FINAL REPORT OF THE STUDY DATA ON THE CLASS I MEDICAL DEVICE PLANTARI FIT

DEVICE NAME	**PLANTARI FIT**
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SCIENTIFIC TECHNICAL COMMITTEE	**Bio Basic Europe S.r.l.** Umberto Pianca, Claudio Angelinetta, Katia Parmeggiani, Plinio Richelmi, Ornella Pastoris, Cristina Montomoli, Simona Villani, Alma Balestrazzi, Fernando Marco Bianchi, Marta Benedetta Brumana, Alessandra Cantù, Antonella Colombo, Alessandra Di Benedetto, Evelyn Falconi Klein, Laura Mainardi, Silvia Violetti, Antonella Praticò, Daniela Gandini, Francesca Vallotto, Silvia Busoli Badiale, Eliana Regola.
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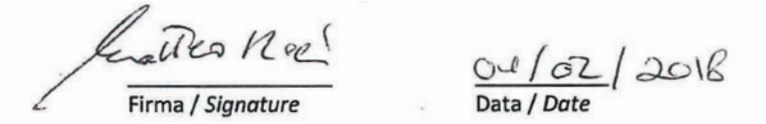

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SYNOPSIS OF THE CLINICAL STUDY

TITLE	Final report of the study data on the class I medical device	
REPORT N°	1701N01A	
NAME OF DEVICE	PLANTARI FIT	
MANUFACTURER	D. FENSTEC SRL	
DURATION TEST	Beginning date	1st February 2017
	Ending date	30th April 2017
DESCRIPTION OF THE PROCEDURES	The PLANTARI FIT medical device has been investigated comparatively (LOT A VS LOT B VS WITHOUT ORTHOTIC INSOLES) in healthy subjects and subjects with knee prosthesis to evaluate its action as physiokinetic-therapeutic support in rehabilitation treatment and as an aid in maintenance of functional performance in follow-up. The device system is to be used only in accordance with the approved Investigational Plan on subjects who have signed an informed consent form. Device use is limited to the approved study investigators.	
INFORMATION ABOUT THE MEDICAL DEVICE	The study shall identify clearly the hypothesis and objectives, primary and secondary, of the clinical investigation and the populations for which the device is to be used in the investigation. These shall include as appropriate the particular: • *Claims and intended performance of the device must be verified. This may include implicit in the intended purpose of the device as well as those made explicit in labeling, instructions for use or promotional material. It should be clearly stated whether or not the determinations of the long-term effect are part of the objectives of the current clinical investigation.* • *Risk and foreseeable adverse device effects that are be assessed* • *Specific hypotheses to be accepted or rejected basing on the criteria and specifications of the evaluated medical device.* **Claims and performance:** PLANTARI FIT are medical devices intended for use in people, including subjects with lower limb prosthesis, who complain balance disorders or instability (ataxia). **Risk and foreseeable adverse effects:** The devices should not be used on wounds or on broken or reddened skin. The products are non-sterile and do not contain any form of medication. If you suffer from specific blood circulation (especially to do with microcirculation) or muscular problems, seek the advice of your physician before applying the orthotics. Do not apply the orthotic insoles if it shows any sign of wear or defects. If any reactions to the plaster occur, for example itchiness or reddening, remove the plaster immediately.	
TYPE OF THE INVESTIGATION	Comparative, monocentric clinical study – 2 groups of 14 healthy subjects and 10 subjects with knee prosthesis. Bothe the groups used LOT A, LOT B and no orthotic insoles.	
CENTER(S) / COUNTRY(IES)	The study was coordinated and supervised by Prof. Matteo Ricci with the support of Dr. Elena Sambugaro.	

SUBJECTS / GROUPS	24 female and male subjects 2 groups of 14 and 10 subjects.
RATIONAL	In some subjects there may be problems related to **orthostatic equilibrium (postural stability)** following central and / or peripheral neurological phenomena (somatosensory) of various entities related to age, BMI and as results of previous intervention. This phenomenon is also present in people with prosthesis in the lower limbs, where it is important to identify an optimal alignment of the prosthesis as a crucial factor in the success of rehabilitation. (E Isakov et al, 1994). In addition to the evaluation obtained by means of stabilometry in relation to the application of orthotic insoles, it is necessary to evaluate the plantar supports by means of static and dynamic baropodometry. (Martina Barzan, 2011) **Equilibrium** is a complex sensor-motor function in charge of maintaining posture, standing up in a condition of movement or immobility of the body with respect to space or vice versa. The feeling of balance and position in space is an integrated function of multiple peripheral sensory information to the brain. Postural stability and motor coordination may fail, manifesting as incoordination, clumsiness in movement. One of the syndromes characterized by imbalance is ataxia, a term that derives from the Greek "ataxia" (lack of order). It can affect eye movements, speech (resulting in dysarthria), individual limbs, the trunk, standing and walking. More generally, we refer to **static ataxia (standing posture)** and to **dynamic ataxia (deambulation),** such as abnormal posture, balance and gait The ataxia also concerns the coordination tests of the whole body and its generally resistant to functional recovery exercises (physiotherapy) and perhaps to motor promotion. It can be of various types: · sensitive, when it affects the proprioceptive peripheral pathways, lemniscal medulla (posterior cords) and thalamic structures. The defects of proprioceptive sensitivity are expressed mainly with motor disorders. A common feature that distinguishes these defects from those of a cerebellar origin is to appear or to worsen when the eyes are closed; · cerebellar, which is caused by lesions that may affect the cerebellum itself or its afferent and efferent connections, both in the spinal cord and in the peduncles and in the pathways along the brain; · vestibular; · cortical (frontal, parietal, temporal). To detect poor balance, examine the proprioception in different measures and cerebellar functions applying a neurological test in orthostatism, the Romberg's test, in which the subject is placed in orthostasis conditioned at 30 degrees with the heels joint and the tips slightly open, limbs along the body or thesis, it is divided into two separate tests: the first with open eyes and the second with closed eyes (Matteo Cardaioli, 2016), thus eliminating the visual

signals that help the maintenance of posture (Hiren Patel et al ., 2010). This test provides a quantitative method of measuring of postural stability and equilibrium integrity during the execution of the two tests, by which it is possible to evaluate the two differences and establish the intervals in healthy subjects (Hans H. Thyssen et al., 1982) and in subjects with lower limb prosthesis from amputations (E Isakov et al, 1994).

In the case of **static ataxia,** id est in the maintenance of the upright posture, the alterations are also manifested for minor disturbances. Following the application of the **Romberg's Test**, multidirectional oscillations, more or less lateralized of the body axis are observed, which can also accentuate up to determine the fall, when the subject, with closed eyes, is affected by a sensitive ataxia (a phenomenon of Positive Romberg).

In the case of cerebellar ataxia, the phenomenon of Romberg is defined as negative, because, despite the presence of oscillation of the body axis, the closure of the eyes does not worsen balance and posture.

In the case of ataxia from labyrinthine disorders the Romberg phenomenon is positive, because the imbalance worsens with the suppression of the visual control, but the eventual fall or the appearance of latero-deviation tends to be "late", developing unilaterally (lateropulsion) and after about a dozen seconds. (Granieri; Tola, 2012)

In addition to the evaluation performed by the Romberg's Test, a **baropodometric examination was applied (static and dynamic analysis)**, which allows to evaluate **the quality of the plantar supports**. The test includes: control in bipodalic and monopodalic orthostatism (**static examination**) and survey of the step during the kinetic evolution of the movement (**dynamic examination**). The examination can be performed barefoot to evaluate pathologies and to identify areas of overload, and with shoes to check the congruity of the correction of the plantar orthosis.
(Riccardo Fenili)

From the static analysis it is possible to obtain parameters that can give indications regarding the characteristics of different conformations of the foot. It is advisable to consider the distribution of loads on the two feet in order to define the entity of the imbalance of each subject. (Martina Barzan, 2011) In **Static Phase**, the Baropodometer acquires the image resulting from the average of eight consecutive impressions, from which derives the distribution of the pressures, the definition of the thrust centers of each foot, the projection of the center of gravity, the calculation of maximum pressure and the pressure surface. (A. Minerva et al., 2008)

The **Dynamic Phase** allows to view, in consecutive recordings and in relation to time, all the data relating to the foot during the normal development of the step. During the dynamic phase it is also possible to control other parameters, such as: the plantar surface during the step; the maximum pressure exerted in each single phase during the passage of the step; the speed of movement of the foot

pressure exerted in each single phase during the passage of the step; the speed of movement of the foot in every single phase; the force exerted by the weight during the support and oscillation phase. (A. Minerva et al., 2008)

