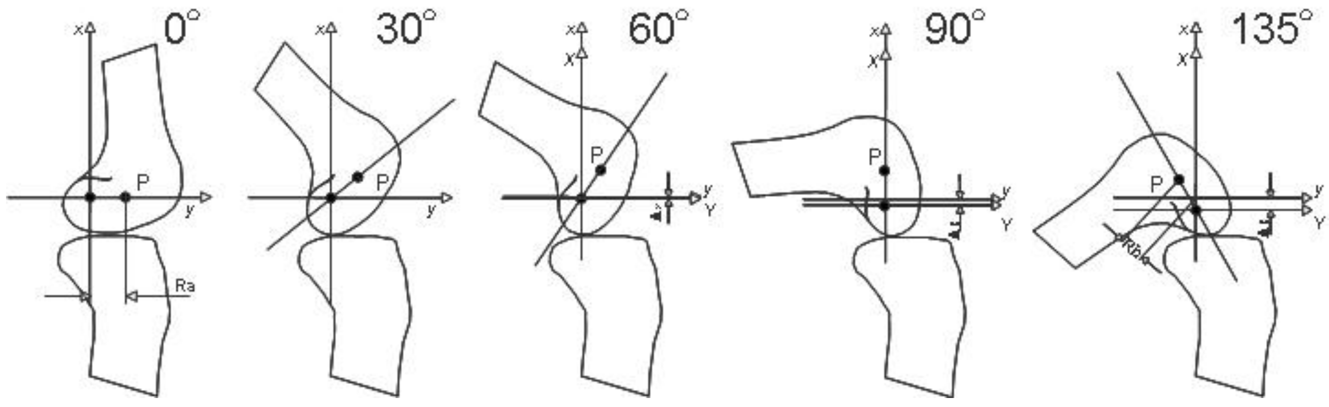
Giancarlo Pellis

KTJ® System

Joint with variable center of rotation that repeats the physiological knee motion

Biomechanics of the knee:

help for the elderly and athletes



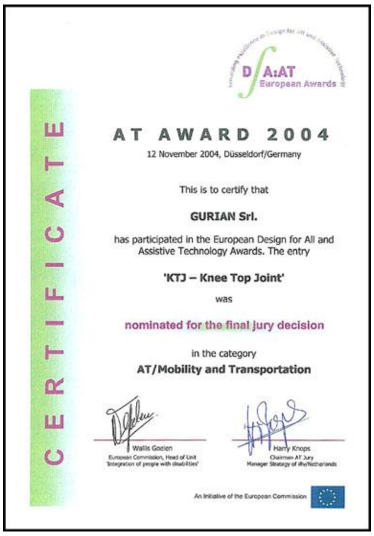
KTJ System awards

*I*st *Award GENIA PATENT WORLD Milano 1997*

MEDAILLE D'OR 28° Salon International des Inventions Genève 2000

PRIX DU SALON NATIONAL ITALIEN DE L'INVENTION
28° Salon International des Inventions Genève 2000

PRIX IFIA
FEDERATION INTERNATIONALE des ASSOCIATIONS d'INVENTEURS
28° Salon International des Inventions Genève 2000



AT AWARD 2004 12 November 2004, Düsseldorf /Germany

Isokinetic 2008 Winner of the poster presentation award Bologna 2008

Presentation

The work describes the implementation of

joint with variable center of rotation

as a mechanical organ that mimics the physiological roto-translational motion of the knee and is applicable to orthopedic devices addressed to knee physical therapy.

The results recorded so far enable us to state that the KTJ devices create favorable conditions not only for the recovery of walking (braces), especially in elderly with degenerative diseases, but also in reducing recovery times postoperatively (applying on the machines for passive gymnastics).

The results of the studies done, may also be considered as a response to what Insall (86) wrote about the **"Lack of significance of studies on the knee kinematics based on anatomical location of the instantaneous center of rotation"**.

The author

Premise

The idea came from the consideration that some athletes while using the "leg extension" (Fig. 1), as sports equipment for the extensor musculature strengthening of the lower limb, complained about knee pain.


Fig 1

Wanting to determine the causes of such pain, it was initially hypothesized the possible incompatibilities between the knee motion as joint subjects of the exercise and the kinematics of the movable arm of the machine that develops around a fixed center.

The bibliographic analysis

To try to determine the reason of the above, initially, was carried out a meticulous bibliographic analysis that almost unequivocally confirmed that the knee has a combined motion between rotation and sliding. In particolarly most of the authors consulted

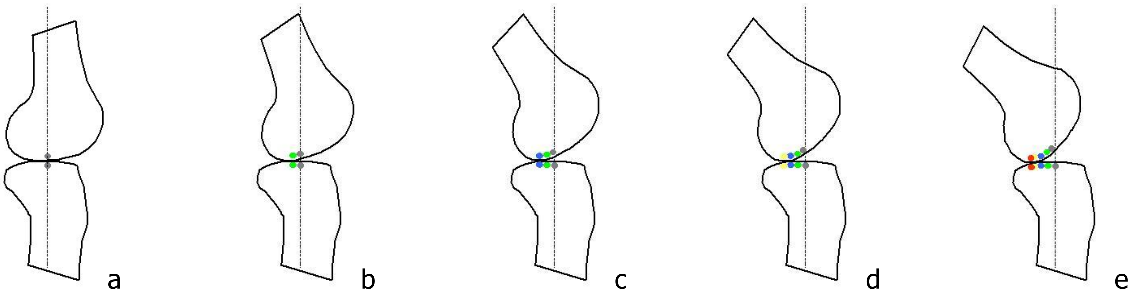
(SMIDT, 1973; FUMAGALLI ET AL.,1977; MARINOZZI end PAPPALARDO, 1977; KAPANDJI, 1977; TITTEL, 1979; FLEISCHMANN AND LINE, 1981; NISSEL, 1985; INSALL, 1986, DRAGANICH et al., 1987; YAMAGUCHI and ZAJAC, 1989; MELEGATTI, 1997; STEINBRÜCK, 1997) agreed that for the first 25-30 degrees of flexion the femoral condyles (femur distal part) roll on the tibial plateau (tibial proximal part)(Fig. 2a, b, c, d, e);

from 25-30 degrees onward, the femoral condyles combine the rotary motion with the translatory one (of sliding) that with the increasing of flexion, becomes more important (Fig. 2f, g, h, i).

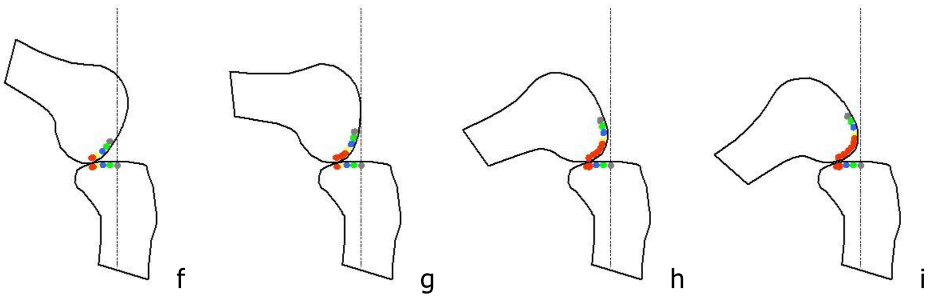
This trend is confirmed by the anatomical conformation of the articular surfaces which constitute the knee : the femoral condyles have a rounded surface with a curvature radius somewhat reduced, but not uniform so that their profile is very similar to those of a spiral, while the tibial plateau are defined plateau because their curvate radius is much wider than those of the femoral condyles.

Fig. 2

Roll phase



Rototranslation phase



Moreover, the development in length of the femoral condyles is almost two times greater than the length of the tibial articular surface.

This prevents the possibility of a pure rolling between the two articular heads, which is limited for the first 25-30 degrees of flexion.

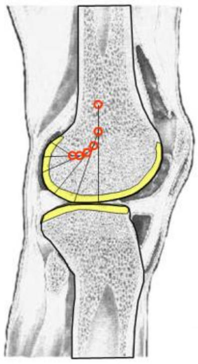
In subsequent degrees, the rolling is combined with a sliding phase which becomes more and more progressive.

In the flexion-extension, the cruciate ligaments retain the articular heads ensuring contact and antero-posterior stability of the knee during the whole movement which proposes a **roto-translational** motion.

Functionally, this system ensure that in the deambulatory support phase (action that in life is repeated innumerable cycles of times), during which the knee reaches a flexion of 20-25 degrees, there is only a rotary motion which mechanically protects the articular surfaces from usury of friction.

More precisely, at every point of contact of the femoral condyle is a corresponding point on the tibial plateau. This means that the mechanical forces, developed by the burdening of body weight, are transmitted by compression, without provoking usury. The compression, in fact, does not provide friction since the load is always transmitted on the same points of the adjacent articular heads in contact and is completely independent from burdening of body weight.

In flexion angles over 30 degrees (thrusts with squatting, relapses, bending -ex. In sky-, pedaling, ecc.) friction action occurs always in a manner directly proportional to the degree of bending reached and the usury is proportional to the subject weight.



The center of rotation

From the analysis of the roto-translational dynamic as reported above, we deduce that in the flexion-extension mechanics, the knee does not perform a pure rotary motion pivoted on a single fixed center, but these moves in function of the degree of flexion reached. By the maximum extension of 25 degrees of flexion the center of rotation remains positioned in a fixed point (**initial center of rotation);** after the 25-30 degrees of flexion the instantaneous center of rotation tends to move in an increasingly important way towards the articular surfaces (**istantaneous center of rotation**) (Fig. 3).

We can, therefore, hypothesize that the variation of the center of rotation causes a change in knee-malleolus length. In fact, the distance between the initial center of rotation and an anthropometric point located on the malleolus of the leg (Ra) is greater than the distance between the instantaneous center of rotation located at the maximum flection and the same point malleolar (Rb) (Fig. 4).

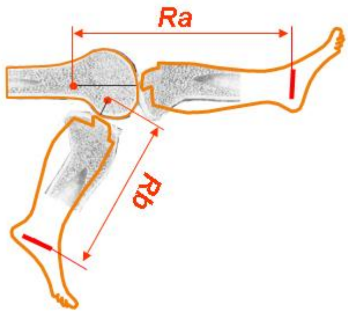


Fig. 4

Consequently if the knee is made integral to a mechanical device that rotates around a fixed center, the difference between the path of the knee and that of the mechanical device, produces a distancing between the articular heads because the mechanical system is "stronger" than the organic one and drags the articular heads on its own trajectory that does not change its amplitude.

This is what happens,during a strengthening exercise of the extensor musculature of the lower limb to the leg extension when the leg is made integral to the movable arm of the machine.

The leg extention

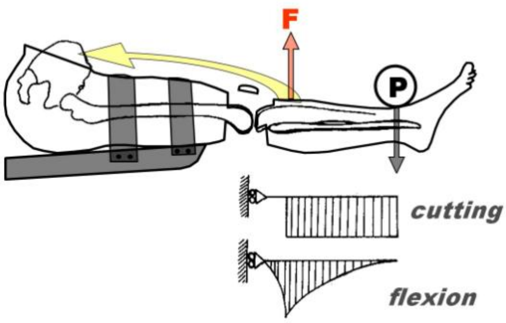
Following the bibliographic analysis it was carried out those on the kinematic mechanism of the leg extension**.**

This equipment is like a chair rather high which is laterally connected with a movable arm of load that vertically runs, along the longitudinal axis of the leg and rotates around a fixed center whose axis of rotation must be coaxial with the horizontal axis which transversely passes to the femoral condyles.

The movable arm in its distal part is connected to a load P that has to be won in leg extension on the thigh by the contraction of the quadriceps muscle (Fig. 5).

When extension is complete, the leg is located in line with the thigh, which remains resting on the seat of the equipment while the leg is without any support.

For a detailed mechanical analysis on the distribution of forces acting in the specific exercise you can then differentiate two situations: one static and one dynamic.



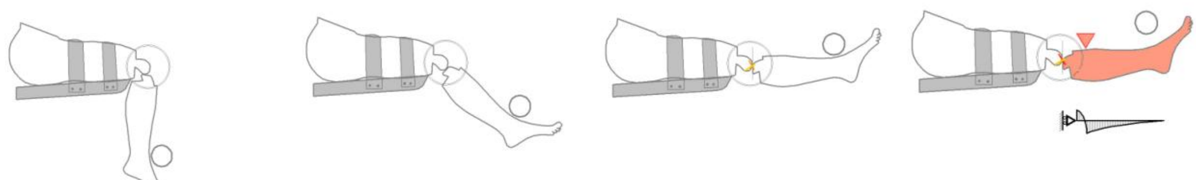
For this purpose the leg itself has been compared to a cantilever beam, hinged on a carriage placed on the articular plane of the knee -vertical plane tangent to the point of contact between the tibial plateau and femoral condyles and restrained by an elastic structure (cruciate ligament) and constructed the diagrams of cutting and flexion (for cutting we mean a force acting on the vertical plane, which has an intensity equal to the applied load in all the points of the beam and for flexion we mean the product loading / arm that is determined in each point of the beam).

In static the cutting and flexion diagrams show a precise balance between the loads acting on the beam (Fig. 5).

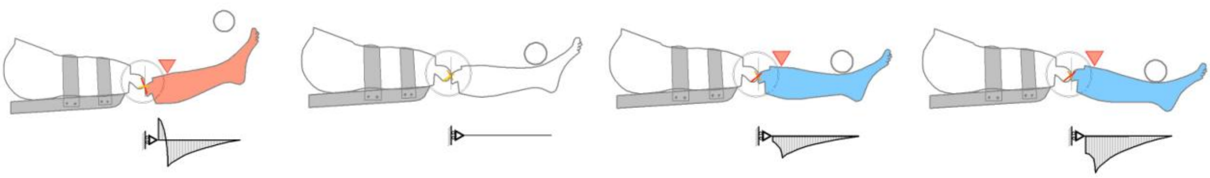
In the dynamics, however, the inertia of the moving masses develops stress of "<u>bounce</u>" that discharge on the cruciate ligaments.

In the extension, in fact, the kinetic energy acquired by the movable arm (Fig. 6a, 6b, 6c) tends to continue the overload against gravity. At full extension, with the maximum contraction of the quadriceps, the point of insertion of the latter on the tibia (tibial tuberosity located at few centimeters of the articular plate) becomes the fulcrum of the system (Fig. 6d) around which the distal part of the leg and foot, dragged by the force of inertia due to motion, continues moving on the vertical plane; to this "rise" is opposed a lowering of the proximal portion (tibia head), which puts traction the posterior cruciate ligament (Fig. 6e).

