controlled trial (RCT) to provide more robust evidence has just been published.[2]

• That RCT is well underway at Mount Sinai Hospital, with the 6-week treatment period for the 104 subjects complete and the 8-weeks outcome data in and processed. The 12-months follow-up data will be available this December, with analysis then delivery of a paper for publication next year.

• A companion RCT led by Dr Michael Schneider of the University of Pittsburgh in Pennsylvania is underway.

• In the meantime the Boot Camp is attracting much international attention in the chiropractic and medical worlds. Dr Ammendolia is much in demand for workshops teaching the Boot Camp methods – with workshops already given across Canada and in the USA and Europe, and being scheduled for Australia and Latin America.

This issue of The Chiropractic Report reviews this important new program, a fine emerging example of what the chiropractic profession and its principles and skills can bring to health care – a natural and conservative approach that is patient-centered, safe and effective, and answers a major and growing area of patient need, disability and cost.

B More on LSS

3. The North American Spine Society (NASS) definition of lumbar spinal stenosis or LSS is "a clinical syndrome of buttock or lower extremity pain, which may occur with or without back pain, associated with diminished space available for the neural and vascular elements in the lumbar spine." First described in 1954, LSS "has evolved from an anatomical concept to a poorly defined clinical syndrome" according to a 20-person international Expert Panel that is conducting broad consultation by means of Delphi Panels to better define standard diagnostic criteria.[6] This is to improve clinical care and research. Chiropractors on the Panel are Dr Kent Stuber from Canada and Dr Michael Schneider from the USA.

The first consultation, with input from 279 clinicians from 29 countries, was to find the most important questions to ask in taking a history. The six most important items to determine, which give an 80% certainty of diagnosis of LSS, are:

• Leg or buttock pain while walking

• Flexion forward to relieve symptoms

• Feeling relief when using a shopping cart or bicycle

• Motor or sensory disturbance while walking

• Normal and symmetric foot pulses – more a matter of examination than questions

• Lower extremity weakness

Questions on other relevant items of history that were considered produced no significant change in certainly of diagnosis. Having dealt with history, the Panel is now consulting and reporting on which other factors increase diagnostic certainty – including physical examination findings, imaging and electromyography.

C Boot Camp Developer

4. Carlo Ammendolia DC, PhD, a graduate of the Canadian Memorial Chiropractic College (CMCC) in Toronto who has now been in chiropractic practice for over 30 years, is Director of the Chiropractic Spine Clinic and the Spinal Stenosis Program at the Rebecca MacDonald Center for Arthritis and Autoimmune Diseases at Mount Sinai Hospital, a teaching hospital for the University of Toronto's Faculty of Medicine. This is a Center with several leading international experts in the field of rheumatology and autoimmune disease. Dr Ammendolia has been based there for 10 years.

Spinal stenosis is a special interest, but only part of his work. At Mount Sinai he combines practice, research and the teaching of medical residents in the non-operative management of mechanical, degenerative and inflammatory spinal disorders. He is highly-regarded by his medical peers, whose one complaint voiced to The Chiropractic Report when we visited last month is that "his excellent results make us look bad".

Dr Ammendolia received his Master's degree (Clinical Epidemiology and Health Care Research, 1999) and PhD (Clinical Evaluative Sciences, 2005) from the University of Toronto. Several appointments from the university include the award of a Professorship in Spine, Department of Surgery, Faculty of Medicine in 2012. Last year he was honored as Chiropractor of the Year by the Ontario Chiropractic Association, the provincial professional association representing Ontario's 3,700 doctors of chiropractic.

For more on Dr Ammendolia, and *spinemobility, "a not-for-profit research and resource centre"* he established in 2014, visit spinemobility.com. The purpose of *spinemobility,* as noted at the website, is "to develop and test treatments and devices aimed at improving mobility and function, and reducing disability, due to spine and other musculoskeletal conditions." The mission is "to reduce pain, suffering, and disability from spine-related disorders through innovative research." All profits from the sale of products and services "are reinvested to support our research program."

