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The Temporary Orthosis-Therapy for Diabetic Foot

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1. Introduction

I was taught Temporary Orthosis-therapy by Dr Robert van Lith, a Dutch Podiatrist, who wrote a book called: "Podologie Appliquée"¹.

This therapy technique is used after a very careful examination of the foot, and of the fitting qualities of shoes; an analysis of the involved pathologies and the right use of the tools. It is thus possible to take out the mechanical trauma of the conflicting areas. The knowledge of the foot "biomechanic", together with the knowledge of TOT allows relieving and curing a "keratopathy".

Mechanical stresses are one of the reasons of the foot ulceration appearance; this therapy represents therefore a relevant one for a diabetic patient.

2. Materials and methodology

My purpose is not to deliver a lesson on TOT: it was thoroughly explained in the author's book. As its name says, this technique has to be used just before the permanent orthosis setting up. It is used during the scarring phase.

Doctor Margreet van Putten, Fontys Paramedische Hogeschool manager in Eindhoven, wrote: "Almost 80% of diabetic ulcers will be cured by offloading the ulcer pressure. Then, you should never take other actions than "unloading the pressure!"(Drôme seminary²).

The list below is not exhaustive but it presents the necessary materials to prepare a temporary orthosis (TO) for the clinical cases described.

2.1 Materials

2.1.1 Adhesive pressure deflection materials

Used products are made by Cuxson Gerrard & Co. Ltd Company, located in England.

¹ Van Lith Robert, July 2003, Podologie appliquée, Edition du Lau, ISBN : 2 84750 052 9, Page 67.

² Van Putten Margreet, van Lith Marie-Josée, van Lith Robert, The diabetic foot, Montelimar Seminary (Drôme, France), March 2002.

These products are :

- Hapla All Wool Felt ®: pure new wool felt, semi-packed in tight.
- Hapla Gold Felt ®: improved felt with anti-infective agent to protect the foot from fungal and bacterium infection. This product is recommended by Cuxson Gerrard Company to be used on sensitive feet.
- Moleskin ®: thin fleece-lined non stretch cotton
- Hapla Fleecy Web ®: cotton jersey with a fleece-lined cotton surface. Transversally stretch.

2.1.2 Non - adhesive pressure deflection materials

- Plastazote ®: thermoformable polyurethane rubber.
- Walk-line ®: non-rigid thermoformable material.
- Thermoformable Latex foam.

2.1.3 Attachment materials

- Hapla band ® (Cuxson & Gerrard) : thin hypoallergenic bandage.
- Micropore ®: (3 M) micro- porous band-aid with high skin tolerance, air permeable. It doesn't cause contact allergy.
- Chirofix ®: (Cuxson & Gerrard) adhesive bandage with good skin tolerance, micro-porous and transversally stretch.
- Oper fix ®: (Iberhospitex S.A.) stretch tape.

2.1.4 Bandages

- Urgotul S. Ag/S.D. ®: Laboratory URGO
- Mepilex Border ® : Laboratory Mölnlycke Health Care
- Biatain ® : Laboratory Coloplast
- Cellosorb Silver Ag ®: Laboratory URGO
- Actisorb ® : Laboratory Johnson - Johnson Medical ltd

2.2 Methodology

The medical examination is essential to find the first cause of the infection (keropathy, wound or ulceration).

One should observe :

- Deformed foot (hallux or toes)
- Deformed tarsus.

One should look for :

- Neuropathy or arteriopathy presence,
- Static position troubles with hyper hold in toes, metatarsal heads, or fifth metatarsus stiloïd.
- Dynamic troubles,
- Limited joints mobility

The association of all these factors makes the diabetic foot a risky foot.

Pathway to the diabetic foot ulceration³:

