## Prolotherapy Spineworks

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## Prolotherapy = ligament sclerosant injections

PLUGGING THE GAP between physiotherapy and surgery (or the Pain Clinic)

## Are you aware of all the options in non surgical management?

## Management of chronic low back pain

According to current evidence base the options for chronic 'non specific' LBP are: Rehab and Pain management Evidence for any injection Rx is 'weak' or non existent Evidence for spinal fusion and disc replacement is controversial and of dubious cost effectiveness

#### Personal statement

- Prolotherapy is currently the only treatment which can in 60% or more of chronic 'nonspecific' LBP make both a short and long term difference to pain and function ( in many cases producing at least 5 -10 years complete remission)
- It is the only treatment which addresses the underlying pathophysiology
- It is the only treatment which reliably alters the natural history of the condition.

## My experience

Used predominately in spinal pain all regions, after failure of manual therapy and rehab (stabilisation training) Audit of 87 cases over last 2 years at Oving Clinic Chichester – 54 responses 72% good to excellent result. (similar results in ROH B'ham, G Brown and R Chakraverty)

Also used in ACJ, ankle, wrist,TMJ and knee.

# Oving clinic audit of prolotherapy results

Patients that received benefit



A 40 year old squash player and solicitor unable to play for 3 years due to recurrent LBP Previous treatment: physic stabilisation exercises, osteopathy for SIJ dysfunction Normal Xrays and MRI shows narrow dark disc with Modic end plate changes at L5-S1 After a course of prolotherapy full return to sport with no recurrence up to 7 years

#### Spinal stability

 What is an unstable spine?
 Surgical definition – radiological evidence of dynamic alteration in osseous components causing or threatening integrity of neural structures Patient's definition – 'my back keeps going out'

'I've got a dodgy back

## Panjabi

Spinal stability is dependent on 3 components:

osseous – ligamentous integrity

motor control

neural control

## History

1832 - Jaynes and Velpeau, sclerotherapy for hernia 1900 Mayer - zinc sulphate/phenol for hernia repair 1935 - Mayer showed fibroproliferation in mammal connective tissue 1955 - G Hackett Am J Surg 89 - Joint stabilisation: an experimental histologic study on ligament proliferation

### clinical development

1956 Hackett published a monograph claiming 82% cure rate in 1600 LBP patients!

progress retarded by reports of 3 cases of paralysis and 2 deaths after inadvertent injection of psyllium seed and zinc sulphate into subarachnoid space

 MJ Ongley 1960 developed a safer solutionvein sclerosant 2% phenol,25% dextrose, 25% glycerine. (No serious complications have occurred since)

## Hackett's referred pain from spinal ligaments

A,B,C,D different points of Posterior sacroiliac ligament

SS sacrospinous ST sacrotuberous SN sciatic nerve referral differentiated



- Facet capsule -- Supra- and interspinous lig

Iliolumbar lig

Short interosseous

Dorsal sacroiliac lig

### Willard's dissection of ligament 'stocking' investing the spine

Spinous processes removed to reveal ligamentum flavum

Iliac crest



## Stabiliser of the lumbosacral junction

 ILL –iliolumbar ligament
 Sp – spinous process
 SI – sacroiliac joint



#### Facet capsule

 Note orthogonal alignment of collagen in capsule to resist strain in flexion (opening)



Effect of fibroproliferant injection provokes an inflammatory repair response

Ligament injection cosmotic shock constrained anage inflammatory mediators granulocytic influx cosmotic and polypeptide growth factors fibroblastic stimulation collage Collage FORMATION cosmotic RETRACTION AND REMODELLING (A. Banks JOM)

## Typical inflammatory repair response curves



#### Basic research

- King Liu 1983 Connective Tissue Research
- 'an in situ study of the influence of a sclerosing solution on rabbit medial collateral ligament and its junction strength'

 16 rabbits 0.1ml of Na morrhuate into each end and mid substance,N/S into contralateral side, 5 times over 6 weeks, by a blinded experimenter

#### results

Increase in ligament mass
increase in thickness
increase in junctional strength
increase in collagen fibril diameter
found only on the experimentally treated side