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D Boot Camp Program

5. Dr Ammendolia explains the origins of his program, and the essence of how it addresses the symptoms of neurogenic claudication as follows:

a. From three systematic reviews of the research evidence completed by him it was clear that "we don't know what works" for the non-operative management of neurogenic claudication.

b. Symptoms are precipitated by standing and walking, which increases the lumbar lordosis, further narrowing the central spinal canal, the cross-section of which is already compromised by LSS due to changes such as disc thinning, facet joint thickening and infolding of the ligamentum flavum. This further narrowing compresses the venous plexus and flow of cerebral spinal fluid within the canals, leading to congestion that diminishe blood supply to the spinal nerves. .

c. This compression/blockage/ischemia and the symptoms arising from it are reduced through leaning forward and/or adopting a pelvic tilt while standing/walking, or by sitting down. Each of these postural changes opens the canal. Posture changes symptoms.

d. This is therefore a dynamic neurovascular condition, not an inflammatory one. The main challenge is how to get patients to make the needed postural changes so they can stand and walk for much longer periods. This requires general and postural education and specific exercises, more fully described below.

e. At the outset patients require help with joint and soft-tissue restrictions. For example, many of them will have shortened iliopsoas muscles from sitting all day trying to relieve symptoms, producing biomechanical restrictions that further increase the lumbar lordosis while standing. This can be addressed with appropriate manual treatments.

5. In the program patients receive 6 weeks instruction and care, with 1 to 3 sessions per week depending upon the severity of their conditions and with each session lasting 15-20 minutes. The three components are:

a. *Education.* A main emphasis is on maximizing function, particularly in walking ability and how to reduce the lumbar lordosis when standing and walking using pelvic tilt repositioning techniques. However patients also receive information and instruction on:

- Causes of pain and disability due to DLSS, its natural history and prognosis
- How to manage symptoms and maintain daily routines using problem solving, pacing, and relaxation
- Reassurance, graded activity and goal setting to reduce pain-related fear and improve self-performance and function

b. *Exercises.* Patients receive muscle stretching, strengthening and conditioning exercises directed at improving overall back and lower extremity fitness and lumbar flexion. Details include:

- Patients receive instruction in specific exercises, during the visit and in an instructional workbook and video that they receive. In each workbook there is an individually tailored, written exercise and conditioning program outlining the type, frequency and intensity of exercises to be performed. These exercises are to be performed twice daily, with an increasing load each week for 6 weeks.
- Tight muscles that promote lumbar extension are progressively stretched, muscles that promote and control lumbar flexion are strengthened.
- Stretching exercises include supine knee to chest and knee to opposite stretches, side posture quadriceps stretches, and standing iliopsoas stretches.
- Core strengthening exercises include supine pelvic tilt and half sit ups, side posture lateral stabilizer exercises and prone lumbar and gluteal extension exercises.
- Patients with very limited walking ability first receive a graduated cycling program, using a stationary, forward-leaning bike, to improve extremity fitness and overall conditioning. Others begin a graduated walking program immediately. All receive a pedometer to provide weekly feedback to patients and practitioners on walking distance and ability.
- Programs and patient compliance with them are reviewed at each visit.

c. *Manual Therapy.* All patients receive manual therapy, aimed at improving the flexibility of the lumbar spine and improving lumbar spine intersegmental flexion, and targeted at the lumbar and thoracic spine, the pelvis and the lower extremities. Specific techniques include:

- HVLA joint manipulation
- Joint, soft-tissue and neural mobilization
- Lumbar flexion-distraction
- Manual muscle stretching

d. *Typical Session.* Specific exercises given and manual therapy techniques used for each patient are chosen based on identified functional limitations or impairments. A typical treatment session, as reproduced in the retrospective study by Ammendolia and Chow, comprises:

- First, further education, reassurance, and positive reinforcement when improvements are observed from the previous visit
- 5 minutes of manually-assisted, mechanical flexion-distraction with the patient prone on a flexion-distraction table. A push-relax technique is used to progressively stretch the muscles (piriformis, gluteus medius, rectus femoris, adductors, iliopsoas)

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RIO 2016 – Chiropractic at the Olympics

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its member national sports chiropractic councils in all world regions.