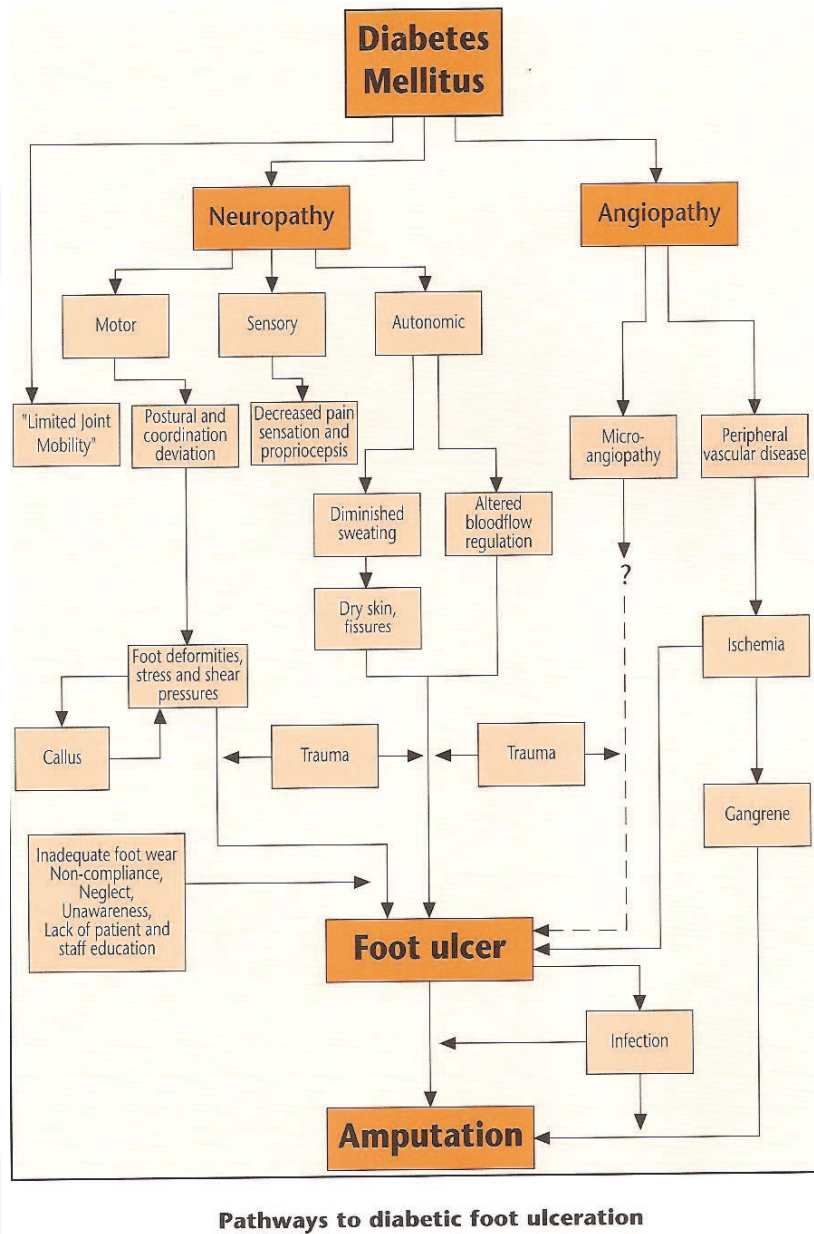


Fig. 1.

We need to discover what kind of stress is responsible for the pathology (chafing stress, pression or compression, twisting).

Mechanical stresses are responsible for kerathonic pathology. They give skin irritation, accelerate cellular mitosis and enhance hyperkeratosis appearance.

³ The International Working Group on the Diabetic Foot, may 1999, International Consensus on the Diabetic Foot, Copyright by the International Working Group on the Diabetic Foot, ISBN : 90-9012716-x. (page 29: Pathways to diabetic foot ulceration.)

It is absolutely necessary to know what kind of stress is responsible for the pathology appearance⁴

It is also necessary to analyze the shoes.

Shoes wearing advice :

- Shoes must be well formed regarding the shape of the foot (length and width)
- Shoes must give a good support because the feet must not slip while walking
- Shoe upper must allow toes to move (mind the height) and, if possible, avoid seams
- Shoe back needs a good stiffener
- Sole must be soft in metatarsis junctions to allow foot flexion and it must be hard on the back part of it (be careful not to have twisting movement of the front part of the sole regarding to the back part of it).

It must be comfortable.

When compression stress is responsible of the pathology, I use a pair of clips to put out of shape locally the leather.



Fig. 2.

Treatment pattern
<ul style="list-style-type: none"> • Cure the conflictual zone by make the stresses disappear (chafing, pressure and twisting), • Correct if possible or protect, • Give a normal function to the articulations again • If needed, fit with prosthesis to ease step development. <p>Conclusion: My aim is to enhance the patient autonomy by protecting his or her walking possibilities.</p>

⁴ Richard, F., TOT training session notes, Nantes, September, 1998.

In case of a risky foot and when it is hard to find convenient shoes, suitable for the foot out shaping, we need to ask an orthopedist to make made to measure shoes.

After the medical examination, I use to make a prevention assessment, I explain all the different treatment steps (correction, protection, contention with a disease if necessary) and I try to make the patient understand that he or she needs to respect his or her feet.

This treatment is carried out after the instrumental gesture

The used materials allow the therapist to adjust himself to the different clinical cases.

The TO is taped on the skin.

Felt TO is put on to offload the hyper-pressured area in order to eliminate the mechanical stresses of chafing (static and dynamic)

The offloading zone delimitation will be found after the palpation of the zone to be protected, apart from the cellulitis (presence of swelling, erythema and heat indication an inflammatory reaction).

The TO shape is adaptable according to the recovery step.⁵

There is no limit: one has just to be inventive and creative.

Hapla Felt is used in 2 mm size, 5 mm or 7 mm to offload the conflicted area..

One needs to take into account the loading capacity of the product (half of it)

The felt can be doubled, or even triple according to the area which needs to be isolated.

In order to make the TO easy to wear, it is essential to bevel the external sides.

The more important the deformation is, the more material will be needed (felt) to allow a better pressure distribution.

If the inflammation is important, it is absolutely necessary to totally stop walking and so the OT will be bigger.

The basic rules and a good knowledge of the materials allow getting a spectacular result.

Nothing is left to chance because everything can be explained.

The immediate elimination of mechanical stress caused by chafing and pressure allows the patient to put on shoes again without feeling any risk.