### Rationale

Ligaments can hurt ligaments are subject to overstrain irreversible strain leads to plastic deformation - leading to incompetence and decrease in tensile strength In the spine, ligaments provide static postural support and passive restraint of normal physiological motion

#### rationale

Panjabi has shown increase in neutral zone for sagittal and horizontal plane rotation at levels of disc degeneration this suggests that a degenerated spine may carry a higher risk for ligament strain during these physiological movements to address the problem of the painful hypermobile segment

At every instant for a rigid body in plane motion there is a line in the body or a hypothetical extension of this line that does not move. The instantaneous axis of rotation (IAR) is this line. Plane motion is fully defined by the position of the IAR and the magnitude of rotation about it. (Panjabi)

## Instantaneous axis of rotation in disc degeneration



Movement of <u>the</u> IAR

FIGURE 2-26 The changes in the location of the instantaneous axes of rotation in lumbar spine motion segment, with and without degenerative disc disease. The axes for the normal discs are shown in the dark areas with longitudinal lines, and those for the degenerated discs are shown in the lighter gray areas. Flexion is represented by **A** and right lateral bending by **B**. Left lateral bending would be represented by a mirror image of **B**. (Data from Rolander, S. D.: Motion of the lumbar spine with special reference to the stabilizing effect of posterior fusion [thesis]. Acta Orthop. Scand., 90 [Suppl.], 1966.)

## A typical load deformation curve of a spinal ligament

NZ neutral zone EZ elastic zone PZ plastic zone



## **Deformation of spinal ligaments**

Experimental work by Panjabi on following ligaments:

PLL posterior longitudinal ligament ALL anterior longitudinal ligament ISL interspinous ligament LF ligamentum flavum CL Capsular ligament of facet SSL supraspinous ligament

Shows greater elasticity of longitudinal ligaments



### Effects of disc injury on stability of a functional spinal unit



FIGURE 1-7 Effects of disc injury on the mechanical properties of a lumbar functional spinal unit are shown. Three states of the disc were investigated: intact, with annulus injury on left side, and after removal of the nucleus. Instability tests were conducted using pure moments of flexion, extension, right lateral bending, left lateral bending, left rotation, and right rotation. The bar graph shows the main motions for the intact and two injuries due to each of the six physiological loads. Annulus injury with nucleus removal produced greater changes than the annulus injury alone. The maximum absolute changes were seen in flexion and left lateral bending. On the percentage changes, it was the axial rotation that exhibited the greatest effect of the disc injury. (Data from Ponjabi, M. M., et al, Effects of disc injury on the mechanical behavior of the human spine. Spine, 9(7):707, 1984).

Clinical Biomechanics of the Spine White and Panjabi Churchill Livingstone

## Flexibility of spine under load

NZ neutral zone EZ elastic zone PZ plastic zone FC flexibility coefficient

A hypermobile person With lax ligaments will show a steeper curve



Klein Dorman and Johnson; J of Neurol and Orthop Surg 1989 • 23 patients injected 6 times at weekly intervals with P2G followed by exercises 3 patients biopsied pre- and 3 months post
 treatment results; range of motion increased in flexion side bending and rotation (p =0.001)pain and disability decreased (p=0.001) collagen fibril diameter increase of 60%



## Sacroiliac ligament biopsy baseline and 3 months post injection



#### Taken from 3 volunteers in Dorman's study

## Electron microscopy of same ligament tissue



#### Selection of patients

- History; intolerance of prolonged static posture
- pain aggravated by bending, lifting, turning over in bed, transitions (the 'dodgy back')
   constant aching
   frequent 'locking' episodes on trivial movement i.e. 'lumbar instability'

## Physical signs

Hypermobility/instability of lumbar segments and or sacroiliac joints Iocal tenderness of ligaments (traumatic sprain palpable crepitus on motion testing positive ligament stress tests Piphasic deflexion/ recurrent disc episodes 'Unstable' lytic spondylolisthesis

#### sclerosant

5 mls of P2G (phenol 2%, Dextrose 25%, glycerine 30%)
5 mls of 1% lidocaine
Or 15-25% dextrose only with lidocaine (see Dean Reeves)

## method

Bony landmarks identified Half a ml of solution injected at each of the ligament attachments Supra- and interspinous ligaments, iliolumbar, short and long sacroiliac ligaments, facet capsules



