

Efficacy and safety of RebelReliever® in patients with knee osteoarthritis

Phase III randomized controlled trial

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INTRODUCTION:

According to OARSI guidelines, management of knee osteoarthritis consists of a combination of both non-pharmaceutical and pharmaceutical treatments, including knee braces. However, evidence is still inconclusive for the benefits of bracing in the treatment of knee osteoarthritis.

OBJECTIVE:

To evaluate the efficacy of the RebelReliever® knee brace in combination with usual care after a 6-week treatment period, in patients with symptomatic medial knee osteoarthritis.

METHODS:

Patients with medial knee OA

D0 Randomization

RebelReliever® GROUP + standard treatment n=32

D8 Fitting

D21 Visit

D49 Visit

CONTROL GROUP standard treatment alone analgesics + exercise program n=35

RESULTS

DESCRIPTION OF THE POPULATION

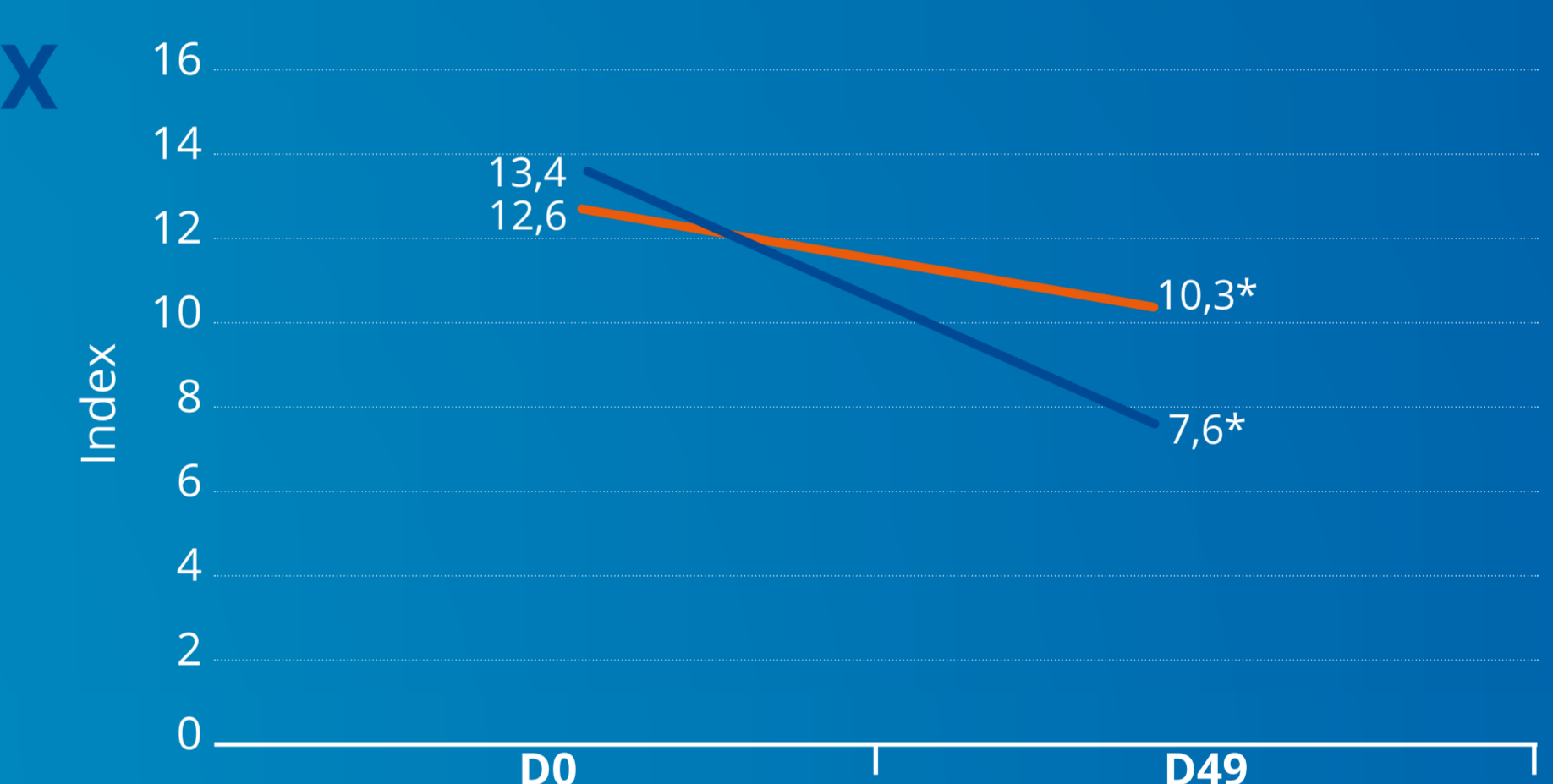
	RebelReliever® (n=32)	Control (n=35)
Mean age	64.8 ± 11.7	66.6 ± 7.2
Female (%)	75	57.1
Mean BMI	29.2 ± 4.4	28.1 ± 5.1
Mean OA duration	8.4 ± 6.8	8.9 ± 7.4
Kellgren-Lawrence grade on target knee (%)		
Grade II	31.3	20.0
Grade III	46.9	62.9
Grade IV	21.9	17.1

