Proof of efficacy for the medicalcare of aids:
Can the body's own biomechanics provide significant measurable evidence of effect in the fitting of insoles?

Parallelstudy 2023

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Abstract:

Introduction:

Everyone wears insoles in their shoes,.... sooner or later!
How can the insert with the "best" effect be quantified for the patient? This study seeks to answer this question by using the degree of head rotation ability.

Question:

As a result of orthotic fittings, **head rotation ability** does not (H^0), or does (H^1) change?

Material and Methods:

With a digital angle measuring device (HMSU) head and neck rotation can be visualised.
The parallel study examines existing data from individuals, collected from 2016 to 2022 with the HMSU, in the context of everyday insole fittings. Compared were barefoot measurement (B) to measurement with fitted insoles (nE) from 1439 persons.

Results:

The comparison was able to show a strong increase in the degree of head rotation with an average improvement of 44°, thus supporting H^1.
This also provides strong proove to manipulations, carried out under the feet affect the biomechanics of the vertically running muscle chains, culminating at the head.

Diskussion:

Possible issius regarding the measurement process and the use of the measuring device are discussed, as well as possible influences that could interfere with the data collection.
By transferring this measurement application (HMSU) to other fittings, a better and resource-saving rehabilitation of patients could be achieved.

Introduction

Everyone wears insoles, ...sooner or later.
For sports support, for prophylaxis or for orthopaedic reasons for rehabilitation.
What is the "right" insole for the patient? It is well known that insoles are primarily intended to eliminate existing foot problems such as pain or restricted movement. Insoles are a medical product[1] that is dispensed millions of times in various forms, not only in Germany and Europe.
A recurring question is how the positive effect of insoles can be proven. Or: Do insoles do what they promise?
These questions are asked by everyone who prescribes, manufactures or wears insoles in their shoes. The question is complicated by the idea that the effect of insoles goes beyond the function of the foot.
A rehabilitation success is classified according to appearance and patient satisfaction.
The question and thus the content of this study is:
How can the organism, without great effort between foot and head, be interrogated, measured and compared whether the intended insole is good for the patient, whether it actually creates rehabilitation?
The following points should be checked:

- How can the current situation, the condition of the body be quickly and reliably recorded or queried?
- What shows us immediate improvements, what shows us deteriorations of a fitting?

There are numerous authors who emphasise the relationship between foot function and, for example, posture[2,3], occlusion[4,5,6] craniomandibular[7],and spinal function[8,9,10,11].

In addition, the concept of bio-tensegrity[12,13] provides a biomechanical basis for our insole fitting with compelling consideration of gravity as well as the "tube pressure" of the individual body sections[14].

If the sensory[15] ground contact of the feet changes, e.g. due to an insole, there could also be changes in the neck and head movement via the biomechanics of the vertical muscle chains of our body.
Especially because of the large distance between foot and head, the changed neck movement could be a valuable indicator for the effect of insoles on the body's own biomechanics.

Increased range of motion, i.e. improved ability to turn the head, is thought to improve overall statics and postural regulation. This is confirmed by principles from physio-, osteo- and podotherapy,

where the function of the upper cervical joints is considered an important parameter for influences of any kind on the body system.
This movement is called Range Of Motion (ROM).
However, a suitable and accurate device is required to accurately record head-neck ROM in a clinical setting. There are systems available to measure the range of neck motion.
However, most systems are inaccurate, difficult to read and do not automatically record the measurements. Other devices are difficult to obtain for regular practice because of the price level. Therefore, a measurement device was developed to easily and quickly measure and record head-neck ROM (HeadMountSupportUnit, HMSU). The validity of this instrument has been established in previous studies.[16]
The present study investigates whether the instrument is able to detect the influence of insoles on head-neck ROM.
If the discriminative ability of the HMSU can be demonstrated, the system could be a tool to objectively determine the effect of insoles.

For the parallel study, the collected HMSU - data from 2/2016 to 12/2022 were used as a basis and the following hypotheses were named:

Null hypothesis H_0:

The ability to rotate the head does not change as a result of an insole fitting.

The alternative hypothesis H_1:

The ability to rotate the head changes as a result of an insole fitting.

Material and methods

ROM was measured using a digital goniometer (HMSU)[17]. This measuring device consists of a sensor[18] and a green line laser[19] as well as a cable to the PC and a hair band. The housing for connecting the individual components was produced using 3D printing. The complete device weighs just under 100g.
The built-in sensor that measures the head rotation is equipped with a 3-axis acceleration sensor, magnetic field sensor (compass) and gyroscope and works as a USB inertial sensor. This can measure 9 degrees of freedom and calculates quaternions as well as independent yaw, roll and pitch angles. It is a complete attitude-and-heading-reference system. According to the manufacturer, the accuracy is given as 1-2°degrees[20]. For the application in this study, only the horizontal readings are read out.
The patients are people of different ages and sexes who have been prescribed an insole fitting by their doctor or have sought an insole fitting of their own accord due to pain in the foot or musculoskeletal system. The patient group was subject to a certain pre-selection only to the extent that patients with a known degenerative cervical spine were avoided. All measurements were taken in the context of a regular insole fitting as follows:

The HMSU is placed on the patient's head with the hair ripe. The vertical laser is aligned centrally in line with the vertical facial axis. This may well be "crooked" if the head is "crooked on the neck". It is important that the head position makes a realistic and lifelike measurement situation possible. The patient looks "straight" and brings the laser to an external zero point in front of him. This zero point is centered via program before each measurement. The patient is then asked to turn his head slowly and as far as possible to the left, back to the zero point and then to the right. The examiner fixes the patient slightly at the shoulders to prevent the trunk from turning. The HMSU transmits the ROM data to a computer programme that displays the angle measurements visually and in tabular form.
Each patient was measured first without and then with the insole fitting.
There were a few minutes between the two measurements. In each case, the measurement with

Founded Datapairs:

634 Patients	1 Datapairs
587 Patients	2 Datapairs
139 Patients	3 Datapairs
59 Patients	4 Datapairs
12 Patients	5 Datapairs
6 Patients	6 Datapairs
2 Patients	7 Datapairs
1430 Patients	**2571 Datapairs**

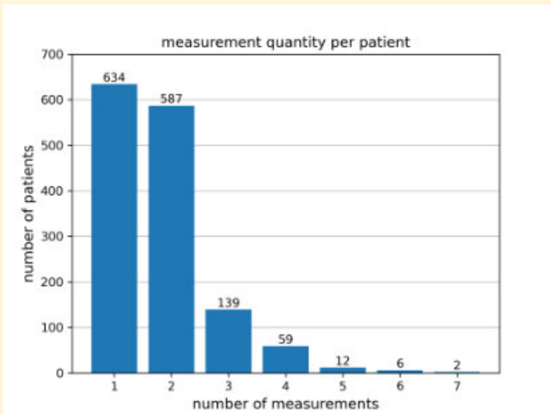


Figure 1: Measurements - persons

the largest ROM, without (B = barefoot) and with insole (nE = new insole) was labelled and stored in the patient's file.
All patients were fitted with individually adapted neurophysiological insoles[21].
From the data pool (2988 patients) that had accumulated from 2/2016 to 12/2022, data from 1439 patients (B) could be analysed. The individual measurements of these data were labelled so precisely that they could be easily correlated and calculated.