In case the patient would suffer neuropathy, the TO would assure scarring.

But this will only be possible provided that everything has been made to constantly offload the injured part during all the scarring time.

As Jean-Louis Richard, Denyse Vannareau et Claire Parer-Richard underlined: offloading the foot is a fundamental measure without which scarring is impossible.⁶

⁵ Richard, F., Transitory TOT: 28th Podiatry discussions seminary, Paris, 2003.

⁶ Richard, J.L. et al. Article : le pied diabétique, Service des maladies de la nutrition et de la diabétologie, CHU de Nîmes, Le Grau du Roi.

Dr Ha Van Georges wrote about this : « the perforating pain cannot be cured if the patient is still walking on it »⁷.

The TO will allow the uninterrupted protection of the conflicting zone while the foot is mobilized during the walk.

And this will retain the walking radius, not to say increase it).

Even when confined to bed, the patient's foot is relieved of stress pressures.

That is why I would like to quote again Robert Van Lith's book "Podologie appliquée"⁸

Thanks to the scientific research team, the Cuxson Gerrard & Co. Offers materials with an unique adhesive system.

We are lucky to enjoy an amazing material technological advancement.⁹

	S aureus (NCTC 10788 ATCC 6538)	Ps aeruginosa (NCIMB 8626 ATCC 9027)	C albicans (NCPF 3179 ATCC 10231)
Time	Hapla All Wool Felt Gold		
Inoculum	4.1×10^6	3.6×10^6	2.8×10^6
14 Days	<10	<10	6.7×10^3

A greater than 5-Log reduction in *S aureus* numbers was seen following seven days exposure to the product. A greater than 5-Log reduction in *Ps aeruginosa* and a 2-Log reduction in *C albicans* numbers was seen following 14 days exposure to the product.

- Staphylococcus aureus is a gram positive bacteria - common on human skin
- Pseudomonas aeruginosa is a gram negative bacteria
- Candida albicans is a fungus

Results from Independent Laboratory testing Nov 08.

Forty samples of Hapla Gold felt were inoculated with either fungi or bacteria.

Fig. 3.

⁷ Dr. Georges Ha Van (Paris), Equilibre N°197 1996 -Qu'est-ce qu'un mal perforant et comment le prévenir ?

⁸ Van Lith Robert, July 2003, Podologie appliquée, Edition du Lau, ISBN : 2 84750 052 9 (Pages 70-71 & 108)

⁹Etude éditée par Cuxson et Gerrard montrant le résultat obtenu avec antimicrobial treatment de l'Hapla glod all felt.

3. Results

I would like to highlight this methodology by exposing several clinical cases: domiciliary care, in my podiatric office or in hospital.

I wanted to present different situations because one can notice that ulceration is different regarding to the place and to the limitation of our skills¹⁰.

