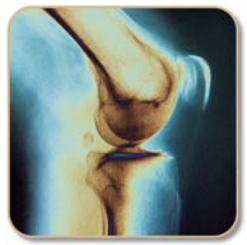
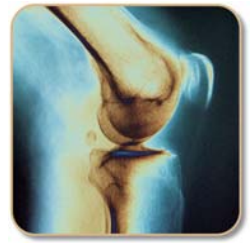
TRB CHEMEDICA
INTERNATIONAL

Clinical studies with Viscoseal® following arthroscopic surgery



viscoseal®

Clinical studies with Viscoseal® in arthroscopic surgery (442 patients)



Shoulder

Funk L. *et al.* 9th OARSI Congress. 2004 (poster) (58 patients)

Cohen D.R. *et al.* 8th EFORT Congress. 2007 (abstract) (20 patients)

Knee

Anand S. *et al.* 9th OARSI Congress. 2004 (poster) (48 patients)

Villamor A. *et al.* 9th OARSI Congress. 2004 (poster) (93 patients)

Mathies B. Knee Surg Sports Traumatol Arthrosc. 2007; 14(1): 32-9 (50 patients)

Hempfling H. Knee Surg Sports Traumatol Arthrosc. 2007; 15(5): 537-46 (80 patients)

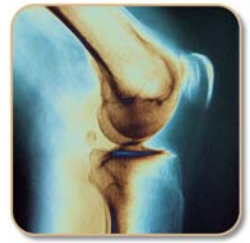
Perez-Caballer A. *et al.* 8th EFORT Congress. 2007 (abstract) (93 patients)

Funk L., Wykes P.R.
Manchester, UK

viscoseal®

Synovial fluid replacement in arthroscopic shoulder surgery – a randomised, prospective, controlled trial

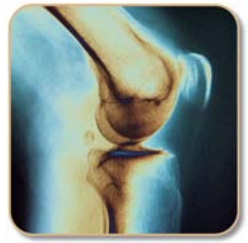
9th Congress of the Osteoarthritis Research Society International
Chicago, USA, December 2-5, 2004 (poster)



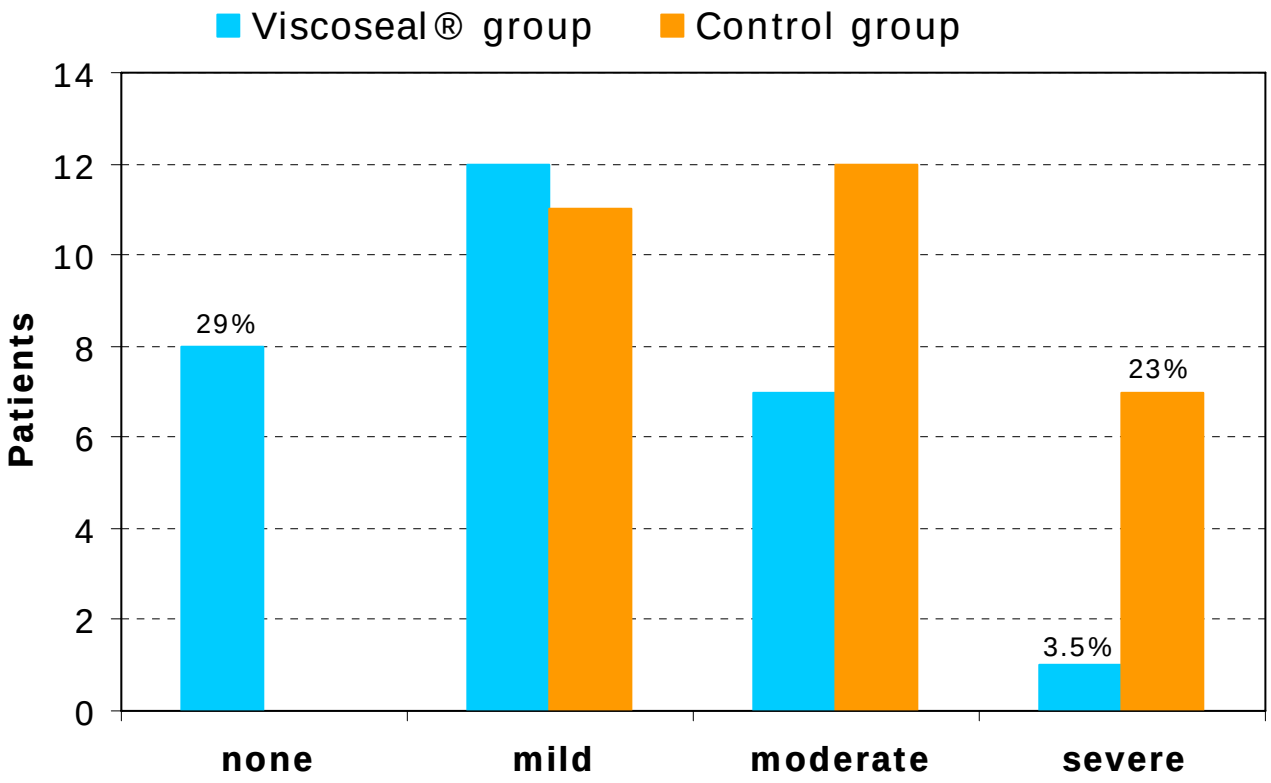
Study design

- Prospective, open, randomised, controlled study
- 58 patients undergoing **subachromial** decompression
- Treatment (n = 58 shoulders):
  - **Viscoseal® group** (n = 28): standard arthroscopy
    + i.a. sodium hyaluronate 50 mg/10 ml
    + 0.5% bupivacaine 10 ml
  - **Control group** (n = 30): standard arthroscopy
    + i.a. 0.5% bupivacaine 20 ml
- Immediate post-operative follow-up (4 hours)

Funk L. *et al.* 9th OARSI Congress. 2004 (poster)



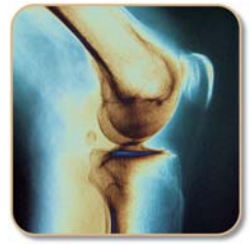
Pain at 4 hours post-op

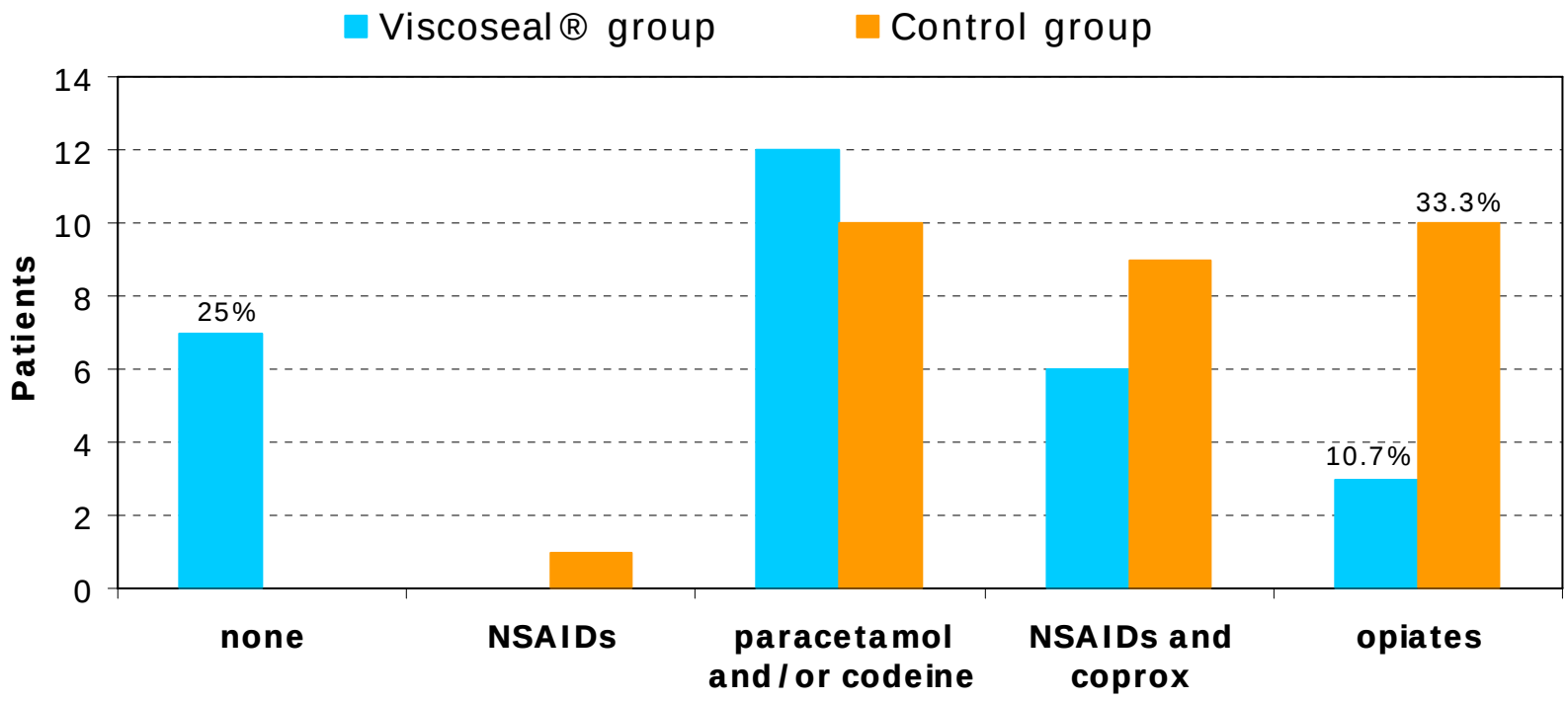


TRB CHEMEDICA INTERNATIONAL

Funk L. *et al.* 9th OARSI Congress. 2004 (poster)

