SOLEMAIDS

Clinical evidence for the effect of orthotics for children with Severs disease

Severs disease – overlooked **but curable**

Severs disease is an overlooked condition among children and adolescents. Most parents or sports coaches have never heard about it, and surprisingly few professionals know how to treat it.

This is not surprising as Severs disease is a fairly under-researched topic within the field of sports medicine. There are clinical studies on the disease itself but hardly any of them document effective ways to treat it.

In the following, we share the results from four recent studies conducted in Denmark on children suffering from Severs disease. The key findings from these studies suggest that:

- Severs is an overlooked disease among children and teenagers [study 1a and 1b]
- Othorthics appear to have a beneficial effect for children suffering from Severs disease [study 2-4]; and
- Solemaids insoles offers effective pain relief for these children allowing them to stay active [study 2-4].

The clinical studies focusing on orthotic relief [study 2-4] are all pilot projects, whose results still need to be validated in more extensive and controlled studies that test Solemaids insoles against other orthotic devices, over a longer period of time, and on a larger group of children.

Despite their limitations, these studies do suggest that the Solemaids insole is a viable orthotic option, which can be used in clinical practice when treating children with Severs disease.

By offering effective pain relief, Solemaids insoles ensure that the child can stay active. In that way, we avoid the physical and psychosocial repercussions of Severs disease on the child's development – which comes from the lack of exercise and social bonding.

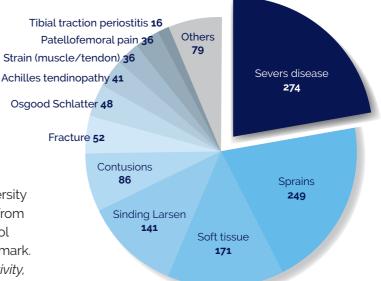
Study 1a and 1b:

Studying physical pain and injuries in Danish school children

From 2008-2011, researchers at University of Southern Denmark gathered data from a representative cohort of 1,000 school children in a local municipality in Denmark. Their study, *The Childhood Health, Activity, and Motor Performance School Study Denmark* (2013) explored whether longer school days has an effect on children's health – specifically, whether these children experienced pain in muscles, joints, back, neck, arms and legs.

The study confirmed that this was the case. Within the category of 'leg pain', around 50 per cent of the children reported that they had experienced leg pain during the course of a school year.

These findings gave way to two other studies (1a and 1b): *Musculo-skeletal Extremity Injuries in School-aged Children with Special Focus on Overuse Injuries, Seasonal Variation and Body Composition* (Eva Jespersen, 2014) and *Musculoskeletal extremity pain in Danish school children – how often and for how long?* (Signe Fuglkjær et al 2017).



Drawing on data from the 'School study', both studies took a closer look at the musculoskeletal extremity pain that the children reported. Dividing the body into regions, the studies mapped the kind of pain and/or injuries the children experienced, accounting for duration as well as diagnosis.

Based on this overview, Fuglkjær's study could conclude that Severs disease was the most frequent complaint in children between 6-12 years of age, with ankle and heel pain peaking around the age of 11.

If scaled to a national level, the data and findings from these three studies indicate that over a 2.5-year period approx. 102,000 cases of Severs disease would be found in Denmark alone.

Study 2: Severs disease – a descriptive, observational study

During 2017, physiotherapist Per Oellgaard systematically collected data from his own clinic in Viborg, Denmark on 469 children and adolescents showing symptoms of Severs disease.

The purpose of the data collection was to establish the prevalence of Severs disease among this group of patients; the typical complaints and consequences of this condition when the child arrived in the clinic; and the subsequent effect of providing child and parents with information about Severs disease and fitting the child with a custom-made insole.

Before seeking treatment, these children had been physically active, pursuing different types of sports that involve running or jumping. When they arrived at the clinic, they had typically experienced pain for 10,4 months.

- 79% of them had reduced their sport activities or dropped out of them entirely.
- 90% of them reported that they had experienced no effect from conventional treatments such as heel cup, rest, exercises, sports tape and other type of orthotics.
- 79% of the patients who consulted the clinic with heel pain did so based on recommendations from other patients, who had experienced positive effects from using Solemaids insoles.

Although this was an uncontrolled study and cannot be used to validate cause and effect of the insole, the data from Per Oellgaard's clinic show that information about Severs disease and the physiology of the foot, combined with Solemaids insole that suspends the heel to relieve the pressure on the apophysis of the calcaneus, helped the majority of children in this study resume their sport activity.