When the load reaches the top dead point, turns "raising" potential energy, that after returning to weigh on the leg (Fig. 6f) creates a condition of "tilt", by lowering the distal part of the leg and foot to which is opposed the lifting of the proximal portion (tibia head); this impulsive action puts in traction the anterior cruciate ligament (Fig. 6g, 6h).



a b c d



e f g h

The alternation of traction on the cruciate ligaments is analogous to a "rebound", which can be highlighted with the abnormal closing of the diagram of flexion (Fig. 6d, 6e, 6g, 6h) and creates a microtraumatic condition which on an healthy knee can be accidentally felt ,while on one traumatized even partially knee, may cause particularly adverse effects and pejorative.

At the phenomena of "rebound" has been attributed the cause of the pain complained by some athletes as initially described.

The discharge of the rebound

To avoid that stress of "rebound" are discharged within the knee, it is essential to anchor all the lower limb to the machine (the thigh to the seat and the leg to the movable arm) so that this "damaging" stresses are absorbed by the mechanical organ.

This operation, however, is not possible with current leg extension because there is a further problem related to the difference in machine / knee trajectory, also highlighted by the biobliographic analysis.

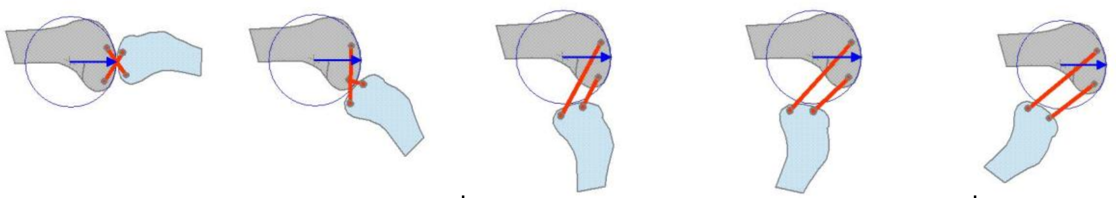
The movable arm moves, in fact, only with a rotary motion around a fixed center while the knee, after the 30 degrees, performs a roto-translational motion.

This implies that if the leg is anchored to the movable arm, it will drag the knee on its trajectory with fixed center.

So:

with the leg anchored in extension, the latter during flexion will be removed from its root with great ligament suffering (Fig. 7a, b, c, d, e)

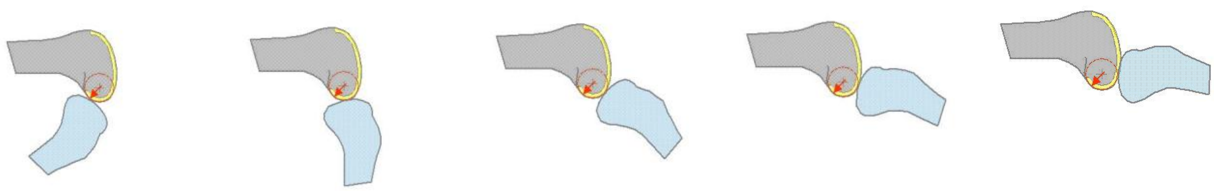
Fig. 7a, b, c, d, e



a b c d e

with the leg anchored in flexion, extension the latter during extension will create a strong compression of the articular heads with severe cartilages and meniscus pain (Fig. 8a, b, c, d, e)

Fig. 8a, b, c, d, e



a b c d e

The resolution of the problem, therefore, must necessarily provide that leg extension proposes a roto-translational movement of the movable arm, similar to those of the knee so that we can anchor the whole lower limb to the machine (the thigh to the seat and the leg to the movable arm) without causing removal situations between the articular heads and at the same time to discharge the "bounce" on the machine structure (Fig.9).

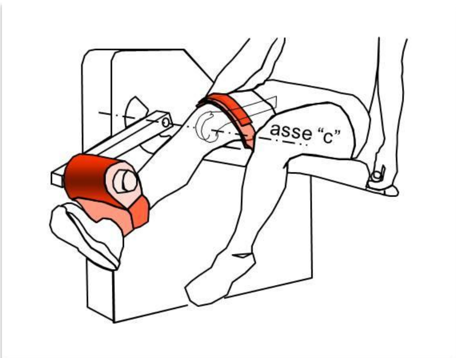


Fig. 9

KTJ system Joint with variable center of rotation

1^{st} part

1 - biomechanical experimental works which contributed to the realization of mechanical roto-translational device

Inspired by what was written by Insall (86) on the **"Lack of significance of studies on the kinematics of the knee based on anatomical location of the instantaneous center of rotation"** the knee motion was analyzed by a mathematical/experimental point of view in order to achieve a mechanical device that respects the physiological roto-translational movement.

Operationally, therefore, the purpose was to verify the variation of the distance between the center of rotation located on the femoral condyles to the various degrees of flexion (Kapandji 1977) and a point anthropometric (external malleolus) located on the leg itself. It should be noted that while the anthropometric point was perfectly traceable, the center of rotation had absolutely no chance to be traced visually or by touch.

1.1. - The realization of the equipment for the evaluation

For this purpose an instrument has been developed, similar to a leg extension, provided with a double-reading device, to be able to simultaneously carry out an angular reading (angular encoder - Fig 1.1) on the degree of flexion of the knee and a linear (linear encoder - Fig 1.1) in order to determine the eventual "length variation" of the leg during flexion.

Both the measuring instruments were connected to a computer for simultaneous storage and processing of measurements taken. The machine was then equipped with a movable seat driven by a motor connected to the computer capable of moving antero-posteriorly the session with a tolerance of 0.1 mm.

Particular care has been taken in the "support system" (Fig. 1.1) of the knee structured in two lateral semi-supports, inclined and converging downward, of which the lateral one could transversely slide and approach to the medial.

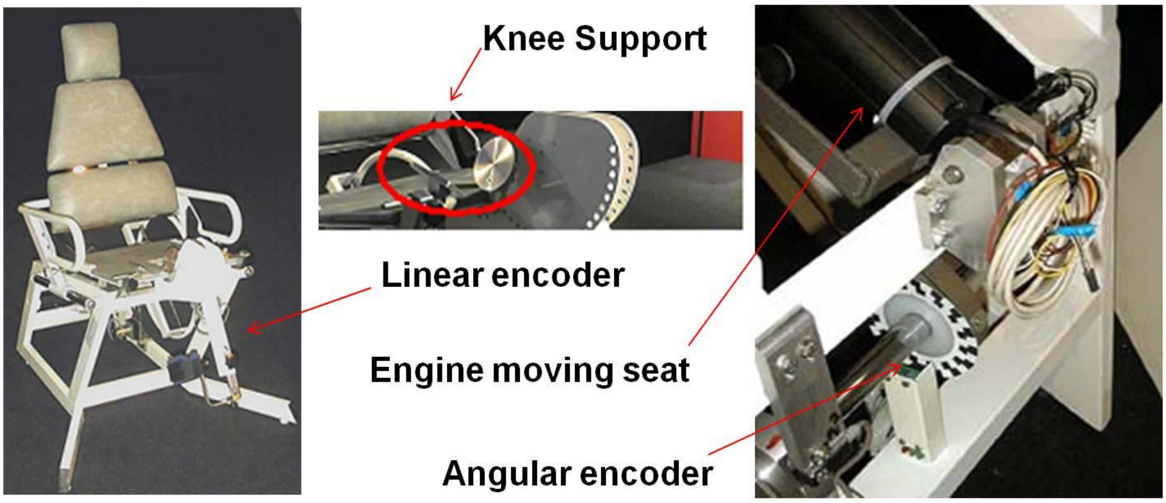


Fig. 1.1

This system has been structured in this way for a double reason:

- the first to ensure that the contact between the popliteal area of the knee and the machine is carried out on "rigid" part of the femoral condyles and not on "soft" muscolar ones (which support of the rear part of the thigh on the seat of the machine), in order not to affect the linear measurement with the swelling of the musclolar ischio-crural mass due to the shortening of the rear compartment of the thigh during flexion;
- the second to allow the possibility, approaching or moving away the two supports,to move vertically the horizontal intercondylar axis of the knee for greater precision in knee / machine alignment.

Procedure of alignment machine / knee

Experimental research of the initial center of rotation

The alignment machine / knee, is performed by executing a flexion-extension with an amplitude of 25-30 degrees after fixing the thigh to the seat of the machine and foot / malleolus (as anthropometric reference) to the the linear feedback placed on the movable arm (Fig. 1.2).

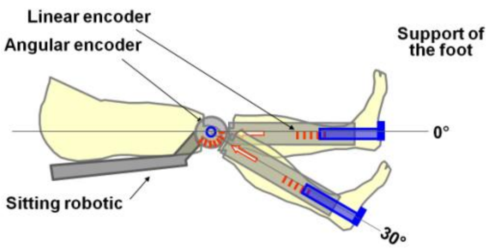


Fig. 1.2

If during the execution of a flexion-extension of about 30 degrees of the leg, so connected to the movable arm of the machine, it is not highlighted any movement through the linear encoder, we can consider that the leg has carried out an arc of a circle centered on the initial center of rotation and the latter coincides with the center of rotation of the movable arm. In this case, we can consider that the transverse intercondylar axis of the knee and those passing through the rotation pin of the movable arm are aligned.

Conversely, when in the first 30 degrees of flexion is highlighted a displacement of the reply, it is determined a condition of non-alignment that movement is processed by the computer which, through the engine, moves the seat to a new location finding the coincidence between the two axis of rotation.

In particular, if the trajectory of the machine is closer that of the leg, the knee is backward and so must be advanced (fig. 1.3a, b, c).

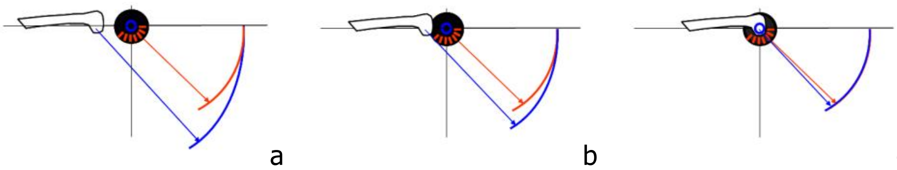


Fig. 1.3 a b c

if the trajectory of the machine is wider than those of the leg the knee is advanced, the knee has to be demoted (fig. 1.4a, b, c).

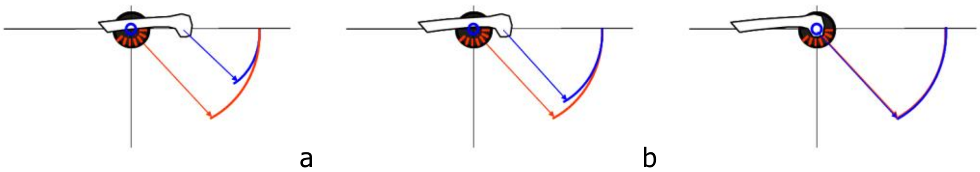


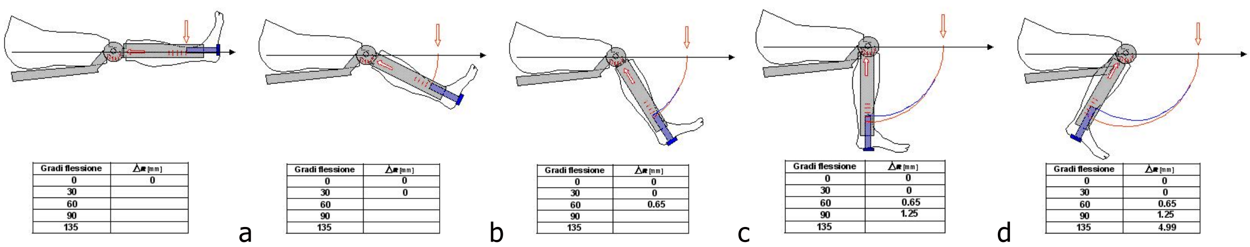
Fig. 1.4 a b c

The "alignment " phase is therefore indispensable to research in an experimental way to the center of initial rotation of the knee and make it coincides with the center of rotation of the movable arm of the machine.

The initial center of rotation of the knee, then, becomes a point of "landmark" necessary to repeat a new evaluation.

The evaluation

After the alignment phase the evaluation is performed by making do to the leg a full flexion up to 135 degrees (goniometric), picking up during the range of motion the values of the return of the foot only to specific angles of flexion (Fig. 1.5a, b, c, d, e).



a b c d e

Fig. 1.5

Using the instrument described it has been conducted the study below, from which was then made the roto-translational device.

1.2 - The ROTOTRANSLATORY motion : Experimental studies, mathematical analysis, orthopedic device.

Pellis G., Di Cosmo F.

Calzetti Editore, Perugia, atti del XVIII edizione del Convegno di Traumatologia e Riabilitazione Sportiva, Bologna, 2009

Premise - Femoral and tibial movement is about, for the first 30° of flexion, the rolling of femur, between 30 and 135 degrees is associated with a progressive anterior translation of the femoral condyles. This means that the center of rotation of the knee is not fixed, but variable depending on the degree of bending joint

A brace for the knee should take into account this fact, largely confirmed by literature.

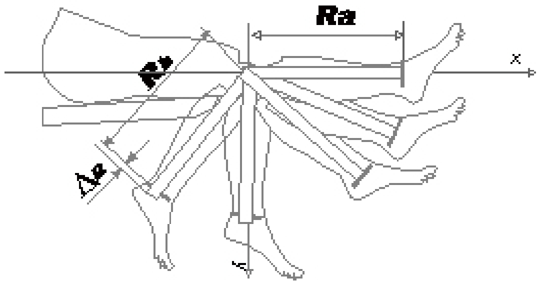
Purpose - The purpose of the study is to demostrate the mathematical basis of the project which are the foundation of a mechanic device that must respect the variability of position of the center roto-translatory of the knee.

Materials and methods - We used a "Leg extension" on which we added a system for measuring the position of the fibular malleolus to the (fixed) center of rotation of the machine. This measure in order to predict the apparent shortening of the leg in flexion. We chose to take the malleolus as a reference distance of the tibial plateau for the difficulty of a direct measurement. Given that, on the sagittal plane, the initial center of rotation of the knee coincides with the intersection of the x,y axes, on this basis we can say that in the full knee extension the x-axis of the leg js co-aligned with the x-axis of the femur. Starting from the hipothesis that in flexion of the knee, the istantaneous center of rotation (P) changes its position relative to the tibial plateau, approaching in the same way, we wanted to quantify the extent of this shift. For this purpose we used a "leg extension" associated with a system for measuring the distance between the fixed center of rotation of the machine and the apex of the lateral malleolus of the leg obtaining an indirect measure of the displacement of the center of rotation relative to the tibial plateau.