OBJECTIVES	**Primary Objective of Efficacy:** Demonstrate that the use of orthotic insoles helps to improve the orthostatic balance (postural stability) and favor the maintenance of functional performance in rehabilitation treatment and follow-up. **Safety Objectives:** During the study side-effects may occur by using the medical device. In order to guarantee the safety of the subject, any side-effects had to be written on the Subject sheet.
QUALITY OF LIFE	During the study, the subjective sensation of comfort referred by the subjects was assessed through personal satisfaction questionnaires. (Attached to this document).
DESIGN OF THE STUDY	Comparative, monocentric clinical study on 24 subjects. The subjects are divided into 2 groups, of which 14 subjects are healthy and 10 have knee prosthesis. They are evaluated in comparative manner previewing no use of orthotic insoles, use of PLANTARI FIT (LOT A) and PLANTARI FIT (LOT B).
PRINCIPLE INCLUSION CRITERIA	Subjects have been selected and included in the study. The selection has been done according to the undermentioned inclusion criteria: · 18-70 years old · healthy subjects (to evaluate the effect of the plantar on the healthy population and to have the norms of the population) · subjects with knee prosthesis (the average age of this group is higher and correlates to the need for surgical treatment in osteoarthritis subjects, also for this the Anova test has been applied, statistically correct given the differences in age and BMI between the two study groups) · Subjects who gave their consent to participate in this test and to use their personal data · promise not to change their usual daily routine · no psychological diseases · no atopy in the anamnesis
PRINCIPLE EXCLUSION CRITERIA	Subjects with the following criteria were not recruited for this test: · sensibility to one of the device component · subjects who do not consent to the use of personal data

TREATMENT SCHEME	Subjects defined as eligible by the investigator and who gave informed consent (attached to this document) were enrolled in the study. They followed the protocol for using the medical device as indicated by the investigator. The subjects included in the study were evaluated as reported in the study protocol, using the same means and the same operator: · STABILOMETRY (ROMBERG TEST) · STATIC AND DYNAMIC BAROPOD
STATISTICAL METHODOLOGY	**I Stage of the statistical study** In the first phase of the statistical processing the descriptive analysis was completed with calculation of the maximum and minimum values, average, standard deviation (SD), median (p50) for each variable of the STATIC, DYNAMIC AND ROMBERG analysis. **II Stage of the statistical study** The second phase of the fundamental statistical study is based on the comparison between lots A, B, SP (without a orthotic insole) for each variable in healthy subjects and subjects with knee prosthesis. A simple analysis of the variations between lots was not performed, but the individual variation between lots for each individual subject was also considered, in order to make the p value even more significant. **III Stage of the statistical study** In the third phase of the statistical study, the variations between prosthesis and healthy subjects were analyzed to evaluate how well orthotics can modify the performance compared to healthy by applying the analysis of variance (Anova test), a case/control comparison is performed taking into account the BMI (which in turn depends on height, weight and age), since this index could have an influence on significance and it is a parameter that distinguishes the two populations compared. The SP tests give the baseline of the case/control groups, the variation lot A/SP and lot B/SP allows to identify if one of the two lots is able to influence the values both in healthy persons and subjects with knee prosthesis, if in positive or negative sense and to what extent.
CONCOMITANT MEDICATION/ CONCOMITANT DEVICE	None. In case of any concomitant treatment it will be reported.
STUDY EXTENSION	No study extension.

SUMMARY

PLANTARI FIT, the medical device underwent a comparative clinical study in order to demonstrate that the use of orthotic insoles helps to improve the orthostatic balance (postural stability) and promotes the maintenance of the functional performance in the rehabilitation treatment and in the follow-up. Compliance to the use and the subjective sensation of comfort referred by subjects are evaluated too.
This clinical study was coordinated and supervised by Prof. Matteo Ricci (M.C. – Specialist in Orthopedics and Traumatology, Sports Medicine) and carried out in association with by Dr. Elena Sambugaro M.C. – Specialist in Orthopedics and Traumatology).
24 female and male subjects were selected and divided into 2 groups of 14 healthy subjects and 10 subjects with knee prosthesis, aged between 18 and 70, who had a deficit of orthostatic balance and plantar support. Subjects of each group were evaluated without the use of orthotics and using PLANTARI FIT (LOT A) and PLANTARI FIT (LOT B).

EXPERIMENTAL PART

DEVICE NAME

PLANTARI FIT

USE

The subjects enrolled, healthy or with knee prosthesis, were evaluated with and without orthotic insoles. The use of orthotic insoles is indicated in the instructions for use.

COMPOSITION

See technical file .

EXECUTION OF THE TEST

INSTRUMENTAL PARAMETERS

Static stability (Romberg's test) by means of a force platform (or pressure platform) for the instrumental evaluation of the posture, which measures the components of the constraint reaction to the ground and the movements with respect to the 3 axes for a firm subject in an upright position of it (Fig.1).

The posturographic analysis is represented by the force platforms, namely devices able to detect and quantify the forces exchanged between body and ground through the plantar regions. The analysis of postural oscillations in quiet conditions and absence of external perturbations is called "static posturography".

In the quantitative study of equilibrium, the biomechanical variables of interest are: Center of Pressure (COP), is the centroid of the pressures applied from every point of the plantar surface in contact with the support base. It is a point located within a plan of interest through which passes the line of action of the resultant force vectors. In standing bipedal station, the COP is located under one of the two feet or between the surface.

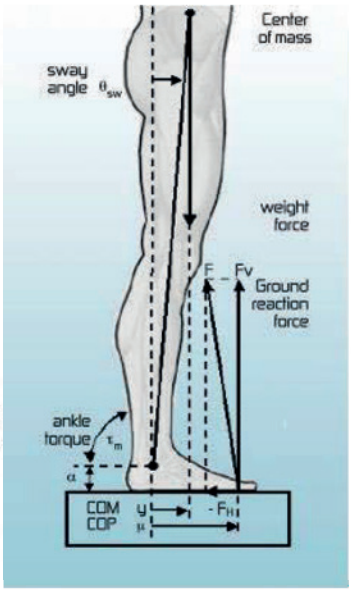


Fig.1. Summary scheme of the biomechanical variables involved in maintaining the upright position

Legend: *Center of Pressure (COP); Center of Mass (COM); Center of Gravity (COG); Center of thrust (CdS); Force of gravity (applied to the COM); Reaction of the soil (applied to the COP); Muscle couple at the ankle; The P highlights dynamic effects related to the accelerations consequent to the activity of the muscles which, by their action, avoid the fall. (Tanzariello, 2012)*

The Center of Mass (COM) is the point of space in which the center of gravity of the weight forces acting on each part of the body. It is usually located in the trunk at the lumbar region.

The Center of Gravity (COG) represents the projection on the ground of the COM.

(Fig.2a-2b)

The force platform registers moment by moment the two coordinates of the Center of Pressure (COP) referring to a Cartesian axis system, defined on its surface. The test involves two tests, one with open eyes (OA) and one with closed eyes (OC).

At the end of the test, therefore, it is available typically a file containing three vectors (Time, COPx, COPy) that provide indications regarding the time course of the COP position, which is graphically represented by the stabilogram (diagram of the x or y coordinate of the COP over time) and the statokinesigram (diagram x vs. y of the COP).

The statokinesigram (**sway**) represents, on the plane, the path made by the COP on the horizontal support surface during the test. The medium-lateral coordinate of the COP is represented on the axis of the abscissas, while the anterior-posterior coordinate is represented on the axis of the ordinates.

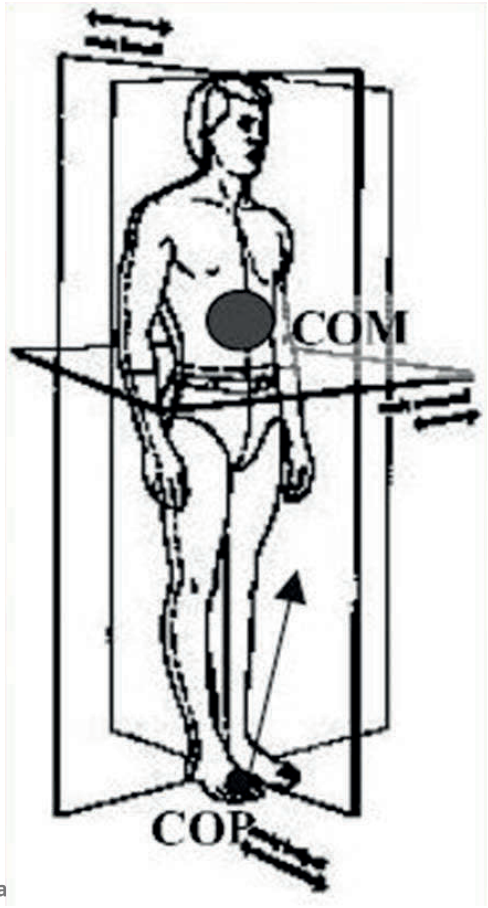


Fig.2a

Fig.2b

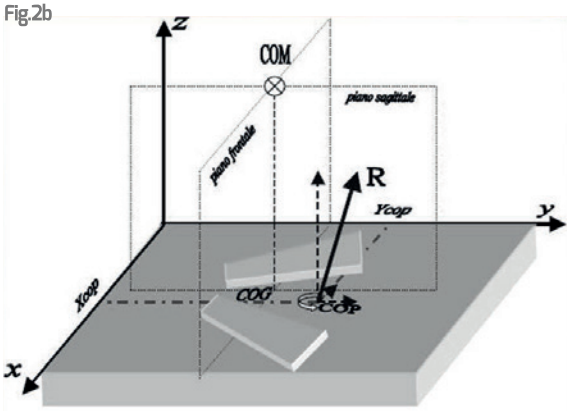


Fig.2a-2b Biomechanical variables in the quantitative study of equilibrium (*Massimiliano Pau*)