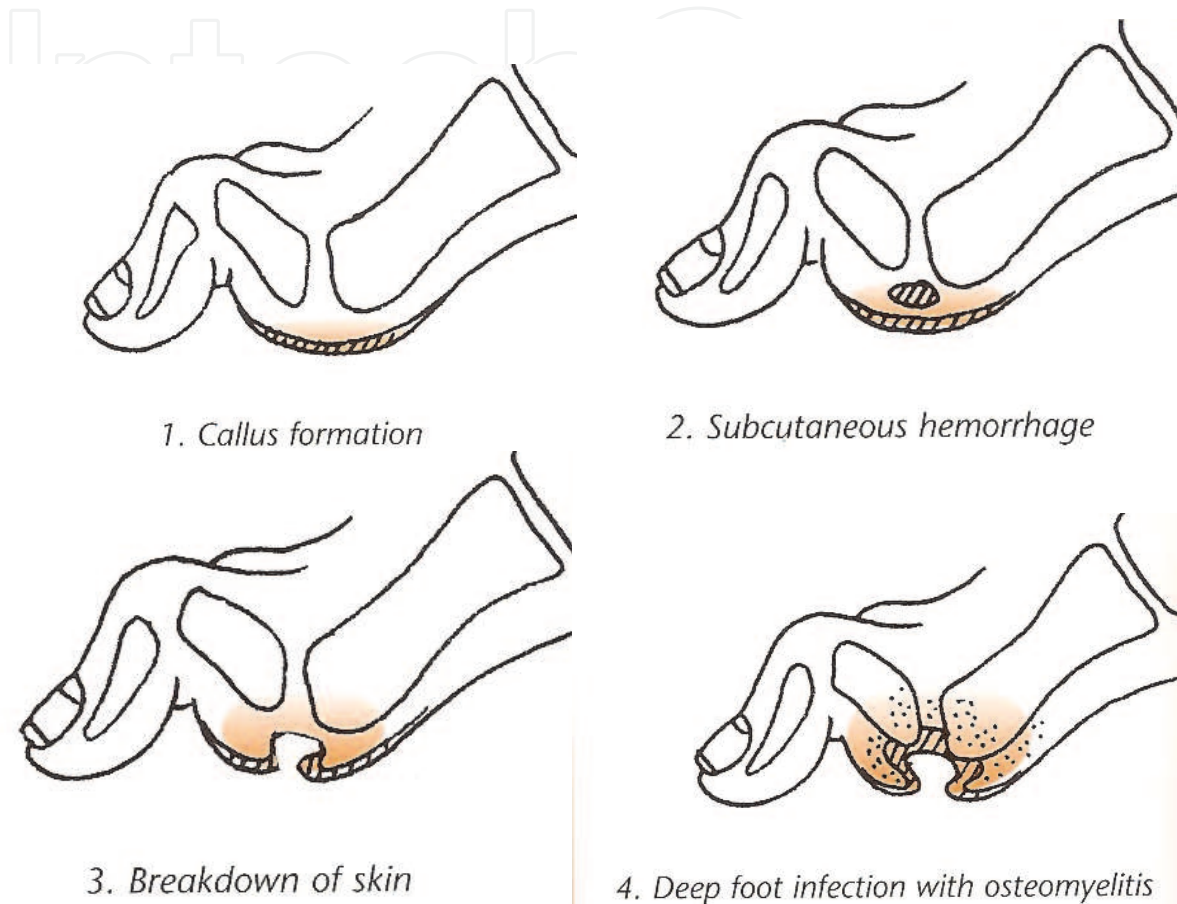


Fig. 4.

The invasive treatment has to be appropriate for the patient's condition.

The follow-up is different when the podiatrist is alone or in a multidisciplinary medical team.

The described cases present treatments on different conflicted areas which helps us to present a wide range of this technique, that is to say:

- Treated patient for a plantar keratopathy , right heel
- Treated patient with plantar keratopathy with a bruise on the metatarsal-phalangeal joint (big toe) reducing and preventing the patient from walking
- TO for an ulceration in order to amputate the fifth toe
- And some impressive cases in hospital.










¹⁰ The International Working Group on the Diabetic Foot, may 1999, Practical Guidelines on the Management and the prevention of the Diabetic Foot, Copyright by the International Working Group on the Diabetic Foot, ISBN : 90-9012716-x.) page 2 :Illustration of ulcer due to repetitive stress.)

Here are some results achieved during some consultations:

- Skin scarring is progressive,
- Mechanical stress elimination prevents or postpones the risk of amputation.

3.1 Domiciliary care

3.1.1 CASE A: Treated patient for a plantar keratopathy, right heel

		
A-1: first consultation	A-2: debridement and total enucleation	A-3: felt TO installing (5 mm felt with an offloading of the conflicted area).
		
A-4: Bandage installing and fixation with Hapla-band	A-5: after two weeks treatment	A-6 et A-7: two steps enucleation with a set with diamonds cracks burrs
		
A-6 et A-7: two steps enucleation with a set with diamonds cracks burrs	A-8: End of the instrumental work.	A-9: Moleskine installing. Which covers the back part of the foot.



A-10 : After two weeks treatment : skin is totally healthy. Apply Hydra-defense balm or Akildia balm (Asepta-Akiléine laboratory). Which delays the keratin implantation.

Fig. 5.

3.1.2 CASE B: Treated patient with plantar keratopathy with a bruise on the metatarsal-phalangeal joint (big toe) reducing and preventing the patient from walking

<p>B-1 : First consultation</p>	<p>B-2 : TO installing (7 mm felt with two layers)</p>	<p>B- 3 : Fixation with Hapla- band with an opening to allow wound access.</p>
<p>B-4 : Medicinal dressing (Biatain) , which has to be changed every 48 hours by the nurse in charge. After the debridement, new offloading is necessary every one or two weeks by the podiatrist.</p>	<p>B-5 : Enucleation</p>	<p>B- 6: TO fitting and Moleskiine fitting.</p>






		
B-7 : After nine weeks, debridement and Moleskine installing.	B-8 : After eleven weeks, debridement	B-9 : Moleskine installing.
		
B-10 : After one month. Without any protection and with an increase of the walking area, skin is wounded.	B-8 : New felt offloading TO fitting. Extra explanation about the importance of this TOT treatment with orthosis device just after the total scarring. Device confection perpetuates the treatment results.	

Fig. 6.

3.2 In my podiatrist office

3.2.1 CASE C: A diabetic patient grade zero, with a fifth metatarsal pain, on the external side

		
C- 1 : first consultation	C- 2 : TO installing Metatarsis head is totally offloaded (5 mm felt)	C- 3 : OT fixation with Hapla Band

