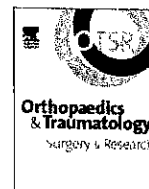




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Original article

# Cryotherapy with dynamic intermittent compression for analgesia after anterior cruciate ligament reconstruction. Preliminary study



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## ABSTRACT

**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 57.5 mg (0–200 mg) with dynamic compression and 128.6 mg (0–250 mg) with static compression ( $P=0.023$ ); corresponding values for morphine were 0 mg 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.

**Level of evidence:** Level III, case-control study.

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## 1. Introduction

Postoperative pain control after knee ligament reconstruction is a key objective regardless of the surgical technique used [1,2], as well as a public health issue, since improving postoperative pain management has a major influence in decreasing hospital length of stay [3,4], improving patient comfort, and expediting rehabilitation [5,6].

Postoperative pain control is achieved by administering standard analgesic therapy, which may be combined with regional nerve blocks [7]. Non-pharmacological treatments also play a role,

most notably cryotherapy, which decreases the local metabolism, thereby reducing the inflammation and pain [8,9]. Cryotherapy was found effective in studies by Raynor et al. and Bleakley et al. [10,11] and is recommended after knee ligament reconstruction by the French National Authority for Health (HAS 2008) [12]. After anterior cruciate ligament (ACL) reconstruction, cryotherapy as adjunctive analgesic therapy contributed to alleviate pain in studies by Waterman et al. [13] and Schroder et al. [14]. Improvements in cryotherapy methods introduced over the years include the dynamic intermittent compression. Compared to permanent static compression, dynamic intermittent compression improves tissue oxygenation, microcirculation, and interstitial fluid circulation, thereby improving soft tissue exchanges (oxygen, nutrients) [15]. Also, cryotherapy combined with dynamic intermittent compression (CDIC) decreases the major risk of skin

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necrosis associated with cryotherapy and static permanent compression (CSPC) [16–18].

We compared the analgesic efficacy of CDIC and CSPC after ACL reconstruction surgery. This is a pilot study, as no previous studies have evaluated the efficacy of CDIC in controlling postoperative pain after knee ligament reconstruction.

Our working hypothesis was that CDIC decreased analgesic drug requirements (primary evaluation criterion) and decreased pain severity, while improving range of knee motion (secondary evaluation criteria) compared to CSPC.

## 2. Material and method

### 2.1. Patients

We conducted a prospective single-centre study of consecutive patients who underwent primary ACL reconstruction by the same senior surgeon over a 3-month period (1st March to 31 May 2012). Patients were eligible if they had isolated ACL tears without meniscal damage and were managed with a short four-strand semitendinosus graft and the Tape Locking Screw® (TLS) system (FH Orthopaedics, Mulhouse, France) [19]. We excluded patients with contra-indications to compressive cryotherapy (pre-operative leg oedema, history of lower-limb deep vein thrombosis, or skin damage), patients on long-term analgesic therapy for another condition, and patients undergoing revision ACL reconstruction.

During the study period, we included 39 patients (16 other patients were excluded). Of the 39 included patients, 20 received CDIC using the Game Ready® device (Coolsystems Inc., San Diego, CA) and 19 received CSPC using the IceBand® device (IB medical, Tranås, Sweden). ACL reconstruction was performed under general anaesthesia in all 39 patients, with no additional regional anaesthesia.

The cryotherapy compression device was applied by the surgeon at the end of the procedure and left in place until hospital discharge.

### 2.2. Cryotherapy compression devices

#### 2.2.1. CDIC – Game Ready®

Specific staff training was necessary before study initiation. Use of the Game Ready® device involved the following steps:

- attachment of the end of the connecting tube to the central unit controller (fully portable);
- application of the selected wrap to the knee;
- activation of the control unit;
- adjustment of the temperature;
- selection of the compression programme;
- activation of the system.

We used compression programme 2, i.e., 30 min on/30 min off at a low pressure, in the post-anaesthesia care unit and until patient discharge (i.e., for 24 h). The temperature was set at 0°C and could be adjusted based on patient tolerance.

#### 2.2.2. CSPC – IceBand®, knee

The splint was positioned by the surgeon at the end of the procedure and was left in place for 30 min every 2 hours for 5 days in all (i.e., until discharge then at home). The device was removed at night.

At each visit, the staff examined the skin carefully for any signs of damage.

**Table 1**

Patient characteristics in the two groups.

	Game Ready® (CDIC) 20 patients	IceBand® (CSPC) 19 patients	P value
Mean age in years (range)	24.2 (15–48)	22.7 (15–41)	0.02
Mean BMI in kg/m <sup>2</sup> (range)	24.4 (20.9–30.7)	25.05 (21.07–32.9)	0.4
Female/male ratio	8/12	9/10	–
Mean operative time in min (range)	38.2 ± 7.3 (31–55)	41.4 ± 6.5 (28–62)	> 0.05

CDIC: cryotherapy with dynamic intermittent compression; CSPC: cryotherapy with static permanent compression; BMI: body mass index.