It is a qualitative graph that immediately expresses the progress of the COP trajectory.
It is not easy to extract unequivocal quantitative information from the sway, so we resort the definition of a series of standardized parameters. (Fig.3a-3b)

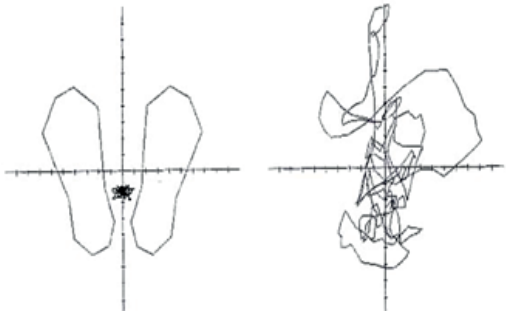


Fig.3a. Statokinesigram
It represents the ground projection of the center of gravity or pressure center; on the left with reference to the platform - on the right the displacement in mm. of the center of gravity
(*Tanzariello, 2012*) (*Massimiliano Pau*)

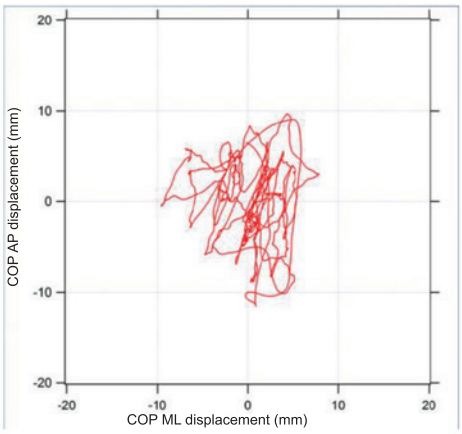


Fig.3b. Statokinesigram (sway) *(Massimiliano Pau)*

The confidence ellipse (or sway ellipse or sway area) represents a measure of the surface amplitude described by the envelope of the positions of the COP, and it is defined as the surface that contains (with 95% probability) the individual points that make up the sway.
About the confidence ellipse we evaluate: Surface (in mm2); Grade of the Major Axis (degrees); Relationship between the axes (eccentricity). (Fig 4)

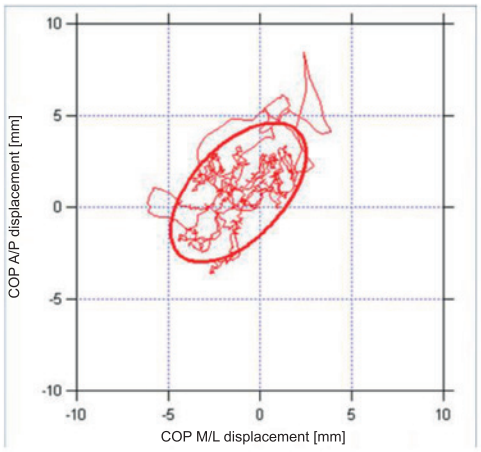


Fig.4.Confidence ellipse (or sway ellipse or sway area)
(Massimiliano Pau)

Static and dynamic baropodometric evaluation by means of a baropodometer for the control of the foot and its functions, useful for the design and correct implementation of orthotic insoles.

Static analysis: The barefoot subject is raised on the platform and in a natural and relaxed position. The instrument acquires the static image resulting from the average of eight consecutive impressions. (Fig.5a-5b-6).

The static analysis provides information on the load points, according to the color scale indicated at the bottom.The points S, C and D should be aligned with each other and positioned centrally with respect to the midfoot.

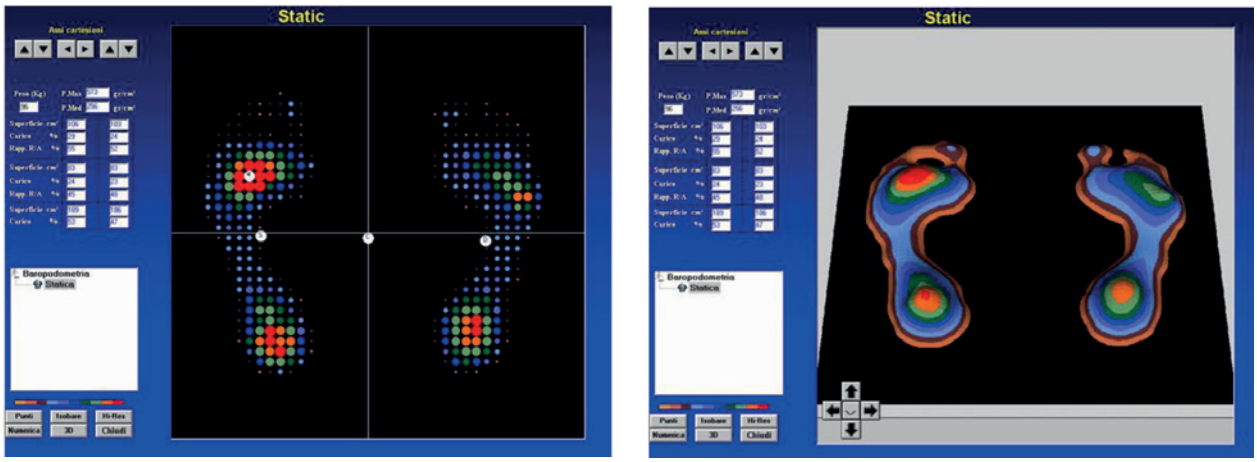


Fig.5a-5b. static analysis

***Legend: M** = maximum load point; C = body center of gravity; S = ground projection of the articular center of the SN limb; D = ground projection of the articular center of the right limb (Ortopedia Barghini)*

(Ortopedia Barghini)