There have long been chiropractors with a growing number of national Olympic teams. What is new is formal inclusion of sports chiropractors within the host sports medicine team providing services available to all athletes and officials in the polyclinic in the Athletes' Village.

LONDON 2012 was the first Summer Olympics to do this, following a similar breakthrough at the 2010 Vancouver Winter Olympics. In London sports chiropractors, osteopaths and physiotherapists worked together in what was widely regarded as the best physical therapies service ever. That led to inclusion of these professions on a similar basis at RIO 2016, with support from the London Organizing Committee and the International Olympic Committee (IOC).

To get a taste of what this feels like from one of the sports chiropractors who served in the RIO 2016 polyclinic, see the report from Dr Clive Bridgham.

There were 18 chiropractors from 8 countries chosen by the Rio Organizing Committee from over 50 applicants. Typically they served for 2-3 weeks, two at a time, two shifts per day, from 10 days before the opening of the Olympics until close of the Paralympics.

Coordinator of Chiropractic Services was Dr Marcelo Botelho of Salvador, Brazil, greatly assisted in preparation for the Games by Dr Tom Greenway of the UK, who had the same role for LONDON 2012. All those providing chiropractic services do so as volunteers, receiving uniforms, facilities and meals but paying their own travel and accommodation.

National teams bringing their own chiropractors ranged from the Philippines, where Dr Martin Camara of Manila now serves as Co-Chair of the Medical Commission of the Philippines Olympic Committee, to the USA, where sports chiropractic doctor Dr Bill Moreau is CMO or Chief Medical Officer for the US Olympic Committee.

In Rio as a competitor was German chiropractor and professional athlete Dr Sven Knipphals, representing Germany in the 100m relay. Dr Khipphals is currently Vice-President of the German Chiropractors' Association.

Marcelo Botelho, Coordinator, Chiropractic Services

The Rio 2016 Polyclinic- An Athlete-Centered Experience in the Olympic Village

*Dr. Clive W. Bridgham (*right*), a chiropractic sports medicine specialist from Barrington, Rhode Island in the USA has over 25 years of experience at local, national and international games events, including the Salt Lake City Winter Olympics with World Olympians Association. He was one of the 16 chiropractors from 8 countries chosen by the RIO 2016 Organizing Committee to serve in the host medical services during the Olympics and Paralympics.*

These services are provided by the host country in a multidisciplinary polyclinic open to all athletes, coaches and officials. Dr Bridgham served over a three week period from July 29 until August 11 during the period in which the polyclinic protocols were tested and established. Here are extracts from his report, reprinted from the FICS News (September 2016).

At first it was like being a mouse in a huge maze of corridors, offices, entries, exits, not to mention protocols. It quickly became an athlete-centered, check your ego at the outside door experience. Being a member of the sports medicine team for Rio 2016 Olympic Games in the Polyclinic of the Olympic Village (OLV) was a superb experience which was built on the efforts of many chiropractic sports physicians over many decades.

On arrival at the Polyclinic we had our meeting of the physical therapies team of physios, chiros, and osteos, introductions all around, and then toured the clinic which included many specialties: dentistry, ophthalmology, emergency room, orthopedic sports medicine, podiatry, osteopathy, massage therapy, and of course chiropractic.

The polyclinic and one shift of the physical therapies team – chiropractors, osteopaths and physiotherapists

The complex also included two state-of-the-art MRIs, one digital x-ray, a cryo pool room, a rehab room with an antigravity treadmill, conference rooms, storage rooms, IT rooms, break areas, and reception.

There was a room for orthotics and support braces for ankles to shoulders, a chiropractic table room, an osteopathic table room, and our main area for physical medicine - the physio room with 12 treatment tables and state-of-the-art physio machines for ultrasound, ems, laser, cryo/compression, and hot moist packs. There was also a Swiss machine for intense pulsed ultrasound. The one exception was that no acupuncture allowed in the clinic. The physios were allowed to perform mobilization but only the chiros and osteopaths were allowed to perform manipulation.