Study 3:

The effect of orthotics in children with Sever's disease: A descriptive cohort study

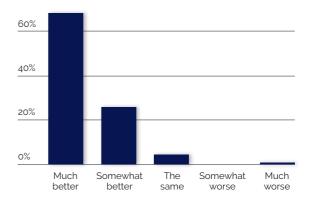
(Christian Clifford Poulsen, 2020)

This study describes the short-term effect of orthotics – specifically the Solemaids insole – on a group of 161 children, treated in a physiotherapist clinic in Viborg and a chiropractic clinic in Odense, Denmark over a period of four months. It also investigates possible prognostic factors in the development of pain intensity, function impairment and social factors.

The study indicates a positive effect of this orthotic intervention when it comes to pain intensity and function impairment:

- 69% of the follow-up responders reported that heel pain intensity had become 'much better', while 26% reported 'somewhat better'.
- mean worst pain in the final two weeks dropped 4.02 points and mean function impairment dropped 3.01 points.
- participation in school games increased by 17%; sport activities by 66% and participation in PE (physical education at school) by 24%.

Heel pain intensity after orthotics (n=74)



As this is an uncontrolled study, it cannot be used to validate cause and effect.

Based on its findings, however, it seems fair to conclude that the application of the Solemaids insole plays an important role in reducing pain and function impairment and promoting physical activity in children with Severs disease – at school as well as during extracurricular sports activities.

Study 4:

Sever's disease treated with the Solemaids orthotic insole: A prospective cohort

(Mads Egsgaard Thomasen, 2020)

As a follow-up to Poulsens initial study, Thomasen conducted a second study to document the effect of the Solemaids insole over a longer period of time.

Thomasen followed a population of 161 children with Severs disease who were treated with the Solemaids insole over a period of six months, quantifying changes in pain and activity levels as well as identifying potential prognostic factors.

The results obtained in this study indicate that improvement is quickly achieved after the intervention with the insole and, for most of the children, pain relief and activity was sustained after six months:

- The children's pain levels decreased over time (from NRS 7.54 to 2.41): at six months, 55% were pain free at six months; 74% had significantly reduced their pain level; and 82% felt their pain was much better compared to baseline.
- The self-reported function impairment went down (from 5.81 to 3.12) and participation in sport, games and physical education increased by 66%. The greatest improvement occurred during the first three weeks (NRS 7.54 to 3.33).
- Playing football and participating normally in sports at baseline were identified as positive prognostic factors for pain improvement.
- Playing handball, experiencing night pain or no pattern of pain, were identified as negative prognostic factors for pain improvement.

Due to lack of a control group in this study, these benefits cannot be attributed to the Solemaids insole alone.

Based on Poulsen and Thomasens studies it seems fair to conclude that there is an indication that the Solemaids insole is a viable orthotic option when treating children with Severs disease.

Notes on methods and study design

Notes for study 1a and 1b

- The study gathered data from 1,000 children in Svendborg Municipality, Denmark. This cohort was assessed as representative of the general population in Denmark.
- The data collection took place between 2008-2014. Weekly text messages were sent to the children's parents to get an understanding of the child's pain in the muscles, joints, back, neck, arms and legs.
- Parents who reported back that their child had been in pain that week, were subsequently interviewed by a chiropractor or physiotherapist. Children with persistent pain were examined and a diagnosis given.

Notes for study 2

- It is a descriptive observational study (no control group) and paves the way for hypothesis generation.
- 492 children with heel pain in the growth plate area were examined and diagnosed.
- 469 were included in the study and received the intervention.
- Baseline information was collected by the physiotherapist (on age at onset, level of physical activity, type of sport, duration, former treatment received) and information was given on the cause of the condition, treatment and prospects.
- As a follow up, the parents were asked to provide their qualitatively assessment of the effect the intervention – three weeks after it had been given.

Notes for study 3

- The cohort included children aged 7-15 with a history of pain in the posterior part of the heel, who also responded positively to the 'squeeze' test.
- The study population was followed over a period of three weeks, during which they also received treatment from their physiotherapist or chiropractor. Questionnaires were filled out at baseline and after three weeks.
- The primary outcome was pain intensity (NRS). Function impairment (0-10), participation in school games, sport and Physical Education were secondary outcomes.
- Baseline information was available from 161 participants and follow-up information was available from 75 participants.

Notes for study 4

- The cohort included 161 children with Sever's disease.
- Participants filled out a baseline questionnaire, which included questions about pain and activity levels and types of activity.
- Follow-up was done at three weeks, three months and six months.
- Pan levels and feeling of function impairment were assessed by Numerical Rating Scale (NRS) 0-10, and activity level were tracked throughout the study.
- Differences quantified via mean values, 95% confidence intervals, proportions and proportion confidence intervals. Chi-squared testing was used to identify potential prognostic factors and univariate logistic regression was used to report odds ratios.
- Follow-up questionnaires were completed by 83 (52%), 85 (53%) and 56 (34.8%) participants, respectively, for each survey. Only 32 (20%) completed all questionnaires.



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