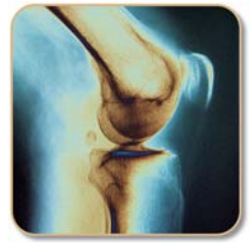
Analgesics required within first 4 hours post-op





TRB CHEMEDICA INTERNATIONAL

Funk L. *et al.* 9th OARSI Congress. 2004 (poster)



Discharge from hospital

- Viscoseal® group: 5.2 ± 13 hours
- Control group: 9.6 ± 5.3 hours
- p = 0.0001

TRB CHEMEDICA INTERNATIONAL

Funk L. *et al.* 9th OARSI Congress. 2004 (poster)

Cohen D.R., Olivier O., Jahraja H.A., Kemp G., Hunter J., Waseem M.

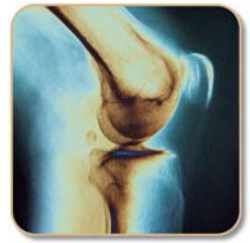
Macclesfield, UK

viscoseal®

Synovial fluid replacement in arthroscopic shoulder surgery

8th Congress of the European Federation of National Associations of Orthopedics and Traumatology

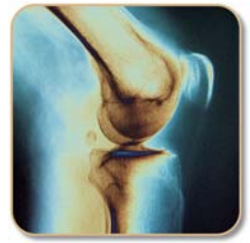
Florence, Italy, May 11-15, 2007 (abstract)



Study design

- Prospective, double blind, randomised, controlled study
- 20 patients undergoing **subachromial** decompression
- Treatment (n = 20 shoulders):
  - **Viscoseal® group** (n = 10): standard arthroscopy
    + i.a. sodium hyaluronate 50 mg/10 ml
    + 0.5% bupivacaine 10 ml
  - **Control group** (n = 10): standard arthroscopy
    + i.a. diamorphine 10 mg/10 ml
    + 0.5% bupivacaine 10 ml
- 24 hour follow-up (1, 2, 6, 12 and 24 hours post-operative)

Cohen D.R. *et al.* 8th EFORT Congress. 2007 (abstract)



Results

Parameter	Viscoseal®	Control	p value*
Early discharge (*i.e.*, on the same day)	40%	0%	0.054
Pain score (VAS)	8%*	ns	> 0.08
Fraction of patients with no pain			> 0.08
Supplementary analgesic drug consumption			> 0.08
Fraction of patients with no pain			> 0.08
Nausea	10%	60%	**0.03**

* Fischer's exact test

TRB CHEMEDICA INTERNATIONAL

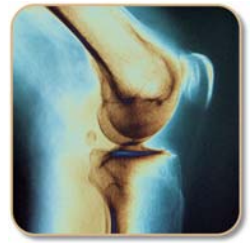
Cohen D.R. *et al.* 8th EFORT Congress. 2007 (abstract)

Anand S., Mitchell S., Bamforth C., Asumu T., Buch K.A.
Oldham, UK

viscoseal®

Effect of sodium hyaluronate on recovery after arthroscopic knee surgery – a randomised controlled study

9th Congress of the Osteoarthritis Research Society International
Chicago, USA, December 2-5, 2004 (poster)

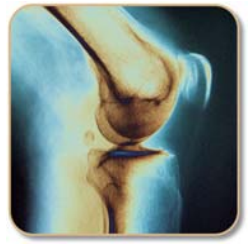


Study design

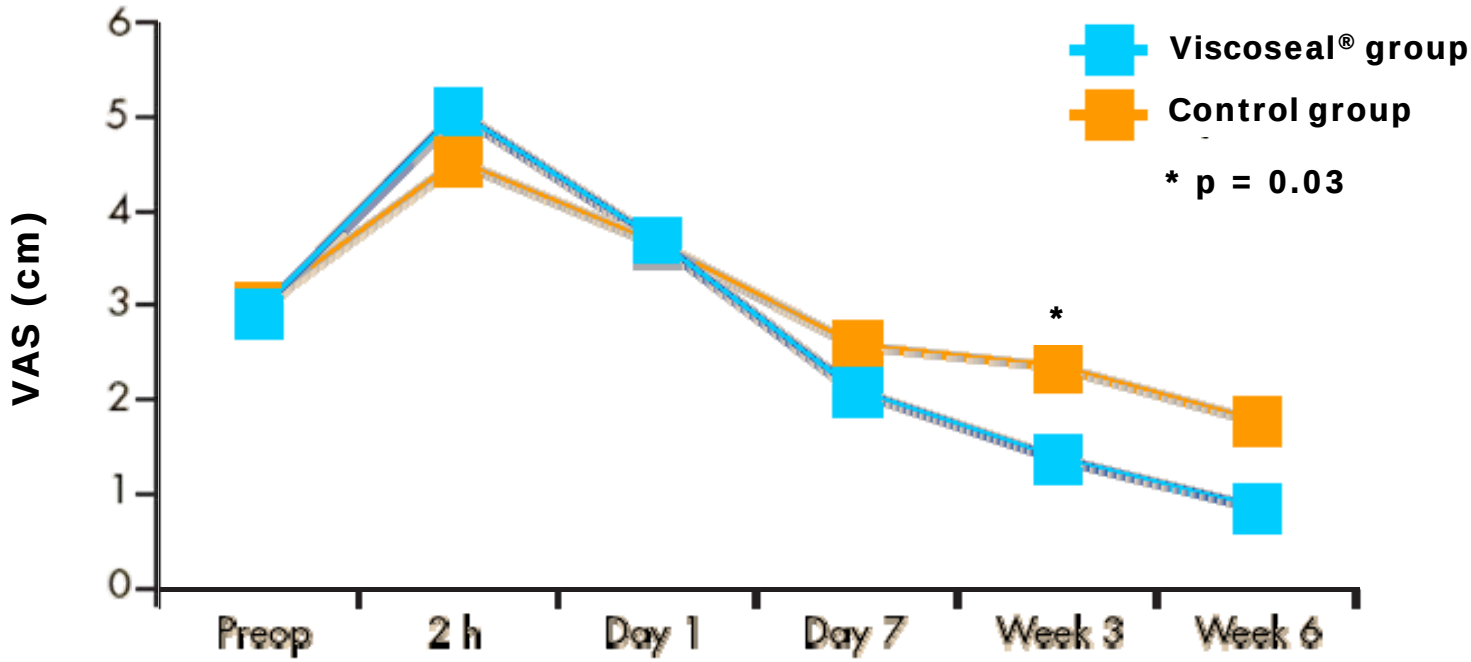
- Prospective, double-blind, randomised, controlled study
- 48 patients with clinical indication for **knee** arthroscopy
- Treatment (n = 48 knees):
  - **Viscoseal® group** (n = 24): standard arthroscopy + i.a. sodium hyaluronate 50 mg/10 ml
  - **Control group** (n = 24): standard arthroscopy + i.a. 0.5% bupivacaine 10 ml
- 6 week follow-up

TRB CHEMEDICA INTERNATIONAL

Anand S. *et al.* 9th OARSI Congress. 2004 (poster)

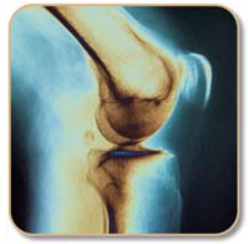


Pain at rest (0-10 cm)