The early morning hours were relatively quiet with only an easy flow of returning athletes, so it was watch and learn and figure out what specialty we each were as we were all dressed the same and our credentials made no differentiation as to our degrees. It was an adaptive process on all sides, learning the subspecialties of each provider. Watching the team develop understanding and work was a great experience.

Our teams were divided into two shifts. On my first day there were only about 2,500 people housed in the OLV, by midway through my rotation the OLV swelled to at least 11,000 occupants. All athletes needed to be seen by one of the MDs and referred to chiro, physio, or osteo, unless coming without injury and being seen to maintain function. Athletes accompanied by their team doctor or team physio were allowed direct access and could either work with us or independently.

I found many team physios and some team MDs were very interested in referring and watching chiropractic services. Pleased athletes spread the word about the clinic and soon the volume increased exponentially. Once the athlete was in the physio treatment area interdisciplinary referrals were allowed and encouraged, providing the athletes with a world-class experience. My first day shift ended at 3pm with a debriefing and a team Rio cheer.

Since there was a full complement of physios and massage therapists they performed the ultrasound, ems, cryo, hot moist pack therapies, taping and massage. As chiros we used manipulation, pin and stretch, Graston, kinesiotaping, and muscle testing. Treatments were performed either in the large physio room, which helped promote cooperation and understanding among the diverse practitioners with differing languages, or in the private chiropractic room nearby. This room had a high-low table with numerous drop sections.

There are so many people to thank for their years of work in making the Rio 2016 Polyclinic the success that it was. Of special note are Dr Marcelo Botelho, the lead chiropractic physician and Felipe Tadiello, coordinator of Physical Therapy Services. Many people were exposed to chiropractic services for the first time. Many new friendships were formed and old acquaintances renewed.

It is amazing what happens when you have a dedicated team of professionals who are athlete centered treating the finest athletes in the world. It was truly a world-class experience, well worth the time to learn how to navigate the maze.

Clive W. Bridgham, MA, DC, DACBSP, ICSSD

Drs Carlo Guadagno and Clive Bridgham in the Chiropractic Room

OCTOBER 16

WORLD SPINE DAY

World Spine Day 2016 – "Straighten Up and Move"

Every year on October 16 people from around the world join together on **World Spine Day** to raise awareness about spinal disorders.

World Spine Day (WSD) is part of the annual Action Week of the Global Alliance for Musculoskeletal Health, formerly known as the Bone and Joint Decade, a multidisciplinary organization in which the chiropractic profession plays an active role.

You and your clinic or chiropractic organization can **and should get involved**! Go to worldspineday.org for much information and many resources to help you.

The WSD theme for 2016 is **"Straighten Up and Move"**, highlighting the importance of physical activity and improving posture as part of good spinal health and prevention of injury. This theme is taken from the program of the same name developed by US chiropractor Dr Ron Kirk in association with Life University and the World Federation of Chiropractic (WFC)

For the past 5 years the Global Alliance, which has UK rheumatologist as its President and includes chiropractors on its International Coordinating Council, has given the WFC the responsibility of leading the development of WSD and its associated website. This recognizes the profession's expertise in spinal health.

In the past year the website is much enhanced, even featuring a new rap video on 'straighten up and move' shot in London. See this at the website – and plan to bring a spinal health event to your community on World Spine Day.

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- Side posture mobilization/manipulation is then performed bilaterally with the lumbar spine in flexion
- That is followed by supine neuromobilization of the sciatic nerve
- A review of previous exercises is then made, with instruction in 2 or 3 new exercises and increase in the intensity and duration of the exercises already performed.

6. From this it can be seen that very substantial commitment and personal involvement in care is being asked of patients, who are typically over 65 years of age - many much older than that. Their potential rewards, however, are great. They may move from being sedentary and depressed, in poor and declining health, unable to walk for 100 or 200 meters and worried that surgery and its risks are their only source of hope, to a state of much reduced pain and disability, the ability to walk for 500 meters or more, a new level of hope and fitness, and a return to independence in their lives.