#### technique

- Inject ligament attachments at 1-2 weekly intervals for 3 6 sessions.
- Advise the patient of increased soreness and stiffness averaging 2 days post procedure
- Recommend walk 3 miles a day and roll over flexions 15 times afterwards (alignment of collagen)
- Review at 6 weeks though it may take 3- 6 months for full benefit to emerge

## complications

- Serious complications are extremely rare. (two dural punctures in 30 years)
- Minor side effects include increased soreness (which can be severe and last for up to a week in 5% of cases). Invariably settles.
- Localised numb patches (neuropraxia cutaneous nerves). Resolve in 8-12 weeks
- Localised tenderness of supraspinous lig
- Allergy and infection almost unheard of.
- Worse? 5%

## What is the evidence?



A new approach to the treatment of chronic low back pain

- MJ Ongley, TA Dorman RG Klein et al Lancet 1987 DBRCT
- 81 patients average duration of pain 10 years
- 40 randomised to proliferant and 41 to saline control
- both groups received initial treatment of LA into sensitive soft tissues but proliferant group also got 50mg steroid and more LA

Ongley

Proliferant group given an HVT versus sham in control
 results: at 1,3, and 6 months disability and pain scores were significantly less in proliferant group (p = 0.001)

A DBRCT of dextrose-glycerinephenol for chronic LBP Klein Eek DeLong and Mooney 1993 J **Spinal Disorders** •79 patients with LBP >6 months randomised to either lidocaine +saline or lidocaine + P2G all had previous CT/MRI and SLR >70 degrees. Litigation/ compensation cases, hip OA, back surgery, radiculopathy excluded

## Klein

- All had initial evaluation of soft tissues with infiltration of LA and steroid into hyper irritable foci and HVT of SIJ and L/S All were advised to to do 30 standing forward flexions, 20 standing extensions, and walk a mile each day for 6 months after treatment
- all had 30 mls, 6 times, into ligs, fascia,capsules from L3-S1 and SIJ

## Klein

- Results:30/39 in proliferant group achieved greater than 50% reduction in pain and disability scores at 6 months and 21/40achieved same in control group (p=0.042)
- subgroup analysis showed that 8 in P2G and 5 in of controls were hypersensitive at initial evaluation

## Klein

• 5/8 and 3/5 failed to improve by 50% on pain and disability scores. Re analysis excluding this subgroup showed 19/35 controls and 27/31 P2G patients achieved more than 50% reduction in pain and disability. Pain grid scores significantly different and higher p values for pain and disability resulted

## Dechow, Davies, and Thompson Br J of Rheum 1999

- 74 patients from outpatient waiting list with chronic LBP randomised to 3 weekly injections of P2G (5ml) +5ml I% lidocaine or saline +LA
- average age 45 duration median 10 years
- radiculopathy, active litigation, obesity, comorbidity excluded but previous back surgery (11%) and hip arthritis not excluded. 39% on benefits and 50% unemployed
- More than 20 of the patients selected by the main investigator were deemed inappropriate for the trial by the operator (Davies) with greatest clinical experience of this treatment (personal communication)

#### Results

McGill short form pain q'naire, VAS pain drawing, MSPQ (somatic awareness), Modified Zung (depression), Oswestry disability, and Schobers spinal flexion outcome measures at baseline 1, 3, and 6 months post treatment no difference at any point ono placebo effect observed whatsoever

# Yelland and Bogduk RCT Spine 2003 (29)

- 110 subjects with chronic LBP average 14 years, disability 13-15 RM scale, VAS 5/10
- randomised to have a) repeated prolo using 20% glucose/ 0.2% lido according to Dhillon or b) saline and each group randomised to have either flexion/extension exercises or normal activity
- two by two factorial design blinded.
- All patients consumed zinc, manganese, hi dose vit C for first 6 months

#### results

At 12 months 46% of prolo and 36% of saline patients had obtained more than 50% pain reduction

- 41% exercise and 36% normal activity had obtained these results
- no statistically significant difference

 At 12 months proportions of patients with >50% redn. of disability: prolo 42%, saline 34% exercise 36%, normal activity 38%