The barefoot measurement (B) shows the initial condition, the measurement (nE) shows the change due to the underlaid new insoles.
The ROM of the barefoot measurement (B) was compared with the ROM of the insole fitting (nE) of 1453 patients.
To evaluate the data pairs, the angular sum of the rotation to the left and right without and with insoles was determined. This resulted in a data pair for each patient with a ROM "barefoot" measured and a ROM with "new insole" measured. Some patients came several times, so there are more measurements than patients.

The significance level for the linked, two-tailed t-test was set at α = 0.005. The evaluation of the data results in a test statistic t = 127.49. The critical value with a degree of freedom greater than 500 to the significance level 0.005, is 2.586[22].

Results:

Change in head rotation ability from "barefoot" and "with insole":
When analysing the data, a normal distribution of the angle sums (ROM) from left and right rotation of the head without insoles was found. In the measurement without insole, the smallest value was a ROM of 67.9 degrees, the largest ROM was 288.6 degrees. The mean value was 176.0 degrees, with a standard deviation of 28.0 degrees.

Messung	Durchschnittliche ROM	Standartabweichung v. durchschnittlichen ROM´s
Barfuß B	176°	28°
Mit Einlage nE	220°	30°
Ergebnis	**44°**	17°

The differences in the patients' head rotation ability when measured with insoles were also normally distributed. In the measurements with insoles, ROM-min was 99.9 degrees and ROM-max 310.8 degrees. On average, the ROM's were 220.0 degrees with a standard deviation of 30.0 degrees.

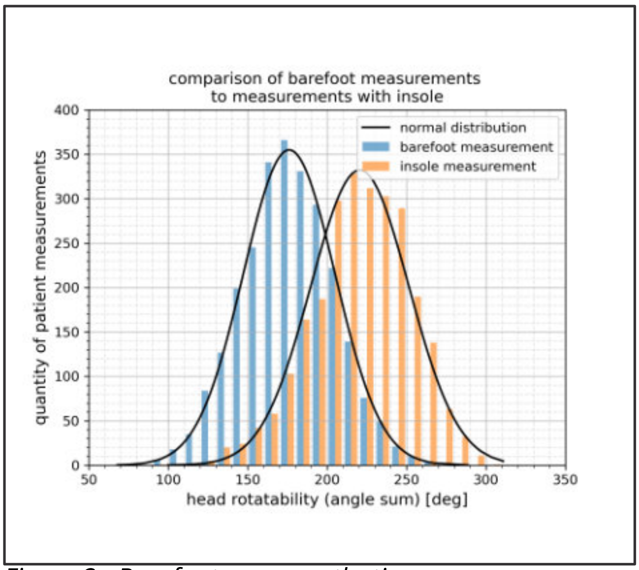


Figure 2 : Barefoot versus orthotics

In 2565 patient measurements, the ROM increased, in 6 patient measurements, the ROM decreased with insertion. The mean change in ROM of the head turning ability to the left and right between the measurement without and with insertion was an increase of 44.0 degrees, with a standard deviation of 17.0 degrees.

To test the statistical significance of these results, we test them against the named hypotheses.
Since the test statistic of 127.49 is greater than the critical value of 2.586, the difference in means is significant. The null hypothesis can therefore be rejected with an error probability of 0.5%. The corresponding correlation coefficient according to Pearson[23] was r = 0.93. The measurements thus show that the insole fitting has a statistically significant influence and a very strong effect on the patient's head rotation ability.

Diskussion

In this study, a significant improvement in head rotation ability was observed in 2565 of 2571 patient measurements after fitting neurophysiological insoles. The 6 measurements with no change or with deterioration could indicate that no insoles are needed (anymore). Possibilities for this could be: rehabilitation or the causative pathology needs to be addressed differently.
The increase in the angular sum of the head rotation from "B" to "nE", to the left and to the right was on average 44° degrees. Comparing B1 to B2 shows an improvement of 16° degrees in head rotation ability. Both values are a strong indication of the positive and also lasting effect of the fitting.
Neurophysiological insoles[24] aim to bring the entire

body statics[25] and biomechanics from a pathological change back to their physiological function. In the long term, the insoles could even become superfluous (depending on the case) (1.5 to 3 years of wear). During the fitting, attention is paid to a pelvis that is as "straight" (neutral-0) as possible, a head rotation that is as symmetrical as possible and a good straightening of the organism.

The simple test set-up required by the HMSU programme makes it easy to measure and document the head rotation ability, referred to here as Range of Motion (ROM), without (barefoot) and with manipulation (orthosis), and thus provide direct evidence of the effect for each patient and, possibly, of the rehabilitation of the musculoskeletal system.

After all, in addition to stability and control of postural regulation, greater range of motion and fluidity of movement are THE rehabilitative goal of any exercise.

Due to the speed and simplicity of the measurement system, this tool can be used well in the daily routine of a company for fittings and their documentation.

The next question is whether the repeated turning of the head leads to a stretching of the muscles and ligaments of the neck, which could lead to an improvement of the head turning ability independent of the insole.

This point can be invalidated by the observation that the ability to turn the head also decreases again when the measurement with the insole is followed by another measurement without the insole, i.e. barefoot again.

At the same time, a kind of muscular memory effect was observed in many patients: When the insoles were removed, the positive effect of the good ROM lasted for a few seconds before it subsided and disappeared. This suggests that the musculature of the postural regulation immediately "remembers" the good support and tries to re-establish this more optimal muscular toni even without the insoles. Further research on this would be extremely interesting.

However, in order to avoid misinterpretation of the measurements, the test persons should turn their heads to the left and right several times before the first test. Basically, there are a few things to consider about the situation itself when taking such measurements. See the appendix: Prerequisite for good measurement results[26]

It also seems important that the test situation is as unexciting and pleasant as possible for the patients. On the one hand, for ethical reasons, it was decided not to fix the shoulders of the patients to fixed devices in order to obtain the most accurate measurement results of the pure head rotation. On the other hand, a fixed fixation of the shoulders would prevent an erection of the posture, which is very popular here.

This critical point is always discussed as a possible weak point in data collection, since it cannot be completely ruled out that the examiner consciously or unconsciously influences the patient's movement. However, experience and an internal study[27] with changing examiners show that trained examiners can estimate very well how the test persons have to be held at the shoulders in order to obtain realistic test results. Within the framework of an individual, personal movement pattern, each patient turns in his or her own way.

