

AVANOS

CLINICAL COMPENDIUM

GAME READY®





GAME READY® REVIEW PAPERS

- 1 Efficacy of the Game Ready® cooling device on postoperative analgesia after scoliosis surgery in children.
- 2 Compressive cryotherapy is superior to cryotherapy alone in reducing pain after hip arthroscopy.
- 3 Cryocompression therapy after elective arthroplasty of the hip.
- 4 Cryotherapy with dynamic intermittent compression for analgesia after anterior cruciate ligament reconstruction. Preliminary study.
- 5 Cryotherapy with dynamic intermittent compression improves recovery from revision total knee arthroplasty.
- 6 Cryo-compression therapy after elective spinal surgery for pain management: a cross-sectional study with historical control.
- 7 A prospective, multi-center, randomised trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery.
- 8 The efficacy of combined cryotherapy and compression compared with cryotherapy alone following anterior cruciate ligament reconstruction.

ABBREVIATIONS

- DVT - deep vein thrombosis
- Hb - hemoglobin
- MUA - manipulation under anesthesia
- NS - not statistically significant
- POD - postop day
- Pts - patients
- RCT - randomized controlled trial
- ROM - range of motion
- VAS - visual analog scale

STUDY	DESIGN	CONCLUSION	
	DEVICE/PROCEDURE	SAFETY	CLINICAL OUTCOMES
<p>Bellon, M., et al. Efficacy of the Game Ready® cooling device on postoperative analgesia after scoliosis surgery in children.</p> <p>European Spine Journal 2019; 28:1257-1264 <Robert Debré University Hospital, Paris , FR></p> <p>www.pubmed.ncbi.nlm.nih.gov/30847706</p> <p>LOE III</p>	<p>Prospective comparative analysis</p> <p>45 Patients 22 - Cooling group 23 - Control group</p> <p>-----</p> <p>Game Ready®</p>	<ul style="list-style-type: none"> • No adverse effects were associated with the brace • No cutaneous lesion • No postoperative infection up to 30 days after surgery 	<ul style="list-style-type: none"> • Game Ready was associated with a significant decrease in morphine consumption at day 1 ($P=0.02$) and day 3 ($P=0.003$) • Hospitalization duration was reduced in the Game Ready group ($P=0.004$) • No differences in pain intensity or percentage of patient mobilized in the standing position were found between groups
<p>Kluber, I., et al. Compressive cryotherapy is superior to cryotherapy alone in reducing pain after hip arthroscopy.</p> <p>Journal of Hip Preservation Surgery 2018; 1-6 <Orthopedic Surgery Department, School of Medicine, Pontifical Catholic University of Chile, Santiago, Chile></p> <p>https://doi.org/10.1093/jhps/hnz048</p> <p>LOE III</p>	<p>Prospective comparative study</p> <p>40 Patients 20 - Compressive cryotherapy 20 - Standard cryotherapy (ice)</p> <p>-----</p> <p>Game Ready®</p>	<ul style="list-style-type: none"> • There were no complications related to the use of Game Ready system 	<ul style="list-style-type: none"> • Pts in the Game Ready group reported significantly lower pain scores compared to pts with standard cryotherapy, VAS 1 (0-3) and 2 (0-5), $P=0.0028$, respectively • Analgesic requirements were lower in the Game Ready group (NS) • 20/20 patients who received Game Ready were discharged on POD1 vs 17/20 who received standard cryotherapy • 18/20 pts in the Game Ready group reported satisfaction with the system and believed that it improved their level of postoperative pain and none requested the device be removed
<p>Leegwater, N.C., et al. Cryocompression therapy after elective arthroplasty of the hip.</p> <p>Hip International 2012; 22(5): 527-533 <Department of Orthopaedic Surgery, Spaarne Hospital, Hoofddorp, The Netherlands></p> <p>https://pubmed.ncbi.nlm.nih.gov/23112075</p> <p>LOE II</p>	<p>Prospective, randomised pilot study</p> <p>26 Patients 12 - Tricot compression bandage with intermittent cryocompression 14 - Tricot compression bandage only</p> <p>-----</p> <p>Game Ready®</p>	<ul style="list-style-type: none"> • One pt experienced DVT in the control group • One pt in the Game Ready group experienced inability to urinate 	<p>Pts in the Game Ready group experienced:</p> <ul style="list-style-type: none"> • Lesser decline in postoperative blood loss • Trend towards less wound discharge • Reduction in leg swelling • Trend towards lower morphine usage (NS) • Shorter hospital stay (NS) • Less pain at 6 weeks postoperatively (NS)