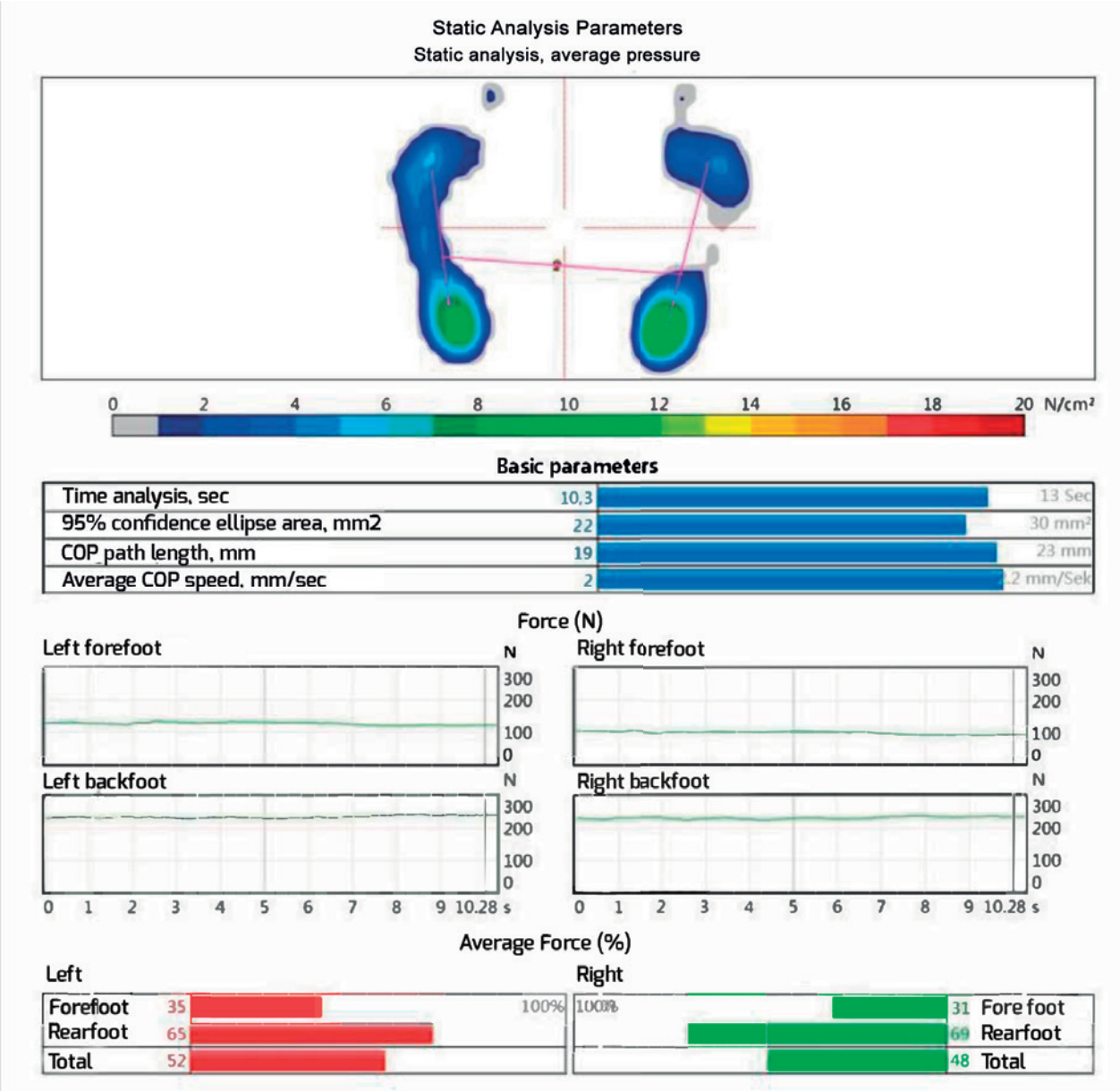


Fig.6. Parameters static analysis

Average pressure, basic parameters, left and right forefoot level (A) and backfoot (R), mean of forces. (Studio Podologico Maria Grande)

Dynamic analysis: The examination is carried out by walking the subject on the platform, to acquire the pressure exerted by each foot on each single sensor, in order to obtain a succession of plantar supports, with representation of the center of gravity for all the stages of registration. (Fig.7a) A correct evaluation involves the execution of at least 4-6 dynamics (each one contains at least one semi-stage or two consecutive footprints in the platform, or one step or three consecutive footprints in the platform). Following the various acquired impressions, the software processes the average pressure impression and the numerical values relative to the quantitative data. This examination must be related to the static survey to verify changes in the values compared to the basic parameters. The study of the movement allows to analyze the actual motor coordination skills of the subject under examination (DCT = Dynamic Coordination Test) and structural pathologies (heterometry-dissymetry, flattening/hollowing, supination /pronation positions, etc.), algogenic reflexes, influences of the visual-vestibular system and CNS disorders. (Fig.7b)

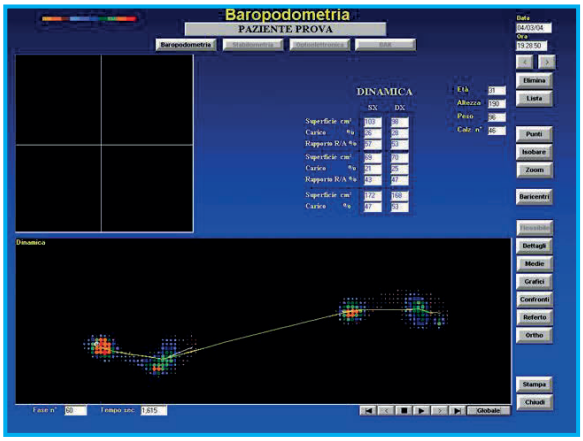
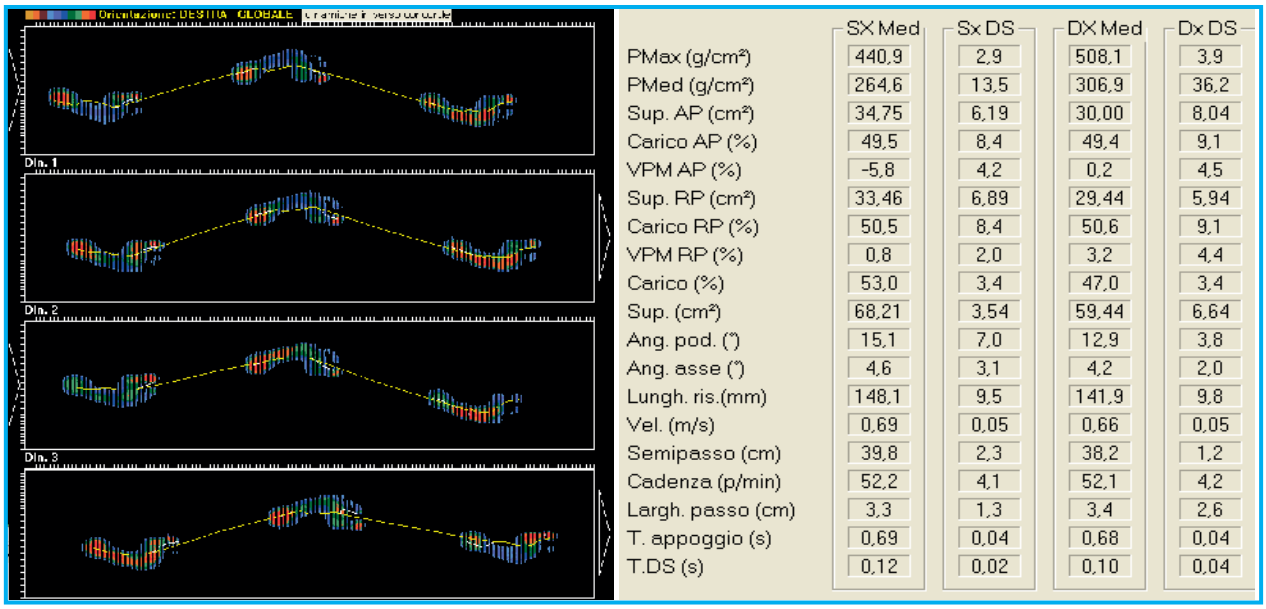


Fig.7a. Dynamic analysis
The yellow line is made up of various barycenters, instant by instant.
(Ortopedia Barghini)



	SX Med	Sx DS	DX Med	Dx DS
PMax (g/cm²)	440,9	2,9	508,1	3,9
PMed (g/cm²)	264,6	13,5	306,9	36,2
Sup. AP (cm²)	34,75	6,19	30,00	8,04
Carico AP (%)	49,5	8,4	49,4	9,1
VPM AP (%)	-5,8	4,2	0,2	4,5
Sup. RP (cm²)	33,46	6,89	29,44	5,94
Carico RP (%)	50,5	8,4	50,6	9,1
VPM RP (%)	0,8	2,0	3,2	4,4
Carico (%)	53,0	3,4	47,0	3,4
Sup. (cm²)	68,21	3,54	59,44	6,64
Ang. pod. (°)	15,1	7,0	12,9	3,8
Ang. asse (°)	4,6	3,1	4,2	2,0
Lungh. ris.(mm)	148,1	9,5	141,9	9,8
Vel. (m/s)	0,69	0,05	0,66	0,05
Semipasso (cm)	39,8	2,3	38,2	1,2
Cadenza (p/min)	52,2	4,1	52,1	4,2
Largh. passo (cm)	3,3	1,3	3,4	2,6
T. appoggio (s)	0,69	0,04	0,68	0,04
T.DS (s)	0,12	0,02	0,10	0,04

Fig. 7b. Dynamic Baropodometry (DCT)
Data acquisition following the execution of the dynamics.
(P. Galasso et al.)

The dynamic examination quantifies qualitatively and quantitatively surfaces and loads, with continuous linear development during the rolling of the center of pressure of the single foot (result of the forces in white color) and of the step (overall result in yellow color). (Fig.8a)
When walking, a polygon of interpodal support is also observed (moment of transfer of the load from

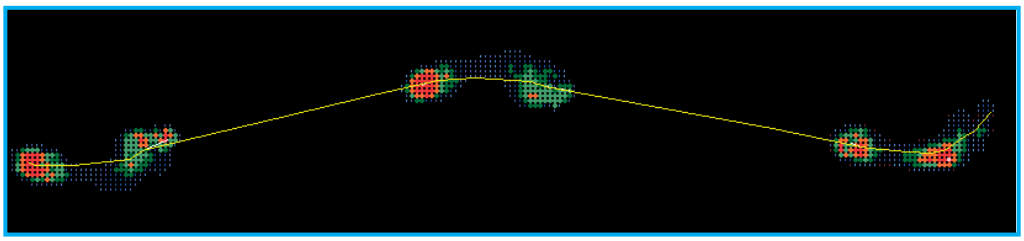


Fig. 8a. Dynamic Baropodometry (DCT) - Step and Interpodal Support
COP of the single foot (resulting of the forces in white color) and of the step (overall result in yellow color) *(P. Galasso et al.)*

one limb to another and therefore of double support), which allows to evaluate qualitatively whether the destabilization of the center of pressure (in the maintenance of equilibrium) can be caused from a wrong contact of the forefoot that comes before or from the backfoot that follows. (Fig.8b)