The best approach has been to grasp the shoulder joints laterally with the hands. Initially, there was the idea of placing the hands on the shoulders, close to the neck. However, this is very uncomfortable for some patients and also puts too much palpatory pressure on head-holding structures that one would like to know are "free" during testing. It also offers little effective support against possible rotation of the shoulder girdle on the part of the patient. Holding the shoulder joints laterally provides a good approach to prevent possible rotation of the shoulder girdle, even in large and strong people.

The actual testing with the placement of the small wedges that are then found in the insole can be done in a few minutes. The insert itself is not placed in one piece, but each wedge is tested for its effectiveness. If the head rotation changes positively due to the added wedge, it remains in place; if it tests negative, it is removed again. Of course, it should also be taken into account that this type of treatment takes a lot of time for the patient. The initial visit is estimated to take 1 hour (the check-up visit half an hour), during which a comprehensive, holistic picture of the patient and his or her physical problems is gathered. This could result in a care-taking effect, which could have a positive impact on the measurement results.

An important point during the first visit is also to advise patients on the correct footwear for use with insoles. Here is a short list of the most common killers: too soft soles, shoes that are too short or too tight, wrong lacing, socks[28] that are too tight, built-in longitudinal arch supports or toe caps that are too long reduce the success of a fitting immensely.,

The patient group is subject to a certain pre-selection, as already mentioned in Material and Methods, only to the extent that patients with a known degenerative cervical spine were avoided, which could affect the results. Controlled studies with randomised groups would be nice here.

A certain placebo effect cannot be ruled out, since the patients are aware that manipulations are being carried out by the wedges under their feet. This is contradicted by the fact that a wrong or disturbing wedge immediately leads to less head rotation. Double-blinding is difficult to achieve here. Studies in which at least the examiner is blinded necessarily require an equal level of training among the participating examiners.

This study shows the great potential of measuring the head rotation ability.
As a further consideration from the positive results, the question arises as to whether every fitting should not be checked for an improvement in head rotation ability. After all, all vertical muscle chains can be tested with this method without much effort. Certainly, there are a few cases where no immediate improvement can be achieved, but here, too, the long-term goal should be an improvement in the ability to rotate the head. Not only insoles, but also shoes, shoe fittings and other aids could then be evaluated in their effect with such a check.
If no improvement of the head rotation ability is achieved with the fitting, this can be an indication that the patient's problem has other causes and cannot be achieved via biomechanical manipulation from the foot. In addition to saving resources, this could also save a lot of frustration for patients and caregivers.

S**ummary**

Can the body's own biomechanics provide measurable proof of effectiveness for the safety by supply with orthoses?
Does an **o**rthose deliver what it promises? Can the effect of insoles be made visible? Is measurable head rotation an indicator for these hypotheses?

Over a period of 6 years, data from 2988 patients were collected using the HMSU measuring system, a digital protractor. From this pool, a total of 2571 data pairs of horizontal head rotation ability could be evaluated from 1439 different patients.
Compared were: Barefoot measurement (B) to supplied measurement with insoles (nE).

By evaluating the data "B" to "nE", a significant increase in the angular sum of the head rotation to the left and right could be demonstrated in 2565 of 2571 patient measurements who were fitted with neurophysiological insoles. On average, the improvement was 44 degrees and thus represents a strong effect.
Head rotation ability is seen as a proven means of testing the effectiveness of insoles. At the same time, this study provided clear evidence that manipulations under the feet affect the biomechanics of the vertical muscle chains that end at the head.

It is discussed how the experimental design can be improved in order to minimise a possible influence by the examiner, as well as possible effects by stretching the muscles and ligaments, care-taking and placebo. The importance of correct footwear is also pointed out. Against the background of the good results, it is finally considered whether a transfer of this measurement application (HMSU) to other fittings is possible, which could at the same time be a trigger for more scientific research.

Due to the simplicity and speed of use of the measuring system, this comparatively inexpensive tool can be used well in everyday operations for restorations and a significant saving of costs and resources can be achieved, since it is already recognised during the test phase how the insert must be constructed. The HMSU system also creates the desired safety in patient care due to its good documentation possibilities.

Further research with a randomised, controlled study design would be desirable.

OSM Michael Weiß

Endnoten

1 MDR: Medical Device Registration. Eine Europäische Richtlinie zum in Verkehrbringen von Hilfsmitteln mit Gesetzeskarakter. Übergeordnete Klinische Bewertung der Sonderanfertigungsprodukte Einlagen, Dokument: DGIHV Klinische Bewertung_Sondereinlagen_2021-01-27, Datum: 27.01.2021

2 Tom Myer, Anatomy Trains, 3. Auflg. 2015, Elsevier Verlag, ISBN: 978-3-4375-6733-9

3 Kirsten Götz-Neumann, Gehen – Verstehen, Thieme, 4. Auflage, 2015, ISBN 9783131323743

4 Dr. P. Ridder, Craniomandibuläre Dysfunktion, 4. Auflage, ELSEVIER, ISBN 978-3-4375-8633-0

5 Dissertation, Katrin Riedlinger: Der Zusammenhang zwischen Temporomandibulärer Dysfunktion und Schmerzen im Bewegungssystem. Eine Querschnittsstudie bei Patienten mit neuromuskulären Erkrankungen, 2008 (Seite 71/73)

6 Dr. Anette Jasper, Verzahnt, Riva-Verlg., 2019, ISBN 978-3-7432-0711-8

7 Dr. med. dent. Jürgen Dapprich, Interdisziplinäre Funktionstherapie, Deut. Zahnärzte Verlag,2016, ISBN 978-3-7691-2998-4

8 Orthopädie-Schuhtechnik, 3.Auflg. 2018, Baumgartner, Möller, Stinus, Verlg.: C. Maurer, Seite 136fff, Kap. 20 Haltung und Haltungsregulation

9 Ina Ter Harmsel(†), Wolfgang P. Schallmey, Podo-Orthesiologie, Seite 17, Kap. 2.1, ML-Verlg, 2020, ISBN 978-3964743541

10 Dr. B. Bricot, Posturologie, 2.Auflage 2017M. Lochner KG Heilbronn, ISBN 978-3-00-045332-8

11 M. Weiß, Blauabdruck – neurophysiologische Einlagen – Schuhe, 2021, Schuh-Werk-Verlag, ISBN: 978-3-9823563-0-3

12 Graham Scarr, Biotensegrity, The Structural Basis of Life, Handspring Published, 2018, ISBN 978-1-909141-84-1

13 Tom Myer´s, Anatomy Trains, 3. Auflg. 2015, Elsevier Verlag, ISBN: **978-3-4375-6733-9**

14 Graham Scarr, Biotensegrity, The Structural Basis of Life, Handspring Publishing, 2018, ISBN 978-1-909141-84-1 Seite 65 ff.