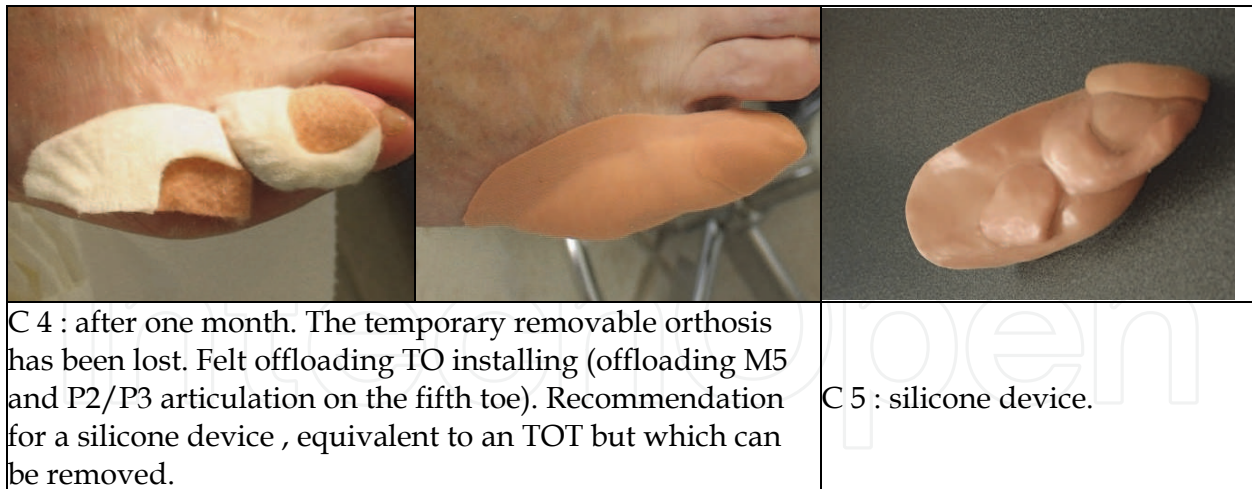


Fig. 7.

3.2.2 CASE D: A diabetic patient grade one (September 2004), she is under oral medication. She presents a bad ulceration on the external side of her third toe, regarding to the distal articulation, due to a too long nail and to the shoes she is wearing (this kind of shoes are to be proscribed for diabetic patients)



<p>D-7 : TO on October 15th</p>	<p>D-8 : debridement</p>	<p>D-9 : On November 29th, Moleskine fitting to avoid suction with felt TO</p>
<p>D-10 : TO has been unsticked and returned, then stuck on a neighbor toe to show how the wound has scarred.</p>	<p>D-11 : the patient has bought a new pair of shoes (17/12/2004).</p>	<p>D-12 : orthopaedic shoes in 2011. This patient has now diabete, grade two.</p>

Fig. 8.

<p>D-13 : Plastazote TO</p>	<p>D-14 : Silicone sub-digital device and Fleecy web under P1/P2 to avoid hyperkeratosis.</p>	<p>D-15 : Ortho-plastic surgery with second toe protection.</p>

Fig. 9.

This patient’s diabete (Diabete Mellitus) comes up to grade 2 in 2009; from then she’s insulin-dependent. She has to cope with an angiopathy and suffers a severe neuropathy.

Thanks to a regular medical follow up and to a healthy life, this patient has still got all her toes.

Since 2010, she wears made-to-measure shoes with an appropriate interior shape, seamless. To avoid an ulceration relapse a under- diaphysis protective and corrective orthosis is installed.

With a regular following and a good care of the nails every two months, the patient feet are protected.

3.2.3 CASE E: A patient with a Charcot foot

		
<p>E - 1 : foot print</p>	<p>E-2 : Debridement and enucleation</p>	<p>E-3 : 7 mm TO fitting</p>
		
<p>E-4 : after one week.</p>	<p>E-5 : Felt TO installing and Moleskine.</p>	<p>E-6 : Orthotic plantar device</p>

Fig. 10.

