GAME READY®

CLINICAL STUDIES OVERVIEW

USING THE GRPRO® 2.1 COLD & COMPRESSION THERAPY SYSTEM

Seven Post-Market Clinical Follow-Up studies have been completed evaluating the benefits of Game Ready's cold and compression therapy system for total knee arthroplasty (TKA), anterior cruciate ligament (ACL) reconstruction [2 studies], total hip arthroplasty (THA), hip arthroscopy, adult lumbar spinal surgery, and scoliosis surgery patients. Benefits of using the Game Ready system after surgery are listed below.

- Reduces patient opioid consumption and may allow for earlier discontinuation of opioid medications in certain patients [1,3,4,6,7]
- May increase patient satisfaction with the recovery process [1,2,5]
- Increased post-operative range of motion in ACL patients [4]
- Decreases pain [1,5,8]
- Lower postoperative blood loss [8]
- May lead to early hospital discharge [shorter length of stay] in some patients. [5,7]

STUDY ONE | Su et al.

1 Su, E.P., Perna, M., Boettner, F., Mayman, D.J., Gerlinger, T., Barsoum, W., Randloph, J., & Lee, G. (November, 2012). A prospective, multi-center, randomised trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery. The Journal of Bone and Joint Surgery 94-B, Supple A: 153-6. https://www.ncbi.nlm.nih.gov/pubmed/23118406

Abstract

(source: https://www.ncbi.nlm.nih.gov/pubmed/23118406)

Pain, swelling and inflammation are expected during the recovery from total knee arthroplasty (TKA) surgery. The severity of these factors and how a patient copes with them may determine the ultimate outcome of a TKA. Cryotherapy and compression are frequently used modalities to mitigate these commonly experienced sequelae. However, their effect on range of motion, functional testing, and narcotic consumption has not been well-studied. A prospective, multi-center, randomised trial was conducted to evaluate the effect of a cryopneumatic device on post-operative TKA recovery. Patients were randomised to treatment with a cryopneumatic device or ice with static compression. A total of 280 patients were enrolled at 11 international sites. Both treatments were initiated within three hours post-operation and used at least four times per day for two weeks. The cryopneumatic device was titrated for cooling and pressure by the patient to their comfort level. Patients were evaluated by physical therapists blinded to the treatment arm. Range of motion (ROM), knee girth, six minute walk test (6MWT) and timed up and go test (TUG) were measured pre-operatively, two- and six-weeks post-operatively. A visual analog pain score and narcotic consumption was also measured post-operatively. At two weeks post-operatively, both the treatment and control groups had diminished ROM and function compared to pre-operatively. Both groups had increased knee girth compared to pre- operatively. There was no significant difference in ROM, 6MWT, TUG, or knee girth between the 2 groups. We did find a significantly lower amount of narcotic consumption (509 mg morphine equivalents) in the treatment group compared with the control group (680 mg morphine equivalents) at up to two weeks postop, when the cryopneumatic device was being used ($p < 0.05$). Between two and six weeks, there was no difference in the total amount of narcotics consumed between the two groups. At six weeks, there was a trend toward a greater distance walked in the 6MWT in the treatment group (29.4 meters versus 7.9 meters, $p = 0.13$).

There was a significant difference in the satisfaction scores of patients with their cooling regimen, with greater satisfaction in the treatment group ($p < 0.0001$). There was no difference in ROM, TUG, VAS, or knee girth at six weeks. There was no difference in adverse events or compliance between the two groups. A cryopneumatic device used after TKA appeared to decrease the need for narcotic medication from hospital discharge to 2 weeks post-operatively. There was also a trend toward a greater distance walked in the 6MWT. Patient satisfaction with the cryopneumatic cooling regimen was significantly higher than with the control treatment.

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STUDY TWO | Leegwater et al.

2 Leegwater, N.C., Willems J.H., Brohet, R., & Nolte, P.A. (2012). Cryocompression therapy after elective arthroplasty of the hip. Hip International, 22 (05): 527-533. https://www.ncbi.nlm.nih.gov/pubmed/23112075

Abstract

(source: https://www.ncbi.nlm.nih.gov/pubmed/23112075)

Pneumatic compression and cryotherapy have been successfully being employed in the management of acute tissue damage. The Game Ready System (GRS) combines cyclic compression and cryotherapy. No randomised controlled trial has been performed on the effects of combined cyclic compression and cryotherapy in total hip arthroplasty (THA).

We observed postoperative pain, morphine usage, blood loss, wound discharge, patient and medical staff satisfaction, together with the feasibility of a cryocompression machine, total hospital admission time, infection rate, deep vein thrombosis, and short-term prosthesis related problems in this context. Thirty patients, mean age 68 yrs (range 31-83 yrs) undergoing elective hip arthroplasty for end-stage osteoarthritis were included. Control patients (n = 15) received a tricot compression bandage alone, and patients studied received a tricot compression bandage plus intermittent cryocompression therapy 15 times for 30 minutes. Haemoglobin 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). A trend occurred towards lower morphine usage, shorter hospital admission time and less wound discharge in the study group. No difference was found in postoperative pain scores. One event of deep venous thrombosis occurred in the control group. Intermittent cryocompression therefore appears to reduce postoperative blood loss. A trend towards less analgesic use, shorter hospital stay, less wound discharge and less pain at 6 weeks postoperatively was also observed.