### 2.3. Analgesic drugs

In the post-anaesthesia care unit, all patients received intravenous paracetamol and an intravenous anti-inflammatory drug (ketoprofen) in a dose of 100 mg to be repeated if needed. Analgesic drugs were administered according to the standard step-wise protocol with the objective of maintaining the visual analogue scale (VAS) pain score < 3 throughout the hospital stay. Morphine was not given continuously.

### 2.4. Rehabilitation

Rehabilitation therapy was started 4 h after surgery and consisted in assistance with immediate weight bearing, depending on the pain level reported by the patient, in order to provide safe functional self-sufficiency. The cryotherapy compression device was removed during the rehabilitation sessions. Gentle gradual knee mobilization using a passive motion device and active knee mobilization by the physiotherapist were used to obtain knee stability in extension against gravity and early activation of the quadriceps muscle.

### 2.5. Evaluation

The amounts of analgesic drugs used were recorded and the quality of the analgesia was assessed using a VAS pain score at discharge from the post-anaesthesia care unit, 6 hours after surgery (H6), and at hospital discharge on the day after surgery (D1).

Range of knee motion was evaluated at hospital discharge (D1) by the same surgery-department physiotherapist.

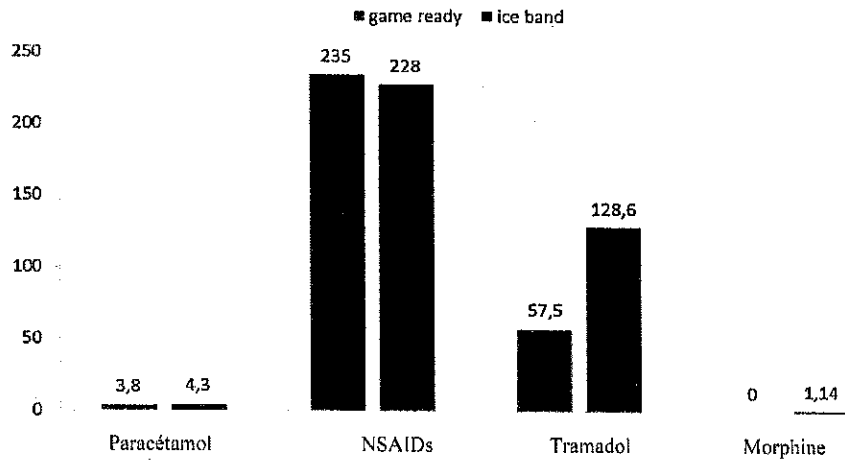
These data were recorded on a standardized case-report form, using File Maker Pro 12 Advanced (FileMaker, Santa Clara, CA, USA).

### 2.6. Statistical analysis

Groups were compared using Student's *t* test and Wilcoxon's test for normally and non-normally distributed data (Shapiro-Wilk test), respectively. Values of *P* lower than 0.05 were considered significant. Statistical tests were performed using Excel 2007 (Microsoft, Redmond, WA, USA; MedCalc™ version 11.6.1.0, MedCalc Software, Mariakerke, Belgium) and XLSTAT 2012 (Addinsoft, Paris, France).

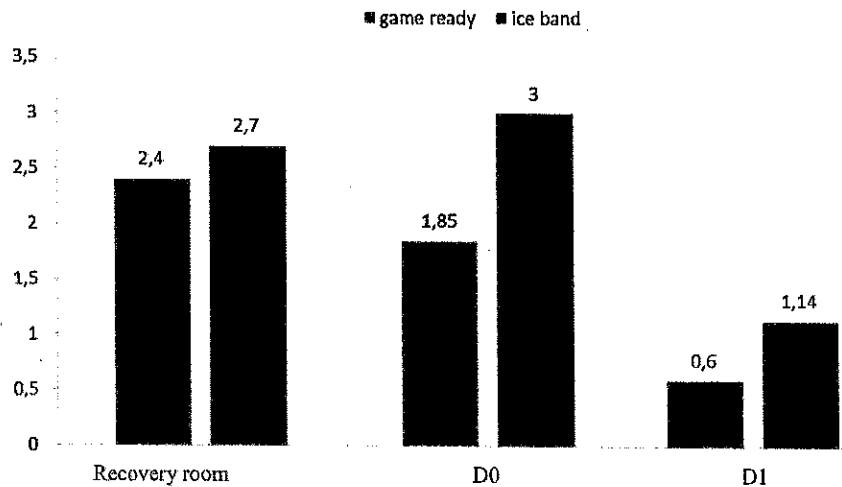
## 3. Results

The two groups showed no significant differences for age, gender distribution, body mass index, or operative time (Table 1). All patients were hospitalised for two days (one day before and one day after surgery) except one patient from the CDIC group, who



	GR Group	IB Group	p
Paracétamol (g)	3,8 g (2 – 8)	4,29 g (3 – 5)	0,19
NSAIDs (mg)	235 mg (100 – 400)	228 mg (100 – 400)	0,4
Tramadol (mg)	57,5 mg (0 – 200)	128,6 mg (0 – 250)	0,023
Morphine (mg)	0	1,14 mg (0-8)	< 0,05

Fig. 1. Comparison of the average drug consumption per patient during the hospital stay. NSAIDs: non-steroidal anti-inflammatory drugs.