Calling R_a the measured distance with the knee extended and R_b that measured with the knee flexed, we concluded that the Δ_R corresponding to R_a- R_b.

The study was carry out on 83 men between 16 and 19 years old (average height cm 173,8 ± 5,89).

Detections were made in the extention, at 30,40,90 and 135 degrees of flexion.



Results - The results have been collected in table 1.2.A

Tab. 1.2.A

Flex [°]	0	30	45	90	135
Average Δ_R	0	0	0,04	1,25	4,99
δ	0	0	0,005	0,22	0,35

They show that the radius of rotation of the knee remains constant up to about 30 degrees of flexion (circular trajectory). For angles above 30 degrees the radius of rotation decreases the value Δ_R.

In other words ,the movement of flexion of the knee after an initial circular trajectory associates a sliding highlighted by the previous decrease of the distance between the center of rotation and the tibial articular surface. The displacement of the point P for first 30 degrees can be represented by the equation:

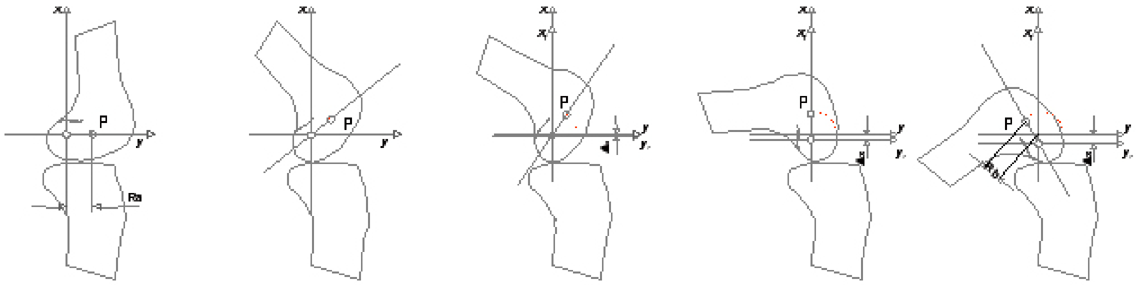
$$x^2+y^2=r^2 = R_a^2$$

which corresponds to a circle and for the next range of motion, until 135 degrees of flexion, by the equation:

$$\mathbf{x = x - x_1 = (R_a - R_b) \cos ø}$$

It seems important to note that, when Δ_x is small enough compared to R_a, moving the center of rotation along the axis X can be neglected.

We then built a mechanical device that allows the projection on it of the rotation center of the knee mimics the physiological movement of it.



This was achived by inserting two pins on a first plante (femoral): a central pin placed at the intersection of the axes x,y and a peripheral one placed at the point P. On a second plate (tibial) , there are also two openings, one peripheral with a circular path for the first 30 degrees ,which assumes a spiral trend similar to the pathfollowed by the point P and a centrel one , that originates at a point corresponding to the intersection of the axes x,y with an extension along the x axis equal to Δ_x as calculate above.
This mechanical system, when used as a hub for a knee brace , is therefore respectful of the dynamic relationships of the articular, bones and capsule-ligamentous components.

Conclusions - The mechanical device repeats the roto- translatory motion of the knee and can be used with advantage in all orthopedic rehabilitation equipments, which assist flexion-extension of the knee movement.

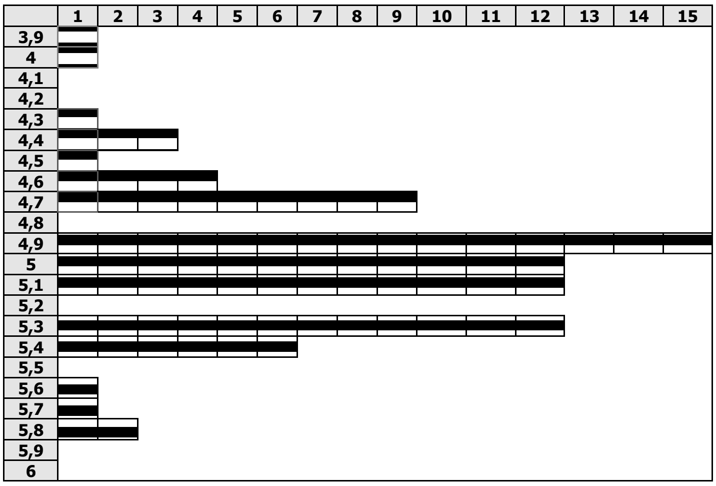
In fact, it does not creat conflicts between the physiological and mechanical trajectory which could trigger voltages damaging to traumatized organs.Further reflections on the parallel knee/device have given rise to the belief that the roto-translatory motion should also apply to an assement tool for a real measure of the degree of flexion-extension of the knee.

This aspect is deeply developed in the study reported in the following pages.

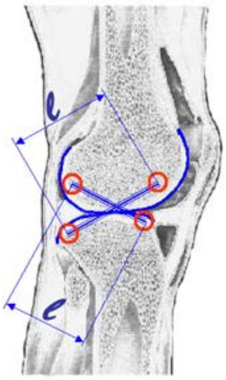
1.2.1 - The statistical verification made on observations

The statistical verification of the observations has been set on the analysis of all experimental data collected for each subject tested.
Placing each single result Δ_R (to 135 degrees) depending on the number of cases represented, there is to determine a distribution characterized by the fact that (Tab. 1.2.1.A):

Tab. 1.2.1.A



the average value (4.99) ± δ Δ_R includes about 2/3 of the observations;
the average value (4.99) ± δ 2 Δ_R includes 95% of the observations;
the average value (4.99) ± 3δ Δ_R includes 99% of the observations



This confirms very clearly that each person has its own articular path.

It can therefore also be said that the articular profile of the rear part of the femoral condyles is a genetic trait of the individual, and the conformation of that profile can be determined as a result of the length $(l \text{ e } l_1)$ of the cruciate ligaments, of their proportion and of the arrangement of their insertion.

1.3. - The automatic longitudinal rotation of the tibia

The articular mechanics of the knee is complex and the type of movement carried out is in direct relationship with the opening angle of the knee. Taking, in fact, as a starting point the extended lower limb, in the first phase of flexion the leg makes a motion of pure rotation. From this angle onwards, we assist to a double movement of rotation and sliding.

In addition to this movement, called roto-translational, the leg itself makes an automatic longitudinal rotation, compared to the thigh, which some authors estimate in the order of 20 degrees due to (fig. 1.3.1. - da Kapandi 87, pag. 89) :

1 - the different development of contour of the femoral condyles, the more extended the outer than the inner;

2 - the shape of the tibial articular surfaces of which the inner concave and convex the external;

3 - the orientation of the collateral ligaments because of the internal collateral ligament tends more rapidly than the outer, this leaves to the external condyle greater freedom of movement because it is oblique.

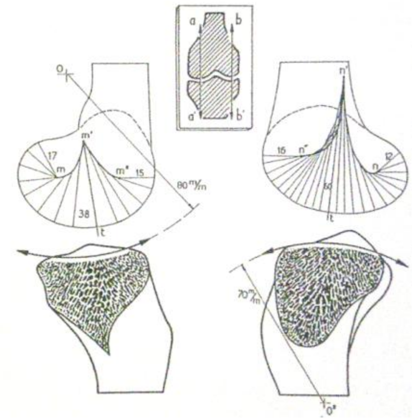


Fig. 1.3.1.

Then there are pairs of rotation determined by the predominantly action of the external flexor muscles (muscles of the leg of goose and popliteal) and by the tension of the anterior-external cruciate at the end of the extension that goes beyond the axis and leads to an external rotation.

When the leg is extended (figures 1.3.2. and 1.3.3.), the contact between the medial femoral condyle and the tibial plateau of the medial compartment falls at point A, while the contact between the lateral femoral condyle and tibial plateau of the lateral compartment, falls at the point B.

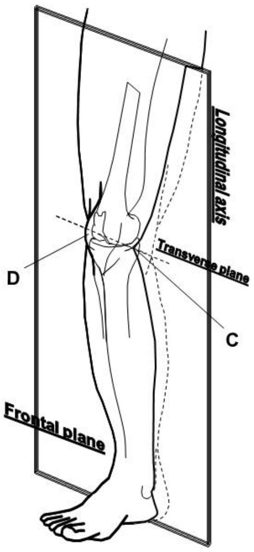


Fig. 1.3.2.

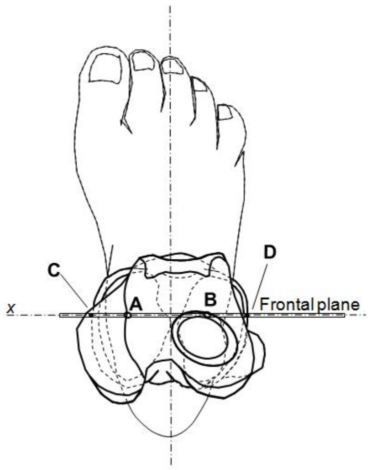


Fig. 1.3.3.

To these points passes a line "x". The longitudinal axes of the thigh meet the line x in two points C and D (fig. 1.3.3., 1.3.5.): in particular the medial axis at point C and the lateral axis at the point D.

Similarly, the longitudinal axes of the leg itself meet the line x in the same points C and D.

Simplifying, points C and D could be identified on the intersection of line x with the medial edge and with the lateral one of the tibial plateau (in view also of the low subcutaneous tissue present in the medial and lateral area of the knee).

At the same points C and D, also pass the symmetry axes of the femoral and tibial arms of the notorious knee braces, which in the extended lower limb, are coaxial.

The line CD is coincident with the transverse axis of the lower limb when the same is extended.

The transverse axis orthogonally intersects the longitudinal axis that passes on the centerline of the human body and laterally extending from the top of the head up to the plane of support of feet. The transverse axis and the longitudinal axis determine the frontal plane that divides the human body into a front and a rear part. When the lower limb is extended, it has a single frontal plane (fig. 1.3.2.).

When the leg is flexed (fig. 1.3.4. and 1.3.5.), the contact between the medial femoral condyle and the tibial plateau of the medial compartment, falls in a point A ', while the contact between the lateral femoral condyle and tibial plateau of the lateral compartment falls at a point B '. To these points A ', B' passes a line "x1". In reality, between the extension and flexion of the knee, an infinite number of pairs of contact points An, Bn are created, which determine as many lines xn refered to any transverse axis determined from the instantaneity of the degree of flexion. During the phase which goes from extension to flexion the segment C-D is pushed forward and simultaneously performs a rotation of about 20 degrees with the center of rotation at point O coincident to that in which the two lines "x", "x1 " intersect each others.

At the end of flexion the longitudinal axes of the leg itself meet the line x in the point D and in a new point C '. The line passing through the points C'-D is the transverse axis of the leg itself with the leg flexed.

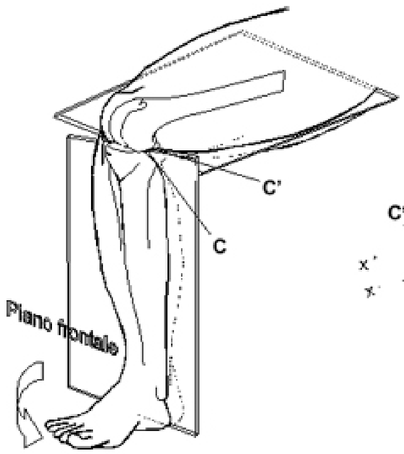


fig.1.3.4.

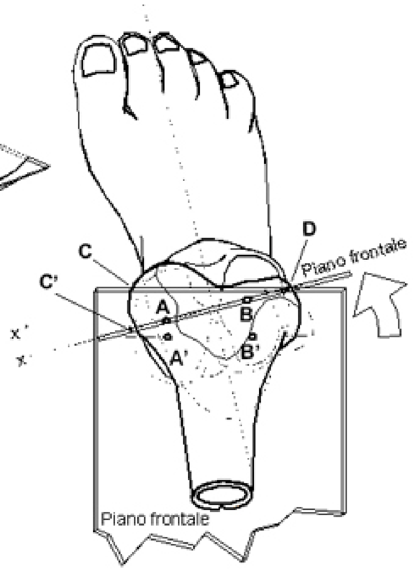


Fig. 1.3.5.

The frontal plane, at the beginning the only one for all the lower limb (fig.1.3.2.), as a consequence is divided in two (fig. 1.3.4.): the frontal plane of the thigh, which remains determined by the intersection between the transverse axis coinciding with the line C-D with the longitudinal axis of the thigh and those of the leg itself determined by the intersection between the transverse axis coinciding with the line C'-D with the longitudinal axis of the leg itself.

The two frontal planes are rotated between each others of about 20 degrees.

1.4. – The new “unit” roto-translation

The movement of the knee flexion occurs during the first 30° according to a circular path around a fixed center (up to 135°) and followed by a roto-translation phase characterized by a progressive decrease of the distance between the instantaneous center of rotation and the articular surface.

However, we have to consider a further movement associated with the roto-translation, which is the automatic longitudinally rotation of the tibia, as a consequence of the different conformation of the femoral condyles, respectively, outer and inner compartment.

More precisely, although keeping the roto-translational motion as a reference, it takes on different values depending on the sector considered (Fig.1.3.1).

Anyway, it is on the anterior-posterior, which is the greater range of motion and that leads us to consider that all the experimental results obtained on the antero- posterior be considered a "middle" of the trajectory of the internal and external sector.

Although roto-translational motion of the knee was known since the early studies (the first model proposed by Rond is dated 1913), the evaluation system has always been limited to a goniometric circular measure (Fig.1.4.1.) and does not take into account the linear translation inevitably involves, after 30° sliding between tool and limb. In fact, if we keep fixed the instrument to the distal thigh, the arm of the goniometer moves relative to the leg; if we keep fixed the instrument to the proximal leg, it is the arm that moves relative to the proximal thigh.

This means that the goniometer is unable to ensure that all points of contact remain constant from the beginning to the end of the assessment, by failinig the main feature of which must be a device evaluation.

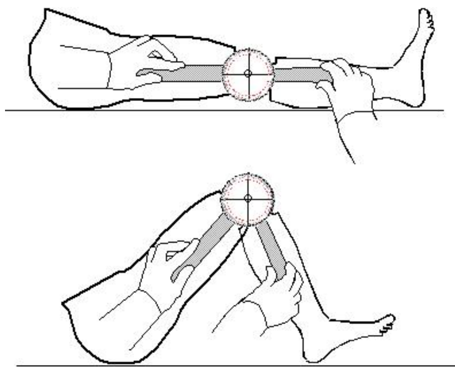


fig. 1.4.1.