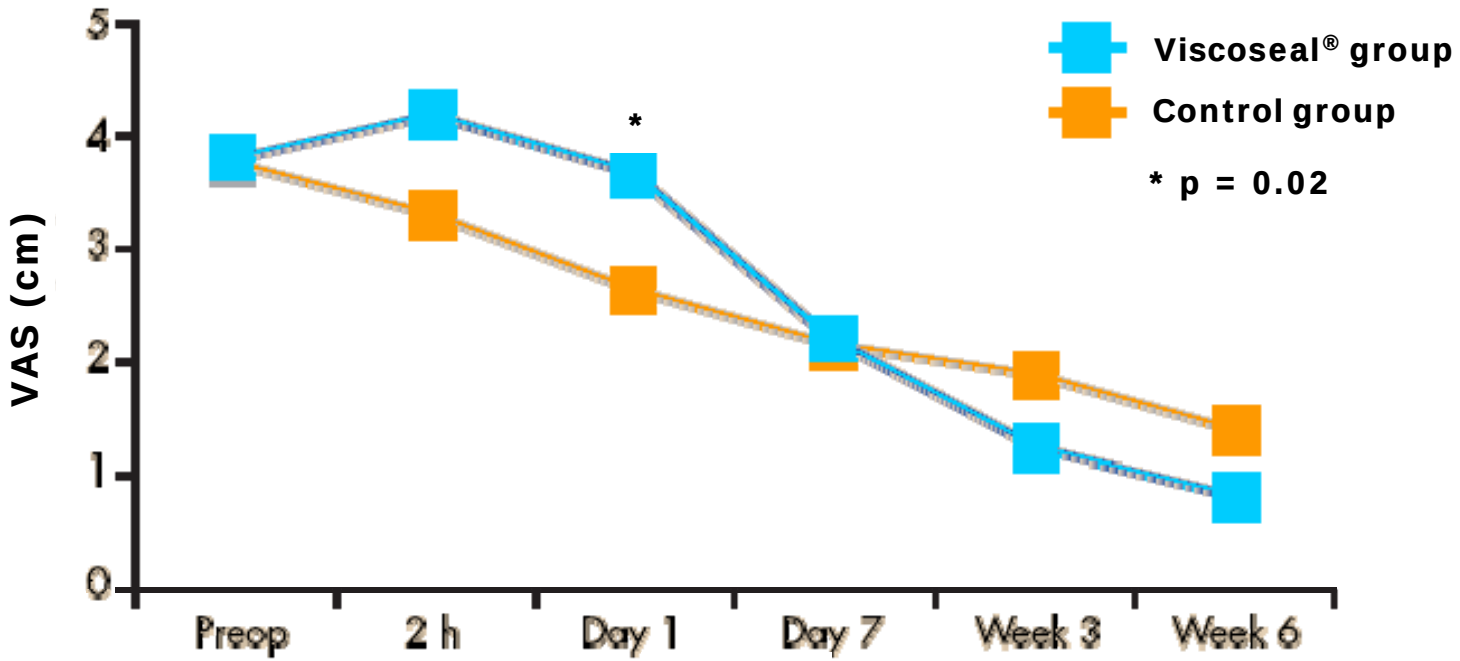


TRB CHEMEDICA INTERNATIONAL

Anand S. *et al.* 9th OARSI Congress. 2004 (poster)

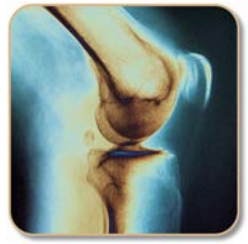


Pain on movement (0-10 cm)

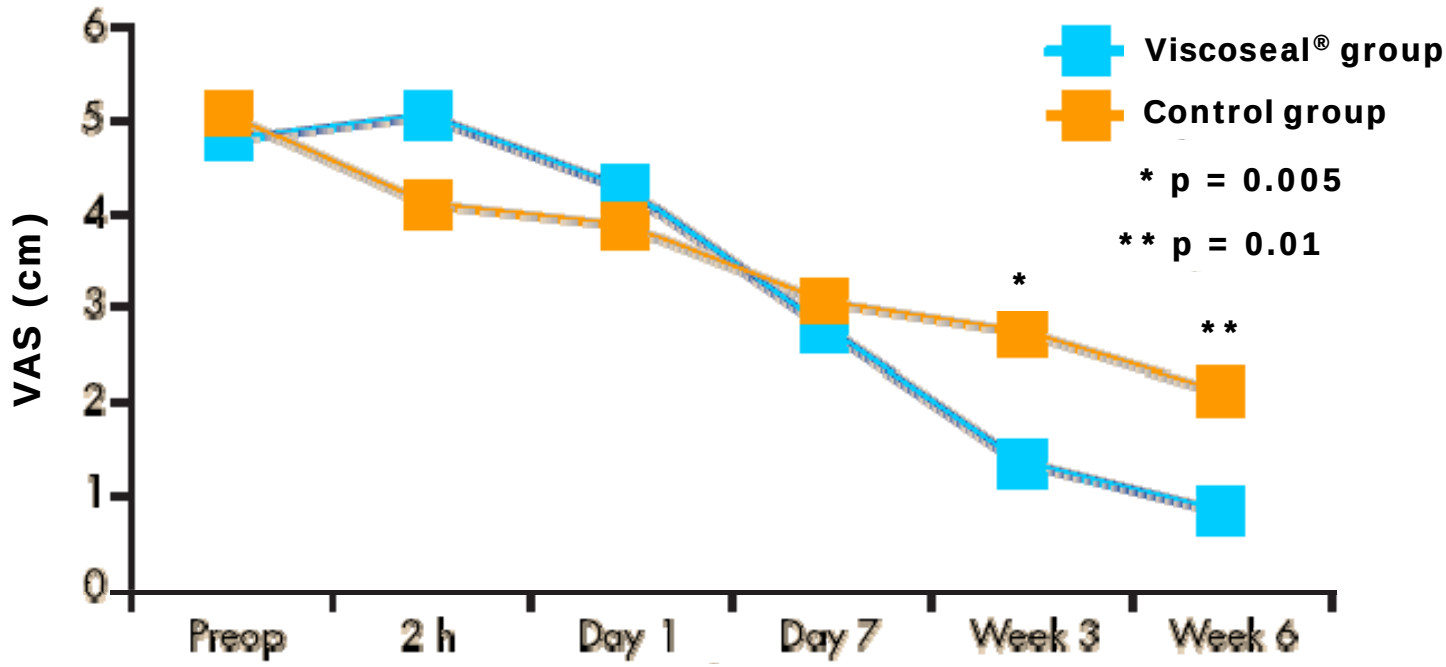


TRB CHEMEDICA INTERNATIONAL

Anand S. *et al.* 9th OARSI Congress. 2004 (poster)

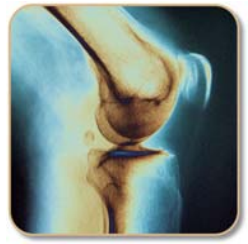


Pain on weight bearing (0-10 cm)

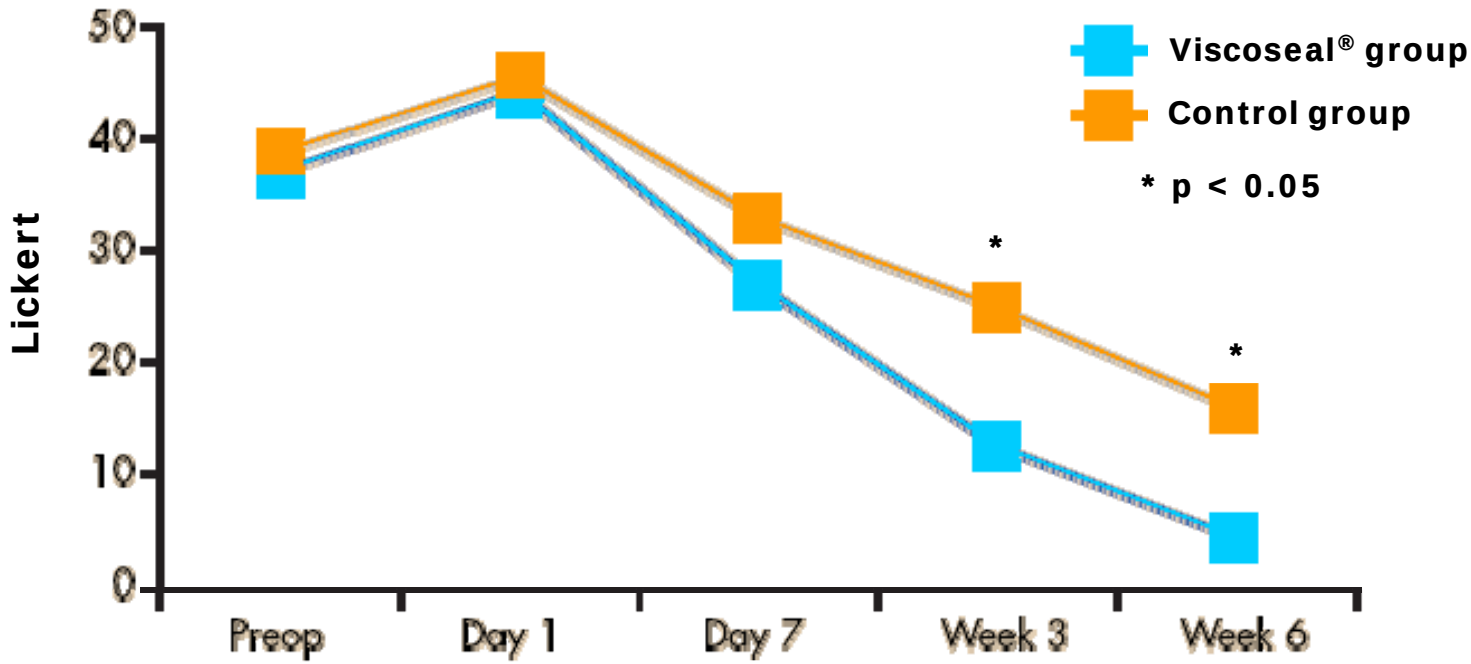


TRB CHEMEDICA INTERNATIONAL

Anand S. *et al.* 9th OARSI Congress. 2004 (poster)

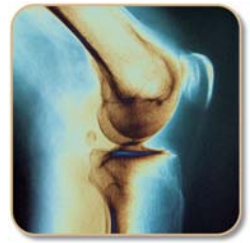


Total WOMAC (0-96)



TRB CHEMEDICA INTERNATIONAL

Anand S. *et al.* 9th OARSI Congress. 2004 (poster)

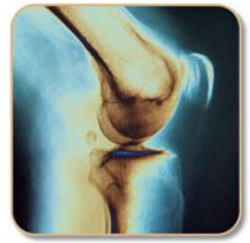


Other secondary efficacy parameters

- Viscoseal® significantly improved the SF-12 compared to bupivacaine.
- Analgesic consumption was significantly reduced at weeks 3 and 6 in favour of Viscoseal®.