That is what the Boot Camp is delivering. We now turn to the emerging evidence to confirm this.

E The Retrospective Study

7. As already mentioned this study by Ammendolia and Chow[1] assessed the results of the above program given to 49 consecutive, eligible patients at Dr Ammendolia's Mount Sinai Chiropractic Spine Clinic over a 3-year period ending in April 2013. Data was extracted from the patient records. Details are:

a. *Patients.* Inclusion criteria were 50 years of age or older, clinical evidence of neurogenic claudication from LSS, and symptoms for more than 3 months. Exclusion criteria included several red flags (spondylitis, neoplasm, infection, metabolic diseases), radiculopathy due to lumbar disc herniation, and psychiatric and/or cognitive disorders.

b. *Outcome measures.* These, measured before treatment (at baseline) and at 6 weeks, were:

i. Physical function, as measured by the physical performance scale of the Swiss Spinal Stenosis questionnaire which has five questions related to walking ability. Raw scores are from 5 to 20, mean scores are from 1 to 4, with higher scores reflecting lower performance and a change of at least 0.1 in the mean score considered clinically important.

ii. Symptom severity, as measured by the SSS symptom severity scale, consisting of seven questions relating to overall severity of pain in the leg and back, pain frequency, numbness, weakness and balance disturbance. Mean scores range from 1 to 5, with higher scores reflecting higher severity and, again, a change of at least 0.1 being considered clinically important.

iii. Functional disability, measured by the Oswestry Disability Index (ODI). Scoring ranges from 100 (worst possible disability) to 0, and a score change of at least 8-12 is regarded at clinically important. The walking section (ODI walk) was scored and recorded separately, and has been shown to be highly correlated to "objective walking distance."

iv. Leg and back pain intensity while walking, measured with the 11-point Numerical Rating Scale from 0 to 10 with 10 being extreme pain intensity. Minimal clinically important difference is estimated to be 1.5 to 2.0.

v. Treatment satisfaction, measured with the SSS satisfaction scale, on which a score of less than 2.5 is considered clinically important and high satisfaction with treatment.

c. *Results.* Patients were much older than 50 years and had prolonged symptoms and disability. Mean age was 70, 65% were female, and the mean duration of symptoms was 11 years for back pain and 8.6 years for leg pain. The mean ODI was 51, indicating severe disability, and the mean ODI walk was 3, indicating moderate walking problems.

Ammendolia and Chow report that this study demonstrated "large statistically significant and clinically important improvements in all outcomes" in this chronic and severely disabled patient population. Importantly, there were no reported adverse events.

Detailed results are shown in Table 1. Improvements, compared with minimum clinically important improvement shown in brackets, included:

- SSS physical function – 0.41 (0.1)
- SSS symptom severity – 0.74 (0.1)
- ODI disability – 15.2 (8-12)
- NPS leg pain – 2.34 (1.5-2)

SSS measured treatment satisfaction was high at 1.54 (2.5).

Strengths of the study are that it included consecutive patients with clinical evidence of neurogenic claudication, the use of validated outcome measures, and clear results. However because this was a retrospective study of a clinical series of patients, with no comparison control group, it represents preliminary evidence only of effectiveness. Another significant limitation – at present - is that there was no long-term follow up published to see if these improvements recorded at 6 weeks at the end of treatment were maintained months and years later. (Follow-up results for over 3 years do now exist and will be presented at ACCRAC in 2017.)

Ammendolia and Chow acknowledge these and other limitations, and that the role of this study was to provide preliminary evidence only and preparation for a randomized, controlled trial (RCT). We now turn to that.

