Summary Report: Treatment of Symptomatic Knee Osteoarthritis Without Surgery

"Intra-Articular Hyalgan in Tandem with Physical Therapy Program for the Treatment of Symptomatic Knee Osteoarthritis"

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HYALGAN FOR OSTEOARTHRITIS OF THE KNEE

The most widely used current medical therapies as treatment for painful osteoarthritis (OA) including nonsteroidal anti-inflammatory drugs (NSAID), pain medications, and injected corticosteroids only treat the immediate symptoms, but have no lasting effects[1].

Over the past two decades, the research into symptomatic slow acting drugs in osteoarthritis (SYSADOA) has shown the promise of substances which have long term, yet delayed, and greater effects than NSAIDs and other widespread immediate symptom relievers [2].

The use of intra-articular visco-supplementation like hyaluronic acid (HA), a co-polymer of N-acetylglucosamine and glucuronic acid, has been shown to have a positive long term effect on osteoarthritis symptoms [3].

Hyaluronic acid is naturally found within the body in joint synovial fluid [4].

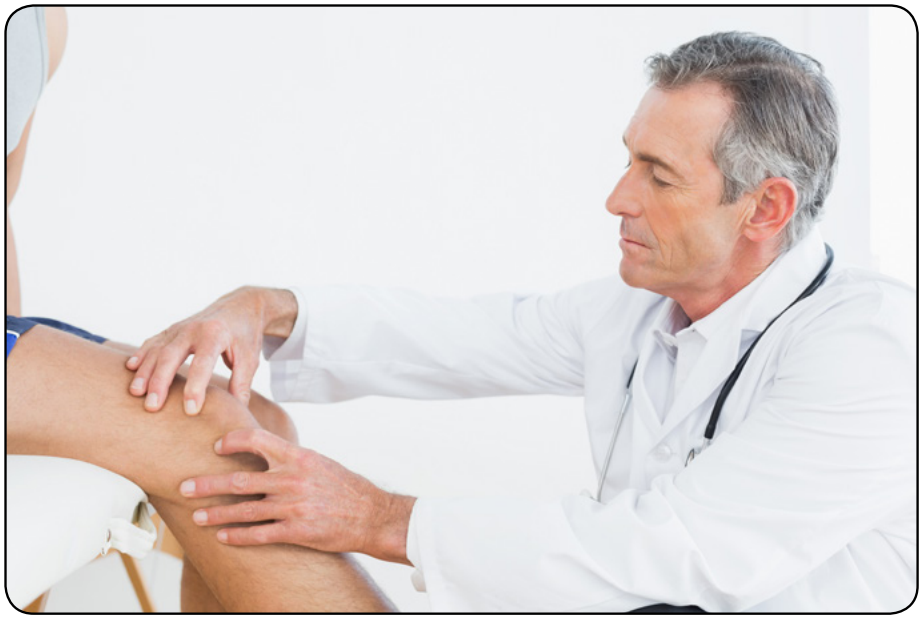
We studied the use of Hyalgan (Fidia S.p.A., Italy), a solution of hyaluronic acid which is extracted from the rooster comb and purified to a molecular weight between 500 and 730 kiloDaltons (kDa), intra-articularly injected in an 8 week proprietary program for the treatment of chronic symptomatic osteo-arthritis of the knee.

5-WEEK NON-SURGICAL KNEE PROGRAM

The program consists of a series of 5 (20mg/2mL) intra-articular Hyalgan injections into the knee synovial joint, once a week, using fluoroscopic guidance to ensure and document successful injection location.

The program also includes mandatory physical therapy 3 times a week as well as the use of an osteoarthritis unloading brace for at least 2 hours after injection.

Injections occur over a 5-week period that begins with an initial patient visit during which Sarapin, an analgesic, or a corticosteroid (Kenalog or Cortisone) can be used to stabilize painful knees prior to physical therapy treatment. A total of 207 knees (53.9%) received an intra-articular injection of either Sarapin or a corticosteroid no less than two days prior to the first Hyalgan injection, administered by the physicians for immediate pain relief (**Table 1**).



Subjects were not included in the study if they did not complete all steps of the program, including all physical therapy sessions and all Hyalgan visco-supplementation shots. The study comprised random patients enrolled in the program at Physicians Rehabilitation at three separate locations in Fort Myers, Naples, and Port Charlotte, Florida. The subjects were asked to report their own pain on a scale of 0-10 (0= no pain, 10= maximum pain) prior to the start of the program (week 1) and upon discharge after full completion of the entire program (week 8). Only subjects who had no change in the use of NSAIDs and other medications for symptom relief during the study period were considered.

PHYSICAL THERAPY IS A KEY COMPONENT

There were a total of 384 knee injection programs studied. Both right (52.9%; N=203) and left (47.1%; N=181) knees were included in the study. The mean subject age was 74.9 years (SD± 8.38) with an age range between 43 and 93 years. The gender distribution consisted of 182 (47.4%) females of average age 74.5 years and 202 (52.6%) males of average age 75.3 years. (**Table 2**)

Researchers found that the use of the physical therapy regimen along with the visco-supplementation Hyalgan injection allowed for almost all, 99.998% (383 of 384), of knee programs were able to achieve some level of relief in pain.