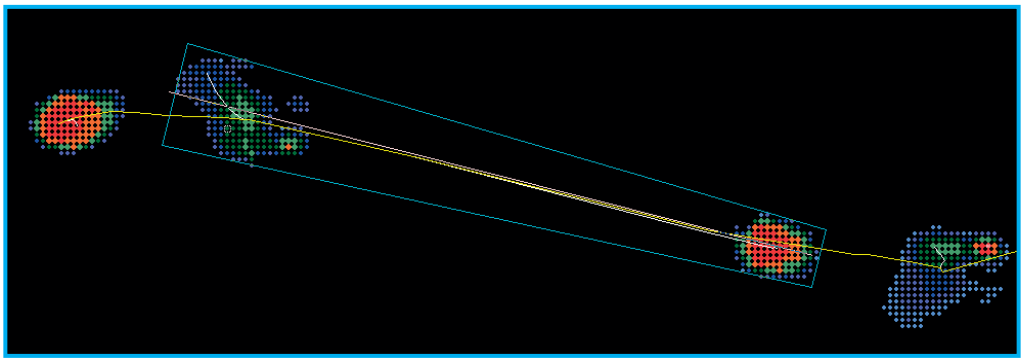


Fig. 8b. Dynamic Baropodometry (DCT) - Step and Interpodal Support
Interpodal support polygon *(P. Galasso et al.)*

SELF-EVALUATION

A series of subjective evaluations were made regarding the product in terms of personal satisfaction and the subjective feeling of comfort. (attached to this document)

STATISTICAL METHODOLOGY

I STAGE OF THE STATISTICAL STUDY

In the first phase of the statistical processing the descriptive analysis was completed with calculation of the maximum and minimum values, average, standard deviation (SD), median (p50) for each variable of the STATIC, DYNAMIC AND ROMBERG analysis.

Standard deviation

The standard deviation or mean square deviation is a dispersion index (that is, a measure of variability of a population or of a random variable) that has the same unit of measurement as the observed values. The standard deviation measures the dispersion of data around the expected value (average)

II STAGE OF THE STATISTICAL STUDY

The second phase of the fundamental statistical study is based on the comparison between lots A, B, SP (without a orthotic insole) for each variable in healthy subjects and subjects with knee prosthesis.

A simple analysis of the variations between lots was not performed, but the individual variation between lots for each individual subject was also considered, in order to make the p value even more significant.

III STAGE OF THE STATISTICAL STUDY

In the third phase of the statistical study, the variations between prosthesis and healthy subjects were analyzed to evaluate how well orthotics can modify the performance compared to healthy by applying the analysis of variance

(Anova test), a case/control comparison is performed taking into account the BMI (which in turn depends on height, weight and age), since this index could have an influence on significance and it is a parameter that distinguishes the two populations compared.

Anova

The analysis of the variance is useful to assess whether the data obtained have a normal distribution between and within the observed groups.

SUMMARIZING TABLES OF THE VALUES

INSTRUMENTAL PARAMETERS

legend

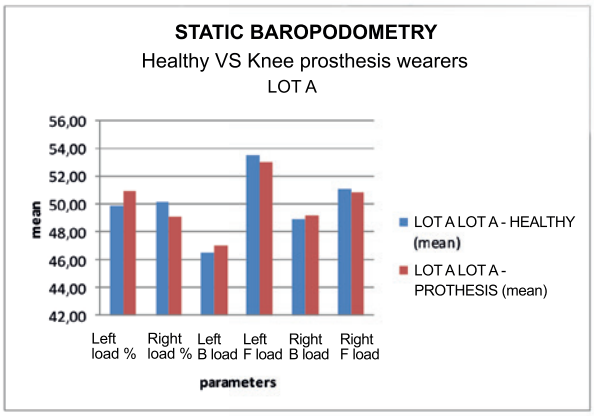
	static analysis	dynamic analysis	Test Romberg
Average DS = standard deviation p50 = median min = minimum value max = maximum value	R = backfoot A = forefoot	E = load/external pressure M = maximum pressure	Ball length = length of ball in mm Ellipse area = surface in square mm OA = open eyes OC = closed eyes

LOT A – PLANTARI FIT

			Variable	N	mean	sd	p50	min	max
Lot A	Healthy	Static	Left load %	14	49.86	2.54	50.5	46.0	53.0
			Right load %	14	50.14	2.54	49.5	47.0	54.0
			Left B load	14	46.50	10.12	46.0	35.0	67.0
			Left F load	14	53.50	10.12	54.0	33.0	65.0
			Right B load	14	48.93	9.21	45.0	38.0	65.0
			Right F load	14	51.07	9.21	55.0	35.0	62.0
		Dynamic	Left E load %	14	50.57	7.90	51.0	33.0	67.0
			Left M load %	14	49.43	7.90	49.0	33.0	67.0
			Right E load %	14	50.50	3.25	50.5	43.0	55.0
			Right M load %	14	49.50	3.25	49.5	45.0	57.0
		Romberg	OE ball length	14	602.95	126.02	576.5	395.0	934.0
			OE ellipse area	14	73.52	62.68	47.4	4.0	210.0
			CE ball length	14	634.28	135.06	602.4	418.0	980.0
			CE ellipse area	14	127.20	108.57	88.0	27.0	367.8
	Knee implant	Static	Left load %	10	50.90	4.98	51.0	41.0	61.0
			Right load %	10	49.10	4.98	49.0	39.0	59.0
			Left B load	10	47.00	6.38	45.0	41.0	60.0
			Left F load	10	53.00	6.38	55.0	40.0	59.0
			Right B load	10	49.20	5.90	49.5	40.0	60.0
			Right F load	10	50.80	5.90	50.5	40.0	60.0
		Dynamic	Left E load %	10	51.10	3.60	52.0	46.0	56.0
			Left M load %	10	48.90	3.60	48.0	44.0	54.0
			Right E load %	10	50.50	3.54	50.5	46.0	56.0
			Right M load %	10	49.50	3.54	49.5	44.0	54.0
		Romberg	OE ball length	10	643.40	134.06	599.3	511.0	934.0
			OE ellipse area	10	71.66	59.40	48.0	4.0	184.0
			CE ball length	10	685.17	134.27	663.1	539.0	980.0
			CE ellipse area	10	149.19	139.26	92.7	27.0	471.0

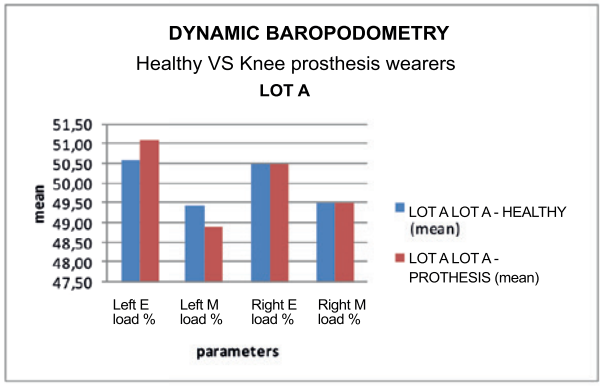
STATIC BAROPODOMETRY

	Lot A	
	Lot A Healthy (mean)	Lot A Prosthesis (mean)
Left load %	49,86	50,90
Right load %	50,14	49,10
Left B load	46,50	47,00
Left F load	53,50	53,00
Right B load	48,93	49,20
Right F load	51,07	50,80



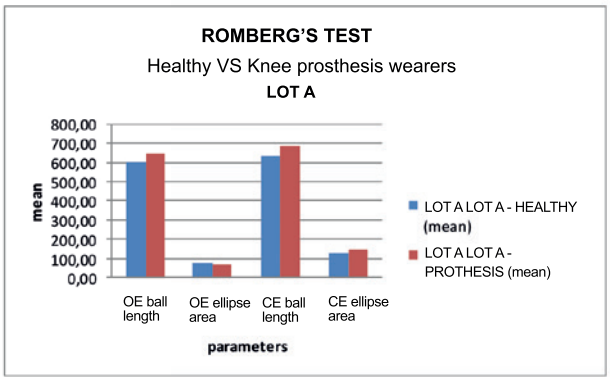
DYNAMIC BAROPODOMETRY

	Lot A	
	Lot A Healthy (mean)	Lot A Prosthesis (mean)
Left E load %	50,57	51,10
Left M load %	49,43	48,90
Right E load %	50,50	50,50
Right M load %	49,50	49,50



ROMBERG'S TEST

	Lot A	
	Lot A Healthy (mean)	Lot A Prosthesis (mean)
OE ball length	602,95	643,40
OE ellipse area	73,52	71,66
CE ball length	634,28	685,17
CE ellipse area	127,20	149,19



legend

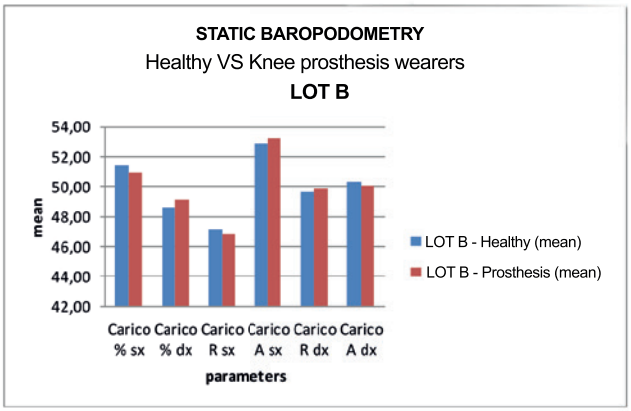
	static analysis	dynamic analysis	Test Romberg
Average DS = standard deviation p50 = median min = minimum value max = maximum value	R = backfoot A = forefoot	E = load/external pressure M = maximum pressure	Ball length = length of ball in mm Ellipse area = surface in square mm OA = open eyes OC = closed eyes