F The RCT

8. The above study was funded by the Canadian Chiropractic Research Foundation, an affiliate of the Canadian Chiroprac-

Table 1. Mean Difference in Outcomes From Baseline

Outcome (n)	Baseline, Mean (SD)	6-week Post-treatment, Mean (SD)	Mean Difference (95% CI)	*P*
ODI (n = 45)	50.8 (13.9)	35.6 (15.6)	15.2 (11.39–18.92)	< .0001
ODI walk (n = 44	3.39 (1.32)	2.43 (1.58)	0.96 (0.65–1.25)	< .0001
SSS symptoms (n = 44)	3.22 (0.62)	2.48 (0.60)	0.74 (0.55–0.93)	< .0001
SSS function (n = 43)	2.28 (0.43)	1.87 (0.60)	0.41 (0.26–0.56)	< .0001
NPS LBP (n = 29)	7 (2.53)	4 (2.48)	2.07 (1.05–3.09)	.0003
NPS leg (n = 25)	7 (1.79)	5 (2.70)	2.34 (1.15–3.53)	.0004
SSS treatment satisfaction (n = 43)		1.54 (0.50)		

CI, confidence interval; *LBP*, low back pain; *NPS*, Numeric Pain Score; *ODI*, Oswestry Disability Index; *SSS*, Swiss Spinal Stenosis Score. *Reprinted from Ammendolia and Chow, JMPT, 2015*

tic Association. The RCT, a much more expensive undertaking, is funded by The Arthritis Society (Canada) and has an expanded and impressive group of investigators. Chiropractic researchers Drs Ammendolia, Pierre Côté, Danielle Southerst and Brian Budgell are joined by prominent medical researchers Dr Raja Rampersaud from the Department of Orthopedics, Toronto Western Hospital and Drs Claire Bombardier and Gillian Hawker from the Division of Rheumatology, Department of Medicine, University of Toronto.

The full protocol for, or design of, the RCT can be read and downloaded for free at the online journal Chiropractic & Manual Therapies.[2] Summary details are:

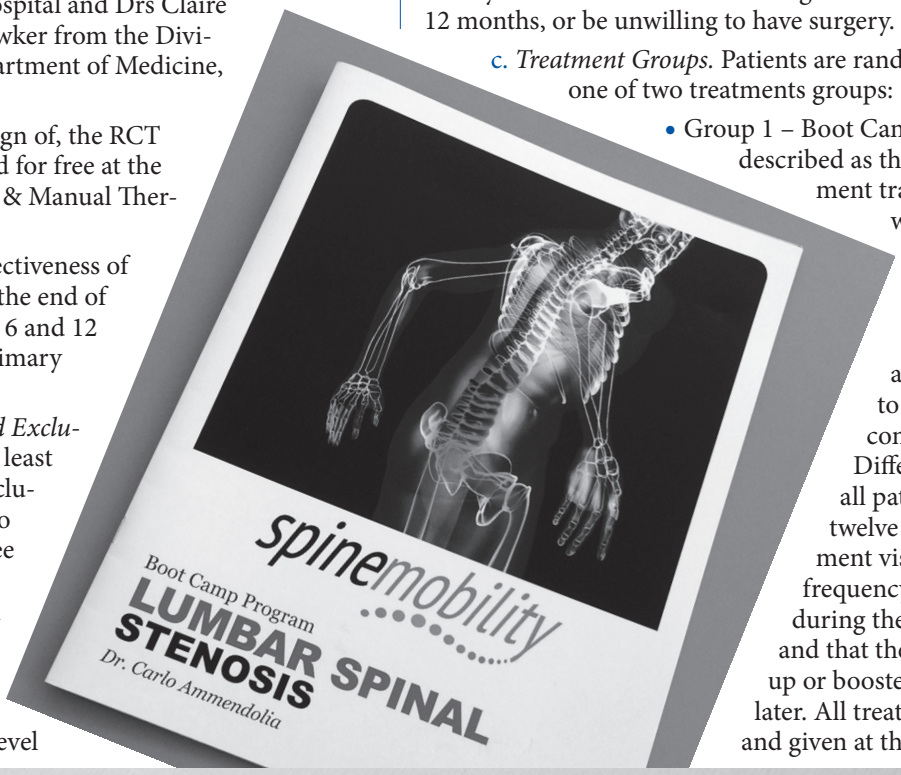
a. *Purpose.* To assess the effectiveness of the Boot Camp Program at the end of 6 weeks treatment, and at 3, 6 and 12 months follow up, with a primary endpoint of 6 months.