#### Further reading

Efficacy of dextrose prolotherapy in elite male kicking sport athletes with groin pain. **Topol and Reeves Arch Phys. Med** Rehabil 86 April 2005 • 24 patients had on average 2.8 injections • 20/24 patients had no pain at follow up at an average time of follow up of 17 months

### M Cusi et al BJSM 2010;44:100-104

Use of prolotherapy in the sacroiliac joint
3 injections of hypertonic dextrose into the dorsal interosseous ligamnet under CT guidance in 25 patients, 6 wks apart
Duration of > 6mths symptoms, after a specific exercise programme of 3 mth for 'unstable SIJ'

Tests : SIJ glide test, post pelvic pain provocation test, ASLR, Gillett test

#### results

76% at 3 mths follow up were better on clinical score and 3 disability measures
 25% lost to follow up

## Metabolic disturbances identified by SPECT CT with a diagnosis of SIJ incompetence

*Purpose* To establish the sensitivity and specificity of cross-sectional scintigraphy [single photon emission computed tomography (SPECT)] combined with computed X-ray tomography (CT) in the detection of sacroiliac joint (SIJ) mechanical dysfunction and evaluate reproducibility of reporting.

*Methods* Patients with pelvic girdle pain either on the basis of peri-partum SIJ dysfunction or trauma were included. These patients were imaged with bone scintigraphy with hybrid imaging with SPECT/CT.

*Results* The study group comprised 100 patients (72 females, 28 males). Trauma accounted for 52 % and the remainder were patients with peri-partum pain. Average age was 43 years and average length of history was >2 years. The major finding was increased uptake in the upper SIJ and posterior soft-tissues/ligaments. Hybrid imaging had a sensitivity of 95 % and specificity of 99 %. Positive predictive value was 99 % and negative predictive value 94 %. Power of the test was 1.0. Reproducibility of the test was good with kappa values of 0.85.

## European Spine Journal 2013 M Cusi



#### Coronal and axial views



#### Fibro proliferants

 'Regenerative tissue therapy'
 Calundruccio J Hand Surg 2003 autologous blood for lat epicondylitis
 Altay et al Clin Orthop 2002 May 398 traumatic needling for tennis elbow

- A 32 year old mother suffering chronic LBP since childbirth now 2 years later and failed to respond to stabilisation physiotherapy adequately. Serola belt helps.
- Sacroiliac joint laxity and positive pain provocation tests for SIJ dysfunction
- After 3 prolo injections pain free 2 months later and after 5 years and second child recently returned for a further course

- A 32 year old rugby playing carpenter, captain of local first team, complaining of recurrent episodes of cervical pain radiating to left arm over 2 seasons since trauma. Plays loose prop.
- Exam reveals asymmetric restriction of cervical spine motion, positive foraminal closing test, negative neurology. Tender C6-7 midline. Xrays show modest disc degeneration lower 2 levels
- Treatment with 3 sclerosant injections a week apart enabled to return to play for further 4 seasons



- A 42 year old mother of 3 with persistent L buttock pain and radiating sharp pains into L leg since leaping over a style 18 months ago. No lasting response to chiropractic or physio.
- Piriformis tight and tender, spine hypermobile generally but no specific indication of SIJ pain source or root irritation
- Required 3 local anaesthetic plus steroid injections into piriformis insertion over 5 months and still the problem tended to relapse.
- Prolotherapy to SIJ ligaments allowed full resolution without recurrence

## Clinical algorithm for LBP

trial of conservative therapy first and exclude yellow flags, stenosis, radicular pain

Proceed to interventions only if level of pain (VAS >5) and disability warrant

Mechanical back pain requires an 'instability history'

- A 38 year old male jogger, slightly overweight suffering recurrent ankle sprains over many years
- Orthotics for hindfoot varus bilaterally and proprioceptive training failed to prevent ankles 'turning over' at least opportunity
- Exam showed lax lateral ligament complex with mild positive anterior drawer signs bilaterally
- A course of prolotherapy after 3 months enabled him to run safely and lose weight effectively



#### Clinical algorithm for chronic LBP



Regenerative tissue therapy for strained ligaments

#### Lumbar instability

Sacroiliac instability

Peripheral joint instability