3.2.4 CASE F: The patient had her third toe amputated

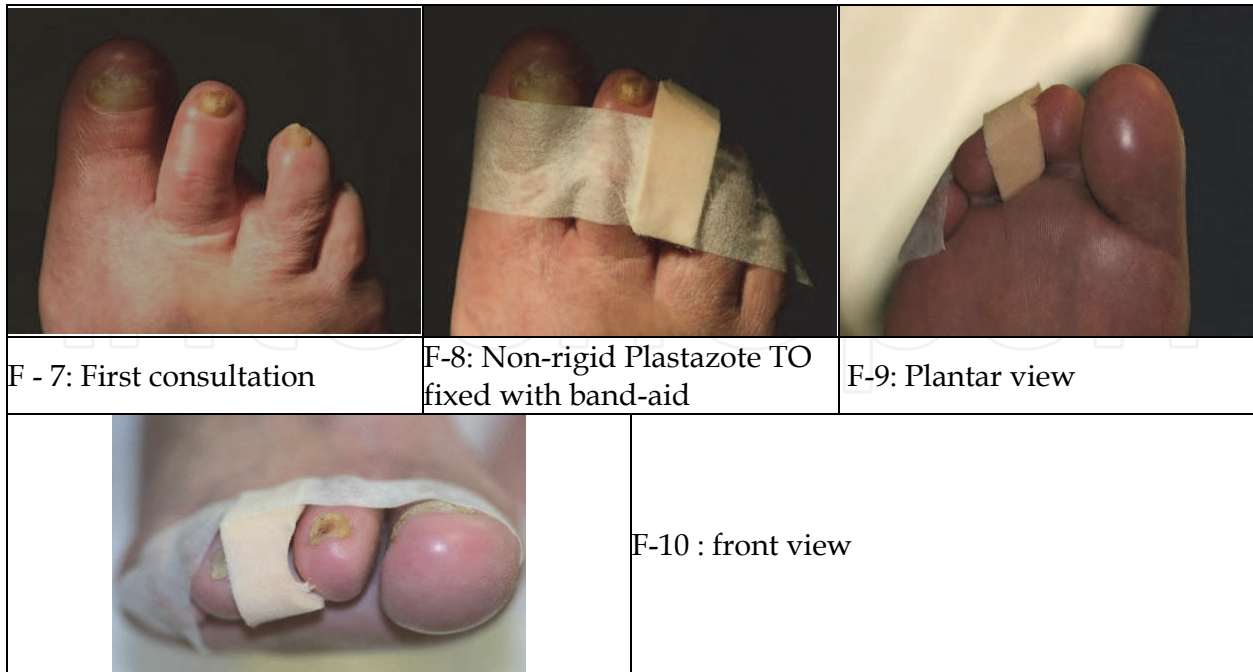


Fig. 11.

3.3 In hospital

Lots of clinical cases are presented in Dr van Lith’s book (Podologie appliquée).

The pictures below have been made and interpreted by Mrs. Marie José van Lith. She works in a podiatric office with a multidisciplinary medical team in the Romans hospital’s endocrinology department (Drôme, France).

She was kind enough to take part in this article writing.

3.3.1 CASE G: The patient here suffered a diabetic retinopathy which stucked her blind. She also had a kidney insufficiency (she was on dialysis twice a week). She died five within the five years

While she was on hospital, first x-rays show a foot which can’t be mobilized therefore no corrective TO is possible, only the protective one can be installed.







		installing, stucked with Oper fix bandage but which will be changed only every 8 days.
		
G-4: Wounds were almost totally healed . Some holes made in the TO allows the nurses to dress the wounds every two days (Actisorb Ag+ covered with Cellosorb).	G-5: A new wound appeared.	G-6: On April the 14 th , after incision of the hyperkeratosis. Skin started to worsen. The general patient's state is declining.
		
G-7: This picture has been made three or four days before the death. Hand distal phalanx are bare-skinned and the patient is now totally blind. No surgery.		

Fig. 12.

3.3.2 CASE H: The patient suffers a toes deviation. Big toe infraductus and total claw of the second toe. This patient is old, diabetic with a kidney insufficiency. He's only treated by a podiatrist. He has very painful angiopathic wounds

		
H-1: On May 13 th 2004. First corrective Hapla Band TO and one inter-digital felt TO.	H-2: On May the 27 th 2004. Fifteen days later.	H-3: Actisorb Ag+ application used all the treatment long.

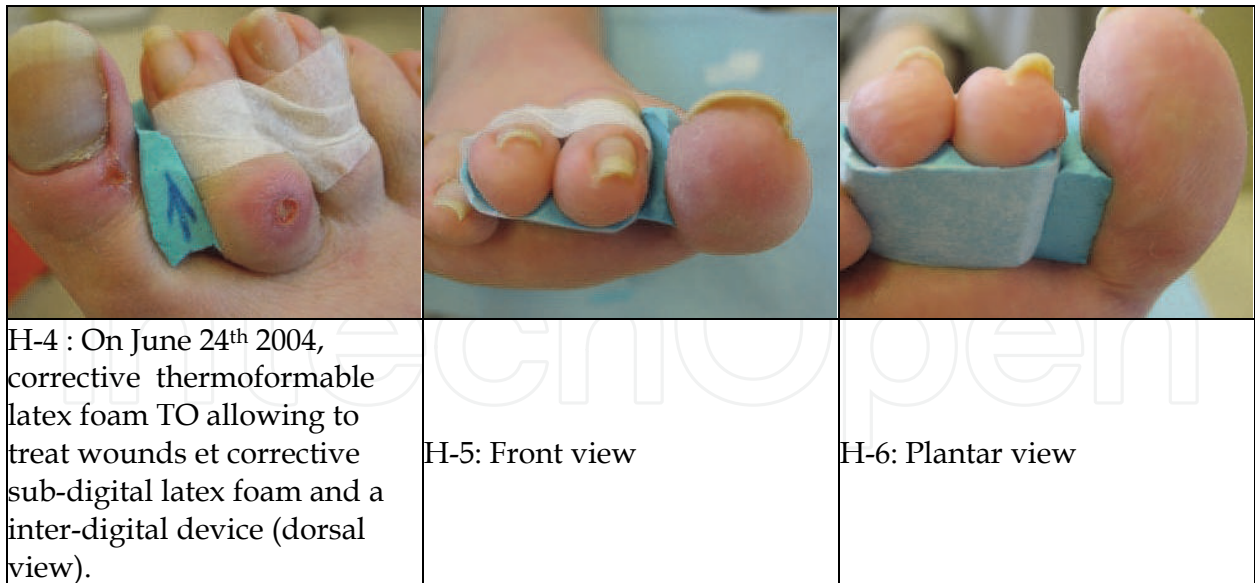


Fig. 13.

The protective TO was possible to fit after the articulations softening obtained by the Hapla-Band TO installing. It is held with Micrope. The silicone permanent orthosis couldn't be made because the patient couldn't reach his own feet.

Only the TO was replaced every 2 or 3 weeks.