Table 3 breaks down the phenomenal results to a categorical assessment compared between baseline/preinjection pain (week 1) and pain at program completion (week 8). Each patient's personal pain change was calculated and put into groups of either no pain decrease, 50% or greater pain decrease, and less than 50% pain decrease. Of the 384 subjects studied, 356 (92.7%) achieved 50% or greater decrease in pain, 28 (7.29%) had less than 50% pain decrease, and only 1 (<0.3%) had no pain decrease (Figure 1 and 2). We also found the average percentage of decrease in pain to be 76.98% (SD± 21.2%). Furthermore, the standardized mean difference (SMD) from baseline pain to pain at program completion was 6.05 (SD± 2.05).

FIGURE 1

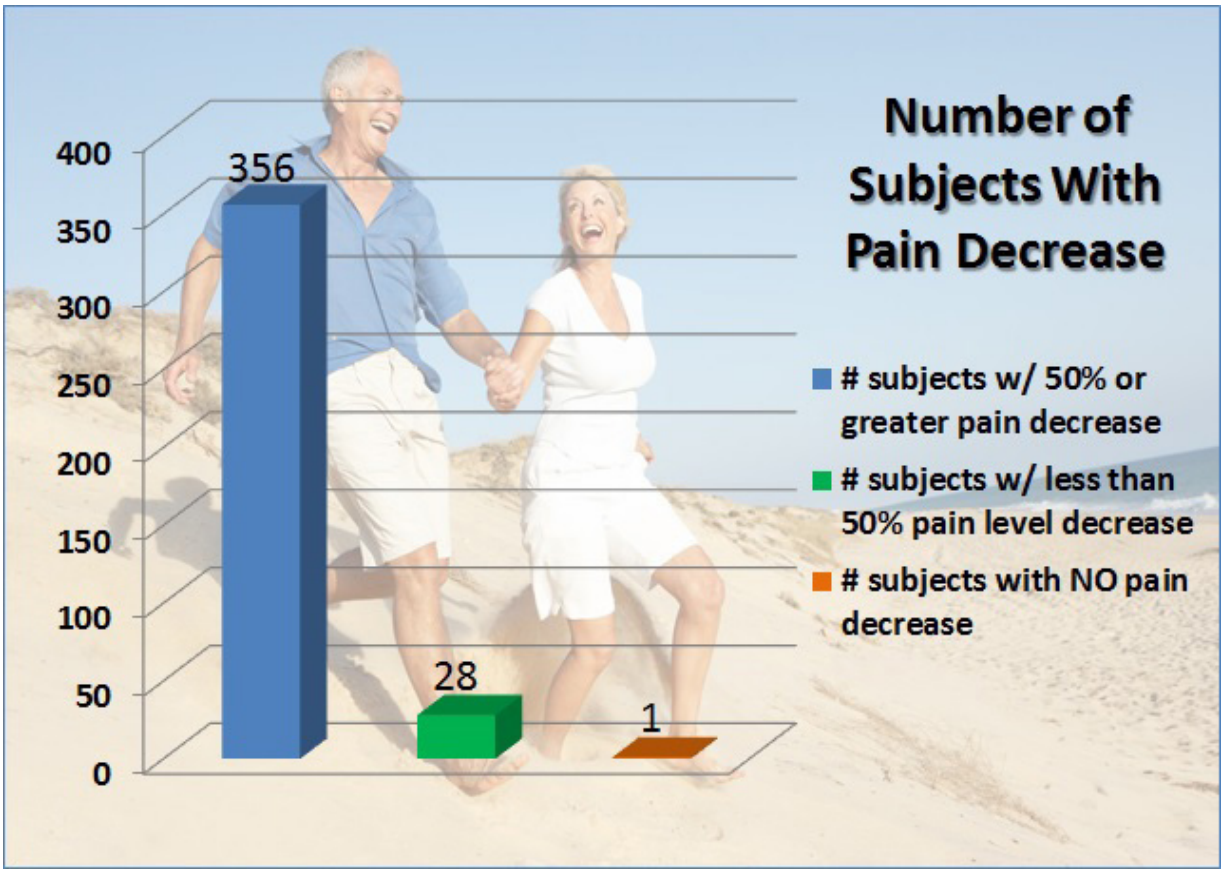


FIGURE 2

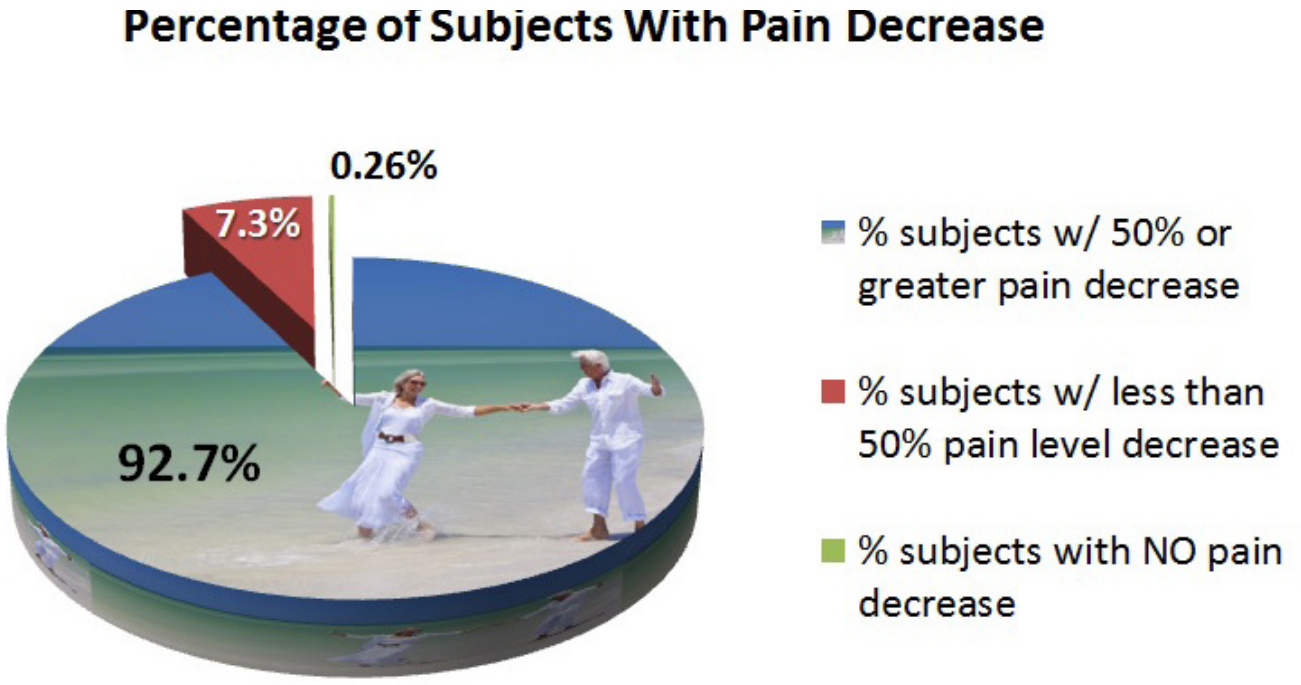


Table 1: Pre-administration of Analgesic and Corticosteriod Shots

	#	%
None	177	46.1
Sarapin	198	51.6
Corticosteroid	9	2.3
TOTAL	**384**	**100**

Table 2: Demographic Characteristics of All Randomized Subjects

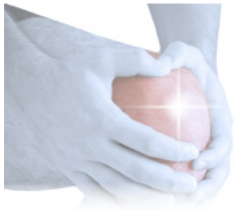
BY AGE (years)	
Mean	74.9
SD	8.38
Range	43-93

BY GENDER					
	#	%	Average	SD	Range
Female	182	47.4	74.5	8.05	46-93
Male	202	52.6	75.3	8.66	43-92

SD=Standard Deviation

