

# Clinical effect of intradiscal application of allogeneic mesenchymal stem cells derived from umbilical cord Wharton's jelly (WJ-MSC) in adults with degenerative disc disease (DDD) treated at bioXcellerator, Medellín, Colombia.

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## Introduction

Based on preclinical and clinical studies, mesenchymal stem cell (MSC) therapy could improve Degenerative Disc Disease (DDD), by modulating the inflammatory response and promoting the natural repair process of the intervertebral disc matrix.

## Objective

The aim of this study was to describe the clinical effect of intradiscal cell therapy with allogeneic Wharton's jelly stem cells from umbilical cord (WJ-MSC) in DDD patients.

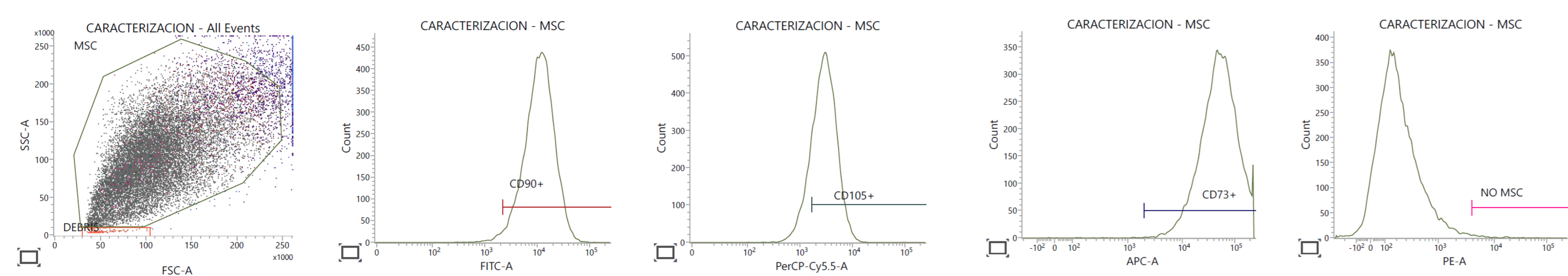
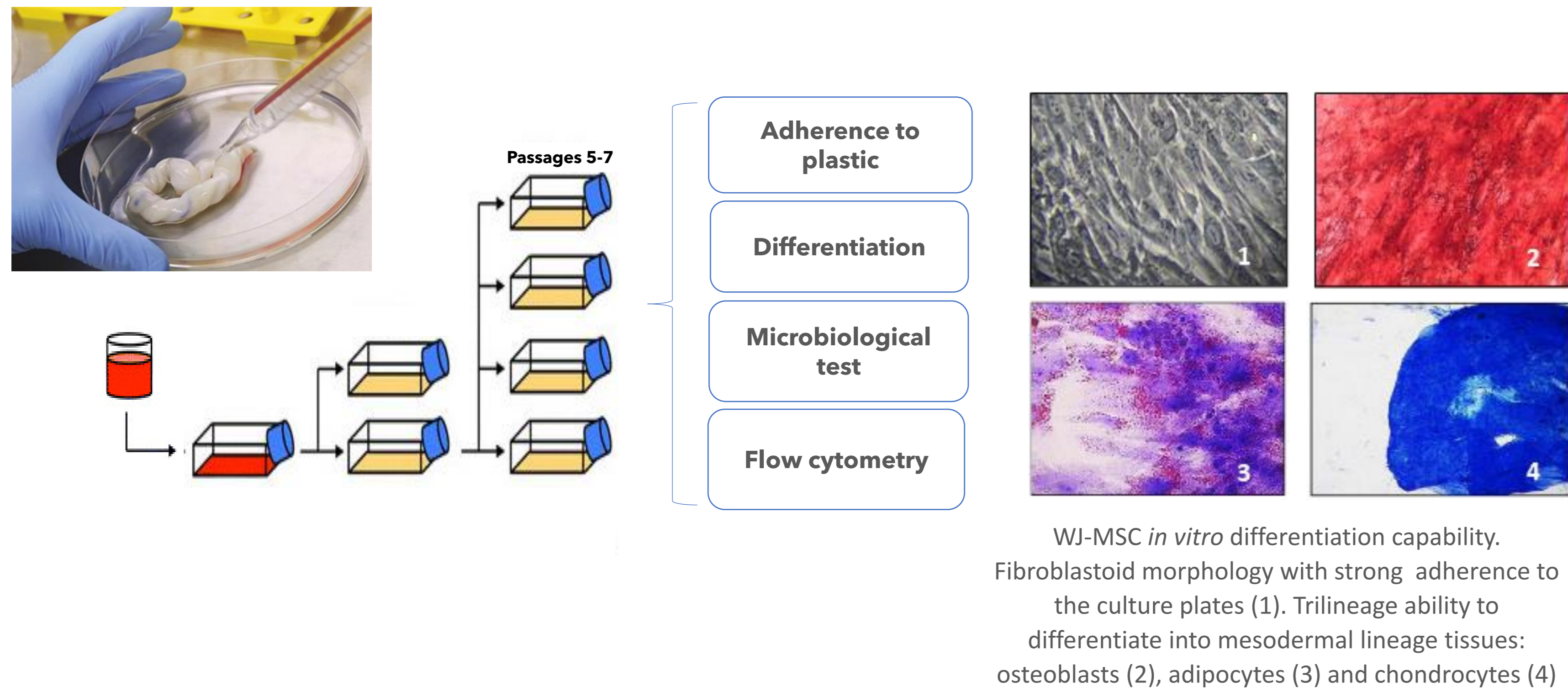
## Materials and methods