15 Dr. Wolfgang Laube, Sensomotorisches System : Physiologisches Detailwissen für Physiotherapeuten, 2009, Verlag Thieme

16 Anhang 2, Messgenauigkeit Anhang 4: 2018, (interne)Studie B (16 Personen). Ein Workshop mit Prof.Dr. G.J. Kleinrensink (NL) und J.P. van Wingerden (NL) zum Thema: »Kritische Überlegung in der wissenschaftlichen Forschung« Rummelsberg.

17 Siehe auch: www.hmsu.de und Anlagen, Anhang 1: HMSU – HaedMountSupportUnit

18 Tinkerforge, http://www.tinkerforge.de, IMU-Brick 2.0

19 Picotronic, http://www.picotronic.de, picopage/de/product/detail/id/356694, LD520-5-3(12x60)

20 Siehe: Anhang 2, Messgenauigkeit

21 Orthopädie-Schuhtechnik, 3.Auflg. 2018, Baumgartner, Möller, Stinus, Verlg.: C. Maurer, Seite 54/55

22 Lothar Papula, Mathematische Formelsammlung für Ingenieure und Naturwissenschaftler, 10. Auflage, ISBN 978-3-8348-0757-1, Seite 514, siehe auch Anlagen, Anhang 5.

23 Der Korrelationskoeffizient nach Pearson (Pearson-Korrelationskoeffizient) ist ein quantitatives Maß zur Beurteilung der Stärke der Beziehung zwischen 2 stetigen Merkmalen (s. Merkmal). Er beschreibt die lineare Komponente des Zusammenhangs zwischen den beiden

Merkmalen

[24] Orthopädie-Schuhtechnik, 3.Auflg. 2018, Baumgartner, Möller, Stinus, Verlg.: C. Maurer, Seite 54/55

[25] Ina Ter Harmsel(†), Wolfgang P. Schallmey, Podo-Orthesiologie, Seite 17, Kap. 2.1, ML-Verlg, 2020, ISBN 978-3964743541

[26] Anhang 3: Voraussetzung für gute Messergebnisse

[27] Anhang 4: 2018, (interne)Studie B (16 Personen). Ein Workshop mit Prof.Dr. G.J. Kleinrensink (NL) und J.P. van Wingerden (NL) zum Thema: »Kritische Überlegung in der wissenschaftlichen Forschung« Rummelsberg.

[28] Anhang 4: 2017, (interne)Studie A (Workshop M. Weiß, L. Aich,16 Personen) Unterschiedlichen Auswirkungen/ Ergebnisse je Person durch Messungen von:
1) mit Schuhen,
2) mit Socken,
3) barfuß,
4) barfuß, mit "Retro" und "Calc" (retrokapitales und calcaneares Element), Rummelsberg.

Side effect of the study:

Can head rotation be used to demonstrate re-habilitation through neurophysio-logical insoles?

In addition to the bullet points already described in the previous study:

Materials and method:

From the same data of the aforementioned pool (1453 patients), a further 528 (B1) patients were isolated who came for a follow-up examination in the period of 3-12 weeks. A 2nd barefoot measurement (B2) was carried out for each patient.

The first measurement (B1) shows the initial condition, the second measurement (B2) shows the change in the patient's ability to turn the head after wearing the insole for 3 to 12 weeks.

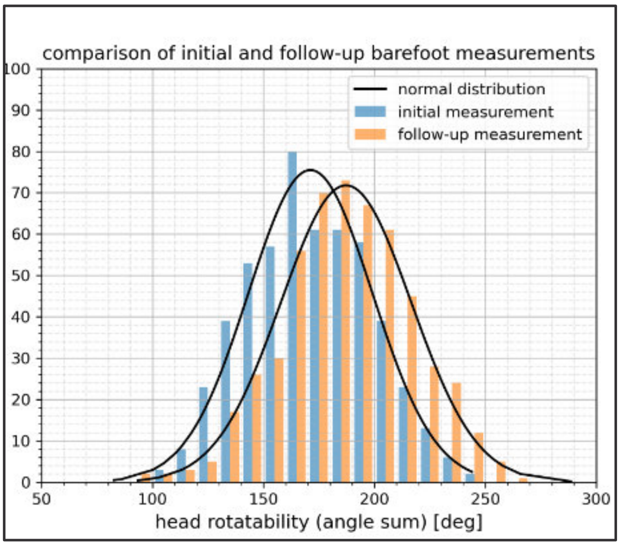
Results:

The comparison of barefoot B1 to barefoot B2 after 3 - 12 weeks with an average improvement of 16° in the ability to turn the head showed the strong rehabilitative effect of the foot orthoses.

The results are shown in Figure 3.

Measurement	AverageROM	Standartdeviation of the average ROM´s
Barefoot B1	171°	27°
Barefoot B2	187°	29°
Result	**16°**	24°

Fig 3: Comparison of first and control date.



Change in head rotation ability after 3 to 12 weeks:
At B1, the 528 patients showed a mean ROM of 171 degrees, with a standard deviation of 27 degrees. For B2, it was 187.0 degrees (SA = 29). Thus, the mean value of the change in ROM is 16.0 degrees, with a standard deviation of 24 degrees. It can therefore be seen that the insole fitting has a statistically significant influence on the patient's ROM after 3 to 12 weeks ($t = 15.00$, $\alpha = 0.005$, $n = 528$). In the barefoot measurement after wearing the foot orthoses for 3 to 12 weeks, patients can turn their head significantly further to the left and right than before the foot orthoses were fitted. The Pearson correlation coefficient is $r = 0.55$ and thus corresponds to a strong effect

Discussion:

The comparison of barefoot-B1 to barefoot-B2 after 3 - 12 weeks with an average 16° improvement in the ability to turn the head was also able to demonstrate the strong rehabilitative effect of the foot orthoses.

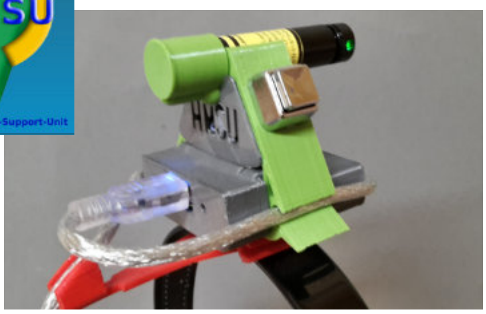
This study shows the great potential of a) measuring the ability to turn the head during the fitting, but also b) of neurophysiological insoles themselves. More intensive research with a controlled study design would also be desirable here.