TRB CHEMEDICA INTERNATIONAL

Anand S. *et al.* 9th OARSI Congress. 2004 (poster)



Conclusions

- Synovial fluid replacement after arthroscopic knee surgery offers significantly improved function and pain relief over the medium term (3-6 weeks).

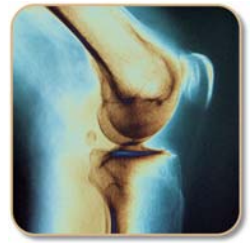
Anand S. *et al.* 9th OARSI Congress. 2004 (poster)

Villamor A. *et al.*
Madrid, Spain

viscoseal®

Viscoseal® aids recovery after arthroscopy – a single-blind, randomised, multicentre study

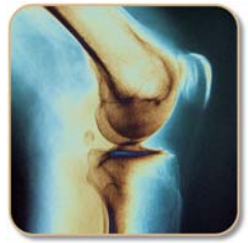
9th Congress of the Osteoarthritis Research Society International
Chicago, USA, December 2-5, 2004 (poster)



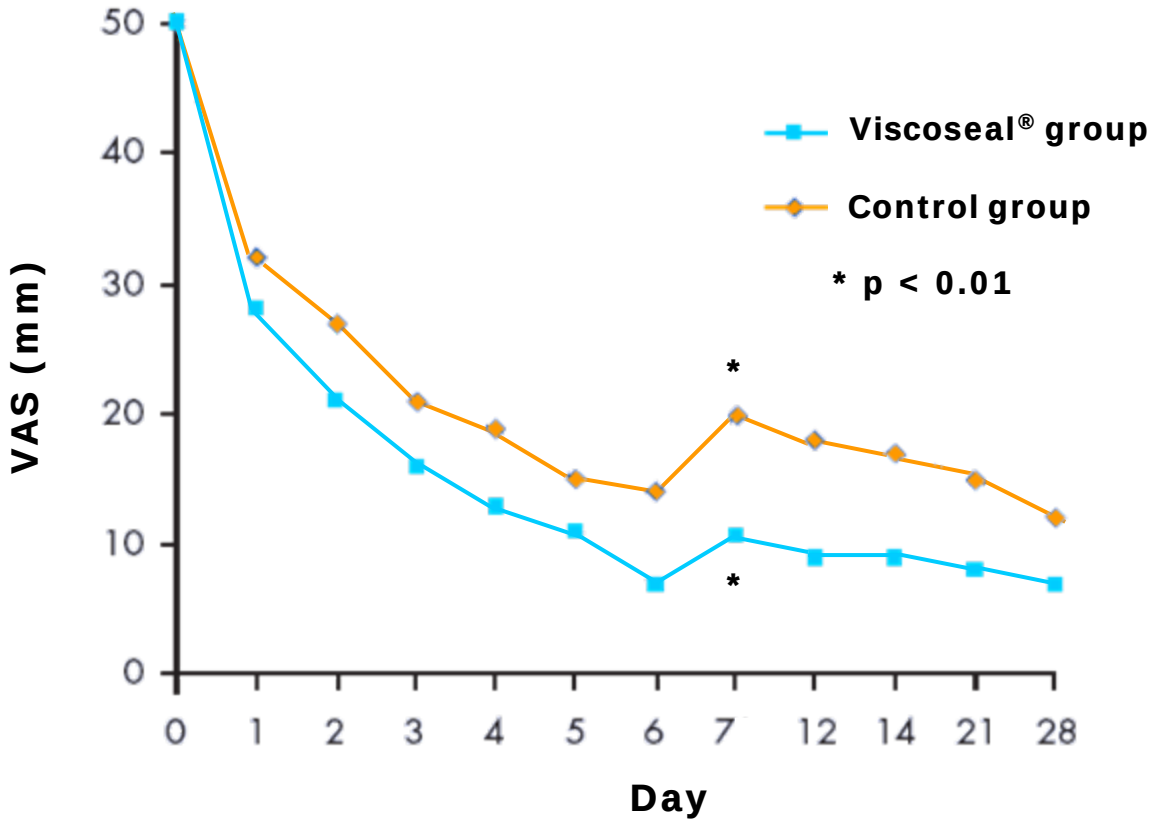
Study design

- Prospective, single-blind, randomised, controlled study
- 93 patients requiring partial meniscectomy and/or osteochondral debridment of the **knee**
- Treatment (n = 93 knees):
  - **Viscoseal® group** (n = 48): standard arthroscopy + i.a. sodium hyaluronate 50 mg/10 ml
  - **Control group** (n = 45): standard arthroscopy
- 28 day follow-up

Villamor A. *et al.* 9th OARSI Congress. 2004 (poster)

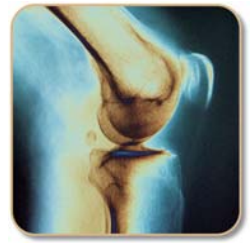


Pain scores (0-100 mm)



TRB CHEMEDICA INTERNATIONAL

Villamor A. *et al.* 9th OARSI Congress. 2004 (poster)



Conclusions

- The results suggest that Viscoseal® accelerates post-arthroscopy recovery during this period by reducing pain and discomfort, and increasing the mobility of the affected knee.

TRB CHEMEDICA INTERNATIONAL

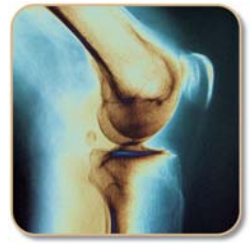
Villamor A. *et al.* 9th OARSI Congress. 2004 (poster)

Mathies B.
Geneva, Switzerland

Effects of Viscoseal®, a synovial fluid substitute, on recovery after arthroscopic partial meniscectomy and joint lavage

viscoseal®

Knee Surgery, Sports Traumatology and Arthroscopy
Vol. 14, No. 1, p. 32-39, January 2006



Study design

- Prospective, single-blind, randomised, controlled pilot study
- 50 patients with evidence of meniscal pathology (MRI) requiring **knee** arthroscopic intervention
- Treatment (n = 50 knees):
  - **Viscoseal® group** (n = 25): standard arthroscopy + i.a. sodium hyaluronate 50 mg/10 ml
  - **Control group** (n = 25): standard arthroscopy
- 1 month follow-up

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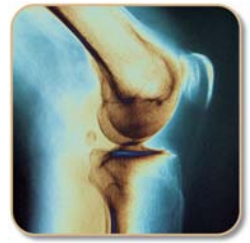
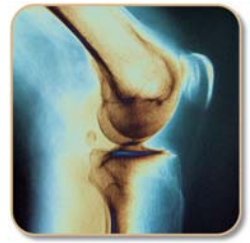
Mathies B. Knee Surg Sports Traumatol Arthrosc. 2007; 14(1): 32-9



