Society for Study and Research into Paraplegia

Clinical and biomechanical validation of the Heat-Formed Composite Plantar Orthotic " OPCT "

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1. INTRODUCTION AND PURPOSE OF THE STUDY

This study entitled "Clinical and Biomechanical Validation of the OPCT concept" was conducted by the Society for Study and Research into Paraplegia (Société d'Etude et de Recherche en Paraplégiologie, 263, rue du Caducée, Centre Propara, 34195 MONTPELLIER cedex 5) on behalf of the SIDAS - PODIATECH Company (ZA Le Parvis, BP 353, 38509 VOIRON CEDEX).

The Heat-Formed Composite Plantar Orthosis (OPCT) concept was developed by the Research and Development Division of SIDAS – PODIATECH.

The main features of the concept could be summarised as follows:

- **Custom-produced orthosis based on casts made directly from the patient's body.**
- **Exploitation of materials with synergistic physicochemical properties.**
- **Use of flat, ready-to-be-formed modules to simplify the assembly of the custom-made orthosis.**
- **Based on modifiable, adjustable units; enhances appearance, environmentally friendly, and improved feasibility with respect to both cost and human resources.**

This concept which has been shown to be effective in the clinical context has long been in use in France and abroad.

Changes in the regulations pertaining to medical devices have resulted in a need for accreditation and scientific validation of outcomes in order to present the technology more convincingly to users, notably prescribers, practitioners, regulatory authorities and the scientific community.

The Society for Study and Research into Paraplegia has been a pioneer in this field, having conducted studies on cushions and mattresses to prevent bedsores under the scientific direction of Dr. F. Ohanna, the Chief Physician of the Centre Propara. This institution is therefore perfectly qualified to fulfil the scientific needs of this study which was conducted between September and December 1998.

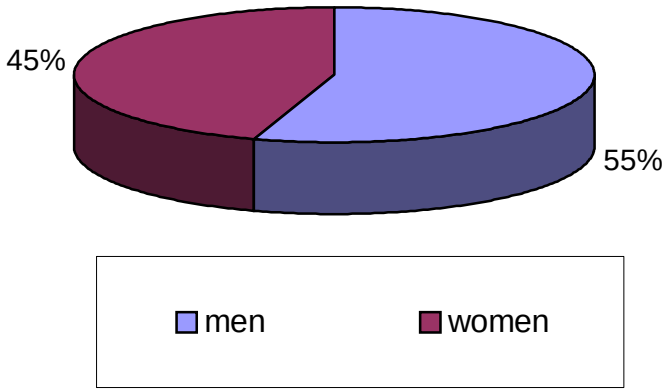
This Report has 41 pages with two appendices* (52 pages). Any interpretation must be based on the information presented as a whole.

* THE APPENDICES AND TECHNICAL DETAILS ON THE OPCT HAVE BEEN REMOVED FROM THIS DOCUMENT

2. STUDY POPULATION

A total of 132 subjects were recruited: 73 men (55%) and 59 women (45%) (Fig. 1).

Fig. 1 : POPULATION



The 132 subjects were divided between the four centres as follows:

- Cabinet de Podologie Venise, Reims: **40 subjects**.
- La Renaissance Sanitaire, Villiers St. Denis: **37 subjects**.
- Ortho Service, Grenoble: **37 subjects**.
- Service Central de Réadaptation Fonctionnelle, Montpellier: **18 subjects**.

The age of the subjects varied between 8 and 86 years (mean = 43.6 ± 21.1)

The weight of the subjects varied between 24 and 112 kilogrammes (mean = 67.9 ± 16.4kg)

The height of the subjects varied between 100 and 192 centimetres (mean = 168 ± 12.9 cm)

3. MATERIALS AND METHODS

(a) Heat-Formed Composite Plantar Orthosis (OPCT):

Technical data on the equipment, materials and processes for the OPCT concept are given on pages 5-14.

(b) Plantar pressure measuring system :

The pressure sensor system used in this study was the Footscan system (RSsscan International, Olen, Belgium) which is based on resistant sensors enclosed in very thin soles. Inside the shoe, the sensors are connected through two cables to a recording system carried on the belt. This system permits totally free, unencumbered movement.

Recording is triggered by means of a remote control. In order to guarantee reliable results, the patient is unaware of when the machine is recording. Recorded data are transferred to analytical software which generates pressure readings and monitors changes in the centre of force.

