# The Use of a High-Tech Knee Pad for Reduction of the Postoperative Effusion after Total Knee Arthroplasty

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## Abstract

**Purpose** After total knee arthroplasty (TKA), pain and swelling, especially in older and less cooperative patients, can limit the retrieval of a good range of motion and muscle tone and consequently the achievement of an optimal function outcome. A high-tech knee pad made of metal fibers emitting infrared energy was used in a group of patients undergoing TKA to assess its efficacy in the postoperative period with respect to a group with a placebo.

**Methods** Twelve patients used knee pads after surgery for 3 weeks and were evaluated using visual analog scale (VAS), Knee Society Rating Score, Cincinnati Knee Rating Score, and painkillers at specific timings.

**Results** At 3 weeks, all scores improved in a significant manner in the treated group compared with the placebo group. At 2 months after surgery, VAS was better in the study group than the control group, whereas other parameters were similar. However, the use of rescue drugs was less in the study group than in the placebo group.

**Conclusion** A high-tech knee pad may contribute to a faster recovery within the first week after a knee replacement, limiting the use of painkillers and allowing a quick functional recovery by the control of pain and postoperative effusion.

**Level of Evidence** Level II, randomized prospective study with small sample size.

**Keywords**
- high-tech device
- knee pad
- postoperative effusion
- replacement
- total knee arthroplasty

## Introduction

Postoperative rehabilitation protocols after knee surgery are crucial to ensure adequate functional outcomes.[1–3] The management of postsurgical inflammation, soft tissue edema, and wound healing represents some of the most challenging targets to ensure an early recovery, particularly after a total knee arthroplasty (TKA). This is of paramount importance in elderly people undergoing knee surgery, given the high social and familiar costs related to prolonged hospital stay, rehabilitation, and medical therapy for the management of pain.

Furthermore, great attention is given to the perception of the result by the patient, seen as the absence of pain and return to daily activities, knowing that this may adversely affect the success of the postoperative physiotherapy and therefore the overall clinical results.[3,4]

The postoperative effusion of the knee associated with pain normally induces an expected delay of the rehabilitative protocol: range of motion (ROM) exercises and muscle strengthening are thus proposed with progressive intensity on the days after the procedure, depending on the patients' tolerance and general health status. Medical and physical

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therapies represent the gold standard to ensure a faster recovery from this condition, however, with significant related costs. Several methods have been proposed to limit pain, effusion, and favoring the healing of the surgical scar with variable results.[5–8]

Recently, far infrared radiations (FIRs) have been advocated for their effects on the vascular flow in animal models. FIRs are invisible electromagnetic waves with a characteristic wavelength ranging from 5.6 to 1,000 µm, which can be perceived as heat by thermoreceptors in the skin.[9–11] Recent studies have indicated that FIR therapy may induce beneficial effects in the treatment of several cardiovascular pathologies (ventricular arrhythmias, endothelial alterations in patients affected by heart diseases) and seem to promote an improvement in the microvascular blood flow and angiogenesis in various animal models.[12]

FIR showed to behave as novel inducers of heme oxygenase-1 gene expression in the human vascular endothelium by the activation of the antioxidant responsive element/nuclear factor erythroid 2-related factor-2 complex signaling pathway.[13] Moreover, FIR stimulated the expression of proinflammatory adhesion receptors and chemoattractant molecules in human endothelium cells blocking the adhesion of monocytes. These processes showed a dependency on the duration of FIR exposure.[13]

High-tech infrared-emitting materials have been introduced to induce such effects. Particularly, a brand new fiber (Nexus-ES, Chimar Srl, Padova, Italy) made of light, ductile, resistant, and highly conductive metal grains (platinum, titanium, and alumine) has been introduced in a tubular structure adapted for knees (Tuactive) (►**Fig. 1**). Body heat, rays of sunshine, and room temperature are able to excite the electrons of these metals, creating a flow of infrared energy along the fibers with a frequency characterized by a wavelength of 4 to 14 µm. This emission of infrared rays flow has showed peculiar properties, such as increase in the rotation and vibration of water molecules, highly represented in a joint after surgery; this mechanism may be involved in the decrease and resorption of the edema after a TKA. To date, it is the first device with such characteristics reported in literature.

The aim of this study is to assess the efficacy of these knee pads in the postoperative management in a population of patients undergoing a TKA compared with a homogeneous group of patients undergoing the same procedure but treated by a standard knee pad.