A retrospective cohort was followed. Clinical outcomes measures included: Short Form-12 questionnaire, Pain Visual Analog Scale (VAS), Oswestry disability Index (ODI), Neck Disability Index (NDI).

**In vitro:** WJ-MSC were obtained using the explant method and expanded until passage 7. Cell-markers expression, *in vitro* differentiation to mesodermal lineage and microbiological tests were conducted.

**In vivo:** Treatment protocol included a single intradiscal dose of  $5 \times 10^6$ /mL cells per disc of WJ-MSC. Follow-ups were at pretherapy time and 3, 6, 12 months after intradiscal application for every patient. An ethics committee approved the research protocol and the patients signed informed consent.

## In vitro results: Isolation and characterization of WJ-MSC



WJ-MSC characterization by flow cytometry. Expression of CD105, CD73 and CD90 was over 84% and negative markers CD45, CD34, CD11b, CD19 and HLA-DR expression was less than 1%

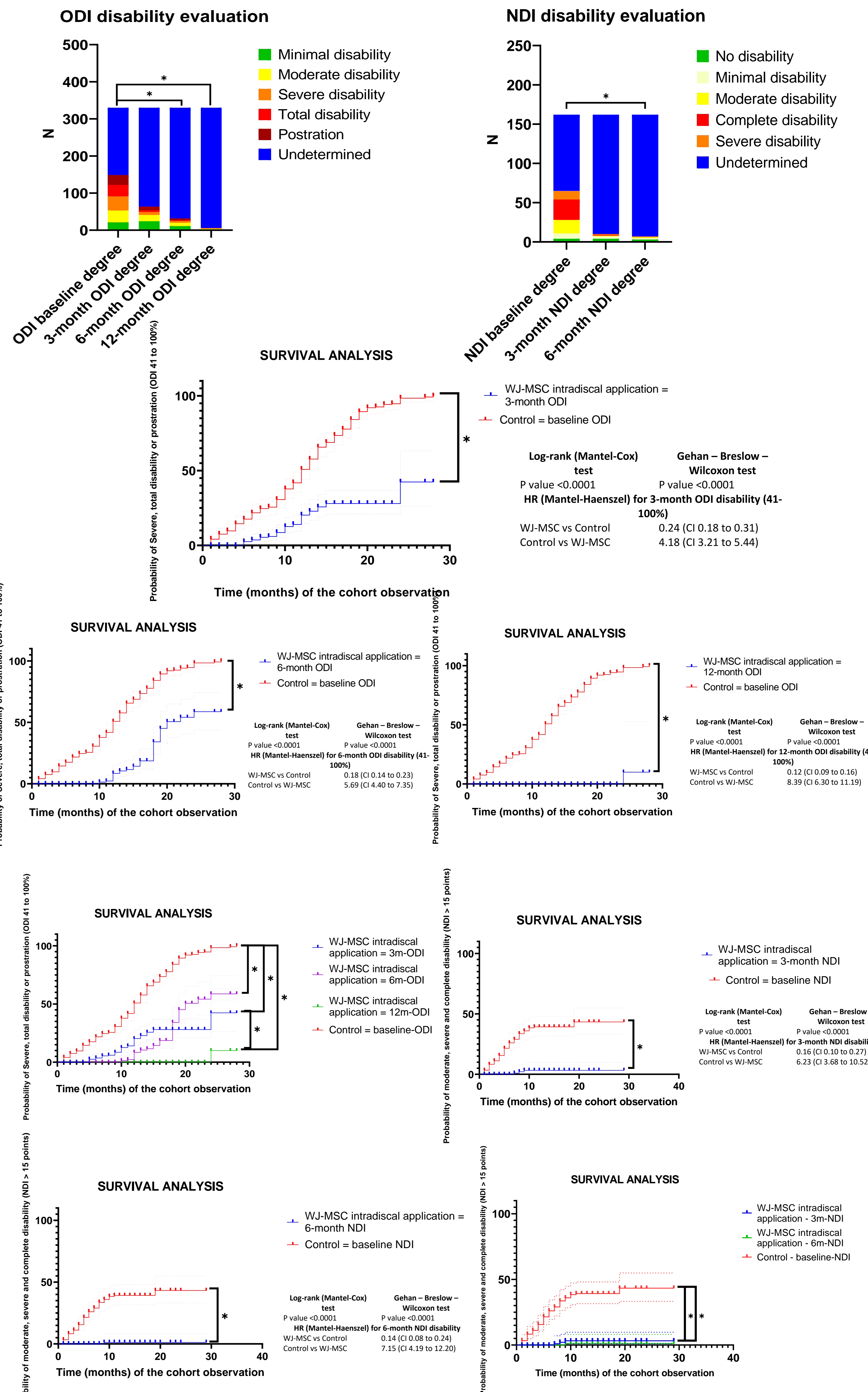
## In vivo results: Safety and efficacy

- ✓ A total of 330 patients were included (September/2020-September/2022). Female (n=46, 13.9%), Male (n=284, 86.1%).
- ✓ Countries: United States (n= 266, 80.6%), Canada (n=18, 5.5%), Other countries (13.9%).
- ✓ Cervical DDD= 162 (49.1%), Toracic DDD= 60 (18.2%), Lumbar DDD= 254 (77%), Sacral DDD= 208 (63%).

Descriptives	Age	Years from DDD diagnostic	Total time (months) from WJMS application to present	VAS (pain evaluation)	BMI	Baseline VAS score	3-month VAS score	6-month VAS score	12-month VAS score	ODI baseline score	3-month ODI score	6-month ODI score	12-month ODI score	NDI baseline score	3-month NDI score	6-month NDI score