An initial static measurement is followed by a dynamic measurement, a cycle which is repeated for each subject with and without the sole.
So, four readings are generated for each patient plus, for the small number of patients with other types of sole, supplementary measurements for the purposes of comparison.
Calibration of the soles and other utilisation modalities of this measurement system were in compliance with the manufacturer's instructions. An example of how the data were processed is given on page 15.

(c) Working method:

Soles were manufactured for subjects specially recruited in the four towns mentioned. According to a pre-determined schedule, all subjects were asked to attend the centre for pressure measurements.

After about ten days, the patients were interviewed about functional parameters, according to the Study Protocol.

(d) Statistical analysis:

GraphPadPrism (version 2) and Excel 97 software were used for the statistical analysis and graphics. Student's "t" test was used for parametric tests and the Wilcoxon test was used for non-parametric tests, with significance thresholds of $p \leq 0.05$ and $p \leq 0.001$.

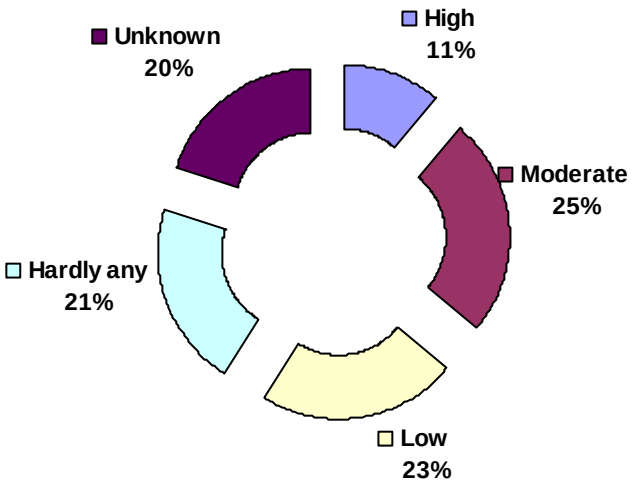
4. RESULTS AND ANALYSES

Daily and physical activities were classified on an empirical basis on the basis of the following categories:

•occupational activity with a high level of physical displacement: 14 subjects,
•occupational activity with a moderate level of physical displacement: 33 subjects,
•occupational activity with a low level of physical displacement: 30 subjects,
•occupational activity with hardly any physical displacement: 27 subjects,
•occupational activity with an unknown level of physical displacement: 27 subjects.

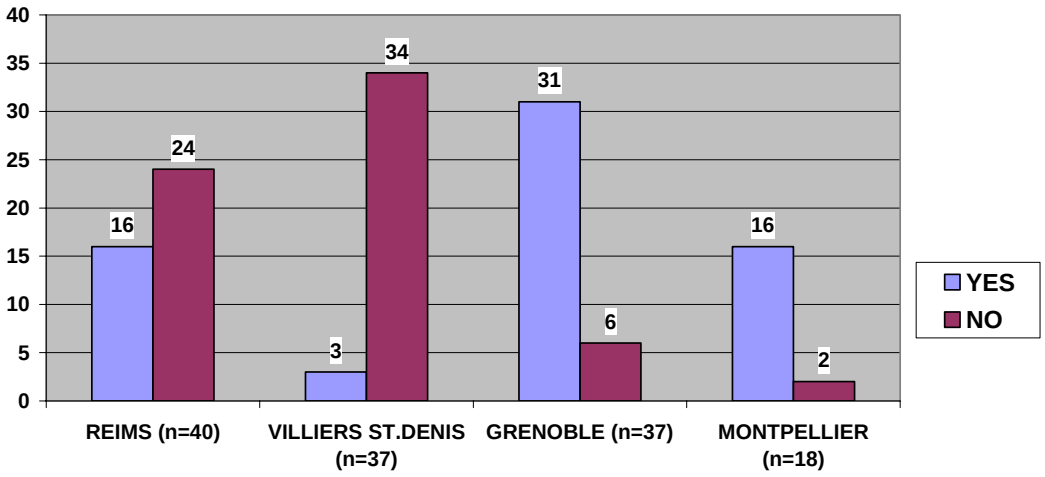
This breakdown (expressed in terms of percentage) is graphically represented in **Figure2**

FIGURE 2: Level of occupational physical displacement



The breakdown (in absolute numbers) according to sporting activities is represented in **Figure 3**.

