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Intraoperative Pedobarography Leads to Improved Outcome Scores: A Level I Study

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ABSTRACT

Background: **The purpose was to compare the clinical outcome scores after additional use of intraoperative pedobarography (IP) in comparison with patients treated without IP.** ***Materials and Methods:*** **Patients with arthrodesis and/or correction of the foot and/or ankle were randomized for use of IP or no IP. American Orthopaedic Foot and Ankle Society (AOFAS) score, Short-Form 36 (SF-36), and Visual Analogue Scale Foot and Ankle (VAS FA) were analyzed.** ***Results:*** **One hundred patients were included. Fifty-two were randomized for the use of IP, and in 24 of those (46%), the correction was modified after IP during the same operation. At mean followup of 2 years, the average scores were higher in the group with IP than in the group without IP (IP/no IP: AOFAS 89.7/78.2; SF-36 90.3/76.3; VAS FA 90.3/76.3; t-test, all $p < 0.05$).** ***Conclusion:*** **The use of IP led to improved clinical outcome scores at a mean followup of 2 years.**

Level of Evidence: I, Prospective Randomized Study

Key Words: Pedobarography; Intraoperative Pedobarography (IP); Correction; Arthrodesis; Clinical Outcome Scores

INTRODUCTION

Operative correction of the foot and ankle have the goal to minimize symptoms and to improve the biomechanical function.[18] Pedobarography is an effective method for the analysis of improved biomechanical function at clinical followup.[22] In 2005, we completed the development and validation of a device and method for intraoperative pedobarography (IP).[14] This method allows static pedobarography in anesthetized subjects in the supine position without significant force distribution differences in comparison with the standing position.[14] IP was used to detect non-optimal biomechanical conditions of the foot allowing us to modify a reduction or correction during the same operative procedure.[14] A prospective randomized controlled clinical followup study was started to evaluate the potential clinical benefit of the system during the operative correction and/or arthrodeses of foot pathologies.[18] The preliminary results showed that a modification of the surgical correction/arthrodesis was made after IP in the same surgical procedure in almost half of the cases.[18] However, it remained questionable if these modifications lead to changes in the clinical outcome. The purpose of this study was to compare clinical outcome with sufficient followup after additional use of IP in comparison with patients treated without IP. Clinical outcome scores were chosen as the principle outcome parameters and not radiographic or pedographic measurements. This reflects the critical importance of outcome assessment regarding evaluation of the efficiency of surgical procedures, and the insufficiency of assessment based on radiographs.[19,21,23,24] Furthermore, no validated score for clinical pedobarography exists for a sufficient comparison.

We hypothesized that the intraoperative changes after use of IP might improve clinical outcome scores in comparison with patients treated without IP.

MATERIALS AND METHODS

Clinical study[18]

A Level 1 study (randomized, prospective, consecutive, blinded, clinical followup) comparing treatment with IP (study group) and without IP (control group) was started on September 1st, 2006. Patients (age 18 years and older) who underwent an arthrodesis and/or correction of the foot and/or ankle except combined ankle and subtalar joint arthrodesis were included. One hundred patients were included between

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September 1st, 2006 and April 11th, 2008 (age, 33 ± 8 years; male, $n = 43$; female $n = 57$). The patients were grouped as follows: ankle correction arthrodesis, $n = 12$; subtalar joint correction arthrodesis, $n = 14$; midfoot arthrodesis without correction, $n = 15$; midfoot correction arthrodesis, $n = 26$; correction forefoot, $n = 33$ (Table 1). Fifty-two patients were randomized for the use of IP, whereas 48 were randomized for no use of IP (Table 1). No score, age, or gender distribution differences between the two groups occurred (scores and age, t-test, $p > 0.05$; gender, chi^2-test, $p = 0.8$). The surgical procedures were performed in one department by two different surgeons. One was the head of the department (MR, 91 procedures, 47 randomized for IP), and the other one was a fellow (SZ, nine procedures, five randomized for IP). General anesthesia was performed in 50 patients (26 with pedobarography), and spinal anesthesia in 50 patients (26 with pedobarography). The type of anesthesia did not affect any of the recorded parameters. All patients were enrolled with followup of 2 years on average (range, 16 to 33 months).The study was approved by the Ethical Commissions of the responsible authority. Informed consent was obtained from all subjects included in the study.