Annexes

Appendix 1: HMSU - HaedMountSupportUnit
Appendix 2: Measurement accuracy
Appendix 3: Requirements for good measurement results
Appendix 4: Studies
Appendix 5: Formula collection L.Papular
Appendix 6: Overview MDR, 41 studies

For further and, or more detailed information on HMSU, examination procedure and case studies, please refer to the following book:
Vom Blauabdruck über neurophysiologische Einlagen zum Schuh,
(From blueprints to neurophysiological insoles to shoes, only in german)
Publisher: Schuh-Werk & Statik, M. Weiß, 2021, ISBN 978-3-9823563-0-3

Appendix 1:



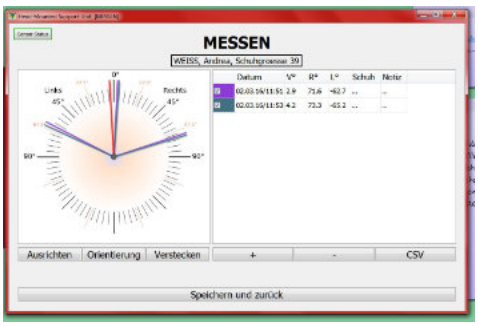
HMSU: Head-**M**ounted-**S**upport-**U**nit,
HMSU is a simple but very accurate, fast and easy to use measuring device. Connected to a computer or labtop, it digitally measures horizontal head rotation. The values are displayed graphically and in table form.

The measuring unit:
A hair band with sensor and line laser (green).

Programme with clients and measuring mask.

The laser is mainly used to calibrate the sensor and thus the measurements to an external "zero" point.

The sensor measures a total of 9 so-called degrees of freedom. The programme only displays the horizontal values so that the device remains a tool that shows results quickly and accurately. This also means that if a test person tilts his or her head back during the measurement, this will not falsify the horizontal readings. To make further turning or tilting values visible, further programming would have to be done. However, it can be assumed that with a better head rotation, the other movement possibilities of the head also benefit. The reason for this is the overall better postural alignment due to the neurophysiological inserts. Of course, this also applies in the negative direction!
With the HMSU, there is now an application technique that includes the entire statics, since all vertical muscle chains from the toes to the head are reflected in the measurements.
So if "manipulations" take place at/under the feet, changes in the statics can be proven if they can be clearly measured above the uppermost joint (atlas-skull base). Positive or negative.
Incorrect insoles, inaccurate shortening compensation, bad shoes, trauma suffered, injuries, etc., all worsen head rotation.
Lesions that actually come from above (teeth / eyes / etc.) and thus lead to less or to disturbing statics or mobility, also restrict head rotation. Thus, after nociceptive (=pain-inducing) occlusion, less head rotation will be measured than before. It is possible that the HMSU even shows the side on which the



disorder lies. However, this still needs to be investigated.

Appendix 2: Measurement accuracy

Attempt to determine the accuracy of the HMSU sensor:

The aim is to demonstrate in practice that measurements are reproducible.

For this purpose, I chose the following experimental setup:

The sensor was mounted on a tripod with a laser so that the rotation point is always the same.

On the wall there were 3 marks (M) each on the left and right:

M1 at approx. 40°,

M2 at approx. 80°,

M3 at approx. 70°.

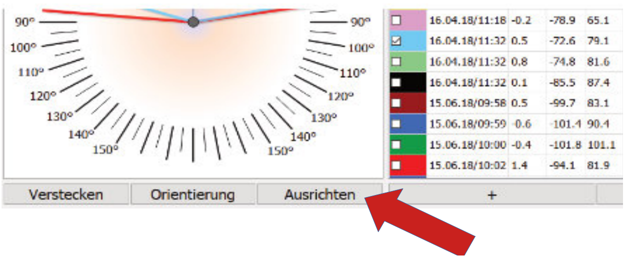
At turning by hand to the left and right, the measuring points M1(10 times) - M2(10 times) - M3(10 times) were approached one after the other.

No centering was carried out for the measurements for M1 and M2. (Table measurement accuracy: column "Ausrichten": **ohne**).

For the 10 measurements of M3, a centering (HMSU, switch: Ausrichten) was set to the central fixed point (0.0°) **before** each measurement.(Table measurement accuracy: Column „Ausrichten“: **mit**)

HMSU, Centering-Switch

The measured values for M1 (yellow), M2 (ochre), M3 (orange) are listed in the table (Fig.11.2).The



line: Cut/10 gives the average values of the respective 10 measurements.This average value (DS) was offset in the columns "L° in % of DS" and "R° in % of DS" with the measurements in percentThese percentages were then summed and divided by 10 again.

Conclusion: the sensor's gyroscope works very accurately and reliably.

See next page:
Table, Measurement accuracy

The IMU Brick 2.0 is equipped with a 3-axis acceleration sensor, a magnetic field sensor (compass) and a gyroscope and works as a USB inertial sensor. It can measure 9 degrees of freedom and calculates quaternions as well as independent yaw, roll and pitch angles. It is a complete Attitude and Heading Reference System. Tabelle: Messgenauigkeit

Versuch einer Genauigkeitsbestimmung des Sensors:

Natürliche Dreh-Bewegung mit der Hand.
Rotationspunkt immer gleich, durch Stativ.
Es wurde versucht, auf beiden Seiten immer die gleiche Markierung zu treffen.

Drehtest, ca. 40°, **OHNE** Mittenkalibrierung (Ausrichten), 10 malige Wiederholung.

Datum	Vorne°	Links°(L)	Rechts°(R)	L+R	Ausrichten	L° in % v. DS	R° in % v. DS	(L°+R°)/2
09.11.16/16:21	-0,1	35,9	40,4	76,4	ohne	102,441	98,673	100,4108
09.11.16/16:22	-0,3	34,9	40,8	75,7	ohne	99,590	99,436	99,5070
09.11.16/16:22	-1,2	35,1	40,8	75,9	ohne	99,947	99,588	99,7535
09.11.16/16:22	-0,7	35,4	41,0	76,4	ohne	101,015	100,046	100,4930
09.11.16/16:23	0,2	35,4	41,6	77,1	ohne	101,015	101,571	101,3147
09.11.16/16:23	0,6	34,8	41,1	75,8	ohne	99,056	100,198	99,6713
09.11.16/16:23	0,1	34,6	41,6	76,2	ohne	98,521	101,571	100,1643
09.11.16/16:23	0,2	35,2	41,1	76,3	ohne	100,303	100,351	100,3287
09.11.16/16:24	-0,2	34,1	41,2	75,3	ohne	97,274	100,503	99,0140
09.11.16/16:24	-0,4	35,4	40,2	75,6	ohne	100,837	98,063	99,3426
Summe	-1,8	350,8	409,8	760,6		1.000,0000	1.000,00000	1.000,00000
SCHNITT /10	**-0,2**	**35,1**	**41,0**	**76,1**		**100,000000**	**100,000000**	**100,000000**

Drehtest, ca. 80°, **OHNE** Mittenkalibrierung (Ausrichten), 10 malige Wiederholung.