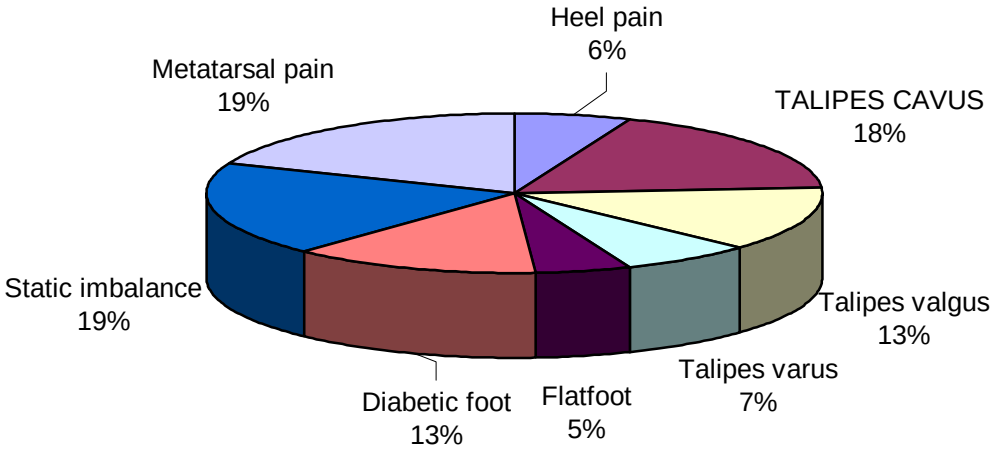
FIGURE 3: Sporting activities



The frequencies of the various pathologies from which the subjects were suffering were the following (expressed in percentages and listed in decreasing order): **(fig 4)**

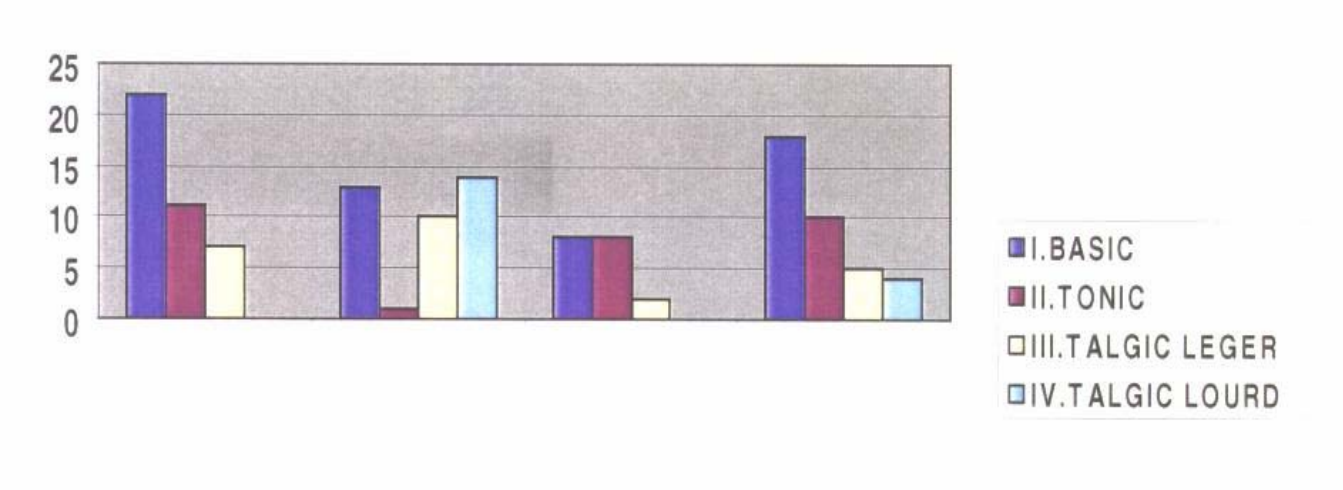
- **Metatarsal pain: 19%.**
- **Static imbalance: 19%.**
- **Talipes cavus: 18%.**
- **Diabetic foot: 13%.**
- **Talipes valgus: 13%.**
- **Talipes varus: 7%.**
- **Heel pain 6%.**
- **Flatfoot: 5%.**

FIGURE 4: Breakdown of complaints



A total of 133 pairs of OPCT type soles were produced and how the various types were distributed between the centres is represented in **Figure 5**.