STUDY THREE | Waterman et al.

3 Waterman, B., Walker, J.J., Swains, C., Shortt, M., Todd, M.S., Machen, S.M., & Owens, B.D. (2012). The Efficacy of Combined Cryotherapy Compression Compared with Cryotherapy Alone Following Anterior Cruciate Ligament Reconstruction. The Journal of Knee Surgery 25 (02): 155-160. https://www.ncbi.nlm.nih.gov/pubmed/22928433

Abstract

(source: https://www.ncbi.nlm.nih.gov/pubmed/22928433)

While cryotherapy has been shown to decrease postoperative pain after anterior cruciate ligament (ACL) reconstruction, less is known of the effects of combined cryotherapy and compression. The goal of this study was to compare subjective and objective patient outcomes following ACL reconstruction with combined compression and cryotherapy compared with traditional ice therapy alone. Patients undergoing ACL reconstruction were randomized to cryotherapy/compression device (group 1) or a standardized ice pack (group 2). Both groups were instructed to use the ice or cryotherapy/compression device three times per day and return to the clinic at 1, 2, and 6 weeks postoperatively. Patient-derived outcome measurements used in this study consisted of the visual analog scale (VAS), the Lysholm knee score, Short Form-36 (SF-36), and single assessment numerical evaluation (SANE). Circumferential measurements of the knee at three locations (1 cm proximal to patella, mid-patella, and 1 cm distal to patella) were also obtained as a measure of postoperative edema. Narcotic medication use was recorded by questionnaire. The primary outcome measure (VAS) was significantly different among groups in the preoperative measurement, despite similarities in group demographics. Baseline VAS for group 1 was 54.9 compared with group 2 at 35.6 (p = 0.01). By 6 weeks, this had lowered to 28.1 and 40.3, respectively, resulting in a significant 27-point decrease in mean VAS for group 1 (p < 0.0001).

However, the small increase in VAS for group 2 was not significant (p = 0.34). No significant differences were noted for the Lysholm, SF-36, or SANE scores either between groups or time points. Furthermore, no significant differences were noted for any of the circumferential measurements either between groups or time points.

Of all patients, 83% of group 1 discontinued narcotic use by 6 weeks, compared with only 28% of group 2 (p = 0.0008). The use of combined cryotherapy and compression in the postoperative period after ACL reconstruction results in improved, short-term pain relief and a greater likelihood of independence from narcotic use compared with cryotherapy alone.

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STUDY FOUR | Murgier et al.

4 Murgier, J. & and Cassard, X. (2014). Cryotherapy with dynamic intermittent vompression for analgesia after anterior cruciate ligament reconstruction. Preliminary study. Orthopaedics & Traumatology: Surgery & Research 100: 309-312, 2014. https://www.ncbi.nlm.nih.gov/pubmed/24679367

Abstract

(source: https://www.ncbi.nlm.nih.gov/pubmed/24679367)

BACKGROUND:
The goal of this study was to assess the efficacy of cryotherapy with dynamic intermittent compression (CDIC) in relieving postoperative pain, decreasing blood loss, and improving functional scores after revision total knee arthroplasty (rTKA).

METHODS:
We conducted a prospective case-control study (level of evidence: I) to evaluate the efficacy of CDIC on postoperative bleeding, pain, and functional outcomes after rTKA. Forty-three cases were included at a single institution and divided in 2 groups: a control group without CDIC (n = 19) and an experimental group with CDIC (n = 24). Bleeding was evaluated by calculating total blood loss, pain at rest was evaluated with a visual analog scale on postoperative day 3, and function was assessed using the Oxford score at 6 months postoperatively. The comparative analysis was performed using the Fisher exact test.

RESULTS:
The CDIC group had significantly lower total blood loss (260 vs 465 mL; P < .05), significantly less pain on day 3 (1 vs 3; P < .05), and a significantly higher functional score (42 vs 40; P < .05) than the control group.

CONCLUSION:
This is the first report dealing with the use of CDIC after rTKA. According to our results, it improves the recovery of patients who underwent rTKA; thus, it should be integrated into our daily practice.

STUDY FIVE | Klaber et al.

5 Klaber I, Greeff E, O'Donnell J. Compressive cryotherapy is superior to cryotherapy alone in reducing pain after hip arthroscopy. Journal of Hip Preservation Surgery. 2019; 0(0):1-6. https://academic.oup.com/jhps/advance-article/doi/10.1093/jhps/hnz048/5610188

Abstract

(source: https://academic.oup.com/jhps/advance-article/doi/10.1093/jhps/hnz048/5610188)

The early post-operative period after hip arthroscopy for femoroacetabular impingement is characterized by pain and swelling. Minimization of pain is of critical importance to the patient, but pain might also reduce patients' compliance to early physiotherapy, delay rehabilitation and hospital discharge. Avoiding early mobilization represents a risk factor for developing capsulolabral adhesions. Compressive cryotherapy (CC) has been shown to reduce pain after knee and hip replacement surgery. The aim of this study was to assess the effect of the inclusion of CC in the pain management and early discharge after hip arthroscopy. A prospective cohort of 20 patients who received CC and 20 retrospectively matched controls who received standard cryotherapy (SC) were compared. The CC was added to the standard post-operative analgesia and rehabilitation protocol.

