
Design: Randomized clinical trial

Population/sample size/setting:
- 82 patients (32 men, 50 women, mean age 51) operated on for unilateral CTS in an orthopedic department in the UK
- All patients admitted to the service for carpal tunnel decompression were considered for the study

Main outcome measures:
- Randomized to open carpal tunnel decompression (n=43) or Knifelight (n=39)
- Follow-up examinations done at 2 weeks when sutures were removed and at 6 weeks when final assessment was made
- Groups had similar levels of perioperative discomfort
- Complications of open procedure included 4 patients with significant pillar pain, 1 with partial wound dehiscence, 1 unexplained thumb pain, 1 with mild stiffness of the fingers, and 1 transient numbness of the index finger
- Complications of Knifelight included 1 with transient numbness of the index finger, 1 with RSD, and 1 with a superficial wound infection; for 2 patients, the Knifelight could not cut the flexor retinaculum and these patients were converted to an open procedure and withdrawn from the study
- At the 6 week follow-up, grip strength was similar in the 2 groups
- At 6 weeks, scar tenderness was greater in the open procedure than for the Knifelight group: tenderness for the open procedure group was reported as none in 3 patients, mild in 18, moderate in 17, and severe in 5; for the Knifelight group, scar tenderness was reported as none in 20, mild in 15, moderate in 4, and severe in no patient
- Return to work was an average of 28 days in the open procedure and 20 days in the Knifelight group
- Resolution of CTS symptoms was similar in the two groups; 37 of 43 open procedure and 36 of 39 Knifelight patients had complete cure of symptoms

Authors’ conclusions:
- Carpal tunnel release performed with Knifelight reduces pillar pain, scar tenderness, and results in faster return to work than open release
- The high cost of the single-use Knifelight device may be offset in lower costs for supplementary postoperative treatment such as PT and NSAID

Comments:
- Eligibility criteria for entry are not clear; all patients who were considered appropriate for surgery at the facility in question were eligible, but those appropriateness criteria are not known
- The incision length of the open procedure is not described (nor is it specified for the Knifelight procedure)
- The two Knifelight patients who had to be converted to an open procedure were excluded from the analysis, but should have been retained (intention-to-treat principle), since failure of the Knifelight device is a pertinent outcome.
- This failure to observe the intention-to-treat principle does not invalidate the comparisons of postoperative scar tenderness; if both patients are assumed to have had severe scar tenderness, the large difference between the groups still remains.
- As the authors report, assessment of scar tenderness cannot be blinded, due to the differences in scar appearance.
- Return to work times would have been more informative if the authors reported the numbers of patients who were working at the time of operation, and if they reported the type of work the patients were performing.

Assessment: Adequate for an evidence statement that Knifelight may reduce postoperative scar discomfort and may allow a shorter time for return to work.