Post-hoc Analysis of Individual Questions from the Australian/Canadian Osteoarthritis Hand Index from a Randomized, Double-blind, Placebo-controlled Trial of Patients with Hand OA

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Background

Hand osteoarthritis (OA) is a frequently occurring form of OA characterized by symptoms including joint pain, stiffness, and swelling which affect performance of activities of daily living. The Australian/Canadian Osteoarthritis Hand Index (AUSCAN) is a key functional survey for hand OA, consisting of 15 questions organized into three subscales: pain, stiffness, and physical function.¹ While AUSCAN results are typically reported as a total index and/or subscale scores, the individual questions are more granular endpoints which are relevant to patients' daily activities such as getting dressed, turning doorknobs and faucets, and cooking. The purpose of this post-hoc analysis was to evaluate the scores from the individual AUSCAN questions from an 8-week randomized, double-blind, placebo-controlled trial of diclofenac sodium 1% gel (DSG) vs vehicle in the treatment of hand OA (Altman RD, et al. J Rheumatol 2009;36:1991-9).²

Methods

Patients diagnosed with hand OA in the dominant hand were randomly assigned DSG (n = 198) or vehicle (n = 187) and applied 2 g to each hand 4 times daily for 8 weeks. Vehicle was identical to DSG except for the absence of diclofenac sodium. AUSCAN questions were scored using a scale of 0 (no pain/stiffness/difficulty)-100 (extreme pain/stiffness/difficulty) at baseline and at weeks 1, 2, 4, 6 and 8. Mean scores for each question were assessed and compared between treatments at each timepoint using Analysis of Covariance (ANCOVA) with baseline as a covariate in the model and with no multiplicity correction.

Results

DSG demonstrated efficacy with reduction of pain subscale question scores at week 6 by 42%-44% (33%-35% for vehicle), stiffness scores by 42% (30% for vehicle) and physical function subscale scores by 39%-45% (27%-33% for vehicle). Statistically significant differences favoring DSG over vehicle were observed at weeks 4 and 6 (the primary endpoints) in all categories and at week 8 in the stiffness and physical function questions. Specifically, the questions with the greatest separation from vehicle at week 6 involved pain when turning and squeezing objects, stiffness upon wakening, difficulty turning doorknobs and faucets, and difficulty getting dressed, all of which are important components of hand functionality in daily living. Questions that did not reach statistical significance demonstrated a trend favoring DSG.

Conclusion

The results from this analysis show that the individual AUSCAN index question scores for DSG reach statistical significance vs vehicle at week 4 and last through week 8. The DSG scores at week 6 demonstrate a 39%-45% improvement from baseline in performing daily activities including turning objects such as doorknobs and faucets, getting dressed, and cooking compared to 27%-35% reductions from baseline for vehicle. These endpoints may be more meaningful to patients than the subscale scores of pain, stiffness and physical function, and may provide healthcare providers better ways to communicate the benefit of using DSG to treat the symptoms of hand OA.

2 AUSCAN Questions

Pain

How much pain do you have in your hand

• At rest?

- When turning objects?
- When gripping objects?
- When lifting objects?
- When squeezing objects?

Stiffness

How severe is your stiffness in your hand

- Upon first wakening in the morning?
- **Physical Function** How much difficulty do you have When turning taps/faucets on? : While fastening jewelry? • When turning a round doorknob : • While opening a new jar? or handle? objects? • When carrying a full pot with • While doing up buttons? your hand?
 - When wringing out wash clothes?

