Pre-operative Application of the Hallufix®-Splint

Excerpts of the results of April 2, 2006 of the observational study of Dr. Ralf Neumann, Munich, commenced April 13, 2005

Application in case of light to medium Hallux-angle and not too rigid toe malpositioning

62 feet of 33 patients were examined. The Hallux valgus angle (= metatarsophalangeal angle, standard value 10 – 12°) was initially tested without and then under burden. Subsequently, the girth of the foot at the location of the ball of the big toe and the metatarsal were measured without and with burden. As expected, the girth at the location of the ball increased more under burden than the metatarsal did.
All measurements were then repeated with the Hallufix-orthosis applied. Passive correction achieved by means of the splint was between 5° and 10°. Especially under burden, the girth of the foot was reduced at the location of the ball as well as the metatarsal by means of the metatarsal bandage and pad.
Subsequently we performed a gait analysis with strain gauges. The test persons were barefoot and walked initially without the Hallufix-orthosis and then with the Hallufix-orthosis without a pad and then with a forefoot pad applied. In most cases the big toe was not under burden when Hallufix was not applied, which caused an unphysiological displacement of the trajectory into the lateral forefoot. Furthermore, an unphysiological burden peak at the location of the metatarsal capitulum 2 to 4 were displayed in line with the concomitant splayfoot. With the Hallufix-orthosis applied there was a considerable increase in burden on the ball of the big toe and the big toe during stance and thus to an almost complete normalisation of the gait line. Burden peaks remained unaltered at the location of the metatarsal capitula 2 and 3 and were only reduced after applying the splayfoot pad.

Prior to the beginning of the study, a patient's X-ray was taken of the left forefoot in a dorsoplantar ray path under burden. After wearing the Hallufix-orthosis regularly during a period of 8 weeks another X-ray was taken with the Hallufix-splint applied. The pre-existing metatarsophalangeal angle (= "Hallux angle") of 40° was reduced to 19° with the splint applied. The pathologically increased intermetatarsal angle (between metatarsals 1 and 2) of 16° (normal values 5 to 11°) was reduced to a normal value of 10° by means of the metatarsal bandage and the splayfoot pad. The DMAA (= distal metatarsal articular angle, defined as the angle between the tangent of the joint surface of the proximal phalanx and the perpendicular to the axis of the 1st metatarsal), which is a measure for congruency or incongruency of the base joint of the big toe (normal value under 10°, i. e. joint congruency), was improved from 33° to 13°. Because the incongruency of a joint is a major predisposing factor for the development of an arthrosis, the Hallufix-splint probably allows protraction or perhaps even prevention of the development of an arthrosis of the base joint of the big toe.

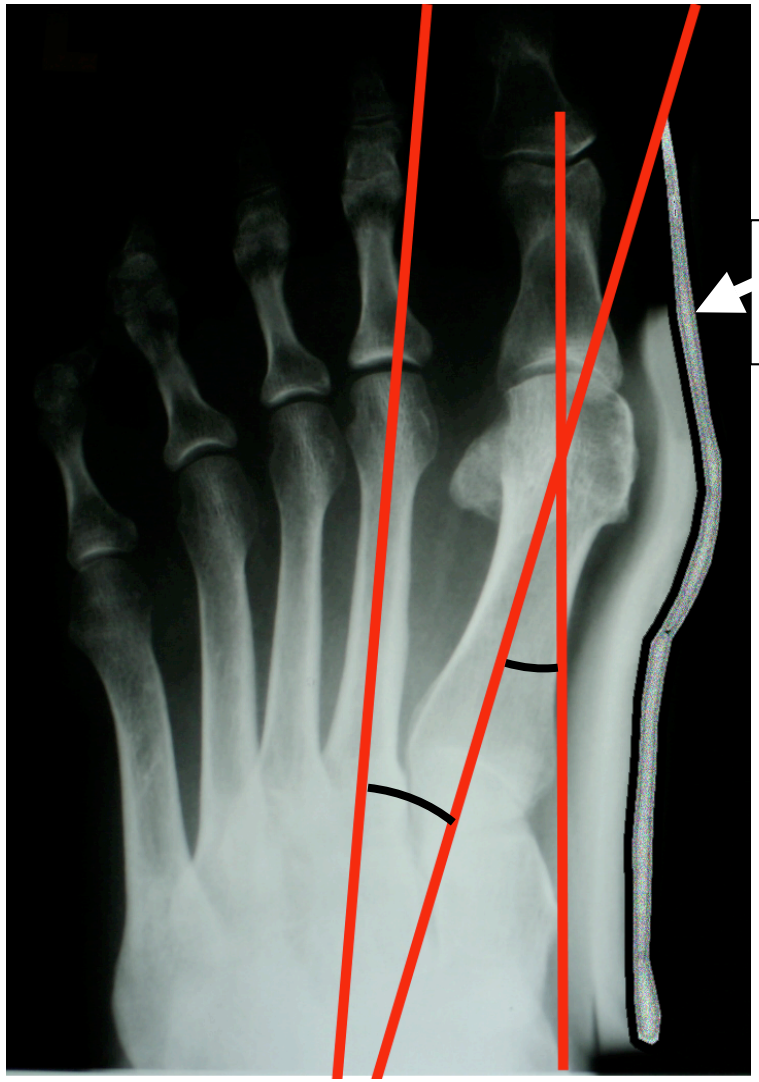
„With the night-splint no improvement of the malpositioning under burden can be achieved. However, in order to attain a permanent improvement of the malpositioning, correcting under burden is decisive. This study proves that the Hallufix-orthosis is an effective device in correcting light to medium severe and not too rigid Hallux valgus malpositioning, particularly in combination with a splayfoot pad."

Hallux-angle	**without Hallufix® applied**	minimum – maximum value	**Average**	**with Hallufix® applied**	Minimum – maximum value	**Average**
Measured foot parameters	Hallux-angle without burden	15° – 46°	**Ø = 25,9°**	Hallux-angle without burden	0 – 20°	**Ø = 10,2°**
	Hallux-angle with burden	13° - 46°	**Ø = 25,5°**	Hallux-angle with burden	0 – 27°	**Ø = 11,0°**
	Passive corrigibility without burden	- 5° - 20°	**Ø = 7,1°**	Passive corrigibility without burden	not applicable	not applicable
Measured foot parameters after wearing Hallufix® regularly for 4 – 6 weeks	Hallux-angle without burden	10° - 45°	**Ø = 22,0°**	Hallux-angle without burden	0° – 25°	**Ø = 7,7°**
	Hallux-angle with burden	10° - 45°	**Ø = 22,6°**	Hallux-angle with burden	0° – 25°	**Ø = 8,4°**
	Passive corrigibility without burden	- 5° - 25°	**Ø = 5,2°**	Passive corrigibility without burden	not applicable	not applicable

Intermetatarsal angle: 16 °
Hallux valgus angle: 40 °

X-Ray without Hallufix-splint

Intermetatarsal angle: 10 °
Hallux valgus angle: 19 °



Hallufix-splint

X-Ray with Hallufix-splint