	Game Ready Group	Ice Band Group	p
Maximal pain recovery room	2,4 (0 – 6)	2,7 (0 – 7)	0,3
Maximal pain in hospital room (Day 0)	1,85 (0 – 9)	3 (0 – 8)	0,16
Maximal pain at the end of hospitalisation (Day 1)	0,6 (0 – 3)	1,14 (0 – 3)	0,12

Fig. 2. Comparison of pain in the two groups.

was discharged two days after surgery because time was needed to find an appropriate place of discharge.

### 3.1. Consumption of analgesics

Cumulative mean paracetamol dose per patient was 3.8 g (range, 2–8) in the CDIC group and 4.29 g (range, 3–5) in the CSPC group

( $P=0.19$ ); corresponding values for ketoprofen were 235 mg (range, 100–400) and 228 mg (range 100–00) ( $P=0.4$ ). Tramadol consumption was significantly lower in the CDIC group: 57.5 mg (range, 0–200) vs. 128.6 mg (range, 0–250) in the CSPC group ( $P=0.023$ ). None of the patients in the CDIC group required step 3 analgesics. In contrast, patients in the CSPC group had a mean morphine consumption of 1.14 mg (range, 0–8) ( $P<0.05$ ) (Fig. 1).

### 3.2. Pain

In the post-anaesthesia care unit, the mean VAS pain score was 2.4 in the CDIC group and 2.7 in the CSPC group ( $P=0.3$ ). Corresponding values were 1.85 vs. 3 ( $P=0.16$ ) at H6 and 0.6 vs. 1.14 ( $P=0.12$ ) at discharge (Fig. 2).

### 3.3. Range of motion

Mean range of knee flexion at hospital discharge was 90.5° (range, 80°–100°) in the CDIC group and 84.5° (range, 75°–90°) in the CSPC group ( $P=0.0015$ ). Fixed flexion was not present in any of the patients.

## 4. Discussion

This study's objective was to compare CDIC and CSPC for the management of postoperative pain after knee ligamentoplasty. Our working hypothesis was that CDIC provided better pain control, thereby decreasing the analgesic drug requirements. This hypothesis was confirmed, as the consumption of tramadol and morphine was lower. Moreover, the range of knee motion at discharge was higher in the CDIC group.

The main limitation of our study is the small sample size ( $n=39$ ), which precluded the detection of statistically significant differences in the consumption of other analgesic drugs or in the VAS pain scores. In addition, we did not evaluate the medico-economic impact of the cryotherapy/compression devices.

CDIC is being developed for sports medicine to expedite physical recovery and to treat peripheral ligament disorders and bone injuries [20,21]. CDIC is also used in rotator cuff surgery [22]. Studies have shown that CDIC benefits the overall management of postoperative patients by stimulating tissue repair processes [23], compared to standard cryotherapy, whose efficacy remains controversial [8,24].

To our knowledge, there is one only study evaluating CDIC for knee surgery. Su et al. [25] conducted a level I multicentre prospective randomised, single-blind trial to evaluate the same CDIC device used in our study (Game Ready®) versus CSPC (Durakold®, CryoCuff). Of 187 patients with complete data, 103 received CDIC and 84 CSPC. CDIC was associated with better range-of-motion recovery after 6 weeks (57% of patients achieved 110° of flexion vs. 49% in the CSPC group,  $P<0.05$ ) and have a tendency to faster recovery of self-sufficiency (with a mean 6-minute walking distance of 29.4 m after 6 weeks vs. 7.9 m in the CSPC group,  $P>0.05$ ). Morphine consumption was lower in the CDIC group (509 mg vs. 680 mg in the CSPC group 2 weeks after surgery, i.e., a 25% reduction,  $P<0.05$ ). Finally, the number of patients requiring early surgical revision was reduced by half in the CDIC group, in which patient satisfaction was significantly higher than in the CSPC group.

In conclusion, CDIC combined with a standard analgesic drug regimen has the following advantages:

- better control of local temperature, which is indispensable to ensure efficacy and prevent adverse effects;
- significant reduction of opiate requirements (tramadol and morphine), which lowers the risk of adverse drug effects;
- significant improvement in range of knee motion on the day after surgery.

These results need to be confirmed in a study providing greater statistical power.

## Disclosure of interest

X. Cassard receives royalties as co-designer of the TLS® system (FH Orthopaedics). J. Murgier declares that he has no conflicts of interest concerning this article.

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