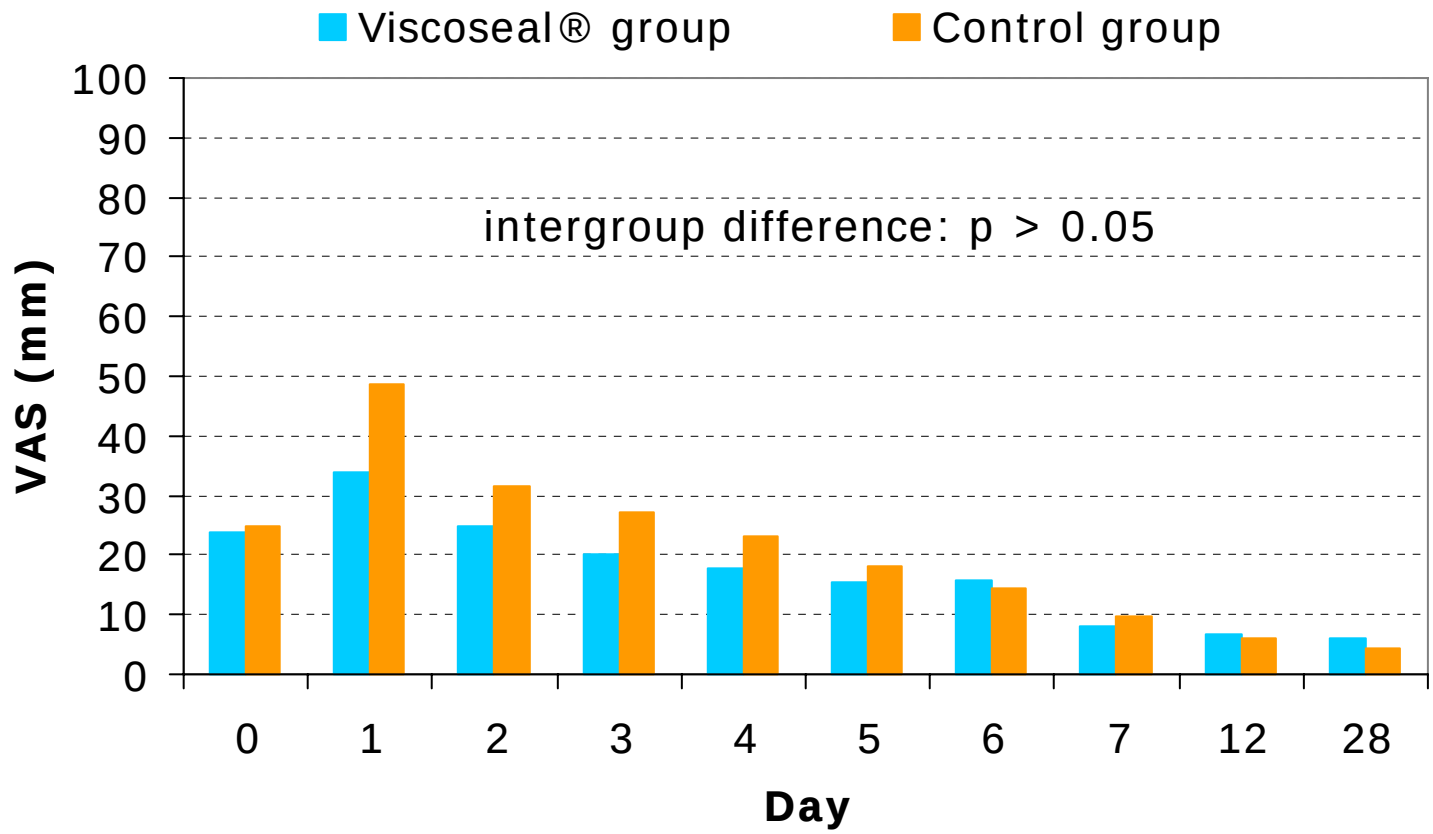
Evaluation parameters

- Efficacy Parameters
  - Pain at rest (100 mm VAS)
  - (Pain on squatting (100 mm VAS))
  - Consumption of escape medication
  - Lysholm score
  - Daily activities (MODEMS)
  - Swelling
  - Efficacy judgement by the patient (5 point scale)
  - Efficacy judgement by the doctor (5 point scale)

Mathies B. Knee Surg Sports Traumatol Arthrosc. 2007; 14(1): 32-9



Pain at rest (0-100 mm)



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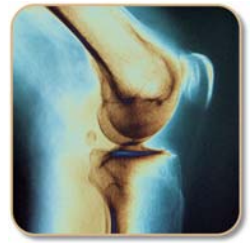
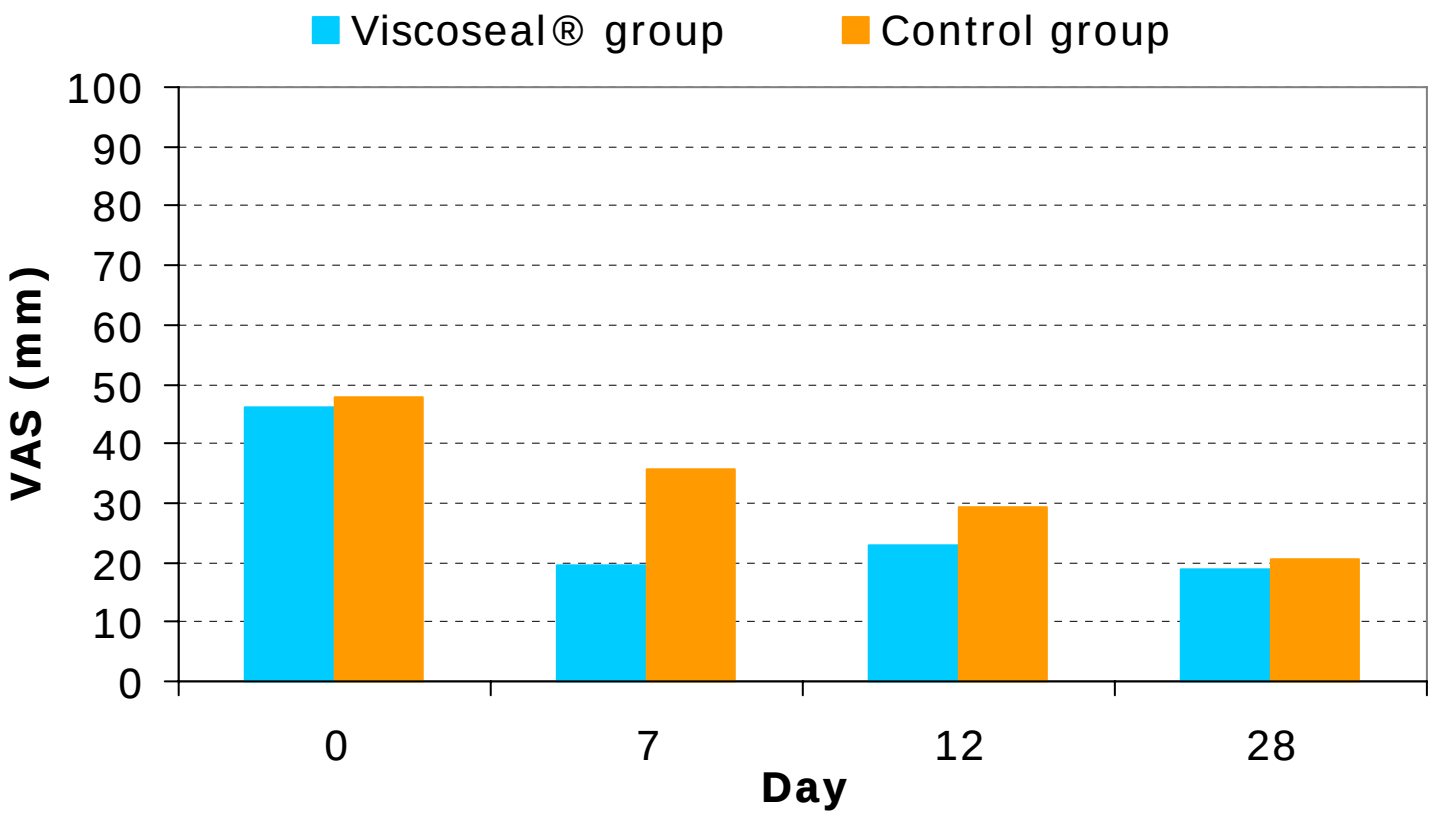
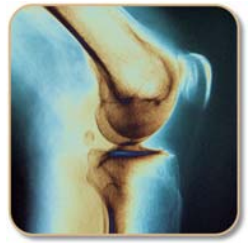


Pain on squatting (0-100 mm)



