Compliance with continuous passive movement is low after surgical treatment of idiopathic club foot in infants

A PROSPECTIVE, DOUBLE-BLINDED CLINICAL STUDY

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Post-operative continuous passive movement (CPM) has been shown to be effective in some clinical studies, but not in others. In the conservative treatment of idiopathic club foot it improved the outcome when combined with physiotherapy. Recently, CPM has been shown to improve outcome after extensive soft-tissue release at six and 12 months, compared with cast immobilisation, however, at 18 and 48 months the outcomes were the same. A limitation of this study was that the recommended duration of CPM could not be verified.

Thus, a prospective, double-blinded clinical study was carried out to investigate patient compliance with CPM treatment which was recommended for at least four hours a day.

Patients and Methods
Between 2001 and 2002, we enrolled 27 consecutive children (16 males, 11 females) with 34 idiopathic club feet undergoing posteromedial release for Dimeglio grade 3 or 4 deformity. Their mean age was 24 months (5 to 75). A total of 11 children had relapsed club feet and 16 had a deformity resistant to manipulation and cast immobilisation of six months duration.

The operations were performed by the senior author (MT), using a standard technique. Post-operatively, a cast was applied for up to ten days, when all children underwent computer-assisted, standardised three-dimensional CPM therapy with a Kinetic 5090 Ankle machine (S&U Medizintechnik, Partenheim, Germany) under the care of a physiotherapist and a technician. During rest periods removable splints were applied. The K-wires, used as part of the standard technique, were removed from all feet between seven and ten days post-operatively.

During a mean hospital stay of 2.37 days (1 to 7), the parents received instruction sheets and repeated practical training on how to use the machine. Beginning on the tenth post-operative day, the unidimensional range of movement of the ankle in plantar flexion/dorsiflexion was started, with gradual increase in range of movement until the end of treatment.

During CPM at home, a technician could be contacted if problems arose. The parents were advised to use the machine as often and for as long as possible, but for a minimum of four hours daily, mainly when the child was asleep to avoid active contrapres- sure. In bilateral cases we recommended equal use of the machine, and for data analysis, treatment time was assigned equally to both feet. The parents and the involved physicians, except the senior author (MT), were not informed about the possibility of measuring the duration of CPM. All parents gave
informed consent for data analysis at the end of treatment. The data for 24 of 27 patients were analysed. Three were excluded because of technical problems.

The CPM machine has sensors which can record whether it is run with or without the foot, and only treatments with the foot are recorded. We could also measure the resistance to ankle movement. If a standardised resistance is exceeded, the movement is automatically reversed. Sensors also record the range of movement (ROM) of the ankle.

After CPM treatment, each foot was treated with a brace at night and physiotherapy for six months. The primary outcome measure was the daily duration of CPM. Secondary measures were changes in the ROM and resistance, comparing the earliest third of treatment to the last third. In bilateral cases, either the left or the right side was selected for analysis by tossing a coin. Group differences were analysed with unpaired t-tests. All tests were two-tailed, with \( \alpha = 5\% \), and p-values < 0.05 were considered to be significant. Data analysis was done by SPSS for Windows 12.0 (SPSS Inc., Chicago, Illinois).

**Results**

The duration of CPM was less than four hours daily in 79% (19) of patients. The mean duration was 126 minutes (11 to 496). In 58% (14) of children the machine was used for less than 1.5 hours a day.

The mean total treatment time It was 5617 minutes (466 to 14790) during a mean of 37.4 days (29 to 56). The machine was mainly used during the middle of the day and rarely at night. The total therapy time per hour according to time of day was 184 minutes (75 to 343), between 0800 am and 1159 am, 315 minutes (84 to 767) between 1200 pm and 1459 pm 253 minutes (85 to 273), between 1500 pm and 1959 pm, and 20 minutes (11 to 31) between 2000 pm and 0759 am. The mean planter flexion improved from 15.2° (10.0° to 20.6°) to 18.7° (10.0° to 33.0°) and for dorsiflexion, from 12.3° (7.4° to 19.4°) to 18.9° (10.0° to 24.1°) both \( p = 0.0001 \), when the first third of CPM was compared with the last third. There were no significant differences of resistance during treatment.

**Discussion**

Continuous passive movement is of use in the early rehabilitation of the knee, shoulder, elbow and hand. Early intermittent or continuous movement promotes metabolic activity, improves blood flow, and facilitates the transport of metabolites from the joint, leading to reduced swelling and oedema.

If CPM therapy is compared with physiotherapy after total knee replacement (TKR), it provides small and short-term benefits. In a prospective, randomised study, use of a CPM machine after discharge following TKR was an adequate alternative, with lower costs and no difference in outcome compared with physiotherapy. However, the duration of CPM treatment at home was not measured, and its optimal duration is undefined. CPM for six to eight hours daily is recommended for adults.

The parents in our study were advised to use an ankle CPM for four hours, or even longer in cases of revision surgery. The duration of treatment in our double-blinded study was less than half the recommended time. This demonstrates poor compliance by parents in spite of intensive training and continual support. One can therefore postulate whether the outcome of a previous study would have been better had compliance been good.

We believe all clinical trials of CPM at home must be interpreted with great caution, unless the exact treatment time is monitored electronically or by a third party.

A limitation of our study was the relatively low number of patients. However, we have demonstrated that ROM increases significantly during CPM. This may be the basis for the significant improvement in the Diméglio score at six and 12 months after posteroomedial release and CPM treatment. Our results agree with those of other reports.

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**References**