STUDY	DESIGN	CONCLUSION	
	DEVICE/PROCEDURE	SAFETY	CLINICAL OUTCOMES
<p>Murgier, J. and Cassard, X. Cryotherapy with dynamic intermittent compression for analgesia after anterior cruciate ligament reconstruction. Preliminary study.</p> <p>Orthopedic & Traumatology: Surgery & Research 2014; 100(3): 309-312</p> <p><Service d'orthopedie-traumatologie, hospital Pierre-Paul Riquet, Toulouse, FR></p> <p>https://pubmed.ncbi.nlm.nih.gov/24679367</p> <p>LOE III</p>	<p>Prospective, case-control study of consecutive pts</p> <p>39 Patients 20 - Dynamic intermittent compression + cryotherapy 19 - Cryotherapy + static compression (IceBand®)</p> <p>-----</p> <p>Game Ready® IceBand</p>	<ul style="list-style-type: none"> • No adverse events were reported 	<p>Pts in the Game Ready group:</p> <ul style="list-style-type: none"> • Took fewer opioids • Did not require step 3 analgesics (morphine), ($P<0.05$) • Required significantly less tramadol, ($P=0.023$) • Had higher knee flexion at hospital discharge ($P=0.0015$) • Pain scores were not statistically significant between groups
<p>Murgier, J., et al. Cryotherapy with dynamic intermittent compression improves recovery from revision total knee arthroplasty.</p> <p>The Journal of Arthroplasty 2017; 1-4</p> <p><Department de chirurgie Orthopedique et Traumatologique, CHU Toulouse, Toulouse, FR></p> <p>https://pubmed.ncbi.nlm.nih.gov/28465126</p> <p>LOE III</p>	<p>Prospective, case-control study</p> <p>43 Patients 24 - Dynamic intermittent compression 19 - Control (cold pack)</p> <p>-----</p> <p>Game Ready®</p>	<ul style="list-style-type: none"> • 2 cases of infection recurrence in each group • 1 case of DVT in each group • 1 case of extensor mechanism disruption in the Game Ready group 	<ul style="list-style-type: none"> • Total blood loss was lower in the Game Ready group ($P<.05$) • Transfusion rate was lower in the Game Ready group ($P<.05$) • Mean lowest Hb level was lower in the control group ($P<.005$) • Pain at rest on day 3 was lower in the Game Ready group ($P<.05$) • Cumulative morphine intake at day 5 was not significantly different between groups • Oxford score at 6 months postoperative was higher in the Game Ready Group (42 vs 40, NS)
<p>Nabiyev, V.N., et al. Cryo-compression therapy after elective spinal surgery for pain management: a cross-sectional study with historical control.</p> <p>Neurospine 2018; 15(4): 348-352</p> <p><Department of Orthopaedics, ARTES Spine Center, Acibadem Ankara Hospital, Ankara, Turkey></p> <p>https://pubmed.ncbi.nlm.nih.gov/30531660</p> <p>LOE III</p>	<p>Prospective cohort study</p> <p>40 Patients 20 - Dynamic cryo-compression therapy 20 - Historical control</p> <p>-----</p> <p>Game Ready®</p>	<ul style="list-style-type: none"> • No cold-related wound complications, including frostbite or transient nerve palsy occurred the Game Ready group 	<ul style="list-style-type: none"> • VAS scores were lower in the Game Ready group at most time points after surgery and statistically significant in the PACU, 6, 36, 66, 72 hours post-op, at discharge, and 8 weeks postoperatively • Cumulative analgesic consumption was lower in the Game Ready group and statistically significant for all analgesics: Paracetamol, Tenoxicam, Tramadol

