

Game Ready® Injury Treatment System

Health Technology Brief

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Game Ready® injury Treatment System, also known as Game Ready Accelerated Recovery System, is a cryotherapy device with compression. The device pumps cold water through a sleeve around the affected limb and may provide intermittent compression at the same time by inflating and deflating the sleeve. The Food and Drug Administration (FDA) classifies the Game Ready® system as a powered inflatable tube massager/cold water circulating pack. It is intended to treat post-surgery and acute injuries to reduce edema, swelling and pain where cold and compression are indicated.

The efficacy of Game Ready® for treating post-surgery injuries to reduce pain and swelling has been examined in seven studies as referred to by the manufacturer, including three randomized controlled trials (RCT) and four non-randomized studies (NRS). Only some of the studies were designed properly to address the key question: is Game Ready® (or a cryotherapy device) more effective than conventional treatment (*e.g.*, ice plus static compression) in reducing pain and swelling in post-operative patients. We reviewed all these studies in detail and summarized the study characteristics and main outcomes in Table 1.

In a RCT, Su et al. (2012) randomized 294 patients undergoing total knee arthroplasty (TKA) to either the group treated with Game Ready® cryotherapy device or the group treated with ice and static compression to evaluate whether there would be differences in pain, swelling, range of motion, functional testing, and consumption of pain medication. The patients were evaluated by physical therapists blinded to the treatment arms. Range of motion (ROM), knee girth, six minute walk test (6MWT) and timed up and go test (TUG) were measured pre-operatively, and two- and six-weeks post-operatively. A visual analog pain score (VAS) and narcotic consumption were also measured post-operatively. No difference was found between the two treatments throughout the study in all primary outcomes, including ROM, knee girth, 6MWT, TUG and VAS scores. As a secondary outcome, narcotics consumption was lower in the Game Ready® group compared to the control group at up to two weeks post-operation (509 mg vs. 680 mg morphine equivalents, respectively). However, the difference diminished after the first 2 weeks. It is unclear if the dosage difference in the short term was clinically significant, especially since there was no difference found in VAS scores between groups. This study with fair quality addressed the key question as to whether Game Ready® (or a cryotherapy device) is more effective than conventional treatment (*e.g.*, ice plus static compression) in reducing pain and swelling in post-operative patients. The results clearly suggest that Game Ready® is not superior to the conventional treatment with ice plus static compression in reducing pain and swelling, and improving functional recovery after TKA surgery.

The second RCT was a small study with 30 subjects (Leegwater et al. 2012). In this study, the Game Ready® System (GRS) Hip/ Groin- wrap on top of tricot compression bandage was

compared to tricot compression bandage alone in patients undergoing elective total hip arthroplasty (THA) for end-stage osteoarthritis. The primary endpoints were pain reduction (NRS), analgesic use and wound discharge. No difference was found between groups in postoperative pain, morphine use, wound discharge, early mobilization, perioperative blood loss and total admission time, indicating that Game Ready® offers no additional benefit over conventional static compression in pain reduction and function recovery after THA surgery. The only difference found was the hemoglobin level on postoperative day 1 (POD1). However, the difference in hemoglobin level diminished on postoperative day 3 (POD3). Clinical significance of this outcome is highly questionable in this context.

In the third RCT, Waterman et al. (2012) compared Game Ready® cryotherapy device (cold + compression) to ice pack therapy alone to evaluate the efficacy in patients after anterior cruciate ligament (ACL) reconstruction. The primary outcomes were postoperative edema, pain, and patient reported outcome measures. The patients were evaluated at 1, 2 and 6 weeks postoperatively. Because it used ice alone as the comparator, this study did not address the comparative effectiveness of Game Ready® cryotherapy device relative to the standard of care, *i.e.*, ice plus static compression. Nevertheless, no difference was detected in the primary outcomes, including edema, pain/function (Lysholm and SANE scores), and health status (SF-36) either between groups or between time points. Though the authors reported a greater decrease in VAS score from the baseline in Game Ready® group than that in the control group at week 6 post-operation, the validity of this result is highly questionable. The VAS scores were significantly different (54.9 and 35.6, respectively, $p = 0.01$) between groups at the baseline (in the preoperative measurement) and the difference was not adjusted statistically, indicating the existence of patient selection bias for this primary outcome measure. Because of the significant difference in baseline characteristics and high attrition rate, this study would be at high risk of bias.