For a proper evaluation of the roto - translational motion of the knee, therefore, it is essential that the device reproduces the same characteristics of the motion with a relevant reference scale.

To make more explicit the above, it is essential to consider the leg with the thigh in line with the longitudinal axis corresponding to the X axis which orthogonally intersects Y axis which perpendiculary passing through the initial center of rotation of the knee.

Automatically, the Y axis cuts horizontally the femoral condyle (Fig.1.4.2.).

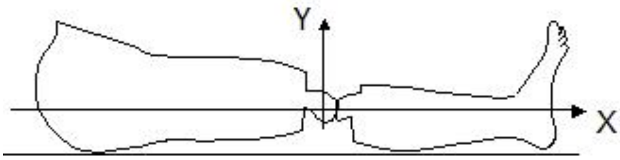


fig. 1.4.2.

To describe the progressive shift of the axis of rotation of the knee, determinated that Ra is the first radius of rotation that lies on the Y axis (Fig. 4), the trajectory of flexion-extension of the leg on the thigh can be analytically defined:

for **α** < 30 ° knee motion can be described as a system disk that rotates around a fixed center (initial center of rotation): the trajectory performed by the point P (as a distal end of radius Ra) has the equation of a circle $X^2+Y^2=Ra^2$;

for 30° ≤ **α** < 135°, the center of rotation moves towards the articular surface by an ammount equal to $\mathbf{\Delta_x}$.
The new coordinates of point P become :

$$X1 = X + \Delta_x$$
$$Y1 = Y + \Delta_y$$

The equation of the center of rotation of the knee (instantaneous center of rotation) turns out to be:

$$X1^2 + Y1^2 = Rb^2$$

When Rb is the true radius of rotation that change with the change of **α** with Rb<Ra.

When **α** is the angle between the X axis and the radius of rotation , the values of X, X1, Y1 and Y can be obtained that way :

$$X = Ra \text{ sen } \alpha$$
$$Y = Ra \cos \alpha$$
$$X1 = Rb \text{ sen } \alpha$$
$$Y1 = Rb \cos \alpha$$

So, for a given value of **α** between 30° and 135° the position of the instantaneous center of rotation can be calculated :

$$\Delta_x = X1 - X = (Ra - Rb) \text{ sen } \alpha$$

From 30° of flexion and later (up to 135°) the center of rotation , initially placed in the origin of the reference frame, slides vertically to the articular surface along the X axis by an amount equal to $\mathbf{\Delta_x}$. The radius Ra remains unchanged in its length and drags the point P falling on a spiral path toward the center.

This determines that the distance between P and the origin of the reference system X-Y is reduced (Rb) (Fig.1.4.1. note).

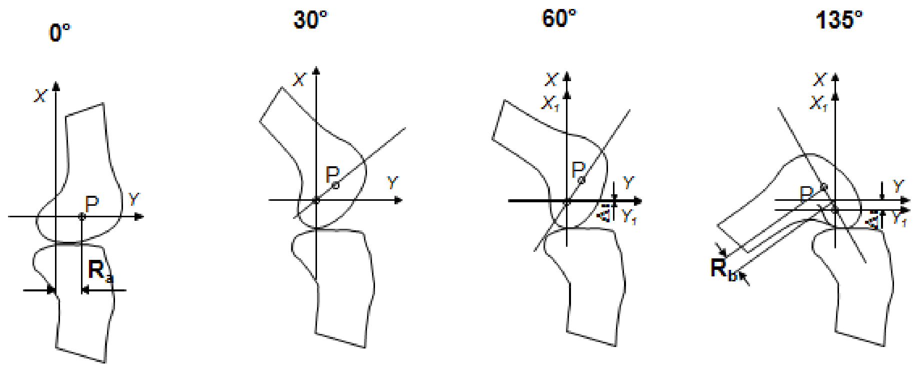


Fig.1.4.2. note - *the analysis shown in the figure has been made keeping the Xaxis as an extension of the longitudinal axis of the thigh in line with that of the leg.*

After the 30° , therefore , Rb, whose first end is always centered in the origin of the reference system X,Y, to change of **α**, will take different angular values than those of Ra, who remains the effective radius of the knee (Fig. 5) .

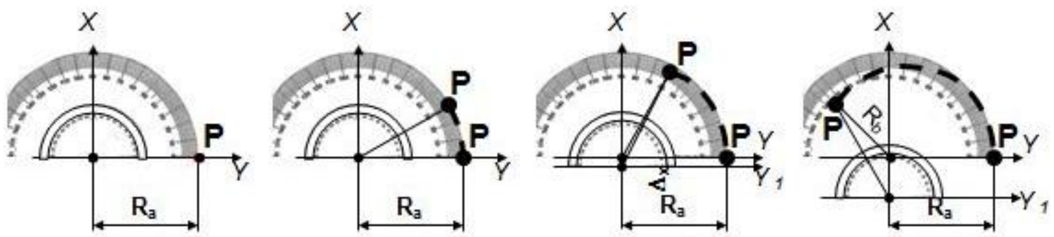


Fig. 1.4.3.

The new reference unit – the roto-translation amount

In roto - translational motion the point P follows a curve with a spiral trend falling towards the center, while the other end of the radius Ra slides along the X axis.

This implies that the scale for the real evaluation of the angle of the knee seen as a reversal of the Y- axis must be built according to the different movement of the two ends of the radius Ra.

The division into notches on the angular scale in no longer as regular as usual in a goniometer but raises above 30°, a subdivision according to the modified axial translation.

In fact, given that the end of P of the radius Ra varies according to the following values :

$$Y1 = y$$

$$X1 = Ra \text{ sen } \boldsymbol{\alpha} - \boldsymbol{\Delta_x}$$

And observing two different readings on the scale (corresponding to different angles and at different experimental progressive values $\boldsymbol{\Delta_x}$) we have :

$$X1_{\mathbf{1}} = Ra \text{ sen } \boldsymbol{\alpha 1} - \boldsymbol{\Delta_{x1}}$$

$$X2_{\mathbf{1}} = Ra \text{ sen } \boldsymbol{\alpha 2} - \boldsymbol{\Delta_{x2}}$$

from which :

$$X1_{\mathbf{1}} - X2_{\mathbf{1}} = Ra\,(\text{sen } \boldsymbol{\alpha}_1 - \text{sen } \boldsymbol{\alpha}_2) - (\boldsymbol{\Delta_{x1}} - \boldsymbol{\Delta_{x2}}).$$

From this report we deduce that the difference increases because of ($\boldsymbol{\Delta_{x1}} - \boldsymbol{\Delta_{x2}}$) the discordant development from X axis with a consequent increase of the distance between two points after reading on the angular scale (Fig.1.4.4.).

It seems important to point out that at 90° perpendicularity is perfectly appropriate in the two systems, which, however, differ from the vertical sliding Δ_x of the instantaneous center of rotation of the new gradual scale.

After the 90° the variation of the distance between the notches (L2-L1) becomes increasingly important.

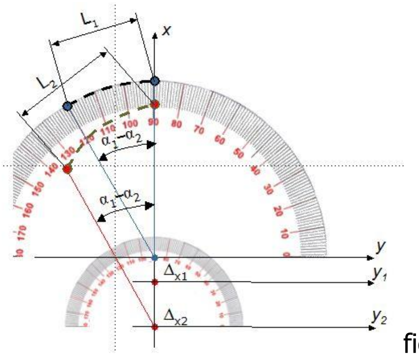
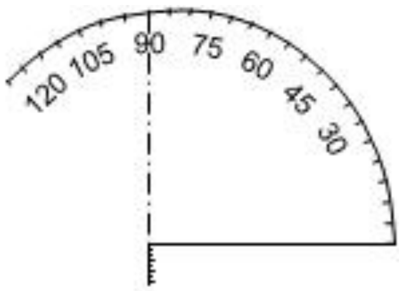


fig. 1.4.4.

So, the new scale was built (Fig. 1.4.5.)



1.4.5.

Other studies

A.1. - Knee theorem

Pellis G.

Variable center of rotation concerning the physiological motion of the knee theorem

Atti del XIX edizione del Convegno di Traumatologia e Riabilitazione Sportiva, Bologna, 2010, Calzetti Editore, Perugia

Declaration

Given the natural flexion/extension movement of the knee as a combination of rolling and sliding during the first 30° of flexion; subsequently the real flexion depends upon the position of the center of rotation.

This implies that there is a difference between the knee angle measured with a goniometric sytem and the real distance between the foot and the axis of rotation.

Hypothesis

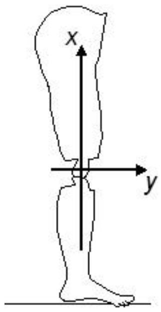
After an initial circular rotating phase, the flexion/extension movement of the knee proceeds with a combination of rolling and sliding (rotary - traslational) motion, which is characterized by the progressive decrease of the distance between the starting rotation and the articular surface.

Thesis

The knee flexion/extension axis achieved after a rolling and sliding motion, is different from the axis measured only with a protractor; thus a correct evaluation of the flexion/extension motion of the knee should consider the instantaneous displacement of center of rotation.

Proof

The position of the instantaneous center of rotation of the knee is initially placed on the x axis as an extension of the longitudinal axis of the thigh, whereas during the full extension of the thigh, it overlaps the longitudinal axis x of the leg itself. In this case the initial center of rotation of the knee coincides with the origin of Cartesian coordinate system xOy.



Note[1]

Provided that R_a is the first rotating radius that lies on the y axis, we could describe the gradual displacement of the axis of rotation of the knee, the trajectory of flexion and extension of the leg on the thigh can be analitically defined as:

according to **α** <30 °, the knee motion can be described as a rigid system that rotates around a fixed center: the trajectory performed by the point P is the equation of circumference

$$x^2+y^2=R_a^2.$$

According to 30° ≤ α < 135°, the center of rotation moves toward the articular surface by an amount equal to Δ_x.

The new coordinates of point P become:

$$X = x + \Delta_x$$
$$Y = y + \Delta_y$$

The equation of the center of rotation of the knee appears to be:

$$X^2 + Y^2 = R_b^2$$

when R_b is the real (effective) radius of rotation changing with the mutation of **α**, when $R_b < R_a$

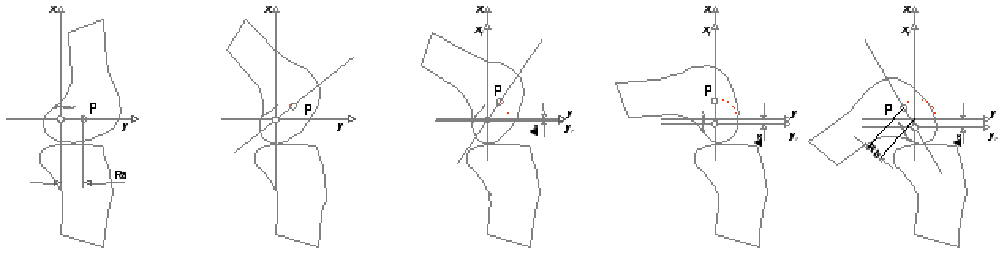
When **α** is the angle between the x-axis and the radius of rotation, the values of x, X, y and Y can be obtained as:

$$x = R_a \text{ sen } \alpha$$
$$y = R_a \cos \alpha$$

$$X = R_b \text{ sen } \alpha$$
$$Y = R_b \cos \alpha$$

So when a given value of **α** is included between 30° and 135° the position of the istantaneous center of rotation can be calculated as:

$$\Delta_x = X - x = (R_a - R_b) \text{ sen } \alpha$$



Pratical application – The new scale angle

As seen from above, it appears that the rolling and sliding motion the peripheral point P follows a curve with a spiral process, receding toward the center.

This implies that the scale for the evaluation of the actual angle of the knee must be established by the sequence of extreme points P of radius R_a, which second end (it initially overlaps with the origin of the reference xOy system) after 30° it moves along the x axis within a degree equal to $\boldsymbol{\Delta_x}$

Therefore the angular reference information on the spiral curve (Fig. 1) must be placed according to the new source xO'Y as a result of the instantaneus shift of the goniometric system along the x axis, when O'= O + $\boldsymbol{\Delta_x}$, as a new instantaneus center of rotation.

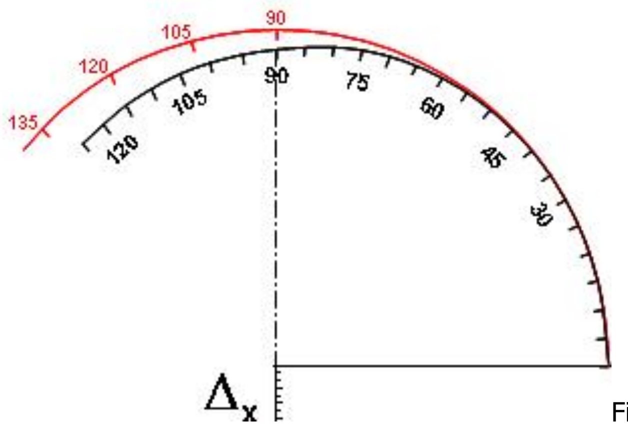


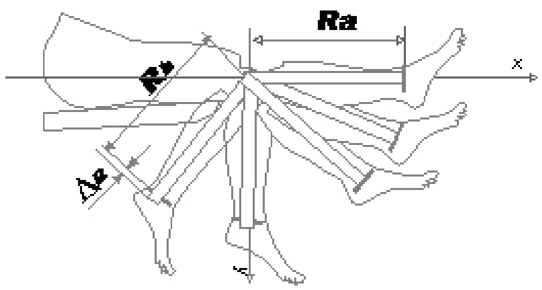
Fig.1

Fig. 1 – Angular scale concerning $\boldsymbol{R_a}$= 13mm and $\boldsymbol{\Delta_x}$= 3,6mm[1]

Reference

1) Pellis G., Di Cosmo F.: Il moto roto-traslatorio: Studio sperimentale, analisi matematica, dispositivo ortopedico, Calzetti Editore, Perugia, Atti del XVIII edizione del Convegno di Traumatologia e Riabilitazione Sportiva, Bologna, 2009.

***Note*[1]**: *the overturning of the Cartesian axes was operated for preserving the established references for the execution of the experimental study .*



A.2. - The goniometric angle and the knee angle - The Correction Factor

Atti del XX Convegno di Traumatologia e Riabilitazione Sportiva, Bologna, 2011, Calzetti Editore, Perugia

Pellis G.