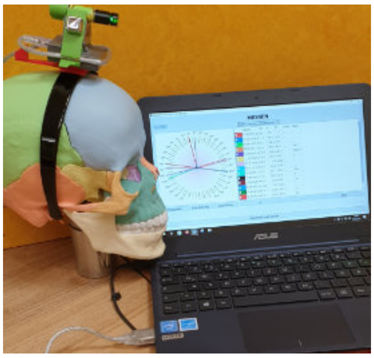
Datum	Vorne°	Links°(L)	Rechts°(R)	L+R	Ausrichten	L° in %v. DS	R° in % v. DS	(L°+R°)/2
09.11.16/16:30	0,0	-79,1	84,1	-163,2	ohne	102,229	98,853	100,462
09.11.16/16:30	0,5	-78,6	84,3	-162,9	ohne	101,502	99,147	100,269
09.11.16/16:30	0,8	-78,2	84,3	-162,4	ohne	101,017	99,074	100,000
09.11.16/16:31	1,3	-78,3	83,6	-161,9	ohne	101,098	98,339	99,654
09.11.16/16:31	0,5	-79,0	83,8	-162,8	ohne	102,067	98,559	100,231
09.11.16/16:31	0,5	-78,6	83,6	-162,1	ohne	101,502	98,265	99,808
09.11.16/16:32	0,6	-78,6	83,6	-162,3	ohne	101,583	98,339	99,885
09.11.16/16:32	0,7	-76,9	85,5	-162,4	ohne	99,402	100,544	100,000
09.11.16/16:32	3,3	-74,4	87,8	-162,3	ohne	96,172	103,263	99,885
09.11.16/16:33	5,9	-72,3	89,8	-162,1	ohne	93,427	105,615	99,808
Summe	13,9	-774,0	850,4	-1.624,4		1.000,000	1.000,000	1000,000
SCHNITT /10	**1,4**	**-77,4**	**85,0**	**-162,4**		100,000000	100,000000	**100,000000**

Drehtest, ca. 70°, **MIT** Mittenkalibrierung (Ausrichten), 10 malige Wiederholung.

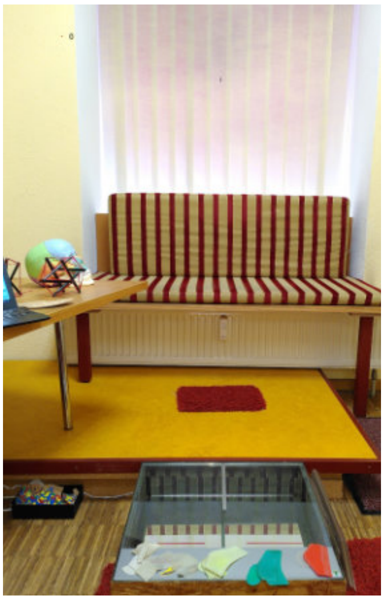
Datum	Vorne°	Links°(L)	Rechts°(R)	L+R	Ausrichten	L° in %v. DS	R° in % v. DS	(L°+R°)/2
09.11.16/17:26	0,0	-71,8	69,9	-141,7	mit	100,253	100,985	100,612
09.11.16/17:27	0,0	-70,3	69,9	-140,3	mit	98,159	101,075	99,592
09.11.16/17:28	0,0	-70,6	69,4	-140,0	mit	98,595	100,262	99,414
09.11.16/17:28	0,0	-69,9	69,1	-139,0	mit	97,635	99,810	98,704
09.11.16/17:29	0,0	-71,1	70,1	-141,1	mit	99,206	101,256	100,213
09.11.16/17:29	0,0	-70,9	67,6	-138,5	mit	98,944	97,733	98,349
09.11.16/17:29	0,0	-70,8	70,1	-140,9	mit	98,857	101,256	100,036
09.11.16/17:30	0,0	-73,8	67,8	-141,6	mit	103,045	97,913	100,524
09.11.16/17:30	0,0	-73,1	69,5	-142,6	mit	102,085	100,443	101,278
09.11.16/17:31	0,0	-73,9	68,7	-142,6	mit	103,220	99,268	101,278
Summe	0,0	-716,3	691,9	-1.408,3		1.000,000	1.000,000	1.000,000
SCHNITT /10	**0,0**	**-71,6**	**69,2**	**-140,8**		**100,0000000**	**100,0000000**	**100,0000000**

Appendix 3:
Prerequisites for good measurement results

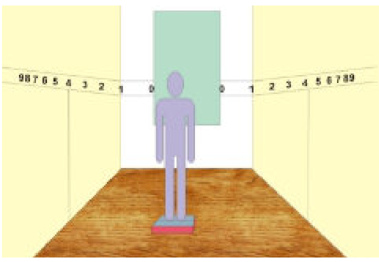
In order to obtain good measurement results, it is extremely important that the patients feel comfortable during the entire procedure. This includes, for example, that the patients do not have to climb onto a raised podoscope first. This is especially important for older people. I recommend that the patient already sits in such a way (on a small platform) that they only have to walk forward to reach the measuring position of the mirror.



Furthermore, the laser should project as evenly as possible onto the left and right walls when the head is turned. This means that the podoscope should ideally be positioned in the middle between the walls that are not too far apart. If this is not possible, it is better to switch off the laser after the central alignment.



A „0“-mark should be placed centrally in front of the patient, on which the patient aligns the laser before each measurement. This 0 mark is aligned with the centre of the surface on which the patient is standing. This is important so that the results can be easily compared. Further scaling on the walls is not really necessary, but it shows the patient that something is happening. (Show effect)



Check whether the laser runs exactly over the centre of the patient's head or face. For example, forehead - nose. If the head is crooked, the laser will be crooked too. That is OK. Then the laser should "cross" with the 0-identification.

It has also proved helpful to hang the cable with plenty of slack over the thumb of one hand so that it does not interfere with the measurement. Please have a try with this before starting, as it depends very much on where the PC or laptop is located. Therefore, the laptop should be placed directly next to the person taking the measurement, so that it can be easily operated. In this way, the patient does not become unsteady between measurements.

Then it is good if clear and precise commands are given:

- Please bring the laser to the centre in front...
- ... now please turn your head to the left as far as possible...
- ... and now turn to the right as far as possible...
- ... and back to the centre again. Thank you.

I sit down after the measurements, use the notes column to clearly name the individual measurements and delete the measurements that are no longer needed. Then I explain to the patient what just happened.

With these tools, it should be possible to achieve good results that can actually be compared.

Appendix 4: Studies

Mini - Studies 2017 and 2018:
At the IFPB congresses 2017 and 2018 in Rummelsberg we were able to do 2 small lightning studies in 2 workshops.

