

**Knee OA 2012 (Dextrose vs  
Exercise Crossover )**

- **Dumais R, Benoit C, Dumais A, Babin L, Bordage R, de Arcos C, Allard J, Bélanger M. Effect of Regenerative Injection Therapy on Function and Pain in Patients with Knee Osteoarthritis: A Randomized Crossover Study. Pain Med. 2012; 13(8):990-999.**

[ **Commentary by K. Dean Reeves, M.D. [www.DrReeves.com](http://www.DrReeves.com) ]**

The next level I study considered was published in the Journal of Pain Medicine and had a clear design of randomization, with randomized exercise control and a crossover design. There is no free pdf.

Here is the abstract: (The following two slides will summarize)

**OBJECTIVE:**

We assessed the effectiveness of regenerative injection therapy (RIT) to relieve pain and restore function in patients with knee osteoarthritis.

**DESIGN:**

Crossover study where participants were randomly assigned to receive exercise therapy for 32 weeks in combination with RIT on weeks 0, 4, 8, and 12 or RIT on weeks 20, 24, 28, and 32.

**PATIENTS:**

Thirty-six patients with chronic knee osteoarthritis.

**INTERVENTIONS:**

RIT, which is made up of injections of 1 cc of 15% dextrose 0.6% lidocaine in the collateral ligaments and a 5 cc injection of 20% dextrose 0.5% lidocaine inside the knee joint.

**OUTCOME MEASURES:**

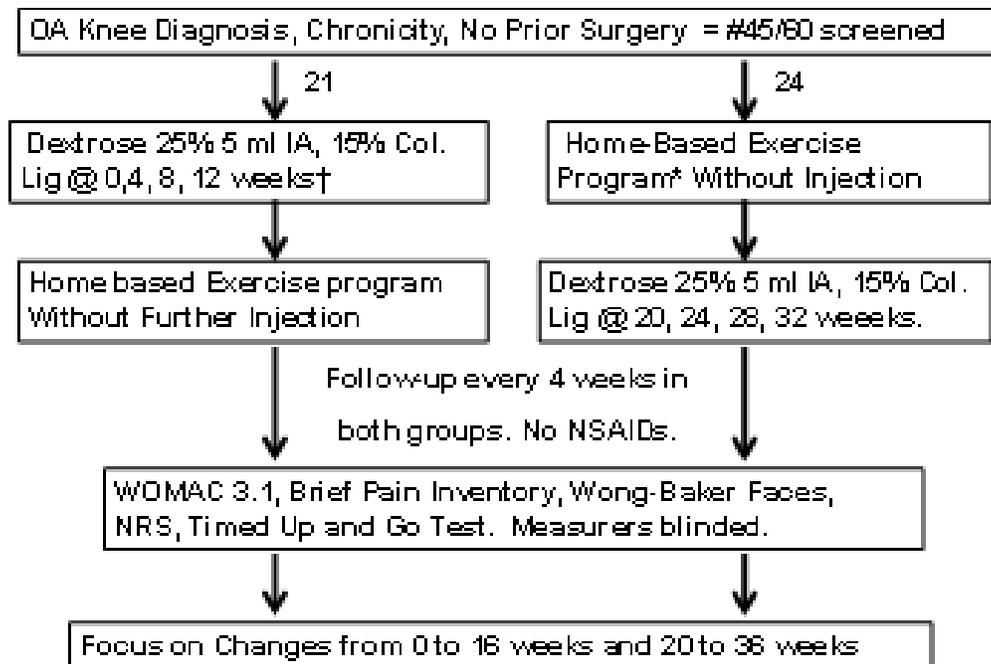
The primary outcome was the Western Ontario and McMaster Universities Osteoarthritis Index of severity of osteoarthrosis symptoms (WOMAC) score (range: 0-96).

**RESULTS:**

Following 16 weeks of follow-up, the participants assigned to RIT presented a significant reduction of their osteoarthritis symptoms (mean  $\pm$  standard deviation:  $-21.8 \pm 12.5$ ,  $P < 0.001$ ). WOMAC scores in this group did not change further during the last 16 weeks of follow-up, when the participants received exercise therapy only ( $-1.2 \pm 10.7$ ,  $P = 0.65$ ). WOMAC scores in the first 16 weeks did not change significantly among the participants receiving exercise therapy only during this period ( $-6.1 \pm 13.9$ ,  $P = 0.11$ ). There was a significant decrease in this groups' WOMAC scores during the last 16 weeks when the participants received RIT ( $-9.3 \pm 11.4$ ,  $P = 0.006$ ). After 36 weeks, WOMAC scores improved in both groups by 47.3% and 36.2%. The improvement attributable to RIT alone corresponds to a 11.9-point (or 29.5%) decrease in WOMAC scores.

**CONCLUSIONS:**

The use of RIT is associated with a marked reduction in symptoms, which was sustained for over 24 weeks.



Subjects either received dextrose injection or a home-based program exercise program.