Combined ankle and subtalar joint arthrodesis were excluded because these procedures were performed in the

Table 1: Principal Surgical Technique and Intraoperative Changes After IP[18]

N (N with IP)	Principle type of correction	Planned correction and implant fixation	Number (percentage), reason and type of modifications after IP
12 (6)	Ankle correction arthrodesis	Equinus, 0° Varus/Valgus planned; three 7.3 mm cannulated screws, two from anterior Tibia to posterior talar body, one from posteromedial tibia to talar neck, one 4.5 cancellous screw from fibula to talar body	2 (33%); in both cases increased forces forefoot/decreased forces hindfoot; talus position was corrected towards more dorsiflexed position
14 (8)	Subtalar joint correction arthrodesis	Talocalcanel angle and Boehler angle* as contralateral side planned; two paralell 7.3 mm cannulated screws calcaneus to talus through posterior facet	2 (25%); in both cases medial hindfoot force shift; correction of calcaneus versus talus position towards lateral
15 (8)	Midfoot arthrodesis without correction including	Talomatatarsal angle 0° dorsoplantar and lateral view planned; 3.5 mm third tubular plate first (second) ray, 3.5 mm lag screws for other fusions	3 (38%); in two/one cases decreased forces beneath $1^{st}/5^{th}$ metatarsal head; correction and TMT fusion in more plantarflexed metatarsal position
26 (14)	Midfoot correction arthrodesis	Talomatatarsal angle 0° dorsoplantar and lateral view planned; 3.5 mm third tubular plate first (second) ray, 3.5 mm lag screws for other fusions	9 (64%); in four/two cases decreased forces beneath $1^{st}/5^{th}$ metatarsal head; correction and TMT fusion in more plantarflexed metatarsal position; in two/one cases increased forces beneath $3^{rd}/2^{nd}$ metatarsal head; correction and TMT fusion in more dorsiflexed metatarsal position
33 (16)	Forefoot correction	Even dorsoplantar position of metatarsal heads planned, for first ray accurate centering of metatarsal head on sesamoids planned; mostly modified Weil osteotomies performed for lesser rays[11], 2.7 mm lag screws used for oesteotomy-osteosynthesis	8 (50%); in four cases decreased forces beneath 1^{st} metatarsal head/sesamoids; re-centering of metatarsalhead on sesamoids followed; in two cases decreased forces beneath 5^{th} metatarsal head; correction and TMT fusion in more plantarflexed metatarsal position; in two/one cases increased forces beneath $3^{rd}/2^{nd}$ metatarsal head; correction and TMT fusion in more dorsiflexed metatarsal position

*, supposed Boehlers angle used.[15] IP, intraoperative pedobarography. All implants from Synthes, Umkirch, Germany.

prone position in which IP was not feasible. The patients were grouped regarding the correction/arthrodesis location. The midfoot was defined as the region including Chopart joint, joints between midfoot bones, Lisfranc/-tarsometatarsal joint, and the forefoot as the region distal to the Lisfranc/tarsometatarsal joint. Correction was defined as intended change of bone position comprising the relevant bones of the defined location in contrast to an arthrodesis without intended correction, i.e., a so-called in-situ arthrodesis. All subjects had a preoperative clinical examination, radiographic assessment and standard dynamic pedobarography. The subjects were randomized into two groups, a) use of IP (study group), versus b) no use of IP (control group). The randomization was performed with 200 prepared envelopes containing a sheet with the term IP or no IP (100 envelopes each). The envelopes were closed, mixed, and stored in a box. One envelope was drawn and opened for each patient. In the IP group, the contralateral foot and the involved foot before the surgical procedure were measured in the preparation area after the beginning of anesthesia. The IP of the foot after the correction/arthrodesis was used after the surgeon considered the correction/arthrodesis process including the internal fixation to be optimal based on the surgeons' experience including the evaluation of the clinical appearance of the foot, and c-arm images.[18] The following scores were used for preoperative and followup assessment: American Orthopaedic Foot and Ankle Society (AOFAS), Visual Analogue Scale Foot and Ankle (VAS FA), Short-Form 36 (SF-36, standardized to a gender and age specific 100-point-maximum).[3,10,13] The times, intraoperative consequences after the use of IP, any adverse effects and the scores were recorded by a physician assistant. The intraoperative time spent of IP was defined as the interruption time of the surgical procedure due to IP. This interruption time comprised the IP measurement and the evaluation of the registered force distribution until the surgeon made the decision that changes based on the IP would be made or not. The interruption time did not include the setup of the system which was performed parallel to the surgical procedure by a physician assistant. The intraoperative consequences of IP were defined by the surgeon during the procedure based on the information of IP.