3.3.3 CASE I: TO for an ulceration in order to amputate the fifth toe



Fig. 14.

3.3.4 CASE J: Where creativeness is needed...

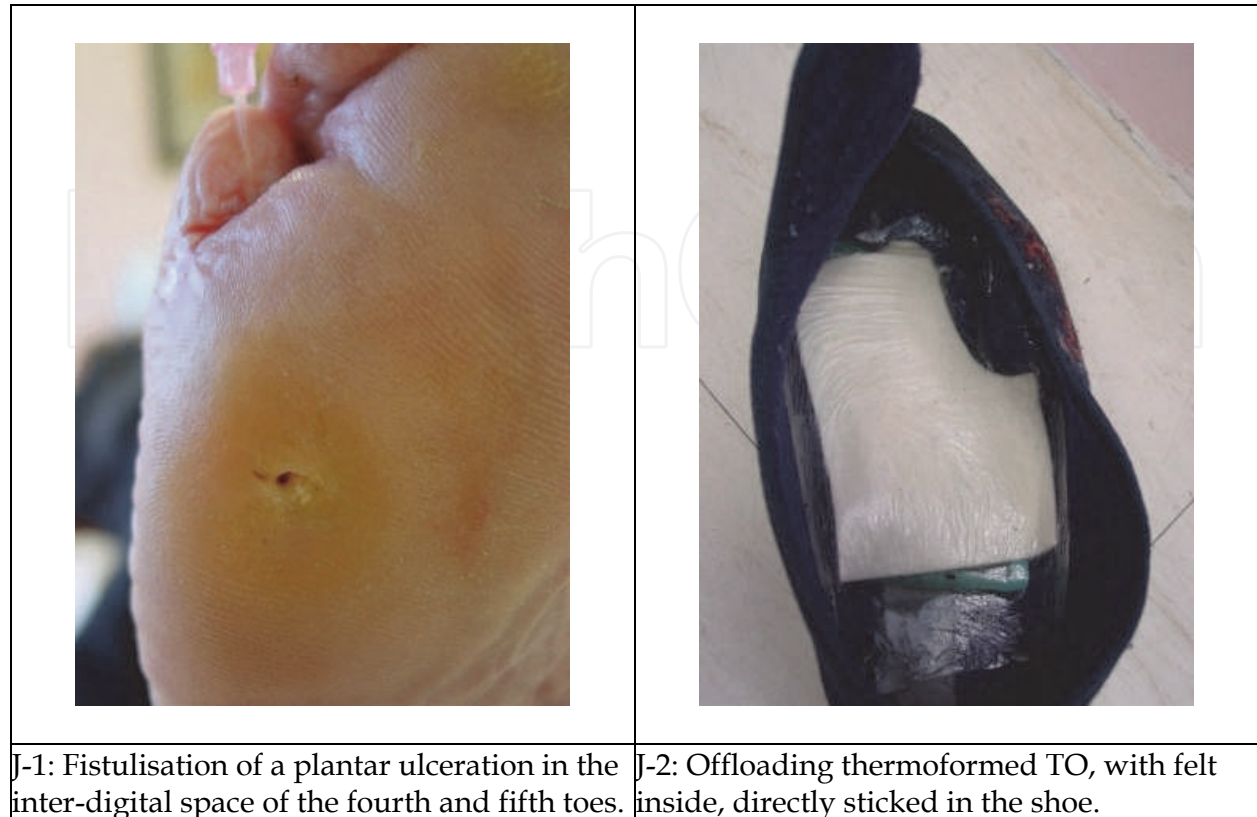


Fig. 15.