SECONDARY ENDPOINT

LEQUESNE ALGOFUNCTIONAL INDEX

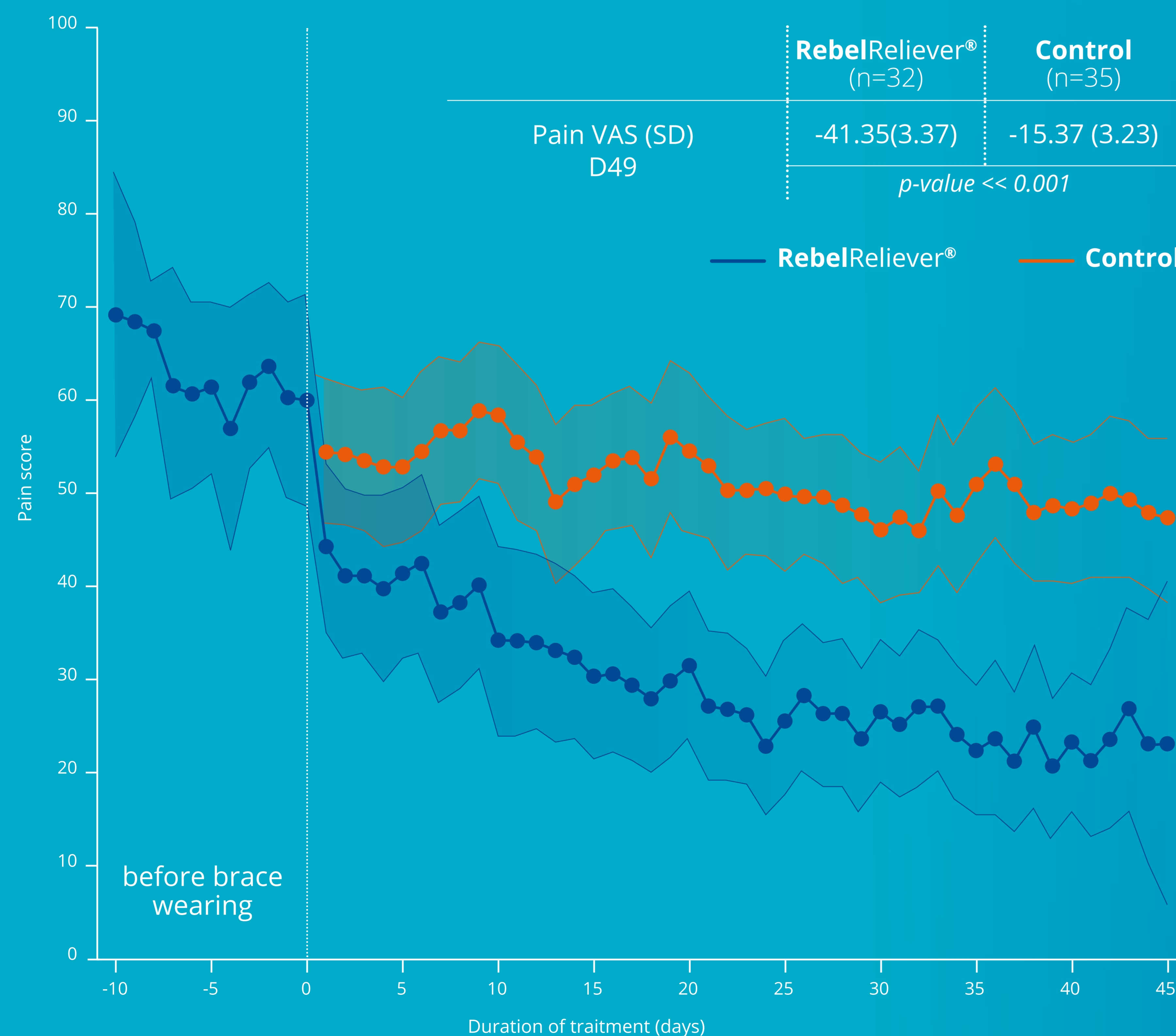
RebelReliever®
Control

*p-value = 0.001



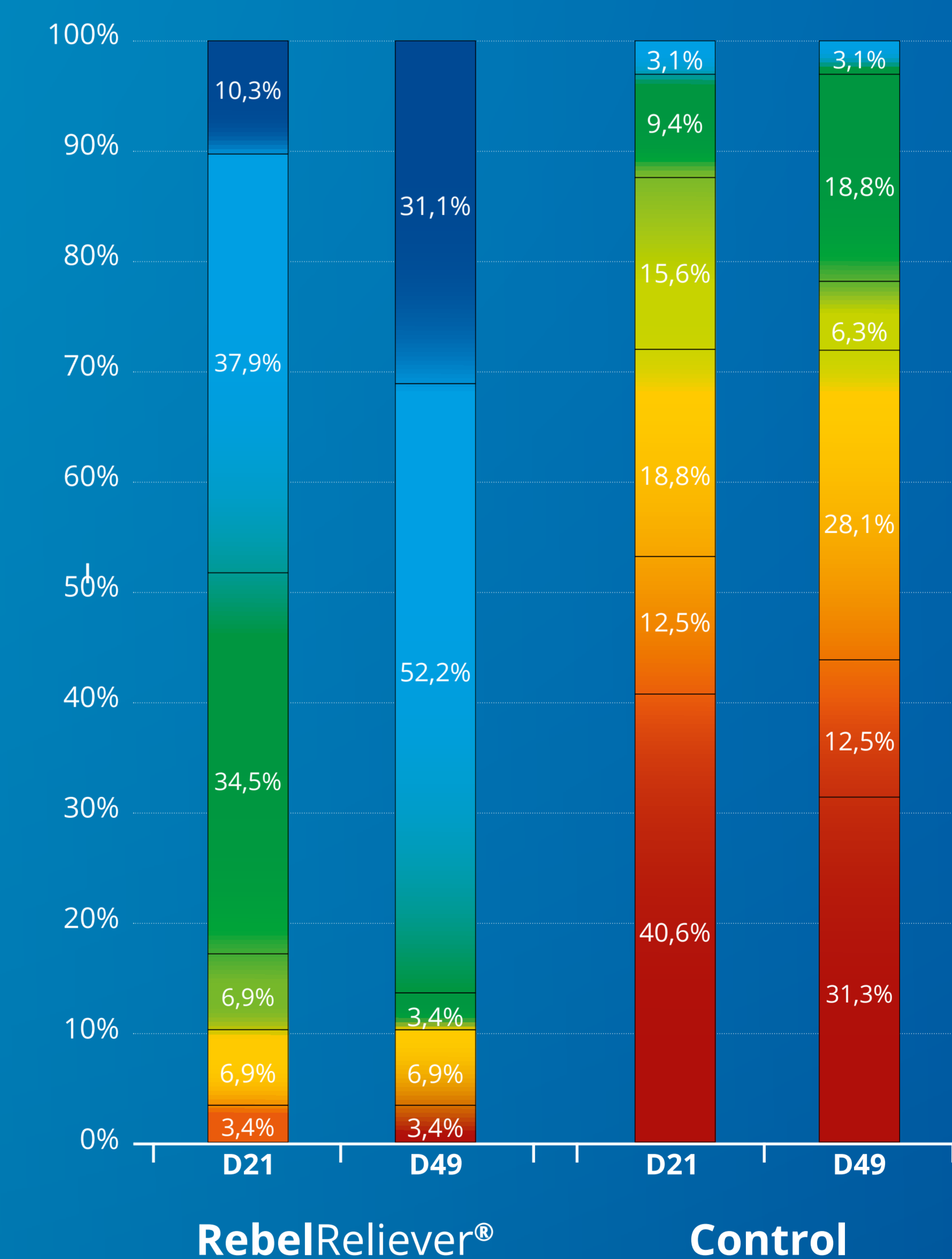
FIRST ENDPOINT

PAIN SCORE EVOLUTION



PATIENT CLINICAL GLOBAL IMPRESSION OF CHANGE

- a great deal better and a considerable improvement that has made all the difference
- better and a definite improvement that has made a real and worthwhile difference
- moderately better, and a slight but noticeable change
- somewhat better, but the change has not made any real difference
- a little better, but no noticeable change
- almost the same, hardly any change at all
- no change (or condition has gotten worse)



RESPONDER RATE (OARSI-OMERACT CRITERIA)

	RebelReliever® (n=32)	Control (n=35)
Pain decrease (VAS) ≥ 50% AND ≥ 20mm OR Lequesne index decrease ≥ 50%	72.4%	34.4%

*p-value = 0.003

CONCLUSION: Superiority of RebelReliever® knee brace + usual care compared to usual care alone was demonstrated. Combining RebelReliever® knee brace with usual care is a powerful non pharmacological therapeutic strategy to handle medial knee osteoarthritis. NCT02021136.