Fig. 5: sole type by centre

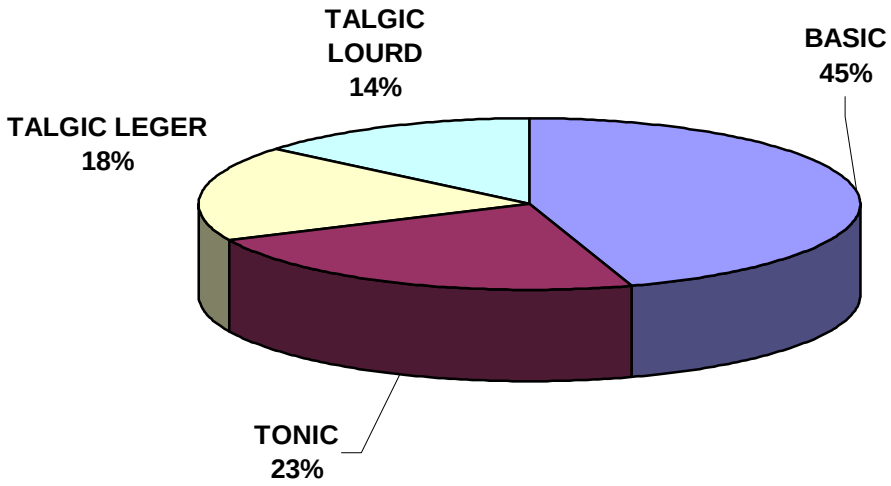


It can be seen that the sole prescribed depends strictly on the complaint with, notably, a high proportion of the "TALGIC LOURD" type at Villiers St. Denis where there are many cases of diabetic foot.
The fact that the patients at the other three sites tended to be more active explains why nearly all the OPCT soles there are of types 1, 2 and 3.

OPCT types for the 133 pairs of soles break down as follows: **(figure 6)**

- **BASIC: 45%,**
- **TONIC: 23%,**
- **TALGIC LEGER: 18%,**
- **TALGIC LOURD: 14%.**

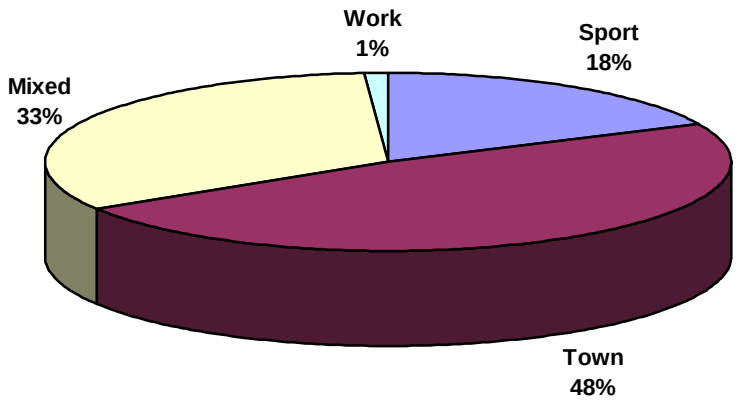
FIGURE 6: Overall breakdown of OPCT types



Sole technical orientations break down :

- **Town: 48%**
- **Mixed: 33%**
- **Sport: 18%**
- **Work: 1%**

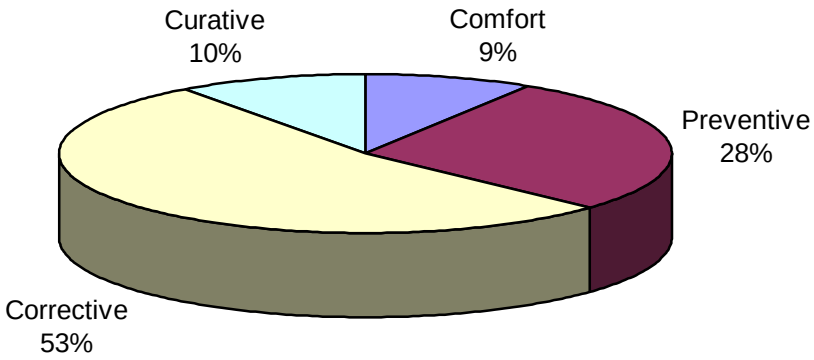
FIGURE 7: Technical orientations



Indications for soles break down as follows:

- **Corrective: 53%**
- **Preventive: 28%**
- **Curative: 10%**
- **Comfort: 9%**