3.3.5 CASE K: Total transmetatarsal amputation

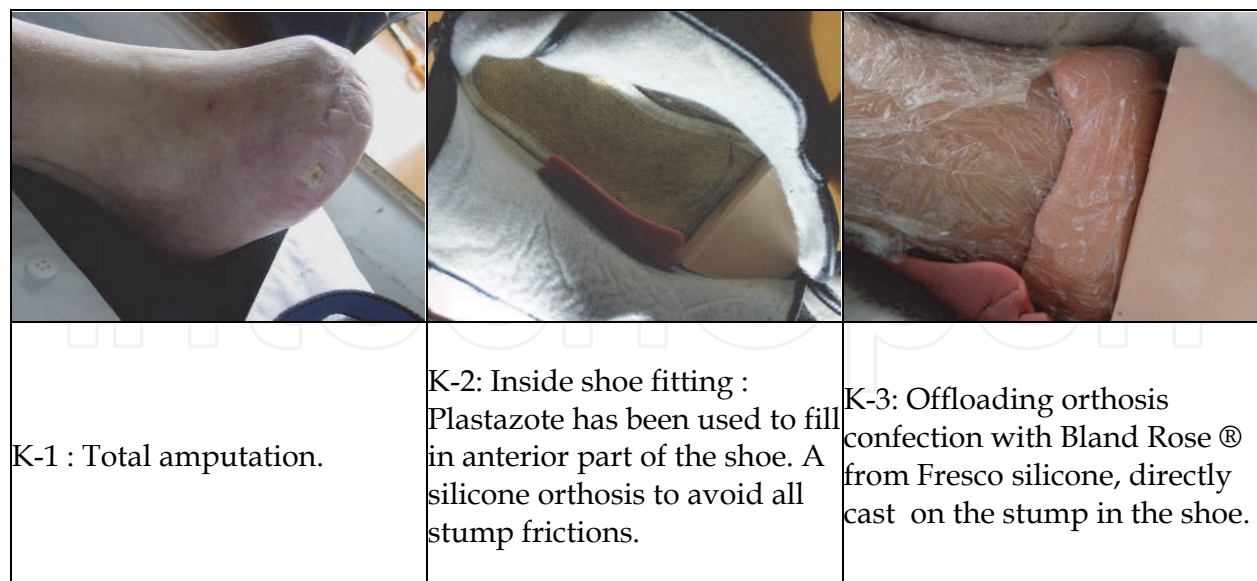


Fig. 16.

The TOT used for this diabetic patient, helps us to understand the specialist's aim: he wanted to educate and hand-hold this patient in his disease's evolution.

The issues of protection and correction in this treatment are essential to make him accept the installing of a digital or plantar orthosis. The podiatrist helps his patient to have a therapeutic behavior to delay as long as possible the amputation.

4. What instances does the TOT method fail?

It is not the TOT method which presents a failure risk but the patient when he or she stops his or her treatment. When the work is properly done, there is no failure.

Precaution to be taken when installing a TO are those of any other treatment:

- The TO must not hurt, it is made to relief the patient.
- The TO helps scarring because of the offloading of the conflicted area.
- The TO is installed on safe areas and out of the irritated ones.
- The TO shape is adapted according to the recovery step.
- The TO opening will be as wide as the conflicted area requires.

Pressures repartition thanks to the TO installed on safe areas offloads the irritated area. Pressure is quite often the aggravating factor.

TOT is a very good therapeutic method in biomechanical pathology of foot. This is a quick technique aiming a immediate relief. This is the best treatment in severe pathologies.

The podiatrist will always try to correct but if it is impossible then, he will choose the TO and the silicone protection devices or the offloading plantar devices).

5. Conclusion

I hope this technique will be found essential to handle ulceration on a high-risk foot of a diabetic patient.

Having used this technique during twenty years now, I still discover the cleverness of this therapeutic methodology.

And as Mrs. Marie-José van Lith said: *“One has to be creative for each medical case he has to deal with”*. It is for me a real pleasure to do so.

During all his career, my teacher (Dr. Robert van Lith) tried to transmit this technique to our colleagues and students.

In 2001, I thought and I told to Dr van Lith that this would be possible by taking the diabetic foot treatment into account (we were on a world- congress of Podiatry in Paris and Dr Margreet van Putten and Mrs. Marie-José van Lith were there).

In 2010, during the Podiatrist International Federation world conference in Amsterdam, Dr van Putten wanted to pay tribute to my teacher, an exceptional man, and when his wife, Marie-José van Lith received this tribute, she announced that she had succeeded in launching TOT in several endocrinology departments; she said: *“This technique is based on medical laws which makes it a real treatment. To treat the wounds of the diabetic foot, this treatment is essential, before all permanent silicone or plantar orthosis which could be necessary after the complete wound recovery”*.

This therapeutic technique should be transmitted to all our foot specialists' colleagues.

In the near future, I hope that this technique will be part of the teaching curriculum for French Podiatrists. I wish the words *Temporary Orthosio-therapy* and *temporary orthosis* will find their definition in the medical terms dictionary (Garnier Delamare).

TOT should be officially recognized as beneficial to the public at large... to ensure a less harrowing future to the diabetic patients.

6. Definition

Temporary orthosio-therapy (Dr Robert van Lith): This technique is called erroneously *Padding* in France. This name was brought in France by Franklin Charlesworth. This is a very inventive technique to achieve an immediate relief, before the use of a permanent silicone or plantar orthosis.

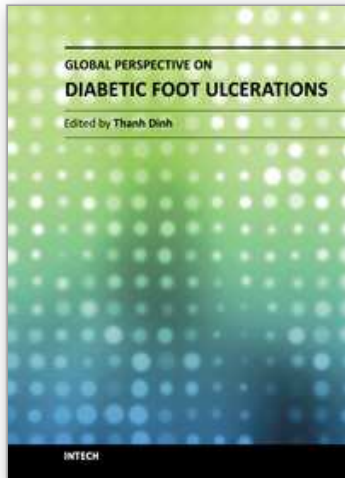
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Over the last decade, it is becoming increasingly clear that diabetes mellitus is a global epidemic. The influence of diabetes is most readily apparent in its manifestation in foot complications across cultures and continents. In this unique collaboration of global specialists, we examine the explosion of foot disease in locations that must quickly grapple with both mobilizing medical expertise and shaping public policy to best prevent and treat these serious complications. In other areas of the world where diabetic foot complications have unfortunately been all too common, diagnostic testing and advanced treatments have been developed in response. The bulk of this book is devoted to examining the newest developments in basic and clinical research on the diabetic foot. It is hoped that as our understanding of the pathophysiologic process expands, the devastating impact of diabetic foot complications can be minimized on a global scale.

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