**Fig. 1** Knee pad. (**A**) Ultrastructure at the electronic microscopy. (**B**) Detail of the knee pad tissue. (**C**) Gross appearance of the device.

## Methods

### Participants

A total of 27 patients at the authors' institution were selected for a single-blind, randomized study on the use of a knee pad after surgery. The study was performed at an interval of 12 months. All the patients were informed about the characteristics of the knee pad and the study, and the Institutional Review Board approved the study based on the Declaration of Helsinki. Inclusion criteria were indication for a primary TKA and possibility to attend the follow-up visits. Exclusion criteria were local or general infections, patients affected by neoplasms or with a history of previous tumors, acute cardiovascular disease, and patients with pacemaker or electric medullary stimulators. Three patients were not able to ensure or attend the follow-up visits and were excluded from the study. Finally, 24 patients were selected and divided into two groups: group A included 12 patients who received a knee pad made of the Nexus-ES fiber, whereas group B included 12 patients who received a similar knee pad made of simple fibers (placebo). Demographic data of the two groups are reported in ►**Table 1** and were substantially homogenous. The mean age of group A was 71.92 years (range: 59–85), whereas the mean body mass index (BMI) was 27.84 (range: 23.9–33.0). The mean age and BMI of group B were 70.36 (range: 61–79) and 28.35 (range: 23.9–33.4), respectively. There was no way to distinguish a Nexus-ES pad from the standard knee pad. The assignation of the knee pads was performed by a sealed envelope system for randomization.

**Table 1** Demographic data of the enrolled patients (expressed as mean values)

| | Age (y) | BMI | Cause of knee OA | *p* Value |
|---|---|---|---|---|
| Group A | 71.92 | 27.84 | 11/12 primary OA; 1/12 posttraumatic OA | n.s.[a] |
| Group B | 70.36 | 28.35 | 10/12 primary OA; 2/12 posttraumatic OA | |

Abbreviations: BMI, body mass index; OA, osteoarthritis.
[a]Nonsignificant difference.

**Table 2** Flowchart of the study protocol and number of recruited patients

| | Selected patients | Inclusion/exclusion | T0 (Preoperative) | T1 (sutures removal: 3 wk) | T2 (2 mo postoperative) |
|---|---|---|---|---|---|
| Group A | 14 | 12/2 | 12 | 12 | 12 |
| Group B | 13 | 12/1 | 12 | 12 | 12 |

### Intervention

All patients were operated by the same surgeon, with the same implant (Genesis II, Smith & Nephew, Memphis, Tennessee, United States), and rehabilitated in a way similar to that described by the institutional protocol for primary TKA. All knee pads were placed in the operated joint at the fourth postoperative day, after two previous medications (the first in the day after surgery associated with drains removal; and the other at the third day). All patients were informed to continuously use the pads. The pad was finally removed at the sutures removal (3 weeks after surgery). The flowchart of the study is reported in ►**Table 2**.

### Outcome Measurements

The clinical evaluation was performed using visual analog scale (VAS), the Cincinnati Knee Rating Scale (CKRS),[13] and the Knee Society Rating System (KSS).[14,15] Each patient was evaluated preoperatively and at the time of enrolling (T0: postoperative day 4), day of knee pad removal (T1: postoperative day 20), and, finally, at the last visit (T2: 2 months after surgery). Other data such as ROM, recovery of an independent walking ability (with or without crutches), and the use of pain modulating drugs were also recorded at follow-up evaluations.

### Data Analysis

Descriptive statistics were provided to display the characteristics of the study parameters (VAS, CKRS, KSS). A Student's *t*-test for independent means was performed to evaluate differences between groups at the time of enrolling (T0), the day of knee pad removal (T1), and at the last visit (T2), whereas a repeated-measures analysis of variance was conducted to evaluate differences within groups over time. The level of significance was set to $p < 0.05$. Data processing was performed using the SPPS version 17.0 statistical software package (SPSS Inc., Chicago, Illinois, United States).

**Table 3** Descriptive statistics of the outcome variable at T0

| Variable | Group A | Group B | *p*-Value |
|---|---|---|---|
| KSS | 45.1 ± 11.5 | 50.3 ± 9.2 | n.s.[a] |
| Functional KSS | 39.6 ± 17.6 | 44.2 ± 15.5 | n.s.[a] |
| CKRS | 39.2 ± 9.1 | 41.6 ± 5.1 | n.s.[a] |

Abbreviations: CKRS, Cincinnati Knee Rating Scale; KSS, Knee Society Rating System.
[a]Nonsignificant difference.