IP[13,14]

A device named Kraftsimulator Intraoperative Pedographie® (KIOP®, R-Innovation, Coburg, Germany, Registered Design No. 20 2004 007 755.8 by the German Patent Office, Munich, Germany) was developed for a standardized intraoperative introduction of forces to the sole (Figures 1 and 2).[14] The pedographic measurements were registered by a custom-made mat with capacitive sensors (model Pliance®, Novel Inc., Munich, Germany & St. Paul, MN) connected to a IBM compatible laptop computer with modified software (model Pliance Expert® spec. IP, Novel Inc., Munich, Germany & St. Paul, MN) (Figure 2). This software allowed

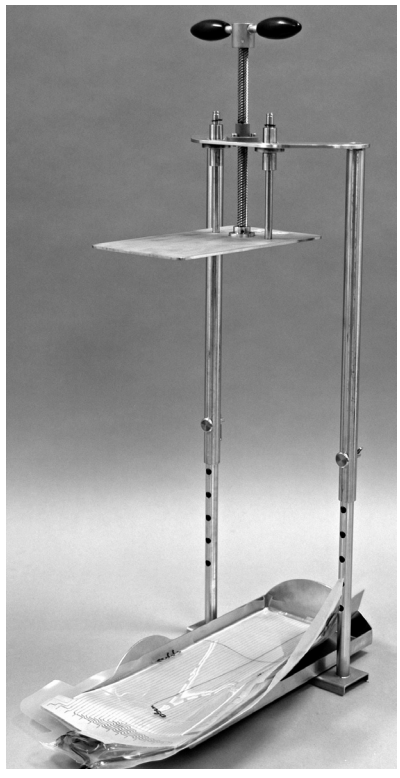

Fig. 1: The device for intra-operative force introduction (Kraftsimulator Intraoperative Pedographie® (KIOP®), registered design no. 202004007755.8, German Patent Institute, Munich, Germany & St. Paul, MN).[14] The custom made mat for force registration (model Pliance®, Novel, Munich, Germany & St. Paul, MN) was covered intra-operatively with a sterile plastic bag and was placed on the KIOP®. The size of the mat was 16 × 32 cm. The mat included 32 × 32 sensors with a sensor size of 0.5× 1 cm.

Fig. 2: IP in use (see Figure 1 legend for definitions).[13]

real-time pedographic analysis including comparison to physiological patterns and the preoperative and contralateral status. The patient was placed in the supine position for an easy measurement. A measurement in the lateral position was possible but much more complicated than in the supine position. A measurement in the prone position was not feasible. If two KIOPs® were available, one should be sterilized. The

unsterile KIOP® could be used in the anesthetic preparation room for the measurement of the healthy ("normal") foot which did not need to be prepped and draped for the measurement, and the affected foot before the surgical procedure. The second, sterile KIOP® could be used for the intraoperative measurement of the affected foot after the correction. If only one KIOP® was available, it had to be sterile. Both feet need to be prepped and draped for an intraoperative measurement. For the measurement, the mat was placed onto the KIOP®. One foot was measured at a time. The foot was placed on the mat and the knee under the stamp. The length of the KIOP® was adjusted to fit the lower leg. The foot was moved to the middle of the mat and the handle was turned to move the stamp down. A force comparable to half body weight was introduced. The goal for force distribution was hindfoot : midfoot/forefoot 60 : 40, medial : lateral 50 : 50 as described for a standing position.[5,12] The force distribution was controlled by positioning of foot and tibia for the medial : lateral distribution and flexion/extension of the knee and ankle for the force distribution hindfoot : midfoot/forefoot. The force distribution was visualized on the monitor of the system laptop.

Statistical analysis and hypothesis testing

The demographic data and the percentage of correction/arthrodesis location were compared between the group with IP versus the group without IP with a chi square test. The scores of all subgroups with different correction/arthrodesis location were compared between the preoperative status and followup with an unpaired t-test. The scores were compared between the group with IP versus the group without IP with a paired t-test. Within the IP group, the scores of the subgroup with changes after IP were compared with the scores of the subgroup without changes after IP with a paired t-test. The null-hypothesis at a $p < 0.05$ level was that there was no score difference between all groups and subgroups.