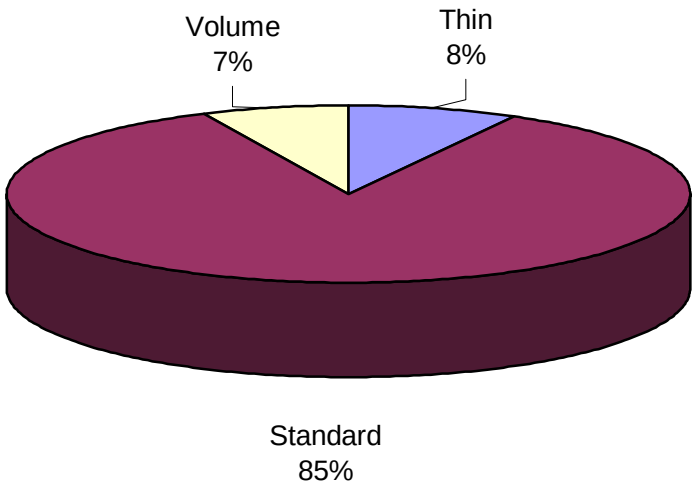
FIGURE 8: Indication for soles



The different fits are:

- **Standard: 85%**
- **Thin: 8%**
- **Volume: 7%**

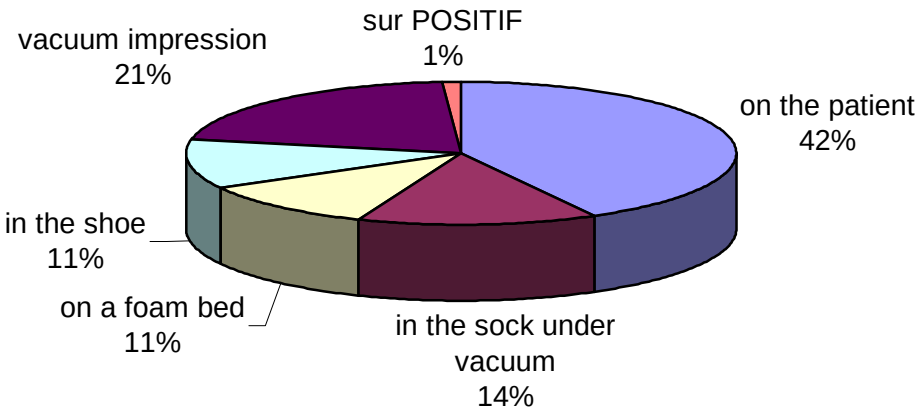
FIGURE 9: Fit



The various heat-forming methods used break down as follows:

- **On the patient 42%**
- **Vacuum impression 21%**
- **In the sock under vacuum 14%**
- **In the shoe 11%**
- **On a foam bed 11%**
- **Positive 1%**

FIGURE 10: Heat-forming methods



Quantitative evaluation (measurement of plantar pressures and pressure surfaces) was performed according to the following table:

Complaint	Major criterion	Secondary criteria
Talipes cavus	**↑ MF + ↑ PS**	**↓ FF ↓ H**
Flatfoot	**↑ MF**	**↓ FF ↓ H ± ↑ PS**
Metatarsal pain	**↓ FF**	**↑ MF ↓ H**
Heel pain	**↓ H**	**↑ MF ↑ FF**
Diabetic foot	**↓ H ± ↓ FF**	**↑ MF**

FF, fore foot; MF, middle foot; H, heel; PS, pressure surface

Results break down between the three following categories:

(a) **Within specifications:** one major criterion + one or two secondary criteria.
(b) **Borderline:** one major criterion with or without a secondary criterion.
(c) **Not within specifications:** the major criterion is not fulfilled.

The following Tables **(1 and 2)** summarise the data collected at the four centres together with the corresponding statistical results.

TABLE 1. Results (compliance with specifications) according to centre

	Reims	Villiers St.Denis	Grenoble	Montpellier
Within specifications	38	30	35	16
Borderline	2	5	2	2
Not within specifications	0	2	0	0

TABLE 2: Statistical results according to centre (*p* values)

	Static measurements			Dynamic measurements		
Centre	**DPmax**	**DPmean**	**DPS**	**DPmax**	**DPmean**	**DPS**
Reims	0.0119	0.0037	<0.001	<0.001	<0.001	<0.001
V.St.Denis	0.7926	0.2292	0.0010	0.9526	0.9977	0.0217
Grenoble	0.4562	0.0625	0.7973	0.9789	0.2648	0.4821
Montpellier	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

KEY:
Dpmax: maximum pressure differences
Dpmoy: mean pressure differences
DSA: pressure surface differences

All comparisons correspond to differences between measurements made with and without OPCT soles.