Table 1. Study Characteristics and Patient Outcomes

Author and Study Design	Patient Population	Treatment/primary outcomes	Outcomes reported	Comments and Quality (risk of bias)
Randomized controlled trials (RCT)				
<p>Su et al. 2012</p> <p>Hospital for Special Surgery, New York, New York.</p> <p>A multi-center RCT at 11 international sites. To evaluate Game Ready cryotherapy device vs ice plus static compression for improving postop</p>	<p>Patients who had total knee arthroplasty.</p> <p>N= 294. 187 patients completed the study (103 [70%] in Game Ready arm and 84 [57%] in the control arm). 64% overall.</p>	<p>Patients were randomized to treatment with Game Ready or ice plus static compression.</p> <p>Both treatments were initiated within three hours post-operation and used at least four times per day for two weeks.</p> <p>ROM, knee girth, 6MWT and TUG were measured pre-operatively, two- and six-weeks post-operative. Pain and narcotic consumption were also measured</p>	<p>There was no difference in VAS scores between the groups throughout the study, and no difference in other primary outcomes (ROM, 6MWT, TUG, or knee girth) between groups.</p> <p>A lower amount of narcotic consumption (509 mg vs. 680 mg morphine equivalents) was found at the first two weeks post-operation in the Game Ready group ($p <$</p>	<p>Game Ready is NOT superior to ice plus static compression bandage in ROM, 6MWT, TUG, knee girth or pain reduction (VAS scores). Though there was greater satisfaction in patients treated with Game Ready system, there was no difference in</p>

<p>outcomes in pts undergoing TKA</p>			<p>0.05). However, the difference diminished after week 2. There was a significant difference in the satisfaction scores of patients with their cooling regimen, with greater satisfaction in Game Ready group ($p < 0.0001$). There was no difference in adverse events or compliance between the two groups.</p>	<p>compliance between the two groups. Risk of bias – moderate</p>
<p>Leegwater et al. 2012 Department of Orthopedic Surgery, Spaarne Hospital, Hoofddorp - The Netherlands Single center Prospective, randomized, pilot study, to evaluate the effect of intermittent cryo-compression therapy following elective THA.</p>	<p>N= 30 (15:15) Patients undergoing elective THA for end-stage osteoarthritis</p>	<p>Treatment group: patients treated with the Game Ready System® (GRS) Hip/Groin- wrap plus a standard tricot compression bandage; Control group: patients treated with standard tricot compression bandage. Randomization took place on the day of operation prior to surgery with the use of sealed opaque envelopes. Each treatment cycle consisted of 30 minutes. The minimum non-GRS-treatment interval was 4 hours. Primary outcomes were numeric rating scale (NRS) pain scores, analgesic use and wound discharge.</p>	<p>No difference was found between groups in all primary outcomes: postoperative pain, morphine use, wound discharge, early mobilization (function recovery), perioperative blood loss, total admittance time. Hemoglobin levels on postoperative day (POD) 1 dropped 2.34 mmol/L in the control group and 1.87 mmol/L in the intervention group ($p = 0.027$). At POD 3 haemoglobin levels were reduced by 2.63 and 2.16 respectively ($p = 0.646$).</p>	<p>Game Ready® offers no additional benefit over conventional static compression in postoperative pain reduction and function recovery after THA surgery Risk of bias – moderate</p>
<p>Waterman et al. 2012 Department of Orthopedics, William Beaumont Army Medical Center, El Paso, Texas Single center Prospective, randomized controlled trial, to evaluate the effect of Game Ready vs ice alone following ACL reconstruction. Assessments of compliance were performed at 1, 2, and 6 weeks postoperatively</p>	<p>N=36. Patients with age 18 to 65 undergoing ACL reconstruction were randomized to two groups (1:1) By week 6, compliance in both groups decreased dramatically (Game Ready: n=5, 28%; control: (n=7, 39%,). Overall attrition: 67%. Only n=12 completed study.</p>	<p>Treatments: Game Ready vs. standardized ice pack. Patients were treated three times per day, and returned to the clinic at 1, 2, and 6 weeks postoperatively. Primary Outcome measurements: postoperative edema, pain, and patient reported outcome measures. Pain (VAS), Knee pain and function (Lysholm knee score and single assessment numerical evaluation [SANE]), and health status (SF-36). Circumferential measurements of the knee obtained at three locations. Narcotic medication use was recorded by questionnaire.</p>	<p>No difference was detected for any of the circumferential measurements either between groups or between time points. No significant difference was detected in Lysholm, SF-36, or SANE scores either between groups or between time points. By week 6 post-operation, VAS in Game Ready group decreased significantly compared to baseline value, whereas no significant change of VAS was detected in the control group. However, VAS scores significantly different between groups (54.9 vs. 35.6, $P = 0.01$) at the baseline, indicating the existence of patient selection bias. Of all patients, 83% of Game Ready group discontinued narcotic use by 6 weeks, compared with 28% of the control group ($p = 0.0008$).</p>	<p>Game Ready does not seem to provide additional benefit in reducing swelling and function recovery compared to ice. The result in pain reduction is inconclusive due to the significant dissimilarity between groups at baseline regarding pain scores. Limitations: 1. Compared to ice alone, not ice plus compression; 2. Significant difference of VAS scores between groups at the baseline; 3. Low compliance rates (high attrition rate - complete data collection: n=12) Risk of bias – high</p>

