

GAME READY CLINICAL STUDIES OVERVIEW

A REVIEW OF GAME READY SPECIFIC CLINICAL EVIDENCE AND CLINICAL BENEFITS

Five 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) and revision total knee arthroplasty (rTKA) patients. As a result of these PMCF studies, there are 12 clinically proven benefits claims for the Game Ready System.

1. Reduces patient narcotic consumption ^{1,3,4,5}
2. Allows earlier discontinuation of narcotic pain medication ²
3. Improves key, measurable physical therapy milestones ^{1,3}
4. Increases patient satisfaction with the recovery process ^{1,4}
5. Reduces blood transfusion rates ⁵
6. Reduces postoperative blood loss ^{4,5}
7. Shortens hospital admission time ⁴
8. Provides less wound discharge ⁴
9. Reduces risk of infection ^{4,5}
10. Decreases pain ^{2,4,5}
11. Decreases swelling ⁴
12. Increases postoperative function ⁵

CLINICAL STUDY ABSTRACTS AND REFERENCES

1. Su, E.P., Perna, M., Boettner, F., Mayman, D.J., Gerlinger, T., Barsoum, W., Randolph, 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.

ABSTRACT (source: <http://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, multicenter, randomised trial was conducted to evaluate the effect of a cryopneumatic device on postoperative 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 postoperation 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 preoperatively, two and six weeks postoperatively. A visual analog pain score and narcotic consumption was also measured postoperatively. At two weeks postoperatively, both the treatment and control groups had diminished ROM and function compared to preoperatively. 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 postoperatively. 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.

2. 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.

ABSTRACT (source: <http://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 (SF36), and single assessment numerical evaluation (SANE). Circumferential measurements of the knee at three locations (1 cm proximal to patella, midpatella, 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, SF36, 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.

3. Murgier, J. & Cassard, X. (2014). Cryotherapy with Dynamic Intermittent Compression for Analgesia After Anterior Cruciate Ligament Reconstruction. Preliminary Study. Orthopaedics & Traumatology: Surgery & research 100: 309-312, 2014.

ABSTRACT (source: <http://www.ncbi.nlm.nih.gov/pubmed/24679367>)

BACKGROUND: Cryotherapy is a useful adjunctive analgesic measure in patients with postoperative pain following anterior cruciate ligament (ACL) surgery. Either static permanent compression or dynamic intermittent compression can be added to increase the analgesic effect of cryotherapy. Our objective was to compare the efficacy of these two compression modalities combined with cryotherapy in relieving postoperative pain and restoring range of knee motion after ligament reconstruction surgery.

HYPOTHESIS: When combined with cryotherapy, a dynamic and intermittent compression is associated with decreased analgesic drug requirements, less postoperative pain, and better range of knee motion compared to static compression.

MATERIALS AND METHODS: We conducted a case control study of consecutive patients who underwent anterior cruciate ligament reconstruction at a single institution over a 3 month period. Both groups received the same analgesic drug protocol. One group was managed with cryotherapy and dynamic intermittent compression (Game Ready®) and the other with cryotherapy and static compression (IceBand®).

RESULTS: Of 39 patients, 20 received dynamic and 19 static compression. In the post anaesthesia recovery unit, the mean visual analogue scale (VAS) pain score was 2.4 (range, 0-6) with dynamic compression and 2.7 (0-7) with static compression ($P=0.3$); corresponding values were 1.85 (0-9) vs. 3 (0-8) ($P=0.16$) after 6 hours and 0.6 (0-3) vs. 1.14 (0-3) ($P=0.12$) at discharge. The cumulative mean tramadol dose per patient was 57.5mg (0-200mg) with dynamic compression and 128.6 mg (0-250 mg) with static compression ($P=0.023$); corresponding values for morphine were 0mg vs. 1.14 mg (0-8 mg) ($P<0.05$). Mean range of knee flexion at discharge was 90.5° (80°-100°) with dynamic compression and 84.5° (75°-90°) with static compression ($P=0.0015$).

CONCLUSION: Dynamic intermittent compression combined with cryotherapy decreases analgesic drug requirements after ACL reconstruction and improves the postoperative recovery of range of knee motion.

4. Leegwater, N.C., Jore, H.W., Brohet, R., & Nolte, P. (2102). Cryocompression therapy after elective arthroplasty of the hip. Hip Int, 22 (05): 527-533.

ABSTRACT (source: <http://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.

5. Murgier J, Cailliez J, Wargny M, Chiron P, Cavaignac (E, Laffosse J, Cryotherapy with Dynamic Intermittent Compression Improves Recovery from Revision Total Knee Arthroplasty, *The Journal of Arthroplasty* (2017), doi: 10.1016/j.arth.2017.03.052.

ABSTRACT (source: <https://www.ncbi.nlm.nih.gov/pubmed/28465126>)

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.