During its natural movement the knee makes a rolling and sliding motion, so the size of the motion itself depends on the position of the center of rotation reached between the articular joints.

This implies that there is a difference between the knee angle measured with a goniometer and the real distance covered by the knee.

The above exposition is confirmed by the fact that while the goniometric system can be guaranteed with a fixed point of reference, after an initial circular rotating phase, the flexion/extension of the knee, a combination of rolling and sliding takes place and thus a gradual decrease in the distance between the instantaneous center of rotation and the articular surface.

This implies that the flexing angle reached by the knee after having done the physiological movement, is different from the corner assessed only with a goniometric system; as a matter of fact, the correct evaluation of the motion of the knee, must take into account the instantaneous displacement of the center of rotation.

To make this concept clearer, it is essential to consider a reference system (x-y) in which the x-axis overlaps with the longitudinal axis of the leg with the thigh when limb is stretched out. The y-axis intersects x in the initial center of rotation of the knee and it anatomically goes horizontally through the femoral condyle.

If we wish to describe the gradual displacement of the center of rotation of the knee, it is essential to establish the first rotating radius R_a.

R_a is placed on the y axis and it extends from the origin center of the x-y untill reference point P (Fig. 1).

During the first 30 ° of flexion/extension (Fig. 1) one end of the radius R_a revolves around the origin of the reference system x.y and the second end (P), follows a circular trajectory.

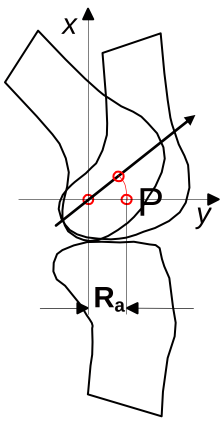


Fig. 1

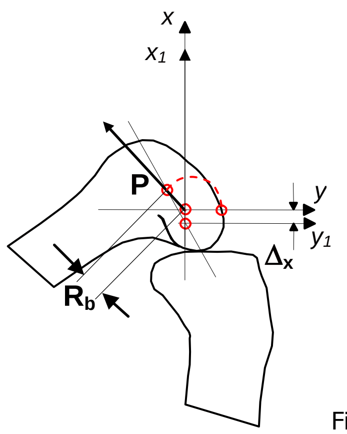


Fig.2

Moving from 30 ° of flexion/extension on (135 °) the center of rotation, initially placed in the origin of the reference system, slides vertically to the articular surface along the x axis by an amount equal to Δx. The radius Ra remains unchanged in its length and drags point P on a downward spiral receding toward the center.

This determines that the distance between P and the origin of the reference system x-y is reduced (R_b).

Therefor, after 30 °, R_b, whose first end is always centered in the origin of the reference system x,y when changing α, it will assume different angle values than those of R_a, which remains the true radius of rotation of 3the knee.

This geometry ensures that for angles ranging from:

0 - 30° - $\mathbf{R_b}$ coincides with $\mathbf{R_a}$

30 - 89° - inclination of $\mathbf{R_b}$ is less than $\mathbf{R_a}$

90° - inclination is equal, but $\mathbf{R_a}$ is shifted compared to $\mathbf{R_b}$ of $\mathbf{\Delta_x}$

91 – 135° - inclination of $\mathbf{R_b}$ is bigger than $\mathbf{R_a}$

Correction factor

As from the above we can state that there is an effective difference between the actual angle at the knee and that angle measured with a traditional goniometer.

These differences are dependent on the distance between P and the origin of the reference system *x-y* ($\mathbf{R_a}$).

In chart 1 these differences are quantified for $\mathbf{R_a}$ = 13mm

Chart 1

α	$α^{\cdot}_x$
45	46
56	56,5
67,5	69
79	80
90	90
101	100
112,5	109
124	116
135	124

Conclusions

Potentially, this difference has got ripercussions in the case of a therapy that may prefigure a device to make the knee flex upon a precise amplitude, the preset range of motion to make the device move, will not be the "GONIOMETRIC" one normally used by all devices currently on the market, and thus the knee will be FORCED (after 90 °) at a bigger angle, an angle that does not match the one required by the physician's prescription.

2 - The realization of the device and the biomechanical checks

2.1. - The mechanical device, roto-translational,with variable center of rotation

By applying mathematical analysis previously reported to the experimental results, it was possible to "draw" the knee path in its physiological motion.

Flex [°]	0	30	45	90	135
Average Δ_R [mm]	0	0	0,04	1,25	4,99
Average Δ_x [mm]	0	0	0,03	1,25	3,59

It was therefore designed a device, structured with two plates, a femoral and a tibial one, on which an handling driven system has been reproduced, which consists of two pins (placed on the femoral plate) which slide into two slots (placed on the tibial plate).

The first pin, central, was placed on one end of the femoral plate (at the intersection of the axes x, y); similarly on the end of the tibial plate a hole has been made as the starting point of a linear slot which develops along the x axis with an extension equal to Δ_x 135 degrees.

The second pin was placed on the femoral plate but on the y axis at a distance Ra (at the point P - Fig 2.1). At the same point, but on the tibial plate, a hole has been realized from which an opening device, circular for the first 30 degrees and, for the remaining 105 degrees, spiral falling towards the center has been developed.

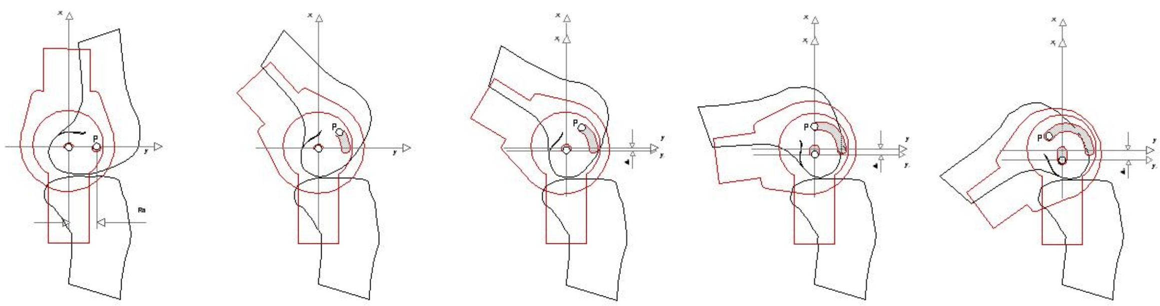


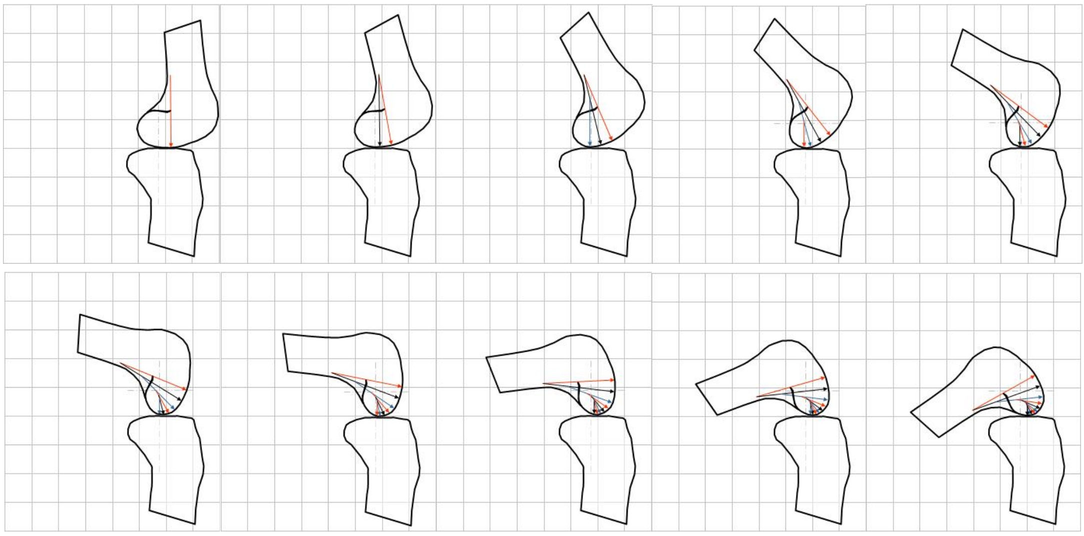
Fig. 2.1

The mechanical device thus structured can be used on all the orthopedic-rehabilitation equipments which assist the knee in its flexion-extension movement

2.2. - From mechanical device to orthopedic device

So that the mechanical design can really be considered an "orthopedic device", two studies were carried out to see if there was a correspondence between what was done and what was described by Insall (86) as "*a specific biomechanical condition in consequence of which the instantaneous center of rotation must fall on the perpendicular of the point of contact between articular surfaces* "(Fig. 2.2).

Fig. 2.2



The same Insall claims that this does not happen when the knee does not have the ability to perform a correct physiological motion, or ***"when the knee is applied an ... orthopedic device which forces the articular movement in a unnatural direction***".

Of the two works below

the first highlights the symmetry between the articular path of the knee proceeds from radiogram to precise angles and a monoplanar model in plastic animated by a joint with variable center of rotation. The precise overlap between the path of the radiological profile and those of the model, highlights a marked similarity between the two trajectories, similarity from which is also deductible the overlap of the instantaneous center of rotation and its consequent perpendicularity with respect to the articular surfaces.

The second study, instead, was set on the analysis of tractions to which cruciate ligaments are subject during flexion-extension, to verify a possible forcing "in an unnatural direction" of the articular heads.

2.3 - Influence of different types of joint for knee braces on the dynamic relationships between the femur and tibia

16° Congresso Nazionale, Società Italiana di Artroscopia, Genova 2003

Pellis G., Di Cosmo F.:

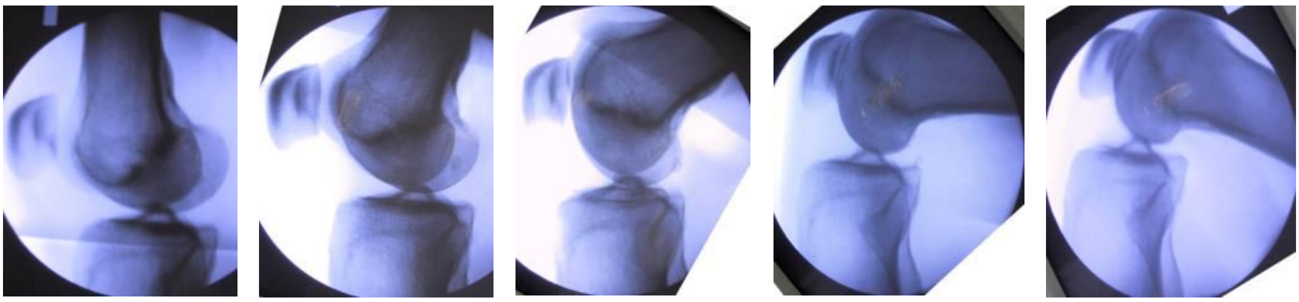
PHOTOGRAPHIC COMPARISON OF ARTICULATED JOINT MODELS REPRODUCING THE MOVEMENT OF THE KNEE

We wanted to assess the possible difference between the movement of the knee and the movement of the various brace joints normally used while dealing with knee traumas.

We based our remarks on the well known fact that the knee has a rotatory-translatory movement, as described by Smidt (1973), Fumagalli et al. (1977), Marinozzi and Pappalardo (1977), Kapandji (1977), Tittel (1979), Fleischmann and Line (1981), Nissel (1985), Insall (1986), Draganich et al. (1987), Yamaguchi and Zajac (1989), Melegatti (1997) and Steinbrück (1997).

The thigh is considered the starting point and the extended leg the 0° angle (Fig. 2.3.1.a). According to articular mechanics, during the first 25-30° flexion the knee has a pure rotatory movement (Fig. 2.3.1.b). From 25° on (Fig. 2.3.1.c, d, e), the rotation is combined with a gliding (forward) movement of the femoral condyles on the tibial flat bone that becomes more and more progressive and prevailing.

fig. 2.3.1.a, b, c, d, e - Radiography of a standard knee at 0°, 30°, 60°, 90° e 110°



a b c d e

We considered also opinions opposite to the above, e.g. Loudon et al (1998), Putz (1995), Townsend Ind. Inc., patent no. EP 0361405A, (04.04.1990), Townsend, Jeffrey H., Williams Robert J., US patent no. WO 9215264° (17.09.92). They are based on the hypothesis that during the flexion-extension the knee has a translatory-rotatory movement, i.e. the femur glides forward on the tibia for 8-9 mm (0-25°); the rotation phase follows from 25° on.

MATERIALS AND METHODS

In our research we reconstructed flat plastic models of the knee reproducing the outlines of femur and tibia with the average dimensions of adult bones. We chose four different kind of knee support joints and fixed them on the flat models.

MECHANICAL DESCRIPTION OF THE JOINTS

The joint used in a knee brace is formed by a mechanical articulation linked to two arms. We fixed the upper arm to the model femur and the lower arm to the model tibia

JOINT WITH FIXED AXIS OF ROTATION

It consists of a pivot reproducing a ***rotatory movement*** around a central axis.

During the flexion, the tibial brace is restrained and the femoral brace follows a circular trajectory around the pivot (Fig. 2.3.2.).

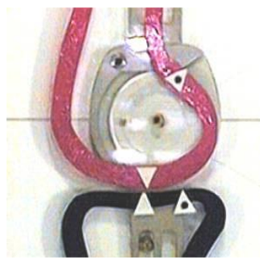
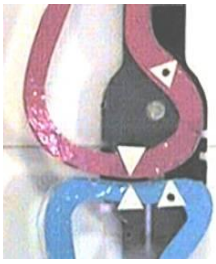


fig. 2.3.2.

JOINT WITH DOUBLE AXIS OF ROTATION

KTJ system Joint with variable center of rotation



The braces are in contact by means of their rounded, gear-wheel-shaped extremities with a pivot in their middle. When one brace turns around its own pivot, the other brace makes the same movement, in the opposite direction.

During the flexion, the tibial brace is restrained and the femoral brace makes a so called ***retrograde cycloid movement*** (Fig. 2.3.3.).

fig. 2.3.3.

JOINT WITH SWITCHING AXES OF ROTATION

It is composed of a plate linked to the upper brace. This plate has two grooves: a little central (transversal) one and a big peripheral (circular) one. Within each groove slides a pivot which is fixed to an external plate.

During the first 25° flexion, the fulcrum is the pivot seated in the upper extremity of the circular groove. It makes the other pivot move forward the entire groove (8-9 mm linear translation), simulating the anterior glide of the femoral condyles on the tibial flat bone.