Nonrandomized studies (NRS)

<p>Bellon et al. 2019</p> <p>Paris Diderot University, Paris, France</p> <p>Cohort study with scheduled patients.</p>	<p>n=45 (23:22).</p> <p>Pediatric patients (<18 yrs.) undergoing surgery for idiopathic scoliosis.</p>	<p>Cooling (Cryotherapy) only vs. no cooling (no treatment)</p> <p>Game Ready was placed on patient at the end of surgery and connected to the cooling system soon after arriving to the PACU and maintained for 24 h after the admission to the PACU</p> <p>The primary outcome – morphine consumption during the first postoperative day; 2nd outcome – opioid consumption at day 3, pain intensity, mobility in the standing position at days 1 and 3 and during hospitalization.</p>	<p>Cooling brace was associated with a decrease in morphine consumption at day 1 (1.7 [0.9, 3.3] vs. 1.2 [0.5, 3.2], P = 0.02) and day 3 (2.5 [0.5, 6.7] vs. 1.2 [0.9, 2.5], p = 0.003), and a reduction in duration of hospitalization (4 [3, 6] vs 3 [3, 4]) days, p=0.004).</p>	<p>No difference found on pain intensity or function recovery (the percentage of patient mobilized in the standing position).</p> <p>Risk of bias – high</p>
<p>Klaber et al. 2019</p> <p>Hip Arthroscopy Australia, Richmond VIC 3121, Australia.</p> <p>Cohort study retrospectively matched controls, to evaluate the effect of cryotherapy + compression on pain, analgesic requirement and early discharge.</p>	<p>N=40 (20:20)</p> <p>Patients in post-operative period after hip arthroscopy for FAI.</p>	<p>Game Ready vs. standard cryotherapy [ice application]</p> <p>Primary outcomes: the percentage of patients discharged in post-operative day one; pain scores (VAS) and analgesia requirement.</p>	<p>No significant difference found in reduction in analgesic requirement (1.75 versus 2.8 doses per patient) or in hospital time.</p> <p>The Game Ready group was reported to have significantly lower pain scores compared to the control group [VAS 1 (0– 3) and 2 (0–5) (P=0.0028), respectively]</p>	<p>There was no difference in patients discharge time and analgesia requirement.</p> <p>Our independent analysis of the data presented in the paper showed that there is no difference between groups in pain reduction. In addition, the VAS scores were so low in both groups, the difference is not likely clinically meaningful.</p> <p>Retrospectively matched controls are associated with a high risk of bias.</p> <p>Risk of bias – very high</p>
<p>Nabiyev et al. 2018</p> <p>Department of Orthopaedics, ARTES Spine Center, Acibadem Ankara Hospital, Ankara, Turkey.</p> <p>Cohort study with historical controls, to analyze the analgesic efficacy of Game Ready therapy after adult lumbar spinal surgery.</p>	<p>N=40 (20:20)</p> <p>Adult patients with lumbar spinal disorders requiring instrumented fusion (up to 5 levels).</p>	<p>Game Ready vs. retrospective controls (no treatment).</p> <p>After the surgical procedure, all patients received Game ready therapy using a surgeon applied trunk wrap covering most of the thoracolumbar area and the iliac crests. The therapy (Game Ready, GRPro 2.1 system, delivers both adjustable continuous flow cryotherapy and intermittent compression. Patients were treated between 12 times during the first 72 postoperative hours, each cycle lasting 30 minutes.</p>	<p>In the post-anesthesia care unit, the mean VAS back pain score was 5.87±0.9 in the treatment group and 6.95±1.0 (p=0.001) in the control group. The corresponding mean VAS scores for the treatment vs. control groups were 3.8±1.1 vs. 5.4±0.7 (p<0.001) at 6 hours postoperatively, and 2.7±0.7 vs. 6.25±0.9 (p<0.001) at discharge, respectively. The cumulative mean analgesic consumption of paracetamol, tenoxicam, and tramadol in the treatment group vs. control group was 3,733.3±562.7 mg vs. 4,633.3±693.5 mg (p<0.005),</p>	<p>No difference in hospitalization time.</p> <p>Compared to retrospectively matched controls with no treatment. The results in pain reduction and analgesic consumption are not surprising, because the effect of cooling and/or compression on pain is expected as a standard of care.</p> <p>Historical controls are associated with a high risk of bias.</p>