## Results

All patients completed the follow-up. No significant complication related to TKA and the use of the pad was recorded in any group. All patients were able to wear the pad continuously. The mean preoperative VAS was 7.5 (range: 5–9) for the patients in group A and 7.3 (range: 5–9) for those in group B. At T1, the mean VAS improved to 3.8 (range: 2–7) in group A and 4.9 (range: 3–8) in group B. At T2, VAS was 0.7 (range: 0–2) and 1.3 (range: 0–4) for groups A and B, respectively (►**Table 3**, ►**Fig. 2**). All differences between groups were significant at T1 ($p < 0.05$). At T2, only VAS showed a statistical difference between the study and control groups. ROM and walking ability were achieved in both groups without significant differences. All differences between groups were significant at T1 ($p < 0.005$). At T2, only VAS showed a statistical difference between the study and control groups. ROM and walking ability were achieved in

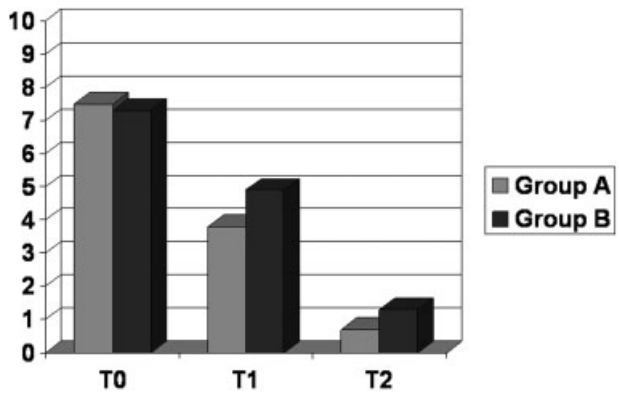


**Fig. 2** Comparison between case and control groups for visual analog scale outcome.

**Table 4** Average values of outcome scores at T0-T2

| Variable | T0 | T1 | T2 | *F*-value | *p*-Value[a] |
|---|---|---|---|---|---|
| Group A | | | | | |
| KSS | 45.1 ± 11.5 | 67.4 ± 11.6 | 77.1 ± 10.7 | 40.5 | $p < 0.001$ |
| Functional KSS | 39.6 ± 17.6 | 62.9 ± 13.8 | 77.9 ± 9.2 | 29.4 | $p < 0.001$ |
| CKRS | 39.2 ± 9.1 | 56.8 ± 8.9 | 65.0 ± 8.7 | 40.1 | $p < 0.001$ |
| Group B | | | | | |
| KSS | 50.3 ± 9.2 | 62.2 ± 8.2 | 75.6 ± 7.0 | 31.2 | $p < 0.001$ |
| Functional KSS | 44.2 ± 15.5 | 59.6 ± 9.9 | 76.2 ± 7.1 | 32.8 | $p < 0.001$ |
| CKRS | 41.6 ± 5.1 | 55 ± 4.3 | 66.8 ± 6.4 | 239.5 | $p < 0.001$ |

Abbreviations: CKRS, Cincinnati Knee Rating Scale; KSS, Knee Society Rating System.
[a]*p*-Values are referred to the differences within groups over time, computed by the analysis of variance.

both groups without significant differences. The use of drugs for pain management was reported by the patients with a mean assumption of oral analgesics of 1.3 (group A) versus 1.6 (group B) in the 3-week interval without any significance. All patients treated by the knee pad reported a subjective positive effect during the 3 weeks of treatment, except in two cases of a slight compression in the first week due to an effusion in their knees. However, they did not refer any need to remove the knee pad. KSS and CKRS showed an increase in both groups (►**Table 4**, ►**Fig. 3**).

## Discussion

The functional outcome of a TKA depends on several factors such as age and characteristics of the patient, indication for surgery, intraoperative technique, postoperative management, and rehabilitative protocol.[5,16–20]

Regarding the postoperative management, wound healing, postsurgical effusion, and soft tissue edema represent important factors influencing the functional recovery. The pharmacological management of pain, the use of taping or pads, and the physical therapy have been proposed with variable results but are not always available in all medical facilities.[4–8] A knee pad with a high technological value has been introduced to allow a quick recovery from postoperative effusion. The rationale consists in the well-known biological property of infrared emitting materials able to induce growth-promoting effects in living organisms.[12,13] Specific in vitro experiments have been conducted over the years, showing proved effects in the growing rats and a sleep-modulatory effect in freely behaving rats.[13,21] Moreover, similar effects have been demonstrated in vivo and in clinical setting on human subjects, in several fields of interests: in patients affected by insomnia, cardiac diseases, and also a blood circulation-enhancing effect in human skin.[13,21–23] The hypothesis of a possible effect on the postoperative soft tissue edema and joint effusion induced the production of a knee pad to be adopted for the postoperative management after TKA. We obtained good effects, and high tolerability and safety of the studied device, as demonstrated by the significant short-term improvement of the resorption