Those that received dextrose injection received 5 ml of 25% dextrose in the knee via a knee-bent approach without ultrasound guidance and 15% dextrose into collateral ligaments in each side. This was given every 4 weeks up to 4 treatments)

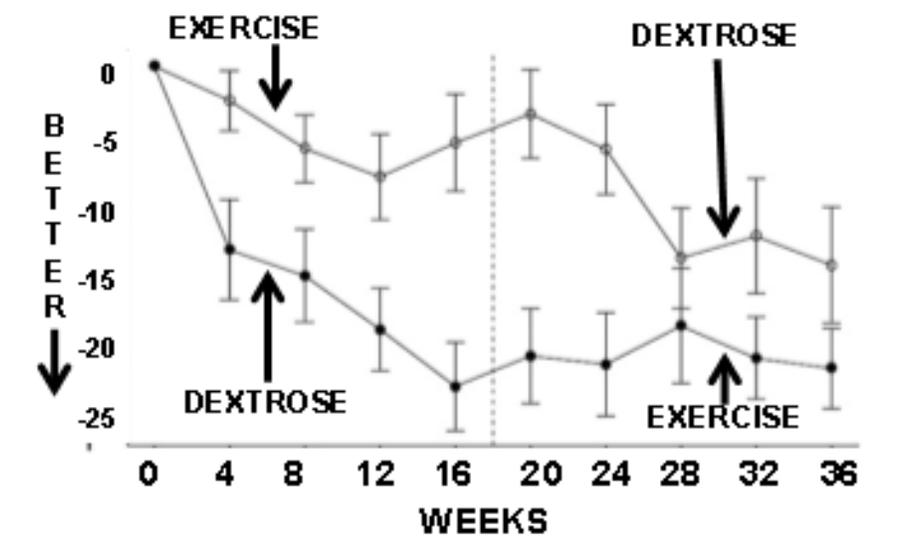
Those assigned randomly to a home based exercise program received four strengthening exercises: (Isometric quads, leg extension exercises with quadriceps roll, straight leg raise, and sitting end range knee extension; three sets of 10 reps daily) This was via instruction by a senior physiotherapist, who reviewed exercises every 4 weeks. The same physical therapist was used throughout the study.

The primary measuring tool was the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) which has a 24 items with 5 points each. Five items are for pain, 2 are for stiffness and 17 are function related.

A Brief Pain Inventory (Short Form) was also used, as well as other secondary measures.

Everyone stayed in their groups for 12 weeks (4 dextrose injections). They then were crossed over to start the other treatment at 20 weeks.

## WOMAC Total Score Change Over Time



The WOMAC score dropped quickly (improved) in those receiving dextrose, and held improvement during the crossover into exercise.

The exercise group improved minimally and then improved rapidly after dextrose injection began such that differences between the groups became much less after three injections of dextrose.

	<b>16 week Between Group Difference (P value)</b>	<b>36 week Difference</b>	<b>Overall Crossover Design Test</b>
<b>WOMAC total</b>	<b>.002</b>	<b>.046</b>	<b>&lt;.001</b>
<b>WOMAC pain</b>	<b>.01</b>	<b>.28</b>	<b>.02</b>
<b>WOMAC stiffness</b>	<b>.02</b>	<b>.01</b>	<b>.002</b>
<b>WOMAC function</b>	<b>.0044</b>	<b>.06</b>	<b>.001</b>

This is the significance of differences on the major measure (WOMAC). The second column shows that most measures were no longer significantly different after each group had the opportunity to receive dextrose. The third column takes into account the information from both portions of the crossover, showing clearly significant differences between the treatments.

## **Data Collection Weaknesses**

- **Group one: 1 dropped out from injection group due to no benefit and 2 due to complete benefit. 18/21 analyzed.**
- **Group two: 3 did not participate once assigned to exercise group , 2 were lost to follow-up and 1 had pain after injections and dropped out. (18/24 analyzed)**
- **Overall these are unlikely to have affected conclusions or significance other than by reducing power in analysis.**

There was some weakness in capture of data but these should not have affected outcome or conclusions significantly.

### Knee Crossover Strengths/Weaknesses

<b>REC</b>	<b>2012 Knee OA Crossover (Dumais et al)</b>	
<b>Good Size</b>	<b>Moderate Size</b>	
<b>Sig Clinically</b>	<b>Very much so.</b>	
<b>Sig Statistically</b>	<b>Yes, unequivocally.</b>	
<b>Adequate F-UP</b>	<b>Limited</b>	
<b>Data Capture</b>	<b>Limited</b>	
<b>Accepted Tool</b>	<b>Excellent tool choice</b>	
<b>Simple</b>	<b>Yes</b>	
<b>Inexpensive</b>	<b>Yes</b>	
<b>Min invasive</b>	<b>Yes</b>	
<b>Grade</b>	<b>Ib (Single study)</b>	

This is a summary of the strengths of this study, with size somewhat small, limited time of follow up to less than 1 year and some limitation of data capture. Since exercise has clearly been shown to be beneficial in knee osteoarthritis, and prolotherapy with dextrose was clinically significantly better than exercise, this is a strong support for prolotherapy.

This treatment would be practical for primary care doctors to perform since it involved injection inside the knee and over the collateral ligaments on each side.