Abstract

A successful and minimally invasive treatment for adolescent flexible flatfoot is subtalar arthroereisis. This study examines the short-term results of subtalar arthroereisis with a new PEEK device (Pit'Stop®); additional research will be required to determine the device’s true potential, but the preliminary findings are very encouraging, with a high success rate and a low complication rate (0.08).

Introduction

Subtalar arthroereisis is an effective and minimally invasive treatment for juvenile flexible flatfoot, with low risk of complications; nevertheless, no worldwide consensus exists about indications, because the risk of pathological evolution and the causes of pain in pediatric flatfoot have not been definitely clarified yet.1

This study aims to analyse the short-term outcomes of arthroereisis with PEEK Pit’Stop® device.

Materials and Methods

One hundred and thirty pediatric patients with flexible flatfoot underwent to endotarsal arthroereisis at the Pediatric Orthopedics Unit in Varese, during 2021-2021 two-year period. All the patients but three were treated bilaterally, for a total of 257 feet. The indications for surgery were: symptomatic flatfoot (pain of foot and leg, early fatigue, etc.), severe flatfoot (III – IV degree) or critical malalignment of the hindfoot (hindfoot valgus > 8º).

Sixty-eight patients were lost at follow up or excluded by criteria: associated surgeries (gastrocnemius recession) or rigid flatfoot.

Therefore, sixty-two patients (124 feet) were included: twenty females (32.26%) and forty-two males (67.74%), with a mean age at the time of surgery of 12.14 years (10.48-14.45). The mean follow up was 12.70 months (range 4.56±27.45).

We implanted PitStop® PEEK endorthesis (In2Bones, Memphis, TN, USA) in all the cases. Patients wore weightbearing casts for three postoperative weeks; a standard protocol of physiotherapy (Figure 1) was indicated after cast removal while intense sport activities (running, jumping, soccer, basketball...) were allowed after ten weeks.

Patients were six-times evaluated: pre- and postoperatively, three weeks, two months, three months postoperatively, and at the time of study. Clinical assessment was associated to validated EFAS Score questionnaire and VAS score. Height, weight and BMI were registered.

Weightbearing X-ray assessment (ante- and postoperatively, three weeks, two months, three months postoperatively, and at the time of study). Clinical assessment was associated to validated EFAS Score questionnaire and VAS score. Height, weight and BMI were registered.

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Informed consent: Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

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The statistical analysis of the data was performed by dedicated software, SPSS 24.0 (IBM SPSS Statistics Inc., USA).

Student t-tests to independent samples or paired samples for normal distribution variables were used for the comparison of the averages. In addition, statistical analyses were performed with bivariate evaluation of the correlations between the variables and the cofactors deepening with the analysis of linear regression to evaluate the effect of the same cofactors on the investigated variables.

The level of significance has been placed at \( p<0.05 \).

## Results

Clinical results are summarized in Table 1.

Preoperative mean EFAS score was 17.71 points (12.00-23.00), while postoperative was 34.50 points (26.00-39.00), with a clear mean improvement of 16.79 points \((p=0.000)\). Preoperative mean VAS was 6.31 points (1.00-10.00), post-operative 2.23 points (1.00-6.00), with a mean improvement of 4.08 points \((p=0.000\); Figure 2).

The mean BMI at the time of surgery was 20.99 (range, 15.80\(\pm\)28.40, std. dev. 3.20).

In the limited follow-up period, no clinical complications and/or early failures were found, except for one case (0.8\%) of wound dehiscence, healed by standard seriated medications.

Table 2 summarizes angles improvements recorded.

A statistical correlation between BMI with the final clinical scores, EFAS and VAS emerged: as BMI increases, the final EFAS tends to worsen \((p=0.000\); standard error 2.081; corrected R2 0.095); as the final VAS tends to increase as BMI increases \((p=0.001\); standard error 0.705; corrected R2 0.080).

No statistical correlations were found between BMI e final angles.

## Discussion

In this study, subtalar arthroeresis with PEEK Pit’Stop® device has been shown to be effective in reducing preoperative pain and improving angles of foot. EFAS values increased and VAS values statistically decreased \((p<0.001)\). Similarly, all angles statistically improved \((p<0.001)\). Our results confirm the results reported by other studies.\(^1,6,7\)

Complication rates were rare (0.8\%), represented by only one case with wound dehiscence. This rate is significantly lower than literature, where 4.8\%\(\pm\)19.3% rates were recorded.\(^1\) Only Indino reported a complication rate close to zero.\(^3\)

Our minimal rate of complications could be partly related to the short follow up; nonetheless, we highlight the absence of chronic residual postoperative pain at sinus tarsi, which usually shows an early onset.\(^1\)

Good stability, safety and efficiency of PEEK Pit’Stop® device is proved by the absence of early ruptures and early mobilization. Further studies are needed to assess long-term results.

There are no correlations between BMI and final angles; nonetheless high BMI are correlated to lower clinical scores, possibly suggesting that subtalar arthroeresis maintains its corrective potential, but with greater functional effort and increased risk of pain and discomfort.

This hypothesis is confirmed by the linear regression studies for the evaluation of the relationships between weight and clinical-radiological outcomes, although the values of R2 close to zero do not allow to make generalized assumptions.

![Figure 1. Post-surgery rehabilitation protocol.](image)
Conclusions

The short-time results of Pit’Stop® device in the treatment of juvenile flexible flatfoot are promising: PEEK device should be considered as a valid option.

Further long-term or prospective randomized studies, preferably comparing different devices, are advisable.

References


Table 2. X-ray angle values.

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<tr>
<th></th>
<th>Average</th>
<th>Min</th>
<th>Max</th>
<th>STD. DEV.</th>
<th>Mean std error</th>
<th>Difference</th>
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<th>Significance (p&lt;0.05)</th>
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Figure 2. Comparison of clinical score averages in the pre- and postoperative periods.