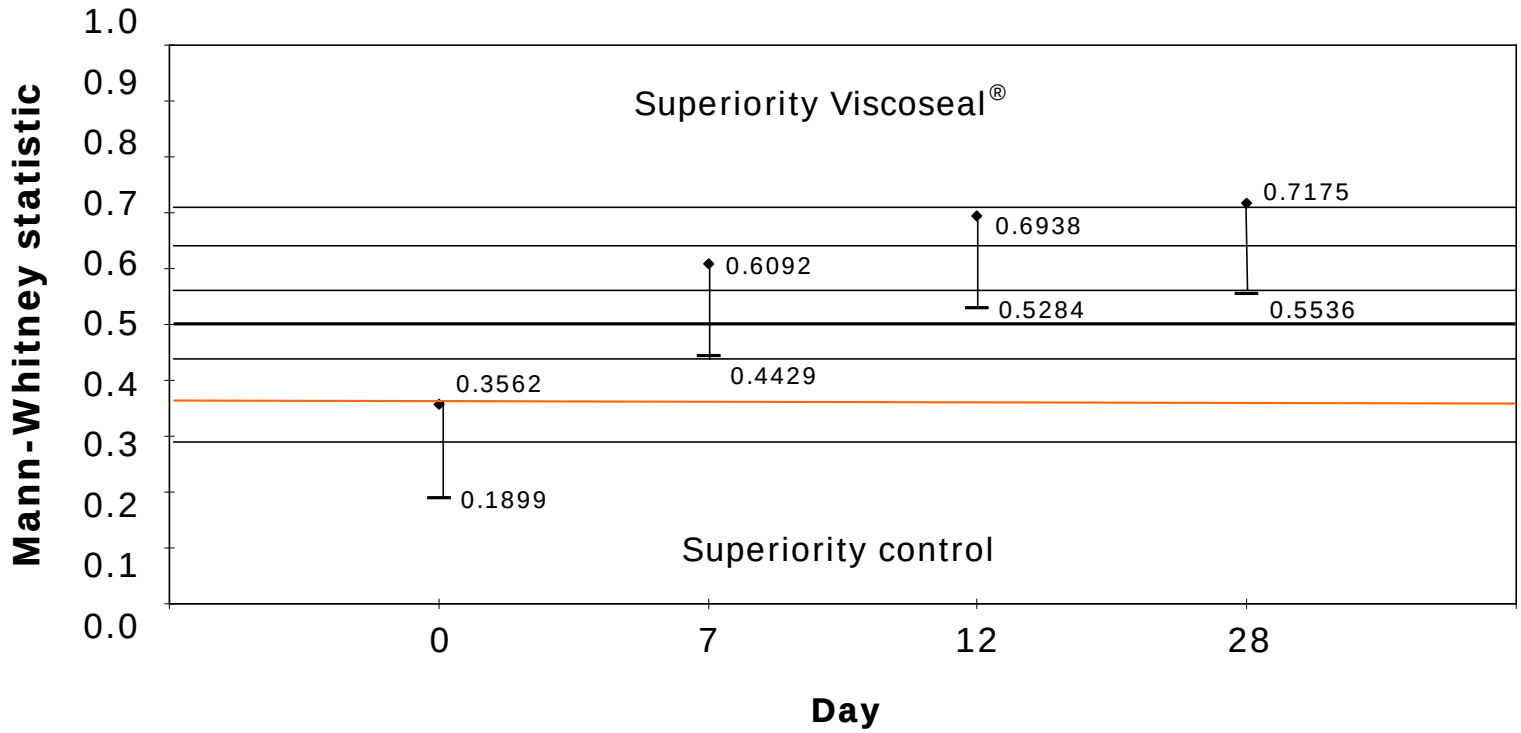
TRB CHEMEDICA INTERNATIONAL

Mathies B. Knee Surg Sports Traumatol Arthrosc. 2007; 14(1): 32-9



Statistical analyses for swelling

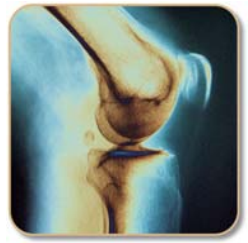
(97.5% CI, one-sided)



0.29 / 0.71 = large difference; 0.36 / 0.64 = medium-sized difference; 0.44 / 0.56 = small difference; 0.50 = equality

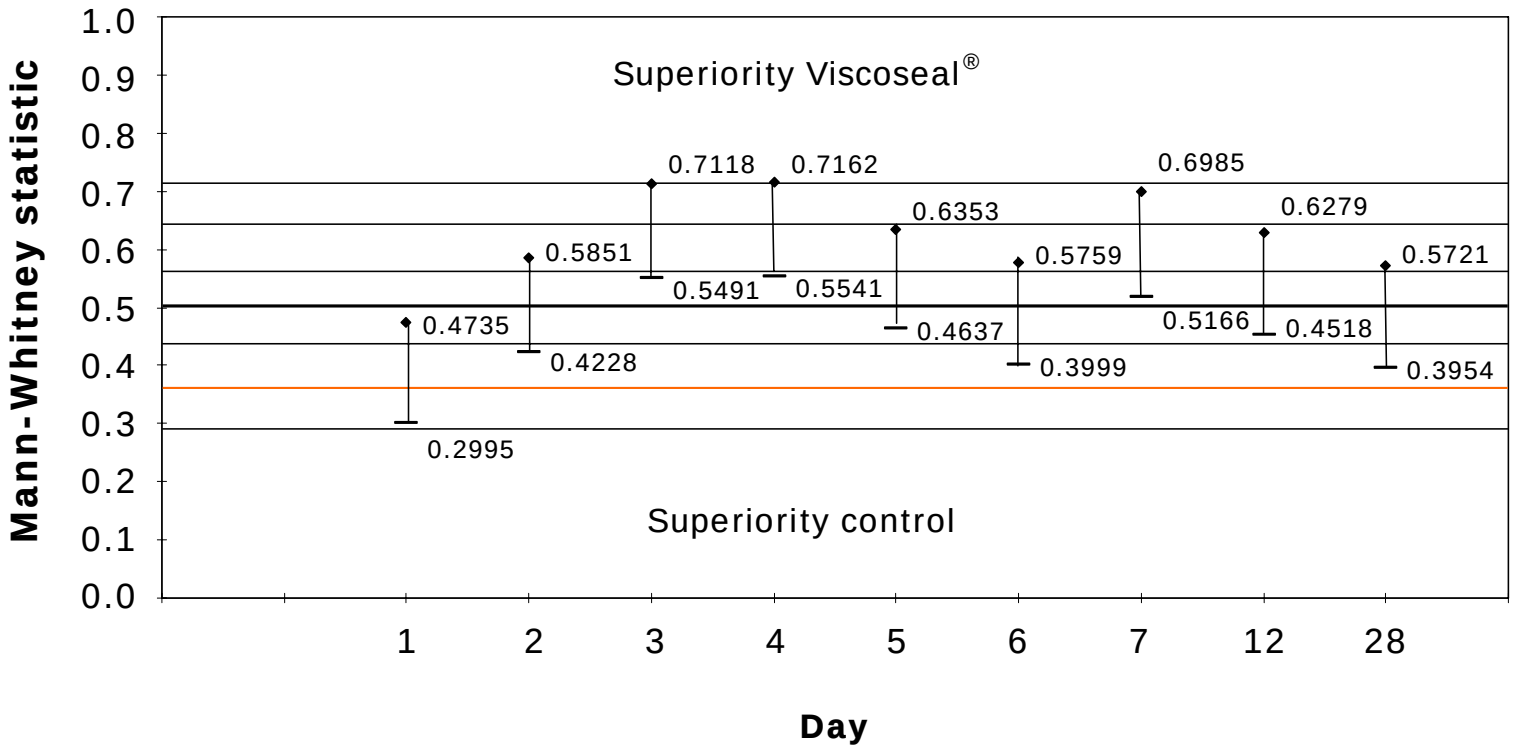
TRB CHEMEDICA INTERNATIONAL

Mathies B. Knee Surg Sports Traumatol Arthrosc. 2007; 14(1): 32-9



Statistical analyses for rescue medication consumption (97.5% CI, one-sided)

Rescue medication: diclofenac 50 mg tablets

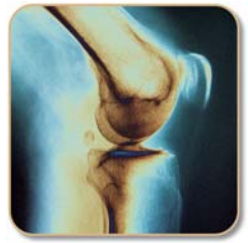


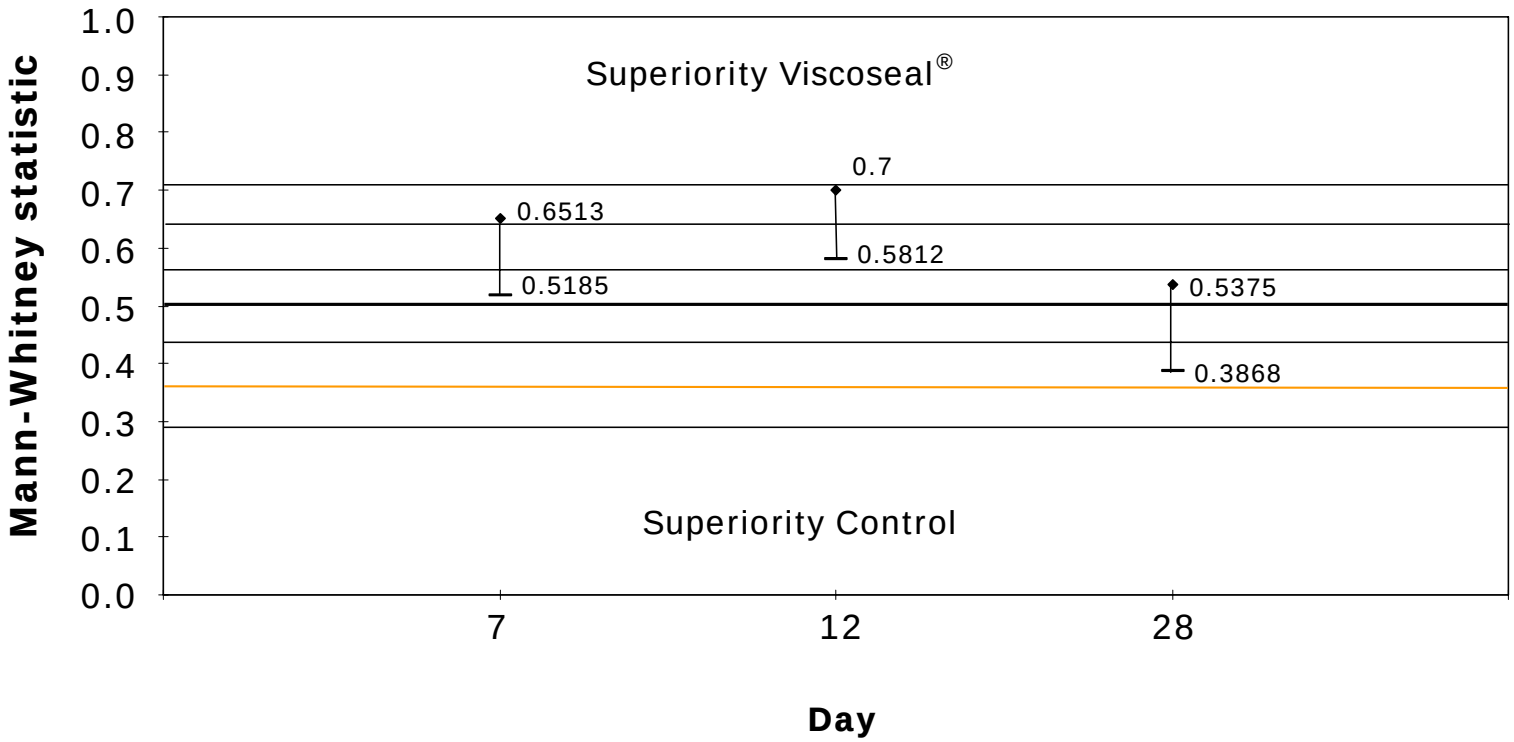
0.29 / 0.71 = large difference; 0.36 / 0.64 = medium-sized difference; 0.44 / 0.56 = small difference; 0.50 = equality