 While peeling vegetables/fruits? • When picking up large, heavy

	Baseline			Week 4				Week 6			
Question	DSG Mean (SD) N=198	V Mean (SD) N=187		DSG Mean (SD)	V Mean (SD)		p	DSG Mean (SD)	V Mean (SD)	Δ	p
Pain Subscale: How much pain do you have in your hand											
at rest?	51.99 (23.339)	52.28 (22.168)	-0.29	32.32 (26.528)	35.12 (26.522)	-3.81	0.1470	29.30 (27.097)	34.37 (26.894)	-5.07	0.0478
when gripping objects?	68.08 (19.019)	68.05 (17.718)	0.03	40.52 (28.211)	45.83 (27.297)	-5.31	0.0327	38.44 (28.144)	44.29 (27.716)	-5.85	0.0188
when lifting objects?	67.61 (20.290)	69.07 (17,895)	-1.46	41.24 (28.882)	48.39 (27.730)	-7.15	0.0136	38.88 (25.669)	45.53 (27.293)	-6.65	0.0231
when turning objects?	71.30 (18.661)	71.46 (17.779)	-0.16	42.59 (28.385)	50.54 (25.183)	-7.95	0.0026	39.85 (29.276)	47.19 (29.264)	-7.34	0.0054
when squeezing objects?	72.69 (18.766)	72.90 (18.305)	-0.21	44.15 (29.216)	51.70 (28.843)	-7.55	0.0049	40.96 (26.738)	48.96 (28.945)	-8.00	0.0028
Stiffness Subscale: How severe is your stiffness in your hand											
after first wakening in the morning?	66.03 (22.779)	66.62 (23.888)	-0.59	40.96 (28.639)	48.40 (29.153)	-7.44	0.0066	38.36 (28.412)	46.82 (30.491)	-8.46	0.0019
Physical Function Subscale: How much difficulty do you have											
when turning taps/ faucets on?	56.70 (25.698)	54.73 (24.292)	1.97	34.92 (27.097)	42.41 (28.046)	-7.49	0.0009	31.94 (27.074)	40.08 (28.000)	-8.14	0.0004
when turning a round doorknob or handle?	61.70 (22.953)	58.48 (23.168)	3.22	36.95 (27.891)	44.37 (28.119)	-7.42	0.0002	34.60 (28.324)	42.37 (28.326)	-7.77	0.0001
while doing up buttons?	63.33 (24.136)	61.44 (23.939)	1.89	39.17 (28.935)	46.74 (29.075)	-7.57	0.0009	34.55 (28.444)	43.88 (29.985)	-9.33	<0.0001
while fastening jewelry?	66.02 (22.349)	64.56 (22.703)	1.46	40.53 (29.557)	47.70 (28.541)	-7.17	0.0022	36.53 (29.837)	45.17 (29.510)	-8.64	0.0003
while opening a new jar?	76.23 (18.929)	76.26 (18.623)	-0.03	49.53 (29.007)	55.11 (29.473)	-5.58	0.0349	46.08 (30.357)	52.96 (29.188)	-6.88	0.0093
when carrying a full pot with your hand?	74.54 (19.442)	73.91 (18.637)	0.63	47.97 (29.083)	53.40 (29.017)	-5.43	0.0249	45.63 (30.549)	51.88 (29.169)	-6.25	0.0104
while peeling vegetables/fruits?	65.86 (22.890)	65.07 (20.219)	0.79	41.27 (28.114)	47.27 (29.066)	-6.00	0.0107	38.08 (28.594)	45.26 (29.304)	-7.18	0.0026
when picking up large heavy objects?	73.27 (20.347)	72.83 (18.325)	0.44	47.72 (29.529)	53.40 (28.672)	-5.68	0.0212	44.45 (30.456)	51.26 (29.011)	-6.81	0.0062
when wringing out wash clothes?	73.27 (20.127)	73.21 (18.614)	0.06	45.74 (29.295)	52.21 (30.074)	-6.47	0.0141	43.03 (30.318)	49.37 (30.071)	-6.34	0.0160

DSG, diclofenac sodium gel 1%; V, vehicle; Δ , difference (DSG – V); p, p-value; **SD**, standard deviation **0** = no pain/stiffness/difficulty, **100** = severe pain/stiffness/difficulty