LOT B – PLANTARI FIT

			Variable	N	mean	sd	p50	min	max
Lot B	Healthy	Static	Left load %	14	51.43	2.82	51.5	47.0	55.0
			Right load %	14	48.57	2.82	48.5	45.0	53.0
			Left B load	14	47.14	8.95	46.5	33.0	65.0
			Left F load	14	52.86	8.95	53.5	35.0	67.0
			Right B load	14	49.64	8.12	49.0	37.0	65.0
			Right F load	14	50.36	8.12	51.0	35.0	63.0
		Dynamic	Left E load %	14	50.07	3.85	50.0	45.0	56.0
			Left M load %	14	49.93	3.85	50.0	44.0	55.0
			Right E load %	14	48.93	6.51	52.0	39.0	59.0
			Right M load %	14	51.07	6.51	48.0	41.0	61.0
		Romberg	OE ball length	14	595.38	124.11	562.0	442.0	902.0
			OE ellipse area	14	128.38	134.75	55.5	16.0	399.2
			CE ball length	14	646.19	129.15	610.5	473.0	961.0
			CE ellipse area	14	105.25	80.73	84.5	9.0	265.1
	Knee implant	Static	Left load %	10	50.90	4.07	51.5	43.0	58.0
			Right load %	10	49.10	4.07	48.5	42.0	57.0
			Left B load	10	46.80	5.71	46.0	38.0	54.0
			Left F load	10	53.20	5.71	54.0	46.0	62.0
			Right B load	10	49.90	6.81	52.0	37.0	57.0
			Right F load	10	50.10	6.81	48.0	43.0	63.0
		Dynamic	Left E load %	10	50.10	3.63	50.5	44.0	56.0
			Left M load %	10	49.90	3.63	49.5	44.0	56.0
			Right E load %	10	50.70	3.86	51.5	42.0	56.0
			Right M load %	10	49.30	3.86	48.5	44.0	58.0
		Romberg	OE ball length	10	614.48	128.96	583.8	477.0	902.0
			OE ellipse area	10	83.20	141.63	35.0	16.0	482.6
			CE ball length	10	677.06	129.26	635.1	552.4	961.0
			CE ellipse area	10	151.15	224.23	87.6	9.0	775.7

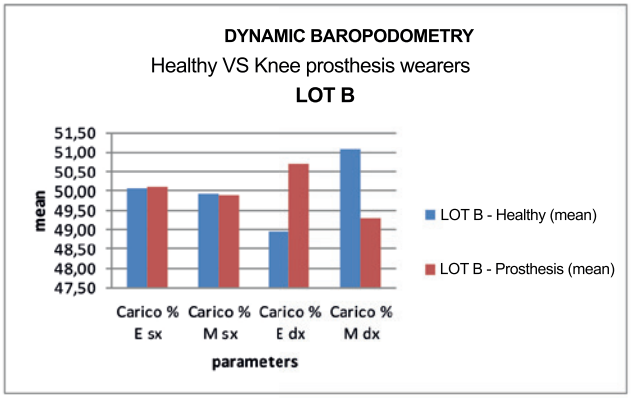
STATIC BAROPODOMETRY

	LOT B	
	LOT B - Healthy (mean)	LOT B - Prosthesis (mean)
Left load %	51,43	50,90
Right load %	48,57	49,10
Left B load	47,14	46,80
Left F load	52,86	53,20
Right B load	49,64	49,90
Right F load	50,36	50,10



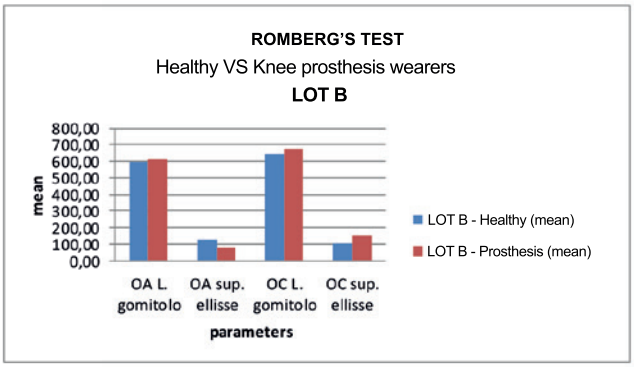
DYNAMIC BAROPODOMETRY

	LOT B	
	LOT B - Healthy (mean)	LOT B - Prosthesis (mean)
Left E load %	50,07	50,10
Left M load %	49,93	49,90
Right E load %	48,93	50,70
Right M load %	51,07	49,30



ROMBERG'S TEST

	LOT B	
	LOT B - Healthy (mean)	LOT B - Prosthesis (mean)
OE ball length	595,38	614,48
E ellipse area	128,38	83,20
CE ball length	646,19	677,06
E ellipse area	105,25	151,15



legend

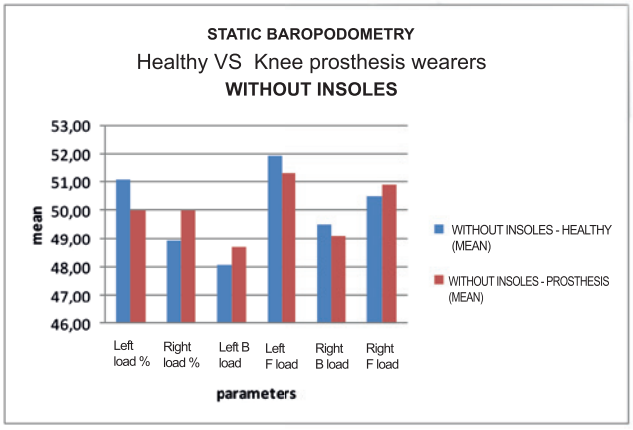
	static analysis	dynamic analysis	Test Romberg
Average	R = backfoot	E = load/external pressure	Ball length = length of ball in mm
DS = standard deviation	A = forefoot	M = maximum pressure	Ellipse area = surface in square mm
p50 = median			OA = open eyes
min = minimum value			OC = closed eyes
max = maximum value			

WITHOUT ORTHOTIC INSOLES

			Variable	N	mean	sd	p50	min	max
Without insoles	Healthy	Static	Left load %	14	51.07	1.69	51.5	48.0	54.0
			Right load %	14	48.93	1.69	48.5	46.0	52.0
			Left B load	14	48.07	10.52	45.0	33.0	67.0
			Left F load	14	51.93	10.52	55.0	33.0	67.0
			Right B load	14	49.50	9.44	49.5	33.0	67.0
			Right F load	14	50.50	9.44	50.5	33.0	67.0
		Dynamic	Left E load %	14	49.57	6.81	47.5	41.0	62.0
			Left M load %	14	50.43	6.81	52.5	38.0	59.0
			Right E load %	14	48.86	4.29	49.5	40.0	57.0
			Right M load %	14	51.14	4.29	50.5	43.0	60.0
		Romberg	OE ball length	14	555.57	108.42	531.6	450.0	877.0
			OE ellipse area	14	164.92	196.52	75.3	14.0	598.0
			CE ball length	14	580.03	111.91	543.4	467.0	877.0
			CE ellipse area	14	125.67	78.78	119.0	42.0	290.2
	Knee impiant	Static	Left load %	10	50.00	2.40	50.5	46.0	54.0
			Right load %	10	50.00	2.40	49.5	46.0	54.0
			Left B load	10	48.70	8.64	46.5	40.0	65.0
			Left F load	10	51.30	8.64	53.5	35.0	60.0
			Right B load	10	49.10	8.16	48.5	38.0	62.0
			Right F load	10	50.90	8.16	51.5	38.0	62.0
		Dynamic	Left E load %	10	50.80	6.36	50.5	42.0	63.0
			Left M load %	10	49.20	6.36	49.5	37.0	58.0
			Right E load %	10	52.00	6.22	50.0	45.0	66.0
			Right M load %	10	48.00	6.22	50.0	34.0	55.0
		Romberg	OE ball length	10	600.39	118.56	572.4	451.2	877.0
			OE ellipse area	10	116.49	158.06	48.3	14.0	492.8
			CE ball length	10	638.64	113.68	625.8	472.0	877.0
			CE ellipse area	10	116.61	90.78	76.1	42.0	300.0