All the results recorded at Reims are statistically significant with particularly significant differences observed in both static and dynamic pressure surface results.

At Villiers St. Denis, the only statistically significant result is that for static pressure surface.

At Grenoble, none of the results neither the static nor the dynamic results were statistically significant.

At Montpellier, all the results were highly significant.

It is worth noting that, although statistical significance denotes an excellent result, the absence of significance does not necessarily mean a poor result. Differences may arise at a number of levels, notably due to errors deriving from the pressure measurement system (sensors, calibration, calculations, etc.).

The results of functional evaluations contribute important information to these quantitative results.

These functional results are presented in the following seven graphs:

FIGURE 11: Static comfort

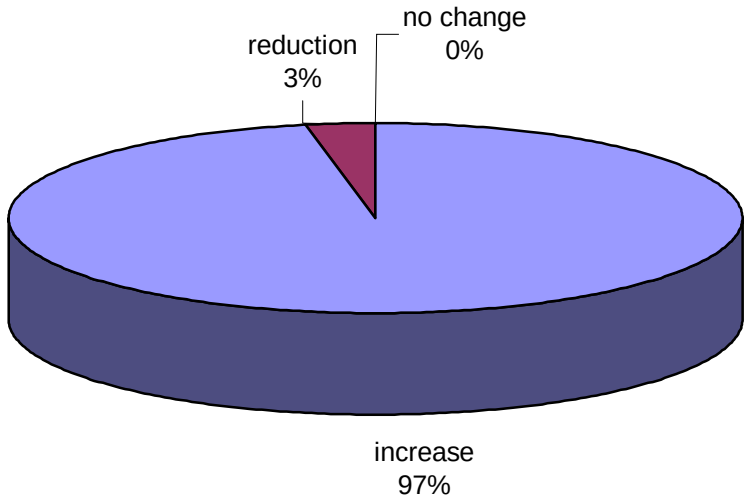


FIGURE 12: Dynamic comfort

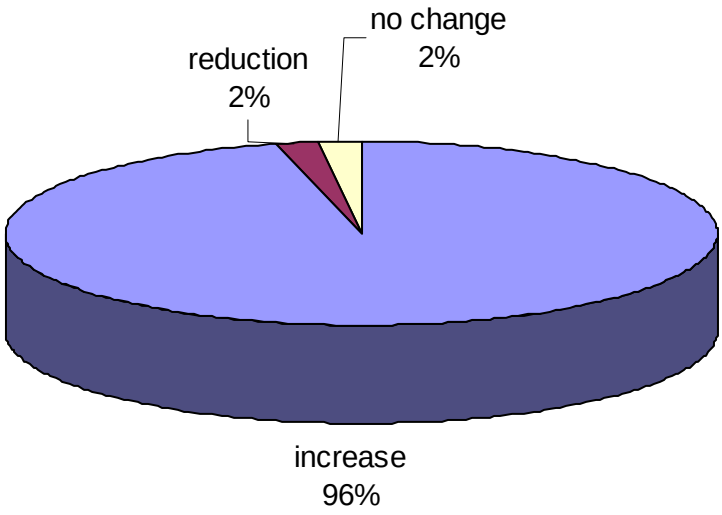


FIGURE 13: Pain

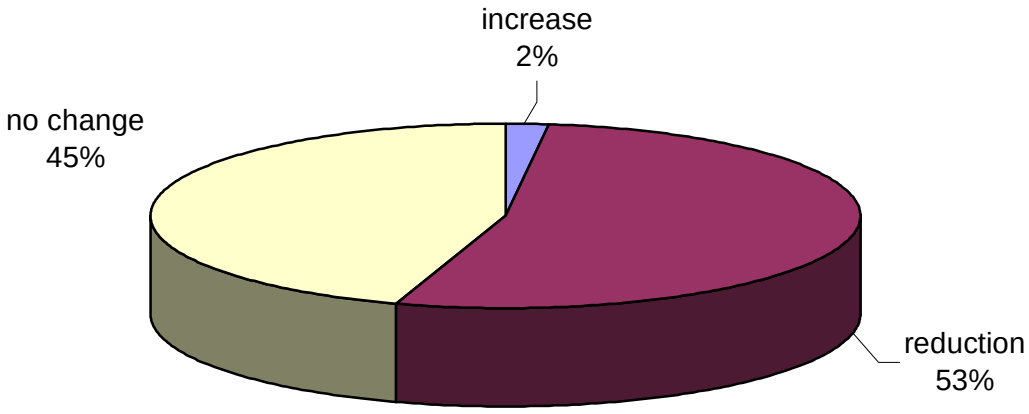


FIGURE 14: Time before onset of pain

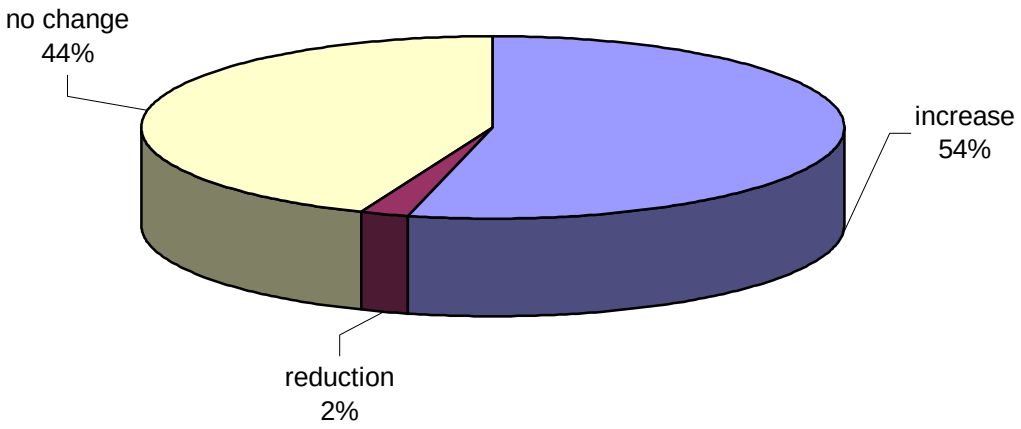


FIGURE 15: Walking range

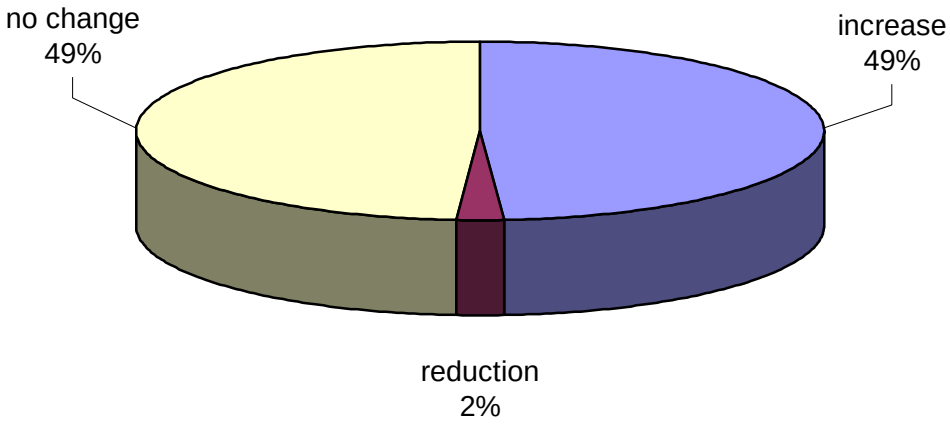


FIGURE 16: Speed

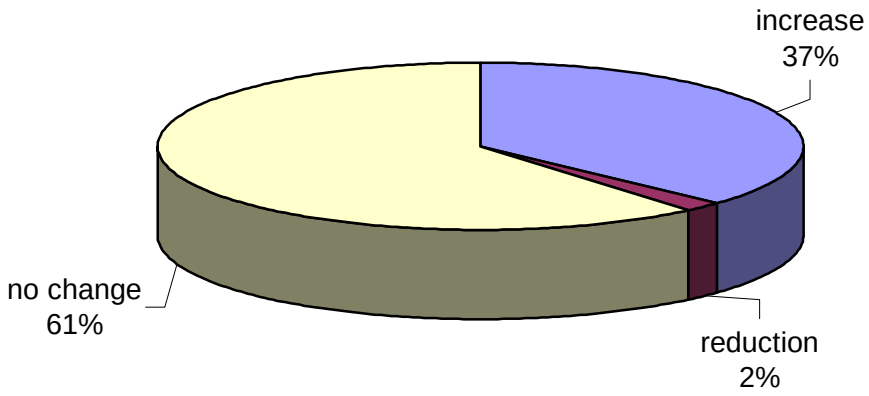
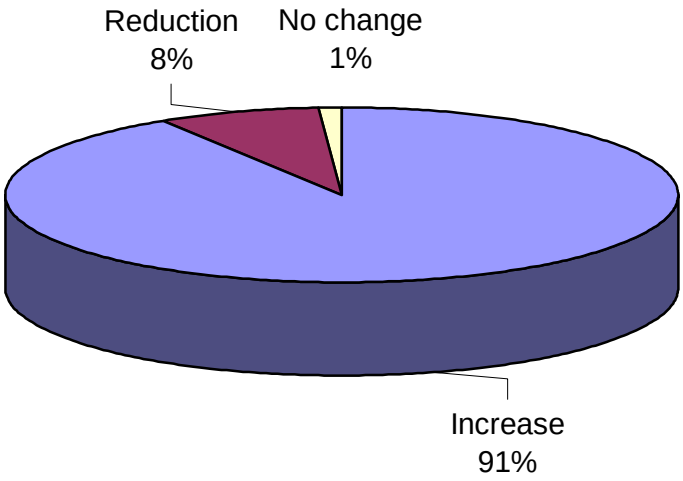


FIGURE 17: Satisfaction



The following Table summarises the functional results:

TABLE 4. Functional results (expressed as percentages)

	Increase	Reduction	No change
Static comfort	97	3	0
Dynamic comfort	96	2	2
Pain	2	53	45
Time before onset of pain	54	2	44
Walking range	49	2	49
Walking speed	37	2	61
Subjective impression	91 (improvement)	8 (deterioration)	1