			53.3±19.5 mg vs. 85.3±33.4 mg (p<0.005), and 63.3±83.4 mg vs. 393.3±79.9 mg (p<0.0001), respectively.	Risk of bias – very high
Murgier and Cassard. 2014 Hôpital Pierre-Paul-Riquet, Toulouse, France A prospective single-center study of consecutive patients.	N=39 (20:19) Patients with postoperative pain following anterior cruciate ligament (ACL) surgery.	Game Ready vs. cryotherapy plus static compression (IceBand).	In the post-anesthesia recovery unit, the mean VAS pain score was 2.4 with Game Ready and 2.7 with control (P=0.3); 1.85 vs. 3.0 (P=0.16) after 6 hrs; 0.6 vs. 1.14 (P=0.12) at discharge. The cumulative mean tramadol dose per patient was 57.5 mg (0-200) vs 128 mg (0-250) (P=0.023); Morphine used was 0 mg vs. 1.14 mg (0-8) (P<0.05). Mean range of knee flexion at discharge was 90.5° (80-100) vs. 84.5° (75-90) (P=0.005)	Edema was not measured. No difference in pain reduction. Risk of bias – high

The other four studies are all nonrandomized studies with either prospective or historical controls. The study characteristics and main outcomes are summarized in Table 1. The sample sizes are small, ranging from 39 to 45. The quality of the evidence is very low. For example, two of the studies (Klaber et al. 2019 and Nabiyeve et al. 2018) used historical controls as comparators, which was associated with high risk of bias. Since the four studies were conducted in different patient populations with varied comparators, it is difficult to draw general conclusions from these observational studies as a whole. Nevertheless, no difference was found in pain reduction in at least two studies. Bellon et al. (2019) found no effect of Game Ready® cryotherapy device (cooling only) on pain reduction compared to no cooling in the pediatric patients undergoing surgery for idiopathic scoliosis. Similarly, Murgier et al. (2014) found no effect of Game Ready® on pain in the patients after ACL surgery compared to IceBand (cooling plus static compression).

Klaber et al. (2019) reported that the Game Ready® group had a lower pain score compared to the ice pad group in the patients undergoing hip arthroscopy for FAI. We examined the data presented in the paper and conducted an independent analysis of the data set. Our results demonstrated that there is no difference between groups in pain reduction. In addition, using the retrospectively matched control as a comparator is associated with high risk of bias. Nabiyeve et al. (2018) reported that Game Ready® was associated with a decrease in pain score compared to no treatment in the patients (retrospectively matched controls) undergoing lumbar spinal fusion. This result is not surprising, because the effect of cooling and/or compression on pain is expected as a standard of care. This study does not address the question of whether Game Ready® is superior to the standard of care (ice and/or static compression) for treatment of edema and pain following orthopedic surgery.

In conclusion, the current evidence shows little net benefit of using the Game Ready® cryotherapy device in patients following orthopedic surgery in reducing edema, pain and hospital admission duration, and improving functional recovery compared to ice and/or static compression.

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