Using non-parametric tests, the percentage of patients discharged in post-operative day one, pain VAS scores and analgesia requirement were compared. The CC group reported significantly lower pain scores compared to SC; VAS 1 (0–3) and 2 (0–5) (P = 0.0028), respectively. A non-significant reduction in analgesic requirement 1.75 versus 2.8 doses per patient was found and 20/20 patients were discharged on post-operative day one versus 17/20 in the SC group (P = 0.23). Patients treated with CC after hip arthroscopy reported lower levels of pain during the early post-operative phase and were able to be discharged home sooner when compared with a matched control group receiving ice therapy alone. A trend towards lower opioid analgesia requirement was observed.

STUDY SIX | Nabıyev et al.

6 Nabıyev V. N., Ayhan S., Adhıkarı P., Cetın E., Palaoglu S., Acaroglu R. E. Cryo-compression therapy after elective spinal surgery for pain management: a cross-sectional study with historical control. Neurospine. 2018;15(4):348-352. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6347345/pdf/ns-1836070-035.pdf

Abstract

(source: https://academic.oup.com/jhps/advance-article/doi/10.1093/jhps/hnz048/5610188)

OBJECTIVE:
Postoperative dynamic cryo-compression (DC) therapy has been proposed as a method of reducing pain and the inflammatory response in the early postoperative period after orthopedic joint reconstruction surgery. Our aim was to analyze the analgesic efficacy of DC therapy after adult lumbar spinal surgery.

METHODS:
DC was applied for 30 minutes every 6 hours after surgery. Pain was measured by a visual analogue scale (VAS) in the preoperative period, immediately after surgery, and every 6 hours postoperatively for the first 72 hours of the hospital stay. Patients' pain medication requirements were monitored using the patient-controlled analgesia system and patient charts. Twenty patients who received DC therapy were compared to 20 historical controls who were matched for demographic and surgical variables.

RESULTS:
In the postanesthesia care unit, the mean VAS back pain score was 5.87 ± 0.9 in the DC group and 6.95±1.0 (p=0.001) in the control group. The corresponding mean VAS scores for the DC 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 DC group vs. control group was 3,733.3±562.7 mg vs. 4,633.3±693.5 mg (p<0.005), 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.

STUDY SEVEN | Bellon et al.

7 Bellon M.,· Michelet D., Carrara N., Vacher T., Gafsou B., Ilhareborde B., Mazda K., Ferrero E., Simon A.-L., Julien Marsollier F., Dahmani S. Efficacy of the Game Ready® cooling device on postoperative analgesia after scoliosis surgery in children. European Spine Journal. 2019; 28:1257–1264. https://link.springer.com/article/10.1007%2Fs00586-019-05886-6

Abstract

(source: https://link.springer.com/article/10.1007%2Fs00586-019-05886-6)

PURPOSE:
The aim of this study was to investigate the opioid-sparing effect of a cooling brace after surgical correction of idiopathic surgery in children.

METHODS:
We compared two consecutive cohorts of patients before and after introducing this technique in our institution. Management of patients was standardized. The primary objective of the study was to investigate the morphine consumption during the first postoperative day. Secondary outcomes were opioid consumption at day 3, pain intensity (at days 1 and 3), the mobilization in the standing position and duration of hospitalization.
RESULTS:
This study included 23 and 22 patients in the control and the cooling cohorts. Cooling brace was associated with a significant decrease in morphine consumption at day 1 (1.7 [0.9, 3.3] versus 1.2 [0.5, 3.2] mg kg−1, P = 0.02) and day 3 (2.5 [0.5, 6.7] versus 1.2 [0.9, 2.5] mg kg−1, P = 0.003), and a reduction in duration of hospitalization (4 [3, 6] versus 3 [3, 4] days, P = 0.004). However, no difference was found on the pain intensity or the percentage of patient mobilized in the standing position. Number of level fused and intraoperative opioid consumption were also different between the two cohorts. However, multivariate analysis found only the use of the cooling brace as significantly associated with opioid consumption at day 1.

CONCLUSION:
The use of this cooling brace allows decreasing the opioid use after surgical correction of idiopathic surgery in children. The current results strongly suggest an interest of this technique in the postoperative management of patients.

STUDY EIGHT | Murgier et al.

8 Murgier, Jérôme, Cailliez, J., Wargny, M., Chiron, P., Cavaignac, E., Laffosse, J.M. Cryotherapy With Dynamic Intermittent Compression Improves Recovery From Revision Total Knee Arthroplasty. The Journal of Arthroplasty. 2017; 1-4. https://pubmed.ncbi.nlm.nih.gov/28465126/

Abstract

(source: https://pubmed.ncbi.nlm.nih.gov/28465126/)

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AVANOS | GAME READY