5. DISCUSSION AND CONCLUSIONS

In the analysis of plantar pressures, results were systematically calculated for forefoot, middle foot, heel and total surface.
The same calculation methods were used for both the static and the dynamic measurements. The third step was selected for each dynamic measurement on an empirical basis Thus, the quantitative results were analysed in the following way:

a) comparison of plantar pressures with and without the sole,
b) comparison of these pressures with respect to the various analysed areas,
c) comparison of pressure surfaces,
d) comparison of the change in centre of force for dynamic measurements.

Thus, for each case, the indication for the soles was first noted, followed by comparisons of pressures and of pressure surfaces with a view to fulfilling the initial objective. Finally, functional parameters were considered.

Statistical results were correlated with the functional results.

Globally speaking, both the statistical analysis and the functional results point up the efficacy of OPCT soles.

There is extensive concordance between quantitative and qualitative results in the Reims subjects, with particularly significant dynamic results.
This observation is associated with the preponderance of "Basic" type soles in this population.
In contrast, none of the Grenoble results are statistically significant although the functional results are as striking as those from Reims or Montpellier (at both of which sites, statistical analysis revealed highly significant results).

The Villiers St. Denis results are less significant and similarly, the variations in the functional results are difficult to account for.
It would appear that some of the measurements were carried out with bandages in place around diabetic feet, a factor that might explain the observed variations.

Comments of patients recorded in the files were as follows:

1. **The sole takes up space inside the shoe.**
2. **The focus of pain shifts.**
3. **It takes some time to adapt.**
4. **Those who had already tried other types of sole tended to prefer OPCT soles.**

Since fewer than ten patients are concerned, statistical analysis is not possible at this stage.

The most dramatic improvements observed in the course of the evaluation were in static and dynamic comfort with about 96.5% of subjects reporting amelioration.
It is also interesting to note the increase in walking range of the order of 50%.
This increase correlates with other, related parameters, including reduced pain (when present), an increased time before the onset of pain, and increased walking speed.

It would be worth re-evaluating at least some of these subjects after about six months for an across-the-board comparison of results.

A vital feature of the OPCT concept is the ease with which it can be applied in disparate situations. The availability of pre-produced modules coupled with the efficacy of the moulding equipment make for fast sole production which of itself underlies a very good cost-efficacy ratio.

The use of electronic sensors in the measurement of plantar pressure and the evaluation of plantar orthosis remains the prerogative of a few, highly qualified organisations. The measurement of pressures at the interface between sole and shoe gives vital information for sole evaluation.
Combining podabarometry with pressure sensors constitutes an approach which makes both reliable diagnosis and objective evaluation possible.