In the second part of the flexion (from 25° to 120°) the fulcrum switches to the pivot seated in the lower extremity of the linear groove. The joint turns around it following the movement of the other pivot in the circular groove. The femoral brace has thus a ***translatory-rotatory movement*** (Fig. 2.3.4.).

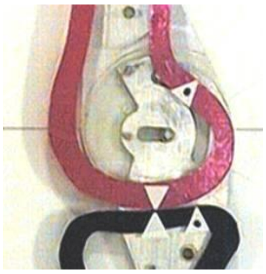


fig. 2.3.4.

ADJUSTABLE ROTATION RADIUS JOINT

It is composed of two plates. One of them has two groves. The first little one goes from the middle of the plate linearly downward. The second one initially (from 0° to 30°) has a circular shape which lately becomes a spiral lightly going to the middle of the plate.

The second plate has two pivots, one is seated in the linear groove and the other in the curvilinear one.

Each plate is linked to the respective brace (femoral and tibial). During the flexion the joint causes a rotatory movement combined – after the first 30° – with a gliding due to the spiral shape of the groove ***rotatory-translatory movement*** (Fig. 2.3.5.).

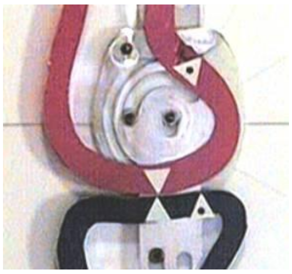


fig. 2.3.5.

THE INITIAL AXIS OF ROTATION

We took as a landmark common to all the joints – in order to uniform the position of the plastic models with respect to their mechanical joints – the initial axis of rotation located with the Nietert (1976) method (Fig. 2.3.6.).

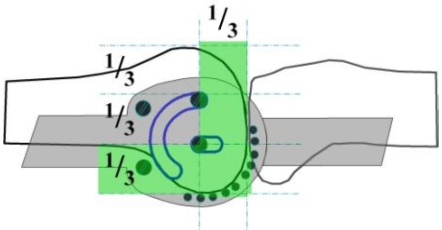


fig. 2.3.6.

We traced a line parallel to the tangent to the posterior outline of the femoral condyle and a line parallel to the tangent to its inferior outline at a distance equal to one third of the anteroposterior length of the femoral condyle. The intersection of those lines locates the initial axis of rotation.

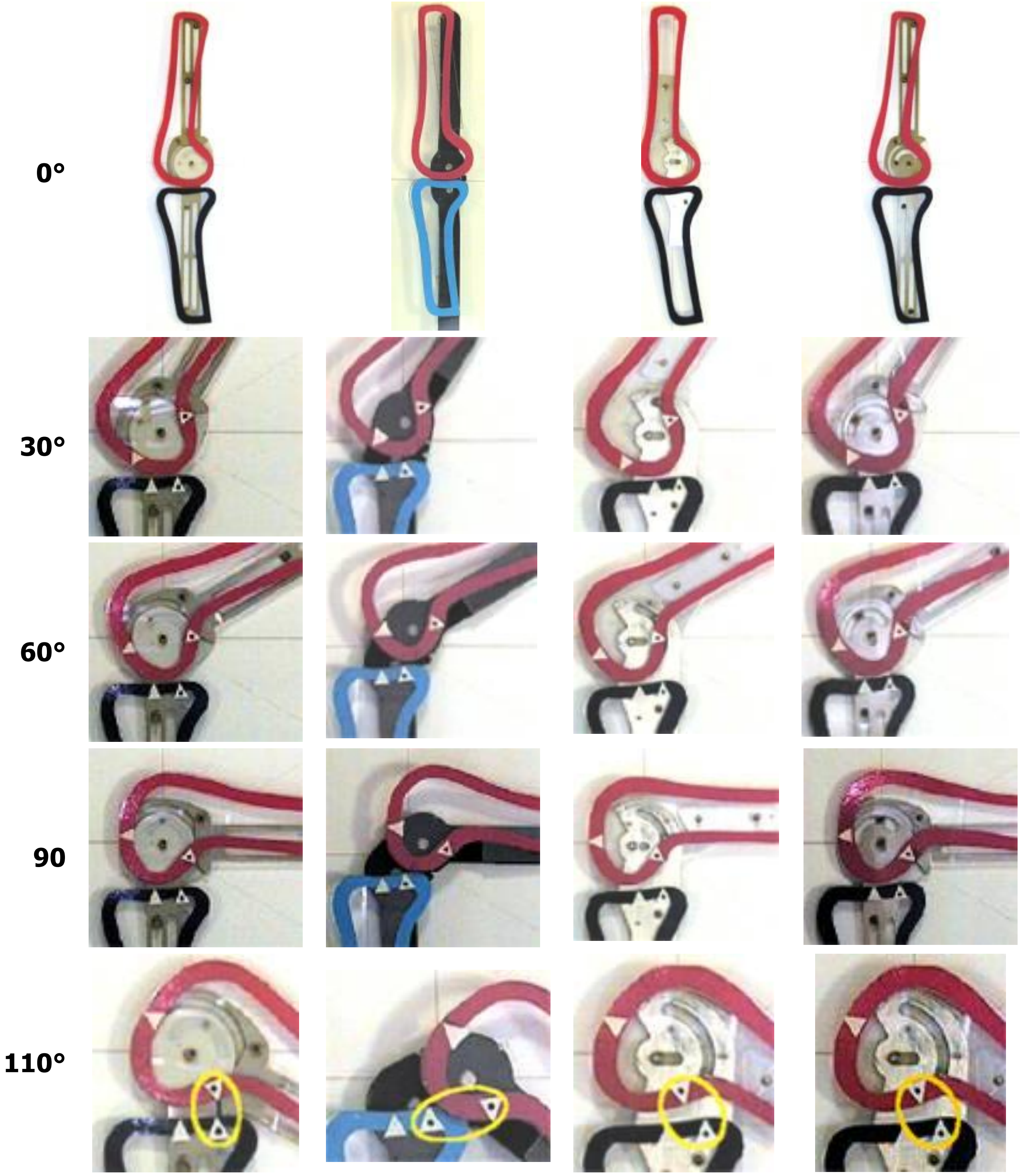
In our models, this landmark has been applied to the joint with fixed axis, to the adjustable rotation radius joint (setting the initial position of the central pivot as initial centre) and to the joint with switching axes (setting the initial position of the central pivot as initial centre). We could not apply this landmark to the joint with double axis because the rotations around the two axes were always simultaneous

The photographic documentation

We took a series of pictures of each model at the following angles of flexion: 0°, 30°, 60°, 90°, 110°.

We put standard distance markers on all models to highlight the possible differences between the trajectory of the natural movement shown by the radiographies and the movement determined by each joint.

	fig. 2.3.2. **JOINT WITH FIXED AXIS OF ROTATION**	fig. 2.3.3. **JOINT WITH DOUBLE AXIS OF ROTATION**	fig. 2.3.4. **JOINT WITH SWITCHING AXES OF ROTATION**	fig. 2.3.5. **ADJUSTABLE ROTATION RADIUS JOINT**



For a clearer comparison we traced:

1 - the radiographic outline (Fig. 2.3.7.a, b, c, d, e)

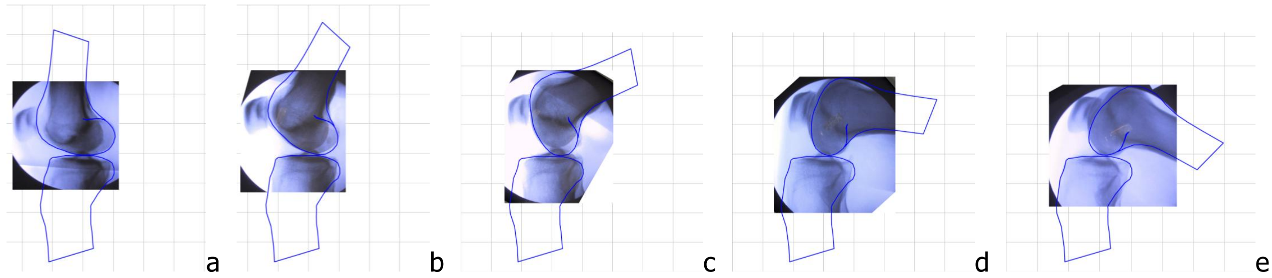


fig. 2.3.7.a, b, c, d, e - radiographic outline

2 - the articular outlines of the models in the different positions (Fig. 2.3.8.a, b, c, d, e)

fig. 2.3.8.a, b, c, d, e – articular outline

There are obvious differences by the overlap between the articular profile and each individual articular contour relative to an "articulated joint".

and superimposed them to (highlighted by the dark background)

Difference between the radiographic outline and the joint with fixed axis.

At the end of the flexion it can be noticed how the outline of the model moves forward and up.

Recent studies fixed this up movement to an average value of 4,99 mm (Fig.2.3.9.).

fig. 2.3.9.

Difference between the radiographic outline and the joint with double axis.

At the end of the flexion the outline of the model is situated in a highly backward position. The femur of the model is lower than the tibial flat bone of the radiography (Fig. 2.3.10)

(fig 2.3.10.)

KTJ system Joint with variable center of rotation

Difference between the radiographic outline and the joint with switched rotation.

At the end of the flexion the model is in a highly forward and upward position respect to the radiographic outline (Fig. 2.3.11) .

(fig 2.3.11.)

Difference between the radiographic outline and the adjustable rotation radius joint KTJ©.

In all the phases of the flexion the model is situated in a position very similar to that of the radiographic outline (Fig. 2.3.12).

(fig 2.3.12.)

CONCLUSIONS

Our research clearly shows that the knee has a rotatory-translatory movement. After 30° of knee flexion the femoral condyle glides progressively forward on the tibial flat bone. This movement should be reproduced by all equipments or mechanical joints guiding the movement of the knee for physiotherapeutic reasons.

If the knee is restrained by a mechanical articulation that does not reproduce this kind of movement, the head of the bones tend to follow the trajectory of the mechanical articulation. This deviation produces tension in articular elements like the ligaments, particularly the cruciate ligaments, the capsule, the menisci and the cartilages.

Our research shows that the joint that better reproduces a movement respecting the order of the phases of rotation and gliding is the adjustable rotation radius joint.

The leg and its mechanical support move on parallel trajectories to allow a perfectly correspondent contact between leg and mechanical disposal during the entire movement.

This avoids all traction of the mechanical disposal on the articular structures and the beginning of tensions within the knee.

These are the main points of the Annex 1 to the Italian Legislative Decree No. 46 of February 24th, 1997 on the essential and general requirements for EC certifications:

> *1. Disposals must be designed and constructed so as not to prejudice the patient's clinical state and safety or the user safety and health.*
>
> *2. During the disposal design and construction the manufacturer must observe all the safety measures, up-to-date with the technological progress.*

Additional Considerations:

The data presented above demonstrate how the articulated joint with a variable centre is the one that the most respects the dynamics of the knee joint, at least as regards the mutual articular relations between the femoral condyles and the tibial plateau.

This implies that there is a greater respect of the articular anatomical structures and the periarticular when the joint is applied to an orthopedic brace.

The observed pattern tends to confirm that the precise overlap between the path of the X-ray profile and the one of the connected model with the variable centrer of rotation, underlines a marked similarity between the two trajectories. This similarity shows the corrispondence between the overlap of the center of instantaneous rotation and its consequent perpendicularity respect to the articular surfaces at each degree of flexion.

2.4. - Adjustable rotation radius articulated joint for knee tutors: relationship between movement and tension on the cruciate ligaments

16° Congresso Nazionale, Società Italiana di Artroscopia, Genova 2003

Pellis G., Di Cosmo F.:

THE PURPOSE OF THE RESEARCH

Taking into consideration that the studies on the kinematics of the knee, based on an anatomic localization of the centre of instantaneous rotation, are hardly significant (Insall J.N., 1986, *Chirurgia del ginocchio* Verduci Editore), our study aimed to determine the tension put on the cruciate ligaments when the bending-stretching movement is imposed by an articulated joint with a fixed centre, or on the contrary, by an articulated joint with a variable centre of rotation.(VRC).

In particular we have verified and compared the traction forces on the cruciate ligaments and the distance to which the two bone heads are constrained by the different movements imposed by the two articulated joints.

THE METHOD USED

A machine for passive gymnastics was used in the research.

A series of tests were carried out using the original arm, which had an articulated joint with a fixed centre. The same measures were carried out with a modified arm: the fixed centre joint was substituted by a articulated joint with a variable rotation radius (VRC) (Fig. 2.4.2.).

fig. 2.4.1.

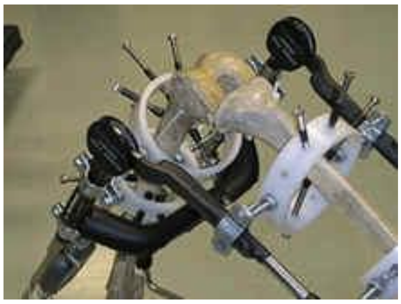


fig. 2.4.2.

The articulation of the knee was reconstructed using a femur and a tibia fixed to the machine using 4 plastic rings (two for the femur and two for the tibia – a distal and a proximal) fitted with screws convergent at the centre in order to be able to clamp the respective bone segments in an exact spatial position.

This enabled the femoral condyles and the flat tibials to be put in such a way as to perfectly re-establish the relation between them that they had during bending-stretching. This clamping system is a much more rigid system than that which you normally get when fixing a protector to the knee, since it does not create any area of elastic compensation determined by the soft parts of the leg and by the elasticity of the protector fabric. This system has been applied, however, to both cases described.

Irrespective of the articulated joint used, it was always the machine which produced the movement and the type of articulated joint which imposed the trajectory of the knee. The alignment between the rotation centre of the machine and the initial centre of rotation of the knee, was determined according to Nietert's method (1976) and then corrected manually since this method did not provide for the centring to be personalized. The correction was made by acting on the screws on the plastic rings. The verification of the centring in all cases had to ensure that the bone heads remained perfectly in contact in the first 30° of movement.

The cruciate ligaments were "reconstructed" using 3 mm diameter Dacron thread and inserted through the perforated bone heads:

- the ACL from the front tibial spine to the inside face of the lateral condyle in correspondence with the fossa where, in nature, the ACL is inserted;
- the PCL from the rear tibial spine to the lateral face of the medial condyle in correspondence with the fossa where, in nature, the PCL is inserted.

A small plastic tube was inserted into every channel formed by perforation, with an internal diameter just slightly bigger than that of the "ligament", in such a way that the latter could always slide without creating chafing caused by the friction of the spongy material of the bone tissue and the strand-type material of the "ligament".

fig. 2.4.3.