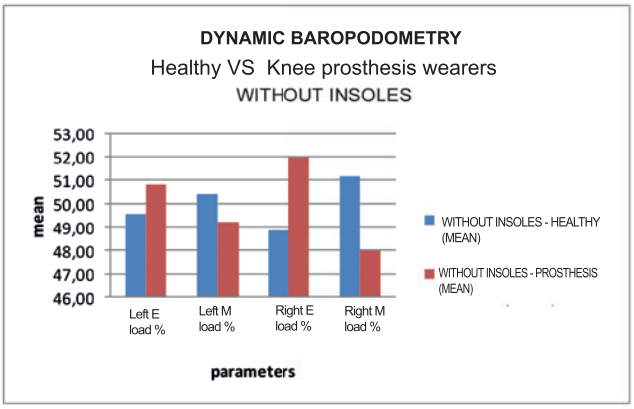
STATIC BAROPODOMETRY

	Without insoles	
	WITHOUT INSOLES HEALTHY (mean)	WITHOUT INSOLES PROSTHESIS (mean)
Left load %	51,07	50,00
Right load %	48,93	50,00
Left B load	48,07	48,70
Left F load	51,93	51,30
Right B load	49,50	49,10
Right F load	50,50	50,90



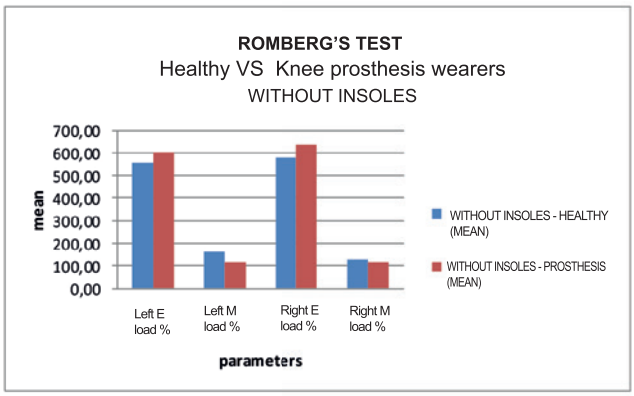
DYNAMIC BAROPODOMETRY

	Without insoles	
	WITHOUT INSOLES HEALTHY (mean)	WITHOUT INSOLES PROSTHESIS (mean)
Left E load %	49,57	50,80
Left M load %	50,43	49,20
Right E load %	48,86	52,00
Right M load %	51,14	48,00



ROMBERG'S TEST

	Without insoles	
	WITHOUT INSOLES HEALTHY (mean)	WITHOUT INSOLES PROSTHESIS (mean)
OE ball length	555,57	600,39
OE ellipse area	164,92	116,49
CE ball length	580,03	638,64
CE ellipse area	125,67	116,61



III STAGE – STATISTICAL PROCESSING

LOT A | LOT B | WITHOUT ORTHOTIC INSOLES

SIGNIFICATIVITY BETWEEN HEALTHY SUBJECTS AND SUBJECTS WITH KNEE PROSTHESIS FOR LOT (P VALUE)

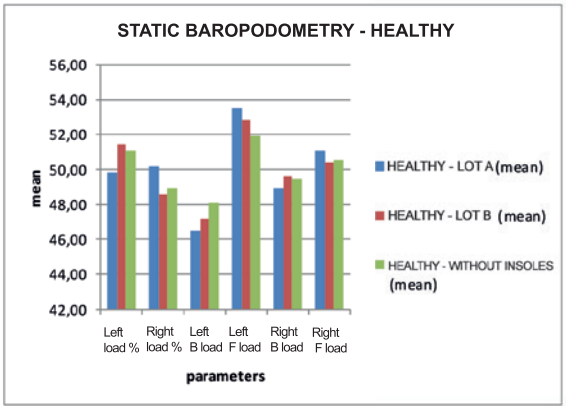
SIGNIFICATIVITY BETWEEN HEALTHY SUBJECTS AND SUBJECTS WITH KNEE PROSTHESIS COMPARISON (P VALUE ANOVA)

STATIC BAROPODOMETRY

	VARIABLE	LOT A	LOT B	WP	P value	P value anova
HEALTHY	Left load %	49.86 -2.54	51.43 – 2.82	51.07 – 1.69	0.2045	0.0816
PROSTHESIS		50.90 - 4.98	50.90 – 4.07	50.00 – 2.40	0.8429	
HEALTHY	Right load %	50.14 -2.54	48.57 - 2.82	48.93 – 1.69	0.2045	0.0816
PROSTHESIS		49.10 - 4.98	49.10 – 4.07	50.00 - 2.40	0.8429	
HEALTHY	Left B load	46.50 -10.12	47.14 – 8.95	48.07–10.52	0.9147	0.6568
PROSTHESIS		47.00 - 6.38	46.80 – 5.71	48.70 - 8.64	0.8032	
HEALTHY	Left F load	53.50 -10.12	52.86 – 8.95	51.93-10.52	0.9147	0.6568
PROSTHESIS		53.00 – 6.38	53.20 – 5.71	51.30 – 8.64	0.8032	
HEALTHY	Right B load	48.93 – 9.21	49.64 – 8.12	49.50 – 9.44	0.9753	0.9518
PROSTHESIS		49.20 – 5.90	49.90 -6.81	49.10 – 8.16	0.9622	
HEALTHY	Right F load	51.07 – 9.21	50.36 – 8.12	50.50 – 9.44	0.9753	0.9518
PROSTHESIS		50.80 – 5.90	50.10 – 6.81	50.90 – 8.16	0.9622	

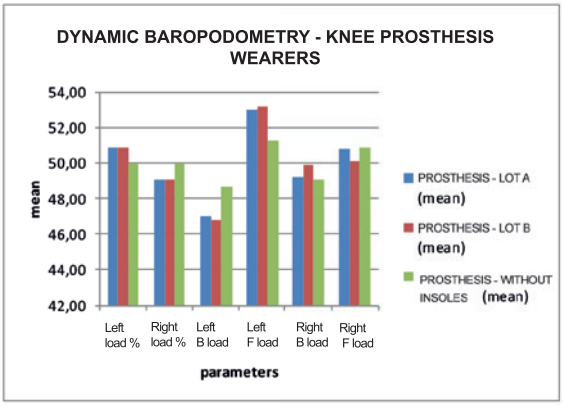
HEALTHY SUBJECTS

	BAROPODOMETRY - HEALTHY		
	Healthy - LOT A (mean)	Healthy - LOT B (mean)	Healthy - Without insoles (mean)
Left load %	49,86	51,43	51,07
Right load %	50,14	48,57	48,93
Left B load	46,50	47,14	48,07
Left F load	53,50	52,86	51,93
Right B load	48,93	49,64	49,50
Right F load	51,07	50,36	50,50



SUBJECTS WITH KNEE PROSTHESIS

	DYNAMIC BAROPODOMETRY - KNEE PROSTHESIS WEARERS		
	Healthy - LOT A (mean)	Healthy - LOT B (mean)	Healthy - Without insoles (mean)
Left load %	50,90	50,90	50,00
Right load %	49,10	49,10	50,00
Left B load	47,00	46,80	48,70
Left F load	53,00	53,20	51,30
Right B load	49,20	49,90	49,10
Right F load	50,80	50,10	50,90

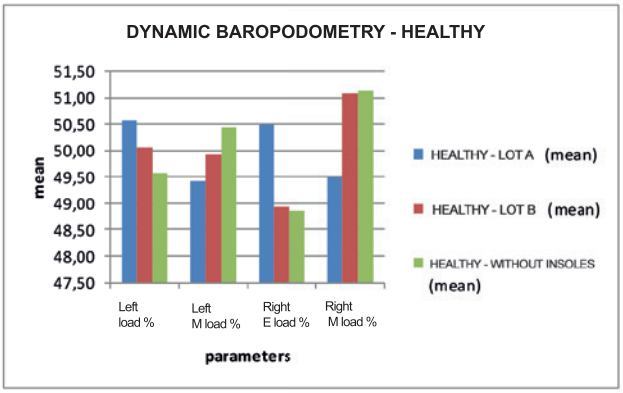


DYNAMIC BAROPODOMETRY

	VARIABLE	LOT A	LOT B	WP	P value	P value anova
HEALTHY	Left E load %	50.57 – 7.90	50.07 – 3.85	49.57 – 6.81	0.9188	0.6556
PROSTHESIS		51.10 – 3.60	50.10 – 3.63	50.80 – 6.36	0.8886	
HEALTHY	Left M load %	49.43 – 7.90	49.93 – 3.85	50.43 – 6.81	0.9188	0.6556
PROSTHESIS		48.90 – 3.60	49.90 – 3.63	49.20 – 6.36	0.8886	
HEALTHY	Right E load %	50.50 – 3.25	48.93 – 6.51	48.86 – 4.29	0.6061	0.3043
PROSTHESIS		50.50 – 3.54	50.70 – 3.86	52.00 – 6.22	0.7424	
HEALTHY	Right M load %	49.50 – 3.25	51.07 – 6.51	51.14 – 4.29	0.6061	0.3043
PROSTHESIS		49.50 – 3.54	49.30 – 3.86	48.00 – 6.22	0.7424	