Table 3: Categorical Assessments of Pain Breakdown:
Level of Pain at Baseline (week 1) and Completion of Program/ Discharge (week 8)

Pain	Baseline (week 1)	%	Completion (week 8)	%
0-0.9	**0**	0	**119**	30.9
1-1.9	**0**	0	**83**	21.6
2-2.9	**1**	0.26	**71**	18.5
3-3.9	**3**	0.78	**55**	14.3
4-4.9	**7**	1.82	**31**	8.07
5-5.9	**29**	7.55	**15**	3.9
6-6.9	**35**	9.11	**2**	0.52
7-7.9	**64**	16.7	**2**	0.52
8-8.9	**129**	33.6	**5**	1.3
9-9.9	**48**	12.5	**0**	0
10	**68**	17.7	**1**	0.26
Total	**384**		**384**	



WORKS CITED OR CONSULTED

- Study by Nicholas Ghanem, M.Sc.

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2] Lequesne M. Symptomatic slow acting drugs for osteoarthritis: A novel therapeutic concept? Rev. Rheum. 1994; 61 (2): 69---73.

3] Altman R, Moskowitz R. Intraarticular Sodium hyaluronate (Hyalgan) in the treatment of patients with osteoarthritis of the knee: a randomized clinical trial. J. Rheumatol. 1998; 25:2203---12 [Publihed erratum appears in J Rheumatol 1999;26:1216]

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PHYSICIANS REHABILITATION
SPECIALIZING IN BACK & NECK PAIN

Ft Myers: 6150 Diamond Centre Court, Bldg.100
Naples: 2828 Tamiami Trail North
Port Charlotte : 4369 Tamiami Trail, 2nd Floor
Sarasota : 3801 Bee Ridge Road, Unit #3