2017, (internal)study A (workshop together with Lydia Aich,16 persons) aims to show the different effects/results per person that can be obtained by measuring
1. with shoes,
2. with socks,
3. barefoot,
4. barefoot, with "retro" and "calc" (retrocapital and calcaneear element),
are to be achieved.

Conclusion:
For the head rotation of the measured persons, starting from a barefoot measurement:
1. the effect of socks, surprisingly not negligible,
2. the effect of shoes, depending on the shoe, as expected, positive or negative,
3. the effect of a fitting, even with a "neutral" Podo underlay, is positive as expected!
It is therefore important to pay close attention to how the patient manages his or her "walking" everyday life in order to achieve good results with a fitting.

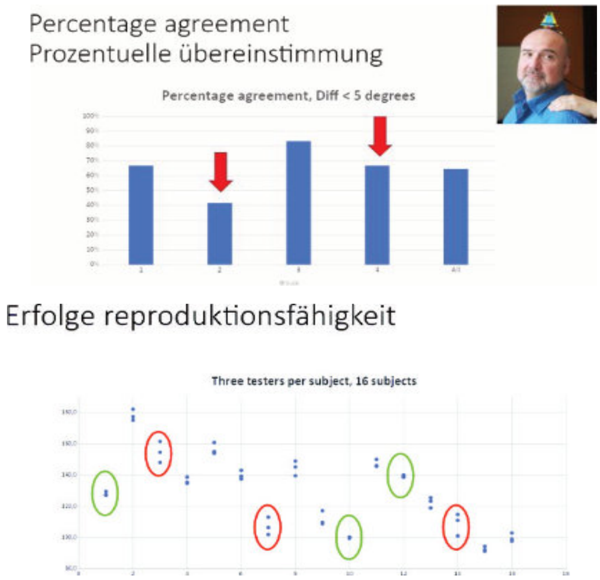
2018, (internal)Study B (16 persons). A workshop with Prof.Dr. G.J. Kleinrensink (NL) and J.P. van Wingerden (NL) on the topic:
"Critical thinking in scientific research".
The 16 participants were divided into 4 groups of 4 'investigators/users'. Each user thus also became a test person.
Basic test: stand, calibrate centre, start measurement, turn head left and right.
So: 1 test person, 3 users, 3 measurements per user/proband.
Groups 1 and 3 **without** repositioning the measuring device.
The measuring device remains on the head when the user is changed.
Groups 2 and 4 **with** repositioning of the measuring device.
Each user repositions the measuring device on the subject's head.

Summary:
System itself is very accurate, even with untrained 'users':
- At < 5 degrees deviation: 67% agreement.
- Positioning of the measuring device has great influence
- System is valid for change measurements ROM (Range Of Motion).
- Correct protocol, very important.
- Training of examiners is very important.

See also the evaluation charts from the PowerPoint slides

Studies in which the HMSU was used:

2018: Sabine Bayr-Seifert
Scientific study paper:
More head mobility (lateral rotation) & muscle relaxation through herbal eye drops: camomile and



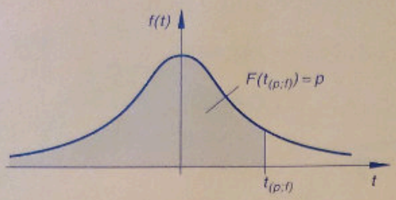
mallow, a ray of hope for tense cervical spine-shoulder patients.
Konzenberg, 2018

2018:
Dr Dietmar Basta, Wolfgang P. Schallmey, Arneborg Ernst:
Influence of an insole with individual sensory feedback on cranio-cervical mobility in stance and foot roll-off behaviour during walking.
ENT clinic in the UKB, with
University of Berlin, Warener Str. 7, 12683 Berlin, Germany
Teaching Institute for Podo-Postural Therapy, Schloßstr. 1, 48336 Sassenberg, Germany
International Federation for Proprioceptive-and Biomechanical Therapies e.V.,
www.ifpb-ev.de

Appendix 5: Formelsammlung L.Papular

Lothar Papula:
Mathematische Formelsammlung für Ingenieure
und Naturwissenschaftler
10. Auflage
ISBN 978-3-8348-0757-1

Tabelle 4: Quantile der t-Verteilung von „Student“



p: Vorgegebene Wahrscheinlichkeit ($0 < p < 1$)

f: Anzahl der Freiheitsgrade

$t_{(p;f)}$: Zur Wahrscheinlichkeit p gehöriges Quantil bei f Freiheitsgraden (*obere* Schranke)

Die Tabelle enthält für spezielle Werte von p das jeweils zugehörige Quantil $t_{(p;f)}$ in Abhängigkeit vom Freiheitsgrad f (*einseitige* Abgrenzung nach *oben*).

	p				
f	0.90	0,95	0,975	0,99	0,995
1	3,078	6,314	12,707	31,820	63,654
2	1,886	2,920	4,303	6,965	9,925
3	1,638	2,353	3,182	4,541	5,841
4	1,533	2,132	2,776	3,747	4,604
5	1,476	2,015	2,571	3,365	4,032
6	1,440	1,943	2,447	3,143	3,707
7	1,415	1,895	2,365	2,998	3,499
8	1,397	1,860	2,306	2,896	3,355
9	1,383	1,833	2,262	2,821	3,250
10	1,372	1,812	2,228	2,764	3,169
11	1,363	1,796	2,201	2,718	3,106
12	1,356	1,782	2,179	2,681	3,055
13	1,350	1,771	2,160	2,650	3,012
14	1,345	1,761	2,145	2,624	2,977
15	1,341	1,753	2,131	2,602	2,947
16	1,337	1,746	2,120	2,583	2,921
17	1,333	1,740	2,110	2,567	2,898
18	1,330	1,734	2,101	2,552	2,878
19	1,328	1,729	2,093	2,539	2,861
20	1,325	1,725	2,086	2,528	2,845
22	1,321	1,717	2,074	2,508	2,819
24	1,318	1,711	2,064	2,492	2,797
26	1,315	1,706	2,056	2,479	2,779
28	1,313	1,701	2,048	2,467	2,763
30	1,310	1,697	2,042	2,457	2,750
40	1,303	1,684	2,021	2,423	2,704
50	1,299	1,676	2,009	2,403	2,678
60	1,296	1,671	2,000	2,390	2,660
100	1,290	1,660	1,984	2,364	2,626
200	1,286	1,653	1,972	2,345	2,601
500	1,283	1,648	1,965	2,334	2,586
⋮	⋮	⋮	⋮	⋮	⋮
∞	1,282	1,645	1,960	2,326	2,576