RESULTS

Perioperative data[18]

The mean preoperative scores were AOFAS, 49.1 ± 24.6; VAS FA, 45.3 ± 21.2; SF-36, 43.1 ± 31.2. The operative procedure was interrupted for IP for 5 minutes and 21 seconds ($\pm$ 39 seconds). In 24 of the 52 patients (46%) the correction was modified after IP during the same operative procedure (Table 1). The changes were done most likely in midfoot correction arthrodeses (64%), and least likely in subtalar joint correction arthrodeses (25%). No further changes in the correction or internal fixation were made after IP. In the 24 cases in which changes after IP were made, the additional time for the changes made including modification of the correction and internal fixation and the following IP was 15 minutes and 13 seconds ($\pm$ 8 minutes and 44 seconds). Complications related to the use of IP such as infection were not recorded.

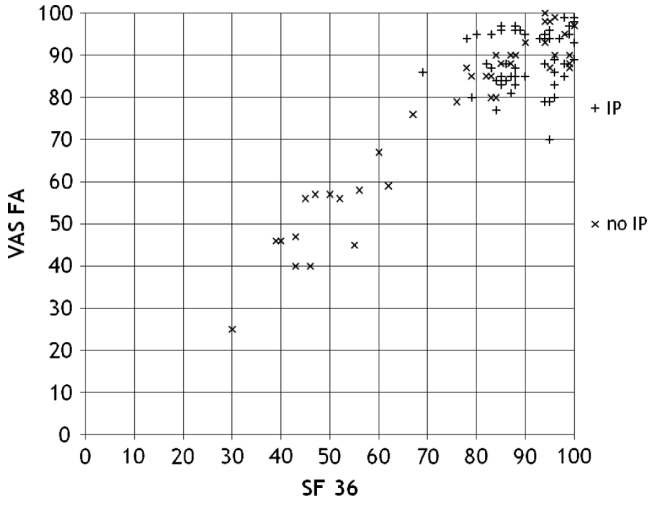

Fig. 3: Scores of SF-36 and VAS FA at followup.

All groups with different location of correction/arthrodesis with or without IP showed higher scores at followup in comparison with the preoperative scores (detailed data not shown, unpaired t-test, $p < 0.05$).

At mean followup of two years, the average scores were higher in the group with IP than in the group without IP (IP/no IP: AOFAS 89.7/78.2; SF-36 90.3/76.3; VAS FA 90.3/76.3; t-test, all $p < 0.05$). Figure 3 shows the SF-36 and VAS FA scores of all subjects with or without IP. Scores of less than 69 were only recorded in cases without IP from the followup assessment. Table 2 shows the results including the AOFAS scores and the statistical comparison of the followup scores between groups with different location of correction/arthrodesis with IP versus no IP. The subgroups midfoot arthrodesis without correction, midfoot correction arthrodesis and forefoot correction showed higher scores with IP than without IP. The subgroup ankle correction arthrodesis showed higher SF-36 and VAS FA scores with IP than without IP but no difference in the AOFAS Hindfoot Scale. The subgroup subtalar joint correction arthrodesis showed higher SF-36 scores with IP than without IP but no difference in the AOFAS Hindfoot Scale and the VAS FA.

Within the IP group, the scores of the subgroup with changes after IP were not different compared to the scores of the subgroup without changes after IP (detailed data not shown, paired t-test, $p > 0.05$).

The null-hypothesis was rejected for the preoperative versus followup scores, and for all score differences of all groups with different location of correction/arthrodesis with IP versus without IP except the AOFAS scores in the subgroups ankle and subtalar joint correction arthrodesis and the VAS FA in the subgroup ankle correction arthrodesis. The null-hypothesis was not rejected for the score differences between the subgroup with changes after IP and the subgroup without changes after IP.

DISCUSSION

IP[13,14]

Pedobarography is a measurement of the force distribution under the sole of the foot which can be performed in a static or dynamic way.[7,8] Over the years, a variety of methods have been employed to study foot pressure.[1,2,6] Many of these techniques have already improved our understanding of the foot and its function, and have had an impact on the way we practice.[1,4,20] The invention of an IP device was driven by the idea to profit from these advantages not only pre- and postoperatively but also intraoperatively.[13,14] The most important predicted benefit was to use the data from an IP assessment to detect suboptimal biomechanical conditions and to have the opportunity for immediate changes of the correction or reduction during the same surgical procedure.