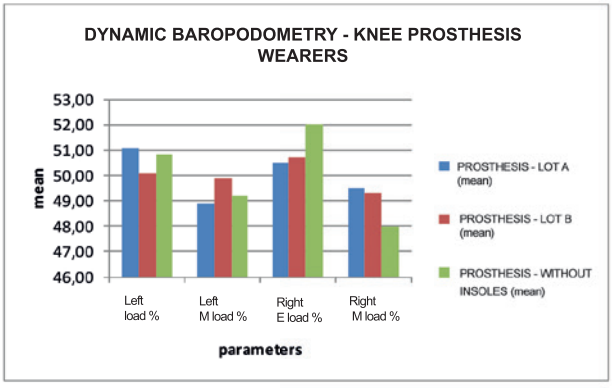
HEALTHY SUBJECTS

	BAROPODOMETRY - HEALTHY		
	Healthy - LOT A (mean)	Healthy - LOT B (mean)	Healthy - Without insoles (mean)
Left E load %	50,57	50,07	49,57
Left M load %	49,43	49,93	50,43
Right E load %	50,50	48,93	48,86
Right M load %	49,50	51,07	51,14



SUBJECTS WITH KNEE PROSTHESIS

	DYNAMIC BAROPODOMETRY - KNEE PROSTHESIS WEARERS		
	Healthy - LOT A (mean)	Healthy - LOT B (mean)	Healthy - Without insoles (mean)
Left E load %	51,10	50,10	50,80
Left M load %	48,90	49,90	49,20
Right E load %	50,50	50,70	52,00
Right M load %	49,50	49,30	48,00



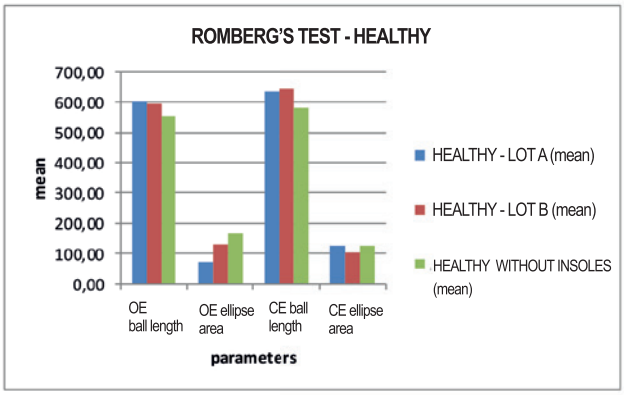
ROMBERG'S TEST

	VARIABLE	LOT A	LOT B	WP	P value	P value Anova
HEALTHY	OE ball length	602.95 -126.02	595.38 – 124.11	555.57 – 108.42	0.5367	**0.0182**
PROSTHESIS		634.40 – 134.06	614.48 – 128.96	600.39 – 118.56	0.7458	
HEALTHY	OE ellipse area	73.52 – 62.68	128.38 – 134.75	164.92 – 196.52	0.2437	0.3610
PROSTHESIS		71.66 – 59.40	83.20 – 141.63	116.49 – 158.06	0.7185	
HEALTHY	CE ball length	634.28 – 135.06	646.19 – 129.15	580.03 – 111.91	0.3426	**0.0019**
PROSTHESIS		685.17 – 134.27	677.06 – 129.26	638.64 -113.68	0.6816	
HEALTHY	CE ellipse area	127.20 – 108.57	105.25 – 80.73	125.67 – 78.78	0.7744	0.6006
PROSTHESIS		149.19 – 139.26	151.15 – 224.43	116.61 – 90.78	0.8657	

OE = open eyes; CE = closed eyes; Measurements in mm

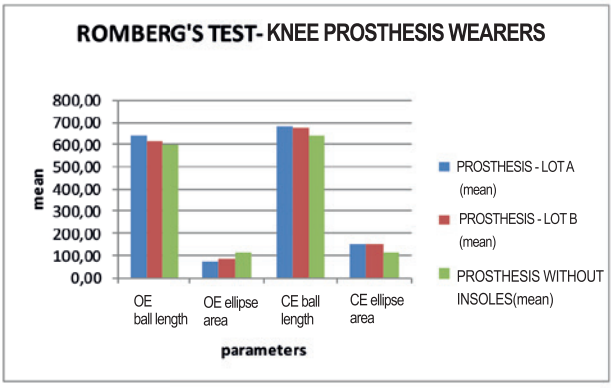
HEALTHY SUBJECTS

	ROMBERG'S TEST - HEALTHY		
	HEALTHY - LOT A (mean)	HEALTHY - LOT B (mean)	HEALTHY WITHOUT INSOLES. (mean)
OE ball length	602,95	595,38	555,57
OE ellipse area	73,52	128,38	164,92
CE ball length	634,28	646,19	580,03
CE ellipse area	127,20	105,25	125,67



SUBJECTS WITH KNEE PROSTHESIS

	ROMBERG'S TEST - KNEE PROSTHESIS WEARERS		
	PROSTHESIS - LOT A (mean)	PROSTHESIS - LOT B (mean)	PROSTHESIS WITHOUT INSOLES (mean)
OE ball length	643,40	614,48	600,39
OE ellipse area	71,66	83,20	116,49
CE ball length	685,17	677,06	638,64
CE ellipse area	149,19	151,15	116,61



PROCESSING AND DESCRIPTION OF THE RESULTS

Significant variations were found in the case / control comparison - healthy / prosthetic subjects for the Romberg's Test.

For **HEALTHY SUBJECTS** the following Anova p value have emerged:

- open eyes test (OA):
  <0.0182: length of sway equal to 602.95 mm of average for lot A and 595.38 mm of average for lot B
  <0.3610: surface of the ellipse equal to 73.52 mm2 of average for lot A and 128.38 mm2 of average for lot B, therefore with a tendency to significance in case of open eyes
- closed eyes test (OC):
  <0.0019: superficie dell'ellisse pari a 127.20 mm^2 di media per il lotto A e 105.25 mm^2 di media per il lotto B
  <0.6006: surface of the ellipse equal to 127.20 mm2 of average for lot A and 105.25 mm2 of average for lot B

Lot A results in greater stability in the length of the sway, especially when the eyes are closed (OC), where the brain control of the subject is less and there is a greater balance induced on the vestibular system.

Furthermore, the **surface of the ellipse** recorded in the open eyes test (OA) becomes an indication of greater stability and balance for **Lot A** in all space planes.

For the **SUBJECTS WITH KNEE PROSTHESIS,** an **analysis of the length of the sway** was carried out, from "without orthotic insoles" altered values with respect to the norms of the normal population (which can be explained with balance alterations related to Age, BMI and previous intervention outcomes), in order to evaluate which lot affects the postural balance of the patient, by evaluating the ΔLot/"without orthotic insoles" (variation in the length of the sway between the lot and the basal value without orthotic insoles).

Length of sway (open eyes):
Δ Lot A/SP = 634.40 mm – 600.39 mm = 34.01mm
Δ Lot B/ SP = 614.48 mm – 600.39 mm = 14.09mm
Length of sway (closed eyes):
Δ Lot A / SP = 685.17 mm – 638.64 mm = 46.53mm
Δ Lot B / SP = 677.06 mm – 638.64 mm = 38.42mm

It follows that the variation and therefore **the effect on postural balance** is greater for **lot A** with both open eyes (OA) and with closed eyes (OC).
As for healthy subjects, the tendency to significance Anova p value <0.3610 of the surface of the ellipse in the open eye test is given by a surface of 71.66 mm2 of average in Lot A vs 83.20 mm2 of average in Lot B, which testifies a greater **stability in lot A**

To the foregoing the questionnaire of personal satisfaction of the subjects and the subjective feeling of referred comfort is added. The preference was 7/10 for Lot A (2/10 indifferent, 1/10 Lot B) with a satisfaction of 4-5 in 100% of the lot A.

It can therefore be stated that Lot A, thanks to the increase in balance and postural stability found in the results obtained by the Romberg's Test, associated with the high degree of personal satisfaction and comfort detected by the subject in wearing the same lot, it can be a valid physiokinetic-therapeutic support and a valid aid in the maintenance of the functional performance in the follow-up.

CONCLUSIONS

According to the obtained results we can state that the class I medical device:
PLANTARI FIT LOTTO A (ACTIVE INSOLES)
on the subjects who underwent the comparative clinical test has confirmed, thanks to the improvement of balance and postural stability as demonstrated by the results obtained through the Romberg's Test, associated with the high degree of personal satisfaction and comfort felt by the subject in wearing the same lot, to be **a valid physiokinetic-therapeutic support and a valid aid in the maintenance of the functional performance in the follow-up.**

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