STUDY	DESIGN	CONCLUSION	
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<p>Su, E.P., et al. A prospective, multi-center, randomised trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery.</p> <p>The Journal of Bone and Joint Surgery British 2012; 94-B, Supple A: 153-156 <Department of Orthopaedics, Hospital for Special Surgery, New York, New York, US></p> <p>https://pubmed.ncbi.nlm.nih.gov/23118406</p> <p>LOE II</p>	<p>Prospective, multi-center RCT</p> <p>11 International sites</p> <p>187 Patients 103 - Cryopneumatic therapy 84 - Ice with static compression</p> <p>-----</p> <p>Game Ready®</p>	<ul style="list-style-type: none"> • No difference in adverse events or compliance between groups • 1 pt in each group had blistering around the incision • 6 pts in the Game Ready group had MUA • 7 pts in the control group underwent manipulation • 11 pts in Game Ready group and 8 pts in the control group had blood transfusions 	<p>2 weeks post op:</p> <ul style="list-style-type: none"> • No significant difference between groups with respect to girth or ROM • Pts with Game Ready consumed fewer morphine equivalents ($P<0.05$) <p>6 weeks follow up:</p> <ul style="list-style-type: none"> • After Game Ready was removed at 2 weeks, there were no differences in narcotic consumption between groups 2 to 6 weeks post op • Similar girth, VAS, ROM among both groups • Game Ready pts walked further than pts in the control group, NS • Pt satisfaction was significantly higher in the Game Ready group • Compliance rates were similar between groups
<p>Waterman, B., et al. The efficacy of combined cryotherapy and compression compared with cryotherapy alone following anterior cruciate ligament reconstruction.</p> <p>The Journal of Knee Surgery 2012; 25(2): 155-156 <Department of Orthopaedics, William Beaumont Army Medical Center, El Paso, TX></p> <p>https://pubmed.ncbi.nlm.nih.gov/22928433</p> <p>LOE II</p>	<p>Prospective, RCT</p> <p>36 Patients 18 - Compressive cryotherapy 18 - Ice pack</p> <p>-----</p> <p>Game Ready®</p>	<ul style="list-style-type: none"> • No cold-related wound complications, including frostbite or transient nerve palsy, occurred in either group 	<p>Compliance</p> <ul style="list-style-type: none"> • Weeks 1 and 2, pts with Game Ready had 100% compliance compared to 83% for the control group (NS) • By week 6, compliance decreased for both groups: 28% Game Ready; 39% Control <p>Narcotic Use</p> <ul style="list-style-type: none"> • 15/18 (83.3%) Game Ready pts discontinued use of all pain medications compared to 5/18 Control group (27.8%) ($P=0.0008$) • Survivorship analysis with continuing use of narcotic medication as an end point demonstrated statistically significant difference between groups ($P=0.0023$) <p>Other Outcomes</p> <ul style="list-style-type: none"> • No statistically significant differences were found in circumferential measurements, post-op VAS scores or subjective patient outcome scores (SF-36, SANE, Lysholm) • Game Ready pts had significantly better VAS improvements when evaluating for mean differences relative to pre-op VAS scores: <ul style="list-style-type: none"> • Post-op week 2 ($P=0.023$) • Post-op week 6 ($P<0.0001$)

There are inherent risks in all medical devices. Please refer to the product labeling for Indications, Cautions, Warnings and Contraindications. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to www.avanospainmanagement.com for product safety Technical Bulletins.
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