Table 2: Results at Followup

Ankle correction arthrodesis (AOFAS Hindfoot Scale used)								
In total ($n = 12$)			**IP ($n = 6$)**			**no IP ($n = 6$)**		
AOFAS	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**
75.7 ± 18.2 34–90	76.9 ± 15.7 39–87	72.3 ± 23.3 24–99	83.3 ± 5.3 78–90	85.7 ± 6.0 78–96	85.0 ± 6.0 77–94	68.0 ± 23.7 34–90	68.2 ± 18.0 39–87	59.7 ± 27.8 24–99
				t-test				
AOFAS, $p = 0.08$; SF-36, $p = 0.03$; VAS FA, $p = 0.03$								
Subtalar joint correction arthrodesis (AOFAS Hindfoot Scale used)								
In total ($n = 14$)			**IP ($n = 8$)**			**no IP ($n = 6$)**		
AOFAS	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**
82.1 ± 10.5 60–94	71.6 ± 19.5 23–88	82.4 ± 15.3 44–96	85.8 ± 5.3 79–94	82.0 ± 6.4 69–88	87.1 ± 5.7 80–96	77.3 ± 14.2 60–92	57.7 ± 22.9 23–84	76.2 ± 22.0 44–96
				t-test				
AOFAS, $p = 0.08$; SF-36, $p = 0.01$; VAS FA, $p = 0.10$								
Midfoot arthrodesis without correction (AOFAS Midfoot Scale used)								
In total ($n = 15$)			**IP ($n = 8$)**			**no IP ($n = 7$)**		
AOFAS	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**
88.8 ± 9.0 64–100	83.6 ± 17.4 46–99	90.8 ± 5.9 77–100	92.9 ± 6.2 80–100	89.8 ± 7.4 80–99	92.7 ± 4.6 85–97	83.8 ± 9.7 64–95	75.8 ± 23.2 46–99	88.4 ± 6.8 77–100
				t-test				
AOFAS, $p = 0.01$; SF-36, $p = 0.04$; VAS FA, $p = 0.05$								
Midfoot correction arthrodesis (AOFAS Midfoot Scale used)								
In total ($n = 26$)			**IP ($n = 14$)**			**no IP ($n = 12$)**		
AOFAS	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**
83.4 ± 14.1 44–100	87.1 ± 12.1 43–99	82.9 ± 18.0 40–100	87.9 ± 8.5 70–100	90.4 ± 6.4 79–99	88.6 ± 8.3 70–100	78.9 ± 17.2 44–100	83.7 ± 15.3 43–99	77.3 ± 23.1 40–100
				t-test				
AOFAS, $p = 0.04$; SF-36, $p = 0.05$; VAS FA, $p = 0.04$								

Table 2: *continued*

Forefoot correction (AOFAS Hallux or Lesser Metatarsophalangeal-Interphalangeal Scale used)								
In total ($n = 33$)			**IP ($n = 16$)**			**no IP ($n = 17$)**		
AOFAS	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**	**AOFAS**	**SF-36**	**VAS FA**
87.1 ± 14.0	87.4 ± 18.5	87.4 ± 16.2	92.9 ± 6.6	95.3 ± 5.8	94.3 ± 6.9	81.6 ± 16.9	79.9 ± 23.1	80.8 ± 19.6
48–100	43–100	46–100	80–100	78–100	79–100	48–100	43–100	46–100
				t-test				

AOFAS, $p = 0.01$; SF-36, $p = 0.01$; VAS FA, $p = 0.01$ (first line mean±standard deviation, second line, range; third line t-test IP versus no IP). AOFAS, American Orthopaedic Foot and Ankle Society; SF-36, Short Form 36; VAS FA, Visual Analogue Scale Foot Ankle.

The introduced method was validated for static intraoperative pedographic measurement.[14] The main question after the validation was whether IP may really lead to an optimized surgical procedure which then improves the clinical outcome in comparison with patients without IP.[14] The hypothesis was that modifications after IP would improve biomechanical function of the foot and might improve clinical outcome.