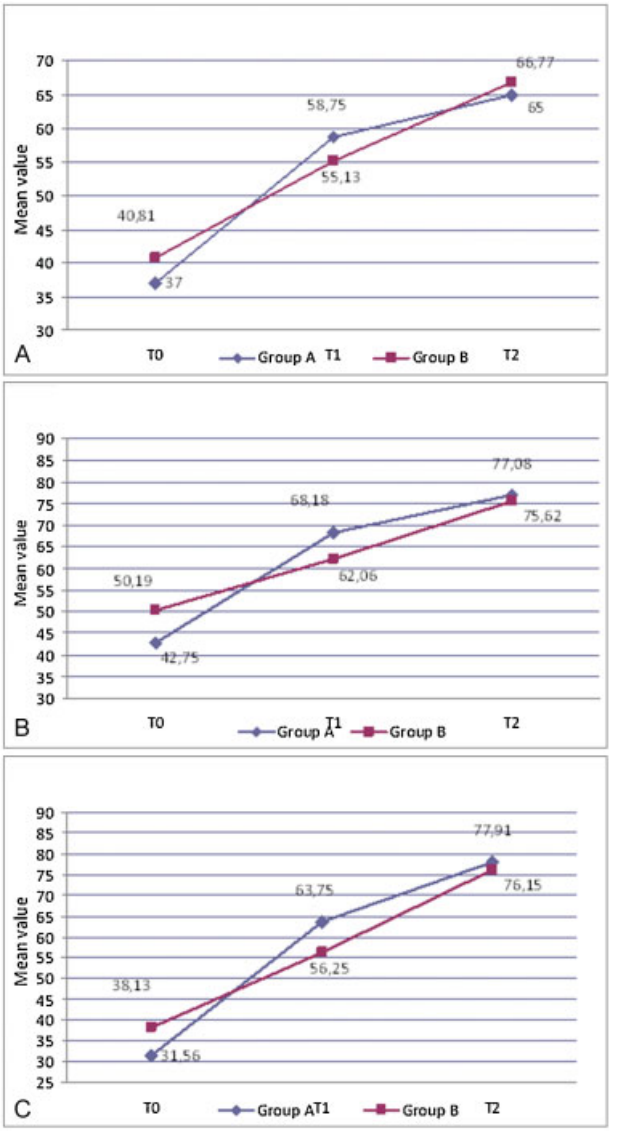


**Fig. 3** Comparison between case and control groups for Cincinnati Knee Rating Score (**A**), Knee Society Rating System (KSS) (**B**), and functional KSS (**C**) outcomes.

of the postoperative effusion and more compliance during the rehabilitative period of treated patients versus those treated by placebo particularly during the first 3 weeks. A slight reduction of the use of painkillers over this period and a positive feedback by the patients are further encouraging aspects to be evaluated.

Several limitations have to be evaluated in this study. First, the limited number of cases has to be considered; this prevents the performing of an adequate power analysis. Also, the evaluation criteria are not completely objective, but conditions such as postsurgical effusion are not evaluable by other tools than those reported.

However, this preliminary study seems to confirm the positive effects of knee pads particularly at the time of removal of the device, when the patients of group A showed better values on VAS, KSS, and IKDC with respect to group B. Most of patients referred less pain and showed better local conditions with respect to the patients treated by the placebo. At the last evaluation, however, all the patients showed comparable results. This may be explained substantially by the positive effect of the high-tech knee pad on the soft tissue effusion, typical of the early postoperative period. The reduction of the use of pain controlling drugs in the first weeks after surgery is another indicator for the potential efficacy of the device.

In conclusion, we believe that the Tuactive knee pad, thanks to its network of high-tech fiber Nexus-ES, may represent an easy and useful option to reduce the effects of the postoperative pain and effusion in knees of patients undergoing TKA, allowing an actual early recovery by wearing a simple pad for few weeks after surgery. This device may also be useful to reduce the drug consumption to control the postsurgical pain, even if a study considering a larger number of patients would be necessary to assess its effectiveness.

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