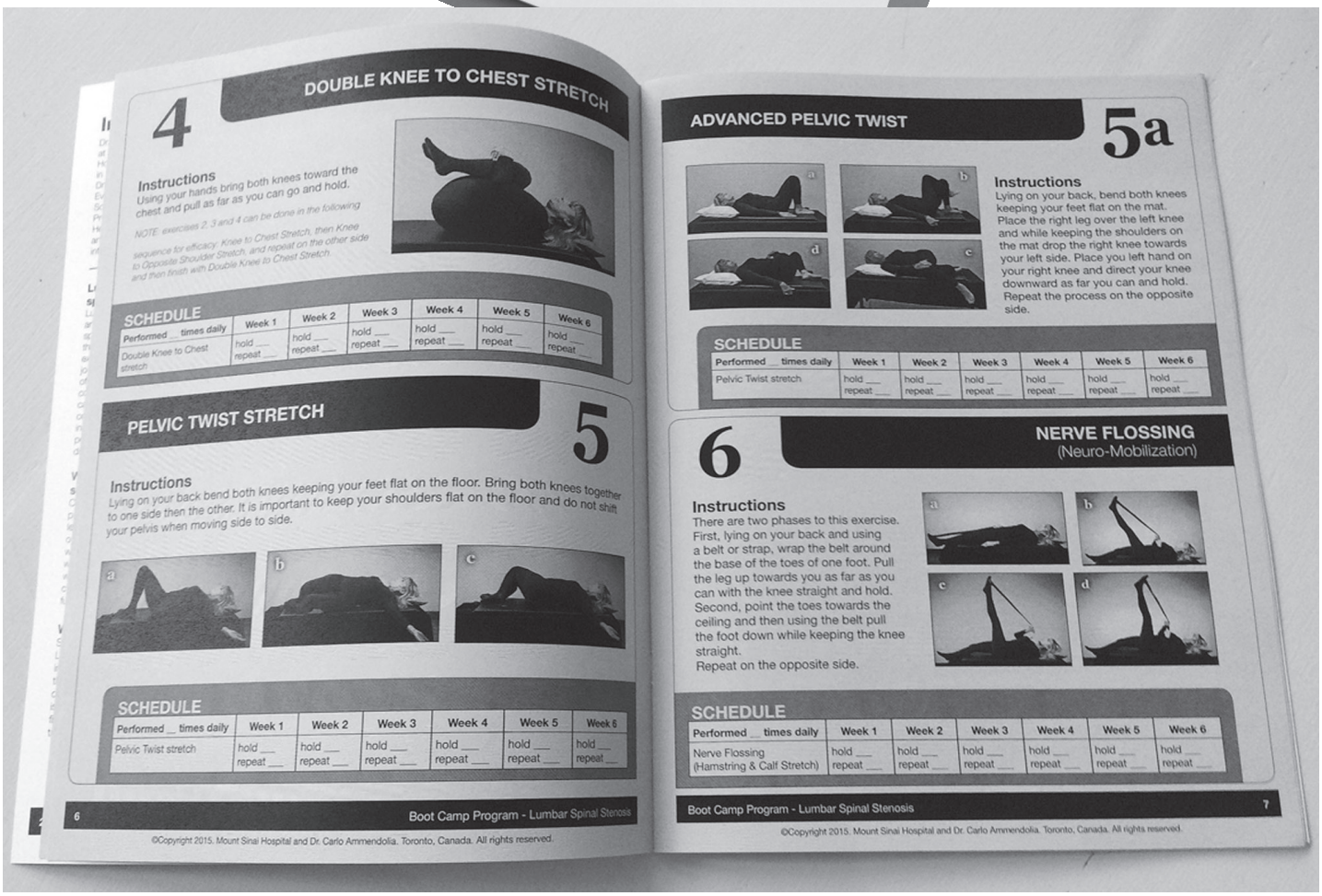
b. *Patients and Inclusion and Exclusion Criteria.* Subjects are at least 104 patients with similar inclusion and exclusion criteria to those in the earlier study (see para 7 a above). However refinements to the inclusion criteria include:

- Imaging must not only confirm spinal canal narrowing, but at a segmental level corresponding to the signs and symptoms of neurogenic claudication being experienced
- Patients must be able to perform mild to moderate exercise, but walk for less than 200 meters and less than 30 minutes continuously without assistive devices
- They must not be considered surgical candidates in the next 12 months, or be unwilling to have surgery.

c. *Treatment Groups.* Patients are randomly assigned to one of two treatments groups:

- Group 1 – Boot Camp Group. This is described as the 'self-management training program with instructional workbook, video and pedometer' group, and patients receive a similar program to the one in the completed study. Differences are that all patients will receive twelve 15-minute treatment visits at a standard frequency or 2 per week during the 6-week program, and that there is one follow up or booster visit 4 weeks later. All treatment is scheduled and given at the Mount Sinai





Chiropractic Spine Clinic in a manner that simulates real practice

• Group 2 – Single Visit Group. This is described as the 'single instructional session with instructional workbook, video and pedometer' group, and patients have a single 15-30 minute session with an experienced chiropractor who is *not* involved in the provision of the self-management program. The visit emphasis is on reviewing the workbook and the structure of the 6-week program it shows. No manual therapy is provided.

All patients are asked to record once per week the maximum number of continuous walking steps, as recorded on the pedometer, and time in minutes before they have to stop walking due to neurogenic symptoms.

d. *Outcome Measures.* All outcomes are being assessed at 6 weeks and then 3, 6 and 12 months follow up. The primary measure is *objective walking capacity*, assessed using the self-paced walking test (SPWT) which is established as the 'gold standard' for measuring this. For this test subjects walk on a level surface unsupported and at their own pace until forced to stop for 3 seconds or more due to symptoms of DLSS, or until 30 minutes have elapsed. An assessor, blinded to which group the patient is from, follows one meter behind the patient with a distance recorder and stopwatch and without talking.

Secondary outcome measures are:

• Physical function, symptom severity, functional disability, and leg and back pain intensity while walking – measured as in the earlier study

• Health-related quality of life – using the SF-36 (Medical Outcomes Study Short-Form Health Survey, version 2) which scores physical and mental dimensions

• Co-morbidities, depressive symptomatology, lower extremity function and balance, fear of falling, use of co-interventions, compliance with programs and adverse events.

Accordingly, there is comprehensive measurement of many outcomes but with a primary focus on the functional improvement of central importance to patients – walking ability measured objectively and in a real world setting.Because measurement of this requires patients to travel to the study site, giving risk of failure to attend and drop out at one of the various follow up appointments, one of the secondary measures is SSS physical function. This includes self-reported walking ability, able to be followed up by telephone.

G Conclusion

9. Even though the early results of the RCT are known to Ammendolia et al. these cannot be made public before completion and publication of the trial. What can be said is that the early results do not appear to be disappointing .

If they and the longer term follow-up results indicate at least a similar level of effectiveness to those in the retrospective study, and particularly if they are supported by results from the second RCT by Schneider et al. underway at the University of Pittsburgh, the Boot Camp will be the first treatment approach proven effective for the management of neurogenic claudication due to LSS. In the meantime Dr Ammendolia has a long line of very satisfied patients.

A final point. Beyond effectiveness, the Boot Camp's safety compared with surgery would confirm it as a first line option for patients. In their recent Cochrane Collaboration systematic review comparing surgical and non-surgical management Zaina, Tomkins-Lane, Carragee et al. found no evidence that surgery was more effective, and advise that "care providers should consider the risk of side effects when proposing surgical options to patients. A side effect rate of 10% to 24% for surgery without clearly superior benefit suggests that clinicians should be very careful when informing patients about possible treatment options, especially given that conservative care options had no associated side effects." TCR

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