TRB CHEMEDICA INTERNATIONAL

Mathies B. Knee Surg Sports Traumatol Arthrosc. 2007; 14(1): 32-9

Statistical analyses for patient's general evaluation (97.5% CI, one-sided)

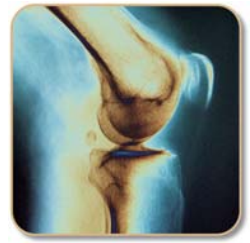




0.29 / 0.71 = large difference; 0.36 / 0.64 = medium-sized difference; 0.44 / 0.56 = small difference; 0.50 = equality

TRB CHEMEDICA INTERNATIONAL

Mathies B. Knee Surg Sports Traumatol Arthrosc. 2007; 14(1): 32-9



Conclusions

- Globally the results showed that patients receiving Viscoseal® at the end of the arthroscopic procedure experienced less pain and improved joint function compared to those patients who received the standard procedure.
- Overall results seemed more to be in favour of Viscoseal® at days 7 and 12.

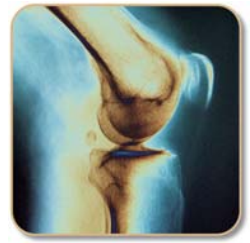
Mathies B. Knee Surg Sports Traumatol Arthrosc. 2007; 14(1): 32-9

Hempfling H.
Murnau am Staffelsee, Germany

Intra-articular hyaluronic acid after knee arthroscopy: a two-year study

viscoseal®

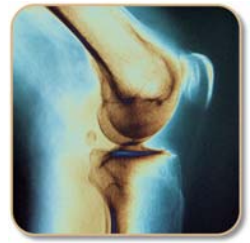
Knee Surgery, Sports Traumatology and Arthroscopy
Vol. 15, No. 5, p. 537-546, May 2007



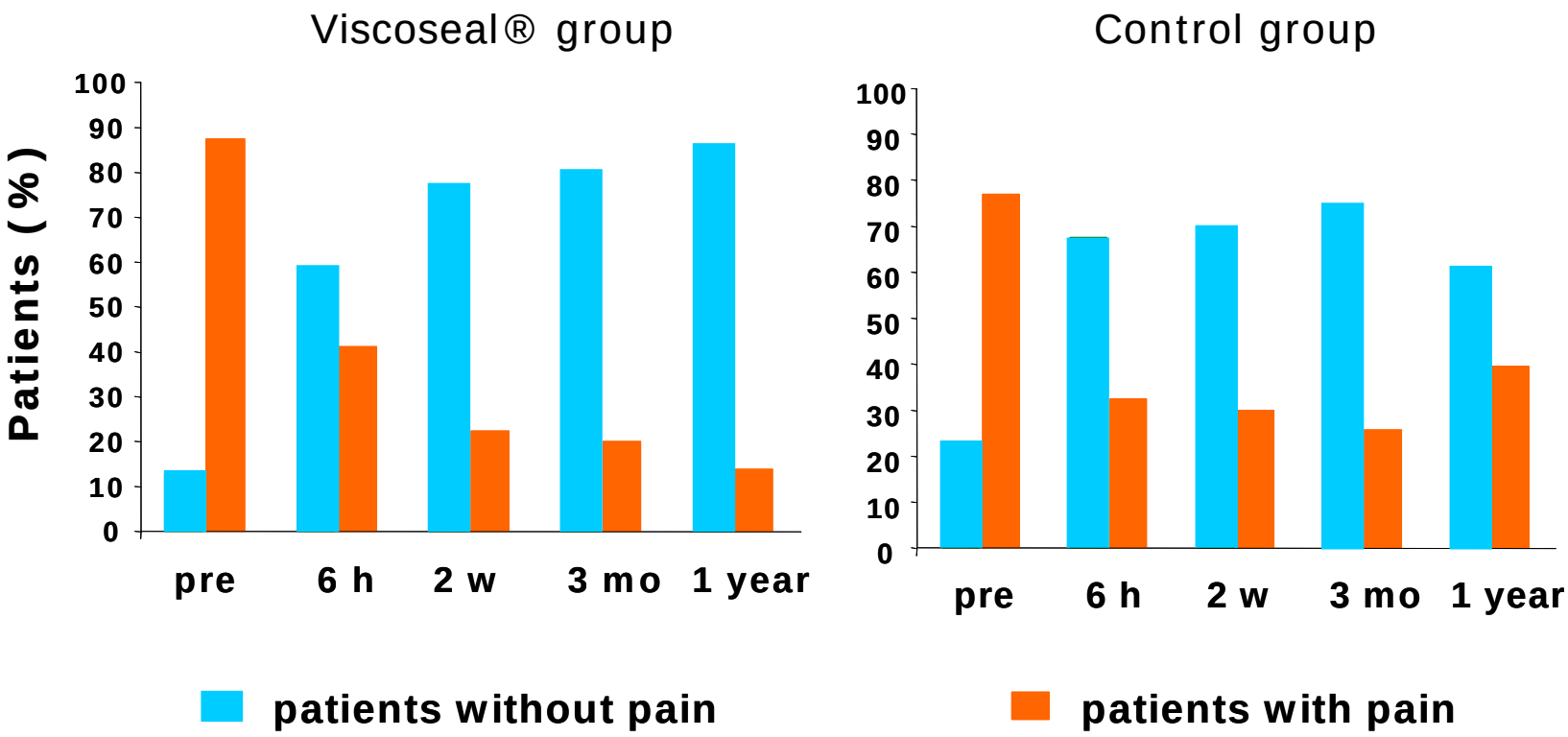
Study design

- Prospective, double-blind, randomised, controlled study
- 80 patients with severe **knee** joint pain in whom arthroscopic joint lavage (+ intra-operative cartilage smoothing) was indicated
- Treatment (n = 80 knees):
  - **Viscoseal® group** (n = 40): standard arthroscopy + i.a. sodium hyaluronate 50 mg/10 ml
  - **Control group** (n = 40): standard arthroscopy
- 12 month follow-up

Hempfling H. Knee Surg Sports Traumatol Arthrosc. 2007; 15(5): 537-46



Pain on walking 100 m (0-100 mm)



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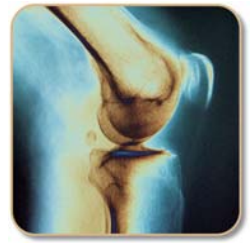
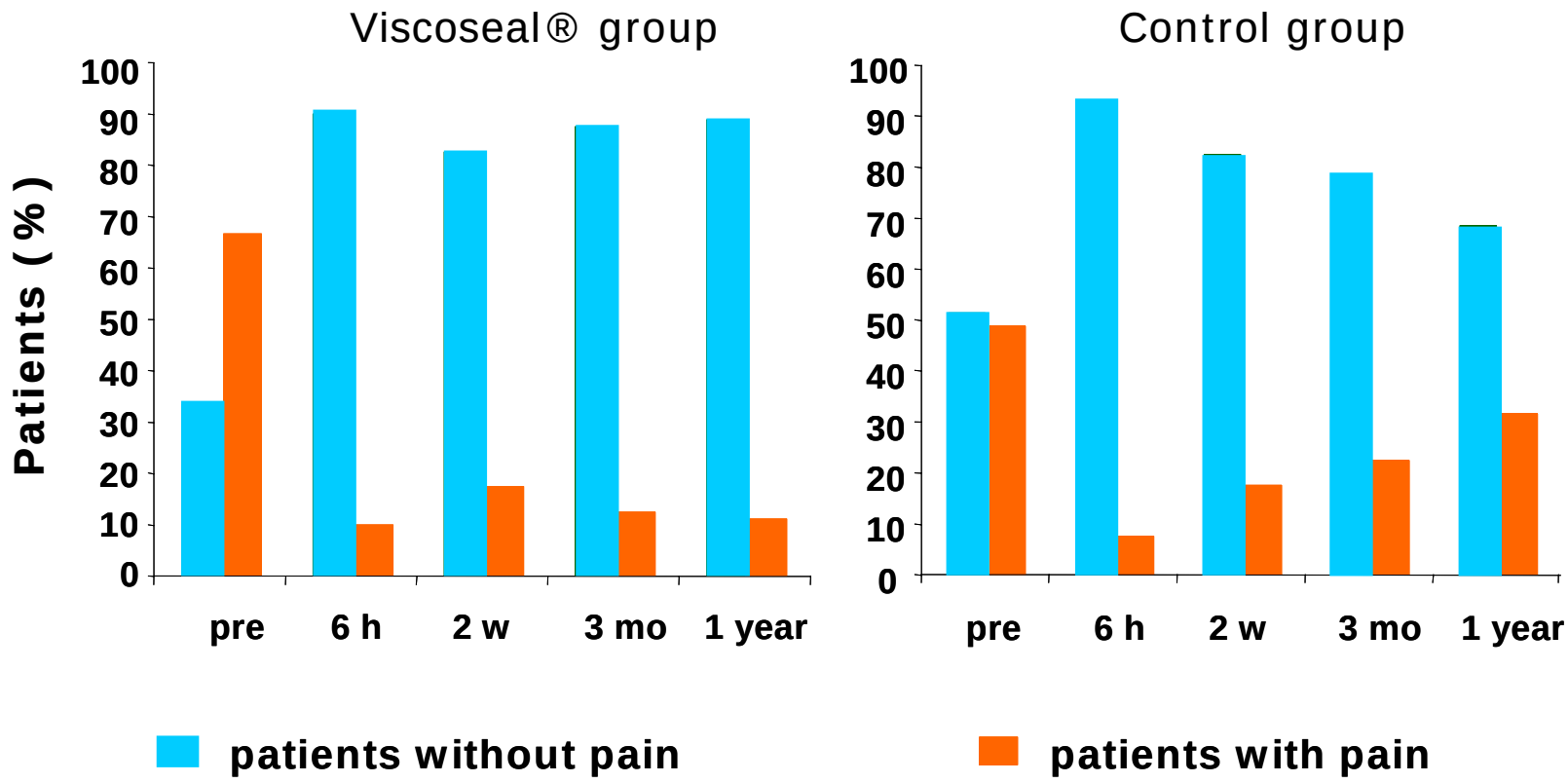
Hempfling H. Knee Surg Sports Traumatol Arthrosc. 2007; 15(5): 537-46