The ACL was fixed on the head of the tibia near the front exit hole, while the PCL was fixed on the head of the tibia near the rear exit hole. Both ligaments, after having passed the femoral condyles, were extended and fastened, at the base of the arm of the machine: a dynamometer was interposed, to measure the traction (Fig. 2.4.3.).

To measure the distance between the articular heads, at every angle reached, a system of shims (0.1 mm) was used, to be threaded between the articular heads at various angles.

ANALYSIS OF THE RESULTS

The complete movement performed by the machine was 0° to 110°. The measurements were taken every 15°. All the measurements concerning distance and traction were carried out at the same time as the movement of the arm was clamped at the desired angle.

As regards distance the results are reported in Fig. 2.4.4.

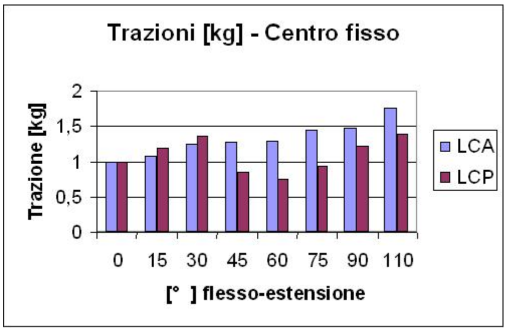
As regards tension on the cruciate ligaments, we report in Tab. 2.4.A the results concerning the fixed centre while those concerning the VRC articulated joint are reported in Tab. 2.4.B.

For every single ligament, at the initial angle of 0° an initial tension of 1.00 kg was given in order to be able to establish any negative tensions.

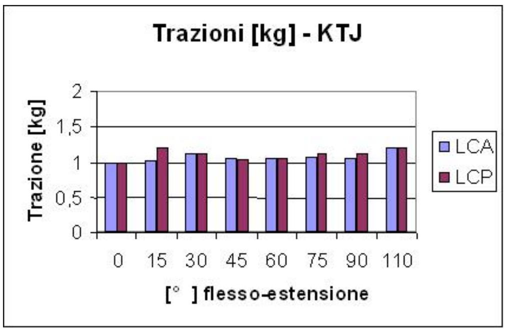
As can be seen in Fig. 2.4.4. the trajectory imposed by the articulated joint with a fixed centre determines a considerable deviation of the articular heads, from 30° bending and more. This does not happen with the VRC articulated joint which always maintains perfect contact with the articular heads.

As far as the forces exerted on the cruciate ligaments are concerned, by analysing the data with the VRC articulated joint (Tab. 2.4.B)) we can observe that the ligaments are subjected to a traction (considerably less than that seen with the fixed centre) which, however, is equivalent, in counter-position, in every fraction of movement; furthermore the tractions are higher during stretching and in maximum bending, positions where the ACL, with the rear-lateral fascicle, and the PCL, with the front portion, have their maximum thickness (Insall 1986) and therefore degree of resistance to traction.

The traction forces found with the articulated joint with a fixed centre, on the contrary, are decidedly asymmetric and of a higher intensity. The asymmetry is due to the fact that the PCL is initially tractioned, then left in the central phase of the movement and, at the end, in the last degrees it is tractioned again, even if only slightly.



tab. 2.4.A



Tab.2.4.B

In **conclusion** we can say that:

the articulated joint with a fixed centre does not give the rotational-translatory motion typical of the knee, thus creating a considerable distancing between the articular heads during bending-stretching, which totally agrees with what Insall reported (1986).

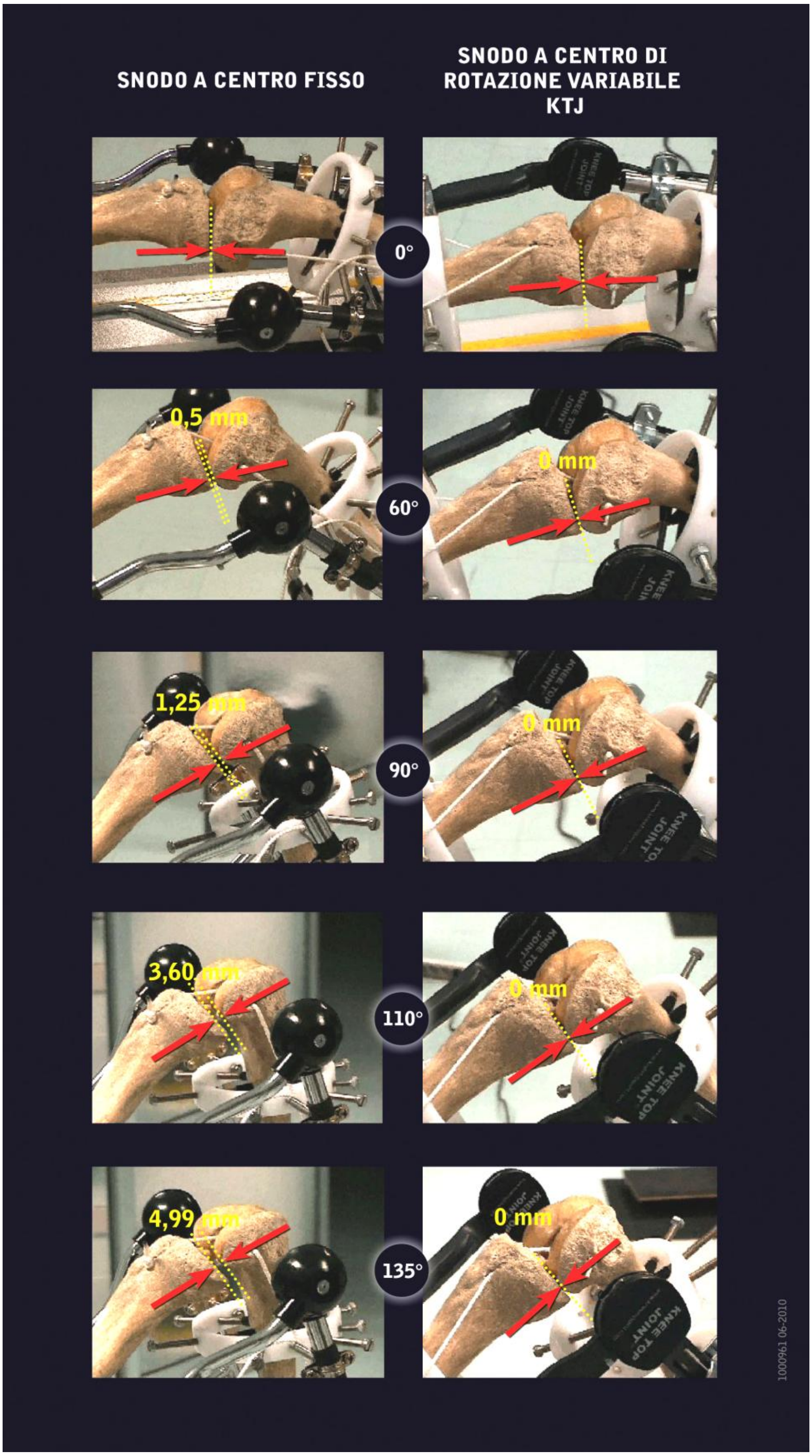


fig. 2.4.4.

KTJ system Joint with variable center of rotation

The VRC articulated joint, on the other hand, gives a rotational-translatory motion which tends to maintain contact between the bone heads and develops very balanced tensions on the cruciate ligaments.

Finally, taking into consideration what Insall reported (1986), about the possibility where the instantaneous centre of rotation does not fall perpendicular to the articular surfaces (or rather when a correct rotational-translatory movement is not performed), we know that "this condition can occur when the articular surfaces or the ligaments, or both, are not in their normal anatomic position, or when an immobilization apparatus or other orthopaedic device which forces the articular movement in an unnatural direction. is applied to the knee".

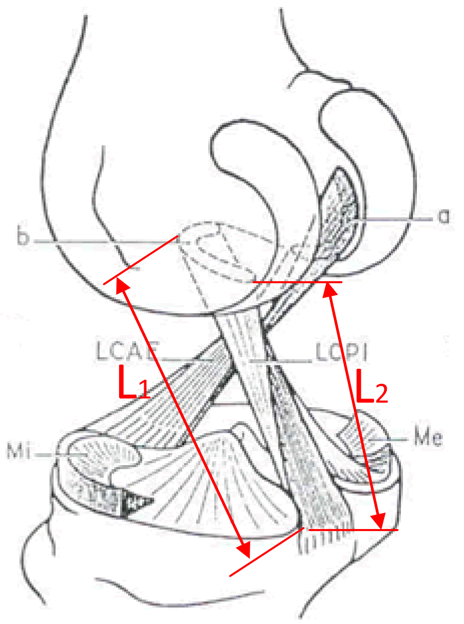
With reference to the data reported, we can state that the VRC articulated joint offers a natural movement, very similar to the physiological one and, therefore, because of this, it is particularly suited for application on any machine which is used for rehabilitation, where any undue stress must be avoided which could further aggravate an already damaged situation. Subjecting a reconstructed ligament to traction with an excessive load is surely not the correct way to cure it.

A reduction of this tension, maintaining perfect contact between the articular heads, also prevents the onset of strong tensions to the collateral ligaments, to the articular capsule and to the meniscus, (we must remember that the latter are connected to the articular capsule and the cruciate ligaments: PCL with the back cornu of the meniscus and ACL with the front cornu of the meniscus.

The KTJ© articulated joint with a variable rotation centre can therefore be applied naturally on knee pads, on passive gymnastic machines and on machines for muscle reinforcement such as leg extension.

2.5. - Other considerations regarding the cruciate ligaments

The data on the tension ACL / PCL from the study reported in the previous pages, agree with what found in anatomy.

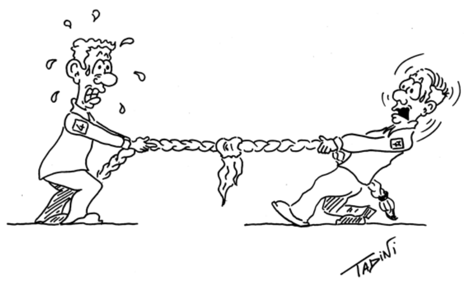


From the descriptions of the tibial ads, in fact, we know that the fibers of the cruciate ligaments have not all the same length and direction; during the movements, therefore, fibers are not placed in tension simultaneously.

Roud in 1913 had already proposed a thesis claiming that during the flexion-extension some fibers of the cruciate were always in tension due to their different lengths. This allows to counterbalances LCA \ LCP tension at any phase of flexion-extension avoiding movements drawer.

The prevalence of tension of a ligament with respect to the other, in fact, would create an imbalance situation similar to those which is determined in the "tug of war."

In addition to this, starting from the mechanical model of Strasser (1917) it was established that the articular profile of the rear part of the condyles exactly represents the curve that wraps the different positions of the tibial plateau between the complete flexion and extension, confirming that not the anterior cruciate ligament, neither the rear cruciate ligament changes the length while the condyl profile remains tangent to the tibial plateau.



From this it follows also that the shape of the condyles is geometrically determined by the length of the cruciate ligaments, from their position and arrangement of their ads.

3. - The opposite theory

From the bibliographic consultations also conducted for patent examination, we also found contrary opinions to roto-translational motion of the knee. The hypothesis formulated in the works of LOUDON ET AL(1998), PUTZ (1995), TOWNSEND Ind. Inc., Patent no. EP 0361405 A (1990), TOWNSEND, JEFFREY H.,WILLIAMS ROBERT J., U.S. patent no. WO 92 15264 A (1992), indicate that in flexion-extension motion the knee proposes a roto-translational motion , that is initially a front slipping of the femur on the tibia of about 8-9 mm (for an arc of 20-25 degrees) , which is followed by a phase of rotation from 25 degrees foward.

This reversal of flexion-extension dynamic of the knee has lets some perplexity that led to a more detailed analysis comparing any similarities between the articular anatomy and physiology.

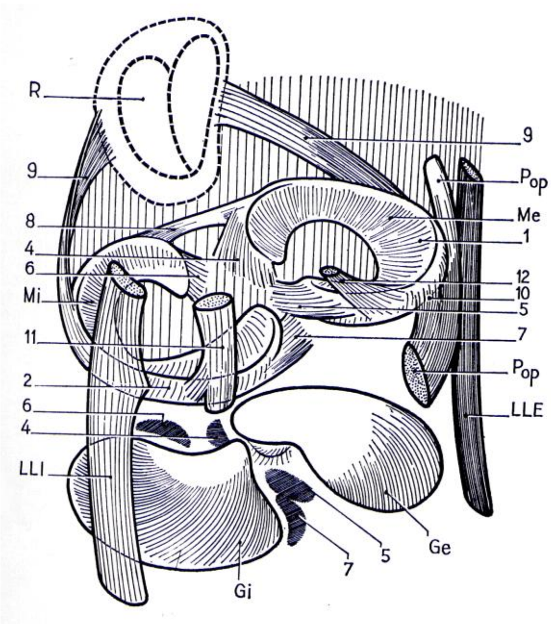
Anatomic - physiologic analysis

Intercondylar eminence: the first perplexity on the initial anterior translation of the femoral condyles on the tibial plateau, is inspired by the mechanics on the axial rotation along the longitudinal axis of the leg that can be carried out only with the bent leg after the 30 degrees (Kapandji 1977, pg 80**).** The same author, in fact, says that only after the initial roll-back of the femoral condyles on the tibial plateau, there is disengagement of tibial condylar eminence that can rotate in the femoral intercondylar fosse where it is stuck with the extended knee (as blocking cause of the axial rotation in extension - Kapandji 1977 pg. 92**).**

From the above, the initial forward translation does not combined with the "disengagement of condylar tibial eminence" which occurs after 30 degrees because the anterior translation itself would tend to keep stuck the massive intercondylar for a wider bending portion.

The movement of the meniscus : further doubts about the transla-rotational theory comes from the knowledge of the physiological slip back of the meniscus during flexion**.** The internal and the external meniscus in fact, in their rear part and in particular with their rear horns, are connected (via an fibrous expansion) respectively to the semimembranosus muscle and the popliteal muscle, which, however, are the motors muscles of flexion: their shortening determines the simultaneous of the flexion motor action and backwards recall of the meniscus (Fig. 3.1.).

The roto-translational mechanical, faithfully interprets this movement, in fact the first phase of flexion, rotation of the femoral condyles provides a backward rollingon of them on the tibial plateau , that is proportional to the angle reached, at the same time with the rearward displacement of meniscus that are dragged back by the same motor muscles used in flexion.