Clinical use

A Level 1 study was started to answer this question.[18] One hundred cases were considered as a sufficient number to further evaluate this method.[18] In 46% (24/52) of the cases of the study group (with IP) a modification of bone position and internal fixation was made after IP during the same surgical procedure.[18] Again, the IP was used after the surgeon considered the correction/arthrodesis process to be optimal based on the surgeons' experience including the evaluation of the clinical appearance of the foot and c-arm images and optional Computer Assisted Surgery (CAS, Vectorvision™, Brainlab, Heimstetten, Germany, see below) and intraoperative three-dimensional imaging (ARCADIS-3D™, Siemens, Munich, Germany).[16,17] The modifications after IP were done most likely in midfoot correction arthrodeses (64%, nine of 14) or forefoot corrections (50%, eight of 16), and least likely in ankle correction arthrodesis (33%, two of 6) or subtalar joint correction arthrodesis (25%, two of 8). The modifications after IP always included a change of bone position and internal fixation. A followup IP then showed a more favorable force distribution pattern, and no further modifications were indicated. We were not surprised about the high rate of changes after IP in midfoot correction arthrodeses because these procedures are known to be challenging especially in the restoration of a plantigrade foot and therefore favorable pedographic pattern.[25] In contrast, the high rate of changes after IP in forefoot corrections was surprising since these cases are often specified as less demanding.[9] Our forefoot cases showed a high potential of suboptimal force distribution after proximal first metatarsal and distal lesser metatarsal osteotomies. We frequently found an increased percentage of force under single metatarsal heads that lead to a modification in the above described corrective osteotomy. The low percentage of changes after IP in the hindfoot is in our opinion caused by the described lower sensitivity of IP in the hindfoot region and not by the difficulty of the correction arthrodesis.[13,14] The same is true for the midfoot arthrodeses without correction. These cases as so-called in-situ fusion are not considered as challenging as midfoot correction arthrodeses because the position of bones, i.e. force distribution is adequate before the surgical procedure.[25] Still, in 38% (3 of 7) of these cases the position of metatarsals was suboptimal during the fusion before IP, and then corrected after IP.

The time spent for the IP of 5 minutes on average was favorably short. However, in the 24 cases in which changes after IP were made, the additional time for the changes made a followup IP of 15 minutes on average a sufficient amount of time. This additional time of 15 minutes seems very acceptable to obtain the improved clinical scores in the group with IP and consequently also in the subjects with changes after IP.

All groups with different locations of correction/arthrodesis showed improved scores at followup in comparison with the preoperative scores whether IP was used or not. This clearly means that IP is not necessary to improve scores with a surgical procedure. However, at mean followup of 2 years, the average scores (AOFAS, SF-36, and VAS FA) were higher in the group with IP than in the group without IP. This is the most important result of this study because the treatment of the subjects of the two groups did only differ in the use of IP (IP in study group and no IP in control group). Scores of less than 69 (AOFAS, SF-36, or VAS FA) were only registered in cases without IP which suggests that low scores were avoided by IP. A different positive effect of IP for different correction/arthrodesis locations was found when the subjects were divided into subgroups. The highest positive effect of IP was observed in midfoot arthrodesis without correction, midfoot correction

arthrodesis and forefoot correction with significant differences in all scores. This was, as described above, expected for midfoot correction arthrodeses but not necessarily for midfoot arthrodeses without correction or forefoot corrections. The higher rate of changes after IP in these subgroups therefore led to more improved scores than the subgroups with lower rate of changes after IP (ankle or subtalar joint correction arthrodeses). The subgroups ankle and subtalar joint correction arthrodesis did not only show a lower rate of changes after IP but also minor score differences at followup.

One significant weakness of the study was the potential conflict of interest since the inventor of IP is the corresponding author and surgeon in the majority of the cases. We were aware of this problem from the beginning, and therefore planned the study as a multi-center trial. However, we failed to find other centers that had the ability to follow the strict study protocol.

We started then as single center-study but are still planning to include other centers in the future. We are conscious that the use of IP in an ongoing clinical study may also alternate the surgical procedures done in the patients that were not randomized for that measurement, by changing the surgeons experience and expectations.[18] This is a potential bias for all studies in which surgeons are involved for more than one surgical procedure which is normally true for all such studies.

Before the beginning of the study, one principle question was the definition of the study group and the control group. We decided to define a group of subjects treated including IP as study group regardless of the potential effect of IP. Consequently, subjects that were treated without IP served as a control group. This definition, however, potentially (as the later study showed), included a group of subjects in which IP was used without any effect in the study group. These subjects in the study group might also serve as a control group like subjects in which IP was not used at all. One could argue that the subjects of the study group without changes after IP might offset the potential differences between study and control group. However, we did observe score differences between study and control group regardless of this possible offset. Another possible definition of subjects would be those with changes after use of IP as the study group and subjects without changes after use of IP as the control group. However, this possibility included IP in both study and control group and was therefore rejected. We chose the first option with IP used only in the study group regardless of the effect but we are aware of the other possibility.

CONCLUSION

At mean 2-year followup in a Level 1 study, use of IP as the only difference between two groups with correction and/or arthrodesis of the foot and/or ankle led to improved clinical outcome scores. Low scores (less than 69 points) were avoided with IP. This study should be critically reanalyzed when longer followup, higher case numbers, and data from other study centers are available.

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