N	330	330	330	330	188	153	64	32	6	149	64	32	6	65	10	7
Mean	47.3	14.0	10.4	5.38	27.7	5.03	3.78	3.00	2.50	55.0	40.1	39.3	36.0	30.7	14.2	10.9
Median	45.0	14.0	10.3	5.00	27.3	5	3.00	2.00	2.00	52.0	32.0	30.0	40.0	30	7.00	8
Standard deviation	12.5	7.36	6.79	1.73	5.40	2.39	2.68	2.49	1.97	30.9	34.1	33.9	21.2	17.1	20.5	10.3
IQR	18.0	0.00	11.4	1.00	6.73	4.00	4.25	3.25	0.75	40.0	45.0	42.0	12.0	26.0	15.0	14.0
Minimum	21	1	0.00	0	17.3	0	0	0	0	0.00	0.00	0.00	0.00	0	0	0
Maximum	85	65	28.8	10	46.0	10	10	9	6	140	128	116	64.0	70	66	28

## In vivo results: Safety and efficacy

- ✓ Previous surgery (n= 79, 23.9%), Fusion/Fixation (n= 22, 6.7%), Disc replacement (n= 5, 1.5%), Laminectomy (n= 7, 2.1%), Microdisectomy/Disectomy (n= 20, 6.1%), Rhizotomy/Others (n= 2, 0.6%).
- ✓ Radiculopathy was present in 168 patients (50.9%) and Medullary narrow canal in 103 (31.2%).
- ✓ MODIC changes (n= 133, 40.3%).
- ✓ Pfirrmann degree of discopathy (degree 1= 4, 1.2%, degree 2= 6, 1.8%, degree 3= 109, 33%, degree 4= 60, 18.2%, degree 5= 13, 3.9%, undetermined degree= 138, 41.8%).
- ✓ Physical therapy regimen (n= 42, 12.7%).



## Conclusion

WJ-MSCs meet the criteria of the International Society for Stem Cell Therapy (ISCT) and the results obtained suggest clinical evidence of regenerative capacity on spine intradiscal matrix through clinical important changes in pain and disability when treating patients with DDD. No serious adverse events were reported.

## Bibliography

Main BJ, Maffulli N, Valk JA, Rodriguez HC, Gupta M, El-Amin SF 3rd, Gupta A. Umbilical Cord-Derived Wharton's Jelly for Regenerative Medicine Applications: A Systematic Review. Pharmaceuticals (Basel). 2021 Oct 27;14(11):1090. doi: 10.3390/ph14111090.