

Oral presentation

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Intraoperative pedography – development, validation and clinical use of a novel method for intraoperative biomechanical assessment

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Introduction

A new device was developed to perform intraoperative pedography (IP). The purpose of this study was to validate the introduced method with standard dynamic pedography, and to analyze the potential clinical benefit.

Methods

Development

For an intraoperative introduction of standardized forces to the footsole, a device named Kraftsimulator Intraoperative Pedographie (KIOP, manufactured by the Workshop of the Hannover Medical School, Hannover, Germany; Registered Design No. 20 2004 007 755.8 by the German Patent Office, Munich, Germany) was developed. The pedographic measurement is performed with a custom-made mat with capacitive sensors (PLIANCE™, Novel Inc., Munich, Germany).

Validation

Step 1

Comparison of standard dynamic P (three trials, walking, third step, three trials, mid stance force pattern), static P in standing position (three trials) and P with KIOP in healthy volunteers (three trials, total force 400 N). For dynamic P and P in standing position, a standard platform (EMED™, Novel Inc., Munich, Germany) was used.

Step 2

Comparison of P in standing position, P with KIOP in awake and anaesthetized patients (three trials, total force

400 N). Patients with operative procedures performed at the knee or distal to the knee were excluded. Patients with general or spinal anaesthesia were included.

The different measurements were compared (t-test, One-way ANOVA)

Clinical use

A randomized prospective consecutive clinical study comparing treatment with and without IP has started on October 1, 2006. Patients (age 18 years and older) which sustained an arthrodesis and/or correction of the foot and ankle are included. All subjects receive preoperative clinical and radiographic assessment and standard dynamic pedography. The subjects are randomized into two groups, a) use of IP, versus b) no use of IP. One-year-follow-up including standard dynamic pedography is planned. The following scores are used: American Orthopaedic Foot and Ankle Society (AOFAS), Visual-Analogue-Scale Foot and Ankle (VAS FA), Short-Form 36 (SF36, standardized to a 100-point-maximum-scale). Intraoperative consequences after the use of IP were recorded.

Results

Validation

Step 1

30 individuals were included (age, 26.1 ± 8.6 years; gender, male: female = 24: 6).

Step 2

30 individuals were included (age, 55.3 ± 30.3 years; gender, male: female = 24: 6). No statistical significant differences of force distribution were found in both steps between the different methods, and between the methods of step 1 and 2 (t-test & ANOVA, $p > 0.05$).

Clinical use

51 patients were included until January 31, 2008 (ankle correction arthrodesis, $n = 8$; subtalar joint correction arthrodesis, $n = 10$; arthrodesis midfoot, $n = 9$, correction midfoot, $n = 5$, correction forefoot, 18). 26 patients were randomized for the use of IP, whereas 25 had no intraoperative measurement. The mean preoperative scores were as follows: AOFAS: 52.3 ± 20.3 ; VAS FA: 46.1 ± 14.0 ; SF36: 52.3 ± 25.3 . No score differences between the two groups occurred (t-test, $p > 0.05$). The mean interruption of operative procedure for the IP was 284 ± 37 seconds. In 12 of 26 patients (46%) changes were made after IP during the same operative procedure (correction modified, $n = 6$; implants modified, $n = 2$; correction and implants modified, $n = 6$). The follow-up has not been completed so far.

Conclusion

Since no statistical significant differences were found between the measurements of the introduced method for IP in anaesthetized individuals and the standard static pedography, the introduced method can be considered to be valid for intraoperative static pedography.

During the clinical use, in 46% of the cases a modification of the surgical correction were made after IP in the same surgical procedure. A follow-up of these patients has to be completed to show if these changes improve the clinical outcome.

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