Formeln:

$$t_{(1-p;f)} = -t_{(p;f)}$$

$$t_{(p;f)} = -t_{(1-p;f)}$$

Appendix 6: MDR, Tabular overview of the 41 studies

DGIHV

Arbeit	Name	Jahr	Thema	Studie	Hilfsmittel	Probanden	Alter	
1	Xu et al	2019	FSP	rand. Kontrolliert, 1-fach blind	3-D-EL	60	31-61	als hilfreich einstufen...
2	Khan et al	2018	Knie Firstpeak, EL m. AR + KnieOrthese	rand. Pilot.	Orthese +AR+EL	20	50-70	Alle 3 =gut
3	Neto et al	2017	Senso-El b. CP Kinder, Gangleistung	rand. Kont. DoppBlind	senso	24	4-12	wirksam
4	Telfer et al	2017	DIAB-II, Druckentl d. EL	CrossOver	Spezial-EL / Normal-EL	20	no 10g filament	weniger Druck
5	Caravaggi et al	2016	Arbeitsschuhe, Druck vergl EL	analyse	Ind-EL / indiv-EL	17	Ca 45	Verringerung des Drucks
6	Choi et al	2015	Hohlfuß, effekte v. EL	untersuchten	EL-Bettg.	20	hohlfuß	weniger Muskelarbeit, mehr effizienz
7	Wrobl et al	2015	FSP	rand. kont. Prospektiv	ind-EL / indiv-EL / keine EL	77	1 Jahr FSP	Ind-EL=best, viel Behandlg. Zusätzl
8	Arts et al	2015	DIAB-II, neurop. + ulcus Druckentl d. EL	prospektiv	Diab-EL	85	Diab-Neuro+Ulcus	Verringerung d Drucks
9	Tang et al	2015	Plattfuß, Druck	untersuchten	EL-Bettg,+ IR	10	15-45	Verringerung d Drucks
10	Chen et al	2015	Fersenverletzung	untersuchten	EL-Bettg,+ 2,5-3cm Fersenkeil	11	18-66	besser
11	El-Hilaly et al	2013	Diab n. Amputat	untersuchten	Diab-EL	20	Amputation	weniger Druck
12	Aminiam et al	2013	Plattfuß, El-Bettg / Senso	analysierten	Bettg / Senso	12	Plattfuß	Sensos möglicherweise sinnvoll
13	Stolwijk et al	2015	Fußbeschwerden allg.	untersuchten	Ohne / mit EL	204	Fußschmerz	eine EL-Form für alle, dann nachbessern
14	Shaw et al	2018	Kniearthrose	syst. Rech + Metaanalyse	EL-Bettg,+ 2,5-3cm Fersenkeil	4 Datenbanken	kniearthr.	mit EL besser
15	Heuch, Gomersall	2016	Diab + Fußgeschwür prävent.	syst. Rech	El, + Schuhe	14 Datenbanken	Diab	könnte gut sein, eher dünne Beweise
16	Ganjehie et al	2016	Innenrotatoio Kinder	untersuchten	Detersions-EL	17	4-10	Kann verbessern...
17	Aboutorabi	2015	Einlagen u Schuhe+Gleichgewicht	syst. Lit. Rech	El	4 Datenbanken	22 Artikel	kann sein
18	Paton et al	2014	Diab. Neurop.+ haltbarkeit v. EL	rand. Kont.	EL	60	diab	12 Monate weniger Druck
19	Lavery et al	2012	Diab + Neurop, Fußgeschwür prävent.	Rand., 1-fach blind	EL	299	diab	El mit weniger Scherkraft = besser
20	Öcgüder et al	2012	Fersenverletzung	untersuchten	EL	14 Datenbanken	Fersenbruch	Bessere Lastübern, kein norm. Gang
21	Bonanno	2011	Fersenschmerz	untersuchten	EL	36	Bis 65	Druck wird reduziert
22	Perhamre et al	2011	Achillesshene	rand. Prospektiv.	EL	51	9-14	Besser
23	Bishop et al	2016	Plattfuß	vergleich	EL / Tape	18	22-29	versorgg sind möglich
24	McPoil et al	2011	Knie	rand.	EL	10	18-40	weniger Schmerzen
25	Mills et al	2012	Knie	rand. Kont.	El / abwarten	40	18-40	EL besser
26	Aboutorabi et al	2014	Plattfüße, Kinder	untersuchten	El	30	Plattfuß	besser mit EL
27	Hlastead et al	2016	Mittlefuß, Arthrose	rand.	EL	33	Mittelfußarthrose	EL hat Vorteile
28	Menz et al	2016	MBT, Gzgg	Vergleich	MBT / EL	102	Gzgg	red. v. Schmerzen
29	Chapman et al	2016	Mittlefuß, Arthrose Druckmessg	rand. DoppBlind	EL / pseudo-EL	33	Mittelfußarthrose	ähnliche Effekte
30	Arnold et al	2018	Senkfuß	experimentelle Studie	EL	18	25	Wahrscheinlich günstig
31	Chia et al	2009	FSP, Fußdruck	Vergleich	EL / Ind. EL FSP-Polster	30	20-65	Elsind nützlich, Fersenpolster schlecht
32	Christovao et al	2015	Kinder mit CP	rand. Kont. DoppBlind	EL, Bettung	20	4-12	Bessere haltg, u. Gleichgewicht
33	Farzadi et al	2015	Hallux u LG, Pelotte, Druck	Quasi experimentelle Studie	EL	16	Hallux	Gute Versorgungsmöglichkeit
34	Mabuchi et al	2012	Senso-EL, Kinder, innenrot. Gangbild	untersuchten	Sensos	10	5,6	besser, schneller
35	Chang et al	2012	Bettung bei rheumatoid Arthritis u.Mittelfußschmerzen	untersuchten	EL	17	rheumatoid Arthrit., .Mittelfußschmerzen	besser mit Memory-Mat.
36	Chen et al	2010	Plattfuß	untersuchten	EL	11	Plattfuß	EL=gut, Schuhe mit u. oh. EL: mehr Forschung
37	Cobb et al	2011	Mehr med. Mobilität mit EL	crossOver, untersuchten	EL	16	wenig Fußhaltung	El könnte gut sein
38	Hurd et al	2010	flexibler Plattfuß, Vorfuß-Varus	Vergleich	EL	15	Plattfuß	könnte gut sein
39	Michalitsis et al	2019	Spitzfuß idiopath. b. Kindern	rand. Kont.	El, Stiefel	15	4-10	könnte gut sein, mehr Forschung
40	Naderi	2019	MTSS b. Freizeitläufern	untersuchten	EL	50	18-22	Verbesserung
41	Khodaei et al	2017	Plattfuß, Cad/Cam/ konfektionierte EL	Vergleich	Cad-Cam-EL / konfekt.-EL	19	18-45	Weniger Druck, kein Unterschied zw Cad-Cam und Konfektioniert, mehr Forschung

Study - Classification:

Foot, Knee, Shoes
Heel spur
Diabetical
Flatfoot, fallen arches
Children