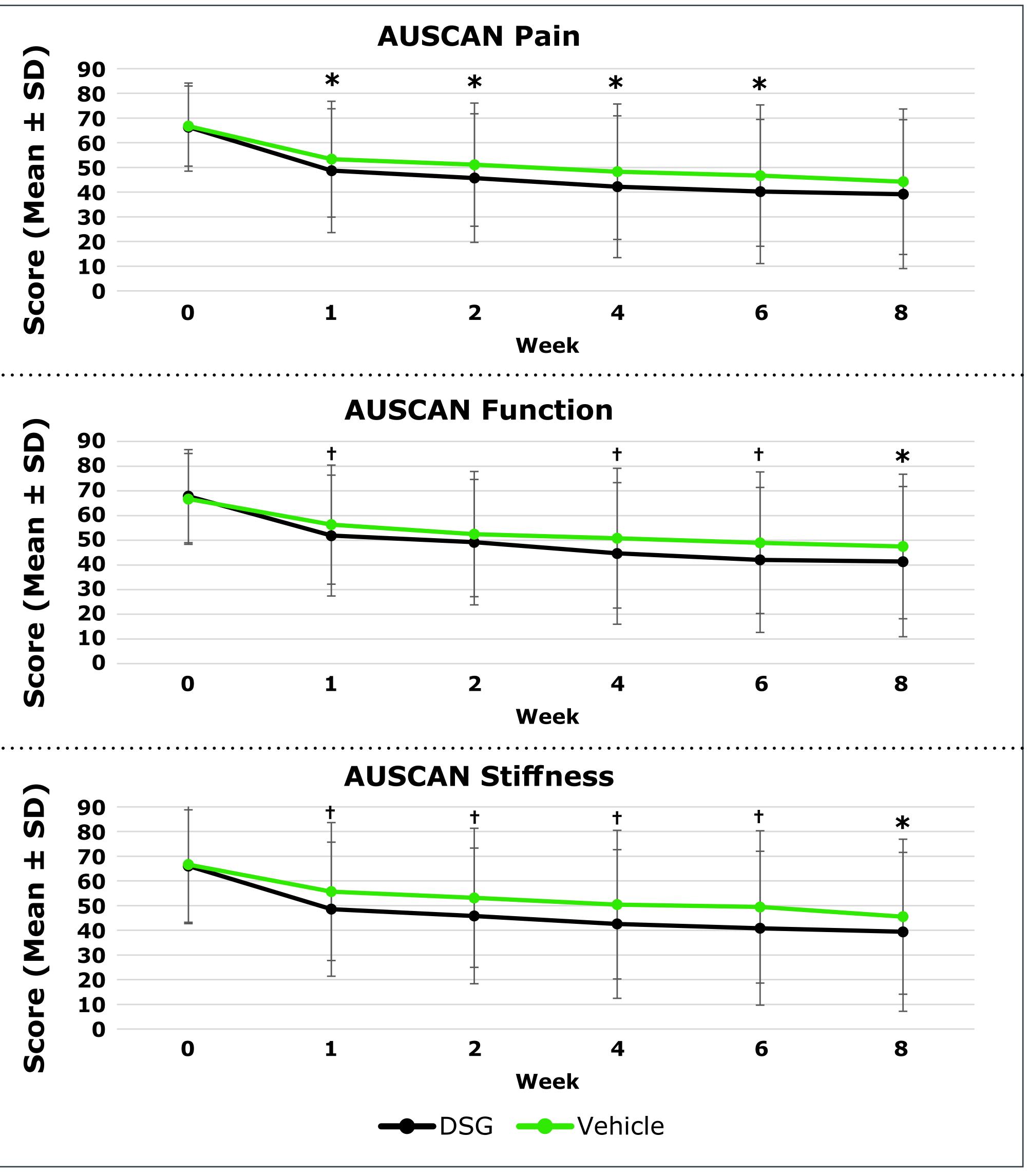


Figure 1. Time profile for AUSCAN Pain, Function and Stiffness subscales. **SD**, standard deviation; *p < 0.05; †p < 0.01

- DSG demonstrated efficacy with reduction of pain subscale question scores at week 6 by 42-44% (33-35% for vehicle) stiffness scores by 42% (30% for vehicle) and physical function subscale scores by 39-45% (27-33% for vehicle).
- Statistically significant differences favoring DSG over vehicle were observed at weeks 4 and 6 (primary endpoints) in all categories.
- Questions with the greatest separation from vehicle at week 6 involved pain when turning and squeezing objects, stiffness upon wakening, difficulty turning doorknobs and faucets, and difficulty getting dressed, all of which are important components of hand functionality in daily living.
- Individual question scores mirrored the time profiles for the AUSCAN subscale scores for pain, stiffness and function.

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Conclusions

- Individual AUSCAN index question scores for DSG reach statistical significance vs vehicle at week 4 and last through week 8.
- The DSG scores at week 6 demonstrate a 39-45% improvement from baseline in performing daily activities including turning objects such as doorknobs and faucets, getting dressed, and cooking compared to 27-35% reductions from baseline for vehicle.
- The individual AUSCAN questions are more meaningful endpoints to patients than the subscale scores of pain, stiffness, and physical function and may provide healthcare providers better ways to communicate the benefit of using DSG to treat the symptoms of hand OA.
- These results demonstrate the clinically significant benefits diclofenac sodium gel 1% offers in improving the performance of daily activities that contribute to quality of life.

References

- 1. Bellamy N, Campbell J, Haraoui B, Buchbinder R, Hobby K, Roth JH, et al. Dimensionality and clinical importance of pain and disability in hand osteoarthritis: development of the Australian/Canadian (AUSCAN) Osteoarthritis Hand Index. Osteoarthritis Cartilage 2002;10(11):855-62.
- 2. Altman RD, Dreiser R-L, Fisher CL, Chase WF, Dreher DS and Zacher J. Diclofenac sodium gel in patients with primary hand osteoarthritis: a randomized, double-blind, placebo-controlled trial. J Rheumatol 2009;36:1991-9.