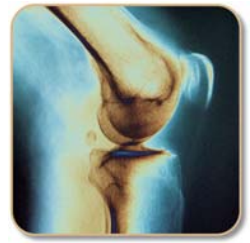


Pain at night (0-100 mm)

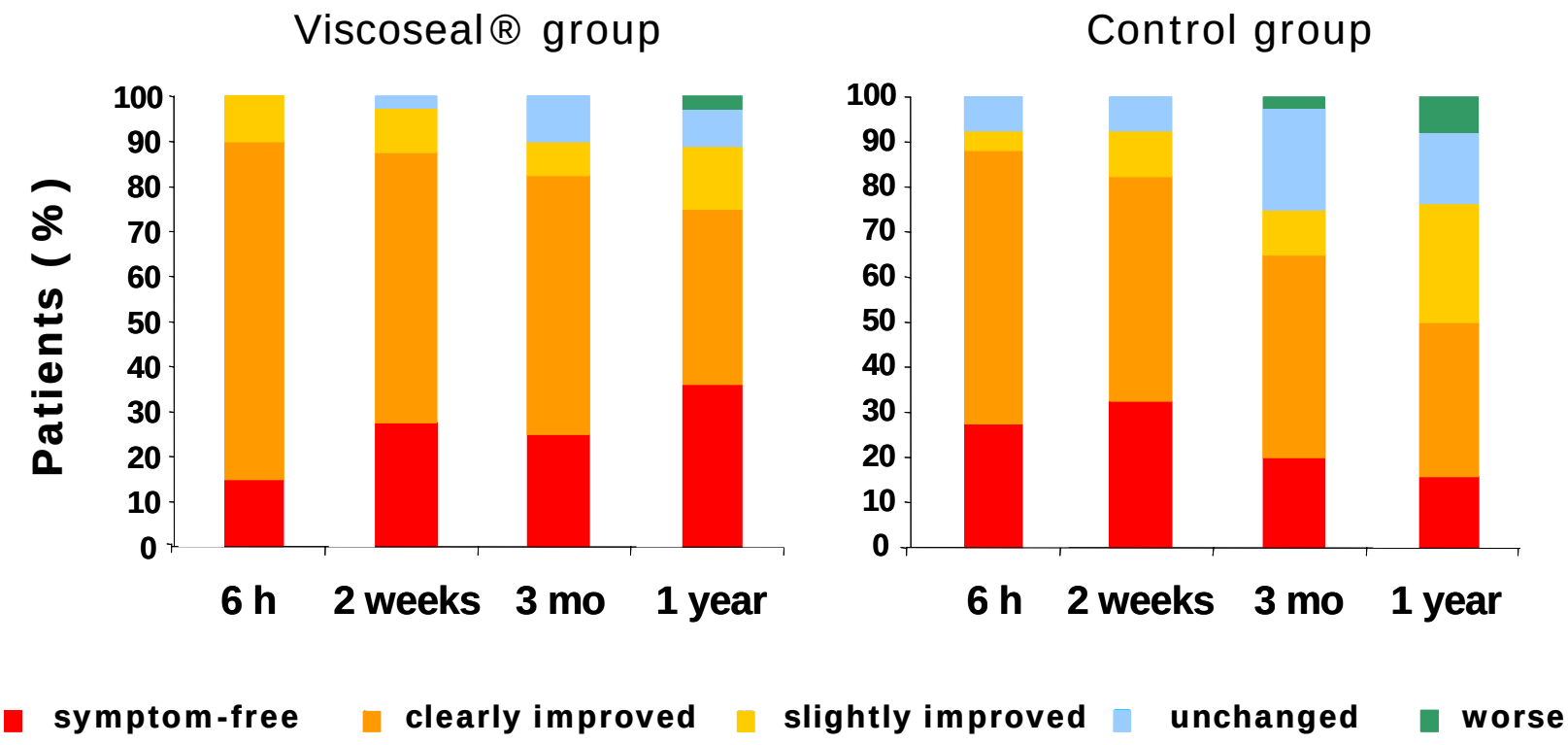


TRB CHEMEDICA INTERNATIONAL

Hempfling H. Knee Surg Sports Traumatol Arthrosc. 2007; 15(5): 537-46



Patient's clinical global impression



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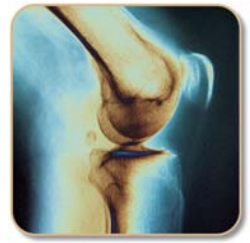
Hempfling H. Knee Surg Sports Traumatol Arthrosc. 2007; 15(5): 537-46



Conclusions

- Globally the results showed that patients receiving Viscoseal® at the end of the arthroscopic procedure experienced better long term results.
- Overall results seemed more to be in favour of Viscoseal® at months 3 and 12.
- The risk-benefit evaluation is in favour of Viscoseal®.

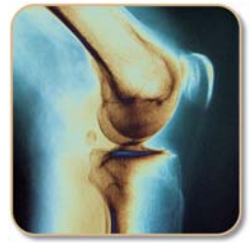
Hempfling H. Knee Surg Sports Traumatol Arthrosc. 2007; 15(5): 537-46

Perez-Caballer A., Alcocer L., Macule F., Vaquero J. Villamor A.
Madrid, Spain

viscoseal®

Use of hyaluronic acid for the treatment of pain in knee arthroscopy

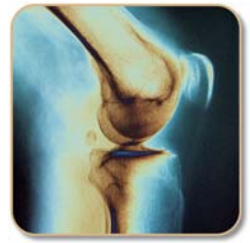
8th Congress of the European Federation of National Associations of Orthopedics and Traumatology
Florence, Italy, May 11-15, 2007 (abstract)



Study design

- Prospective, multicentre, controlled study
- 93 patients requiring **knee** arthroscopic intervention
- Treatment (n = 93 knees):
  - **Viscoseal® group** (n = 48): standard arthroscopy + i.a. sodium hyaluronate 50 mg/10 ml
  - **Control group** (n = 45): standard arthroscopy
- 4 week follow-up

Perez-Caballer A. *et al.* 8th EFORT Congress. 2007 (abstract)



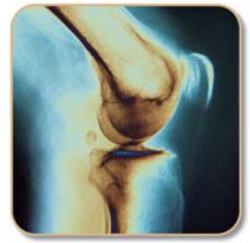
Results

Difference Viscoseal® *vs* control	**1 week post-op**	**4 weeks post-op**
Pain reduction	17%*	maintained
Reduction of other functional symptoms	8%*	ns
Area under the curve of pain (VAS)	39% lower for Viscoseal®	
No adverse events were reported.		

* = significant; ns = non significant

TRB CHEMEDICA INTERNATIONAL

Perez-Caballer A. *et al.* 8th EFORT Congress. 2007 (abstract)



Conclusions

- Significant decrease in knee pain in the first week after surgery.
- Significant reduction in sum of symptom scores.
- These results suggest that Viscoseal® accelerate post-arthroscopy recovery by reducing pain and discomfort, and increasing the mobility of the affected knee.

Perez-Caballer A. *et al.* 8th EFORT Congress. 2007 (abstract)