Legend :
R – kneecap
LLI - internal collateral ligament
LLE - external collateral ligament
Mi - internal meniscus
Me - external meniscus
Pop - popliteus muscle
4 - anterior horn external meniscus
5 - rear horn external meniscus
6 - anterior horn internal meniscus
7 - rear horn internal meniscus
8 - transverse ligament
9 - meniscus-kneecap wing
10 - popliteal muscle fiber expansion
11 - semimembranosus muscle fiber expansion

fig. 3.1.

The transla-rotatory theory ,instead, tends to affirm that in the first phase of flexion 20-25 degrees the femoral condyles anteriorly slip for 8-9 mm while and in any case, the meniscus pulled by the flexor muscles, moving backward. This opposite direction of movement, would bring, without doubt to a serious conflict between condyles and meniscus which might be damaged at each cycle of movement.

***Note**: from the consideration that these degrees of motion correspond to those used in deambulation, we can see that this conflict would result in a short time to complete degeneration of the anterior horns of both meniscus with all the consequences.*

Patent analysis

Another analysis was conducted on the mechanical system which reproduces this movement (TOWNSEND IND. INC., Patent n. EP 0 361 405 A, 1990). This device is formed by two arms, one femoral that has a central pin and a peripheral one and a tibial one on which two openings have been reproduced, a central linear one and a circular peripheral one.

In the first 20-25 degrees of flexion (Fig. 3.2.a, b), the central pin horizontally slides into the central opening with a centered motion on the peripheral pin housed in the upper end of the peripheral slot. From 25 degrees onwards, when the horizontal sliding finished, the fulcrum of the movement jump on the central pin leaving the peripheral free to slide in the circular opening (Fig. 3.2.c, d, e).

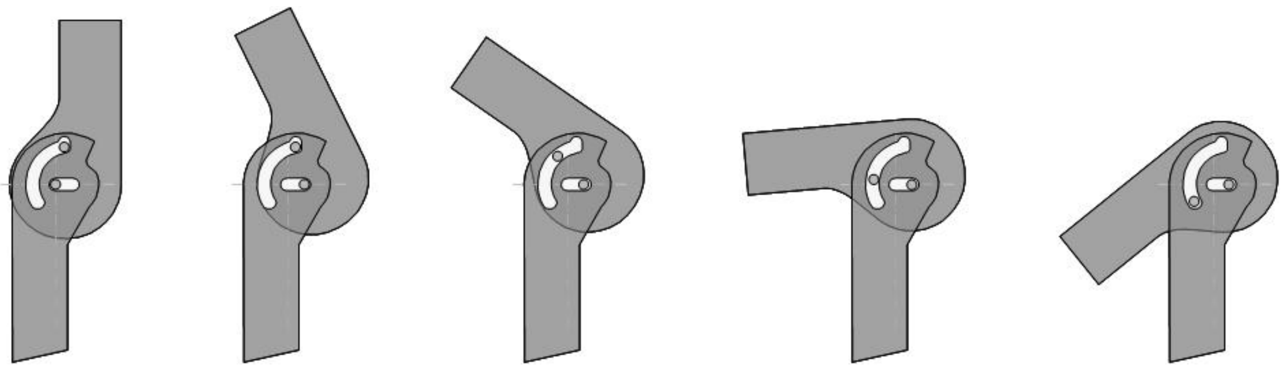


fig. 3.2.a b c d e

In these dynamics, the center of rotation after the sliding phase of 20-25 degrees "jumps" from the peripheral pin to the central pin.

This mechanical shutter that clearly divides the translation and rotation, it is not in accordance with the knee motion becase the physiologichal movement that occurs between the articular heads is without a solution of continuity and has a precise harmony.

Analysis of motion

Further comparison between the two theories, the roto-translational and the transla-rotational, from a practical-motion point of view, was made considering the exercises that are offered in rehabilitation resulting from a knee trauma. This analysis was summarized in a work proposed at the XVII International Congress of Traumatology and Rehabilitation, Bologna 2009, that won between the posters presented.

3.1. -Classification of exercises for the rehabilitation of the knee according to the theory of roto-translational and transla-rotational

XVII International Congress of Traumatology and Rehabilitaion - Bologna 2009

Pellis G., Di Cosmo F.:

Introduction: The knee is the joint that combines an initial rotation (25-30 degrees) with a sliding motion which becomes more and more progressive. This roto-translational theory, has been joined by a more recent that initially provides a front sliding of the femur on the tibia of about 8 - 9 mm (for aa arc of 20-25 degrees), which is followed by a rotation phase. We define this theory transla-rotational.

The purpose of the study - Understand which are the exercises most recommended for proper rehabilitation of the knee, on the basis of the mechanical stresses produced by the motion that any single theory proposes,

in the rotation the points of contact between the surfaces follow one another so that at every point of contact on a surface it corresponds a different one over the other. In rolling there is not friction and usury of surfaces (Fig. 3.1.1.a, b, c, d).

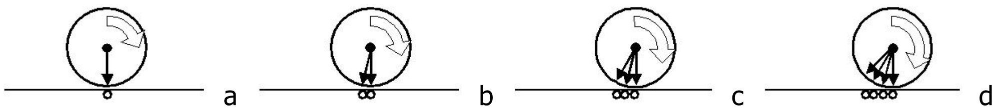


fig. 3.1.1.

in translation to a point of contact on a surface correspond more points of contact on the other. This causes friction and usury between the parts. The higher is the load transmitted, the more intense will be the deterioration factor between the parties (Fig. 3.1.2. a, b, c, d).

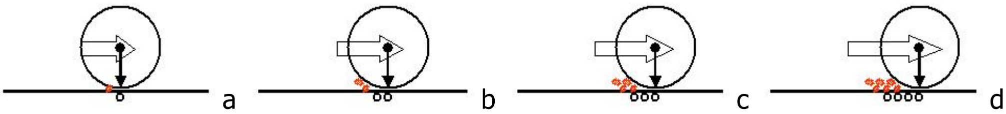


Fig. 3.1.2.

The theories –

The **roto-translation** provides that the articular heads roll for the first 30 degrees and then begin in an ever more important way the sliding (Fig. 3.1.3.)

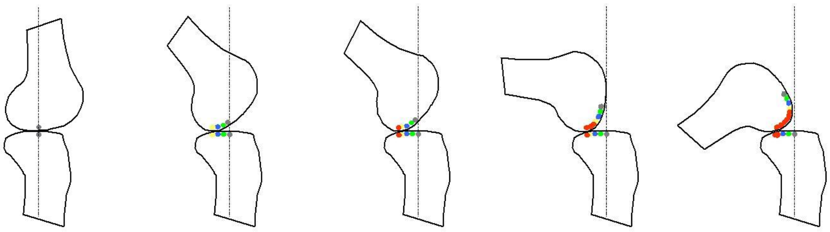


fig. 3.1.3.

The **transla rotation** provides that the articular heads frontly slip for 8-9 cm (about 25-30 degrees) and then roll to the end of flexion (Fig. 3.1.4.)

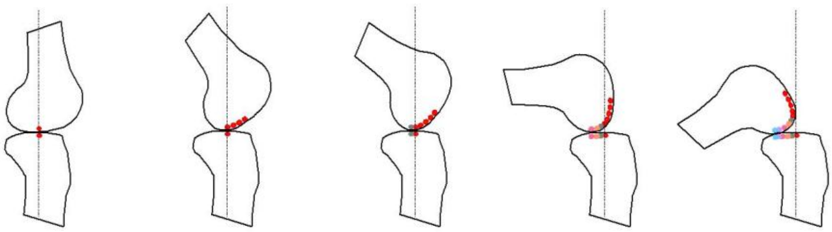


fig.3.1.4.

The bibliographic and patent analysis

The roto-translational theory: we can be note that the scientific works temporally precede by far the date of the invention patent ***Patent n. WO 97/38759 - 1997***

- Draganich L.F., Andriacchi T. P., Andersson G. B (**1987**) Interaction between intrinsic knee mechanics and the knee extensor mechanism, J. Orthop. Res. 5:539-547.
- Fleischmann J, Line R (**1981**) Human anatomy applied to physical education and sport, vol.1, S.S.S., Roma, 303.
- Fumagalli Z, Fusaroli P, Lambertini G, Nesci E, Pasqualino A (**1977**) Human anatomy, vol.1, Piccin ed., Padova, vol. 1, pp 191-195.
- Insall J.N. (**1986**) Knee Surgery Verduci editore, pp. 11, 12-13, 25
- Kapandji I A (**1977**)Articular physiology, Marrapese Ed. Demi s.r.l., Roma, 90.
- Marinozzi G, Pappalardo S (**1977**) The knee joint, morphological and functional problems, Alcmeone,Istituto Superiore di Educazione Fisica, Roma, n.1, pp 25-30.
- Melegatti G (**1997**) Biomechanics of anterior cruciate ligament, Alea Ed., Milano, vol.2, 22-24.
- Nissell R (**1985**) Mechanics of the knee, Acta Ortop. Scand. 56 (supp.216): 5-41
- Smidt G.L. (**1973**) Biomechanical analysis of knee flexion and extension, J. Biomech., 6:79-92.
- Steinbrück K, (**1997**) Rehabilitation des Kniegelenkes nach Kreuzband - Operationen, Orthopädie-Technik, 725-735.
- Tittel K (1979) Functional anatomy of man, Edi Ermes, Milano, 272.
- Yamaguchi G.T., Zajac F.E. (**1989**) A planar model of the knee joint to characterize the knee-extensor mechanism, J. Biomech.,22:1-10.

The transla-rotational theory: we can see that the scientific works are due at the date of the invention patent **Patent n. EP 0 361 405 A , 1990 e patent n. WO 92 15264 A , 1992**

- Putz, **1995**; Loudon et al, 1998.

Studies of comparing between models - From a study on the comparison between the radiograms of a knee-type with the mechanical devices that reproduce the two motions considered, complete with monoplane models that reproduce the articular heads of the knee,we found that: The model that proposes the roto-translational motion is always in a very similar position to those of the radiological profile (Fig. 3.1.5.).

The model that proposes the transla-rotational motion, at the end of flexion, is located in a greatly advanced position and raised with respect to radiological profile (Fig. 3.1.6.)

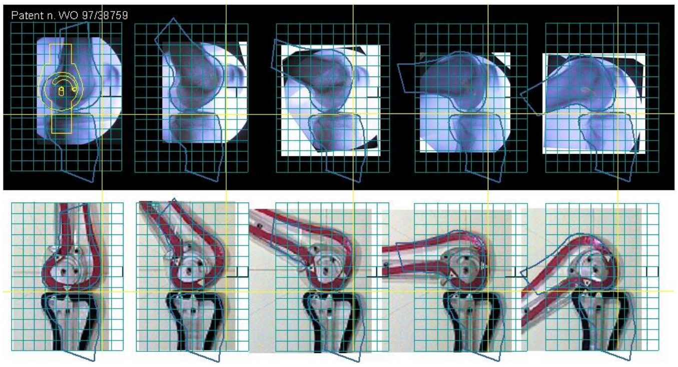


Fig. 3.1.5. - Joint with variable center of rotation

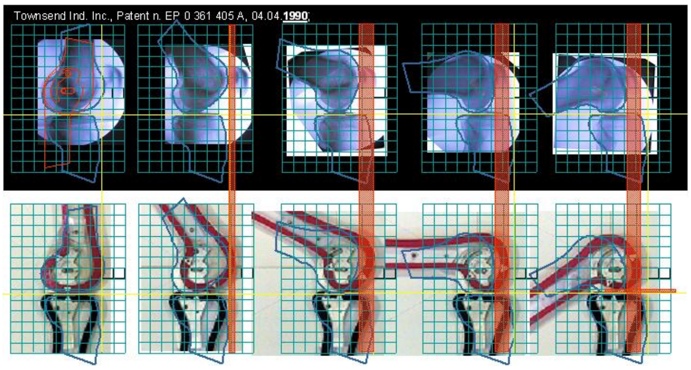


fig. 3.1.6. - Transla-rotational joint

KTJ system Joint with variable center of rotation

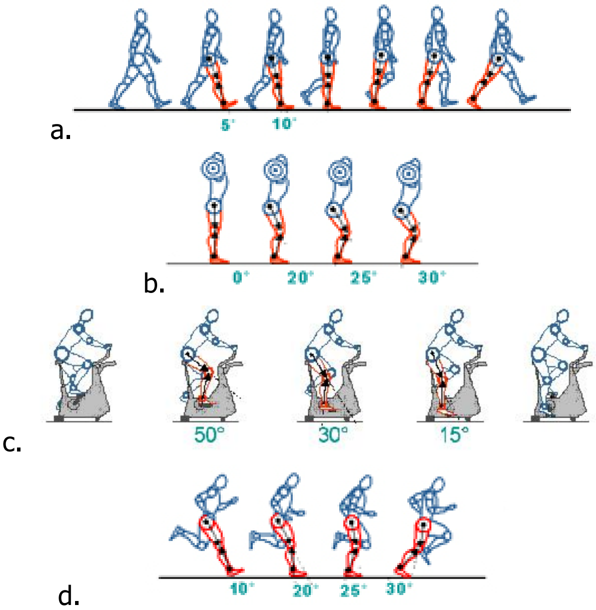
Rehabilitation exercises - should be proposed so that we can achieve the restoration of full flexion-extension function and tolerance of the load of the knee without that this can cause harmful stress to the articulation.

From the analysis of the mechanical stresses that arise in the translational and rotational motion, the exercises to propose in rehabilitation of the knee can be classified according to the hierarchies of intervention of each motion, as "recommended" and "not recommended"

<u>The recommended exercises are those in which take place the rolling between the articular heads, motion which excludes the usury determined by the translation</u>

Moto Roto-translational (recommended exercises): deambulation, bending with open angles, cycling and running slow, ecc. (Fig. 3.1.7. a, b, c, d)

Fig. 3.1.7.



Transla-rotational motion (recommended exercises): bending with closed angles (Fig. 3.1.8.)

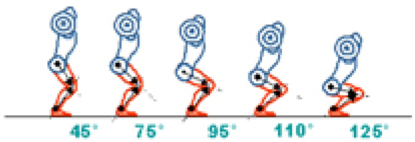


fig. 3.1.8.

Conclusions - In consideration that the biological evolution has always married the concepts of efficiency and conservation, it is difficult to think that particularly useful activities such as deambulation and running can cause friction and usury into an essential joint for life and existence of man itself, such as the knee.

This suggests that the roto-translational theory is the more creditable to the knee motion and that the main exercises on which to base a treatment protocol, are those made with open angles up to 30 degrees, which, using only the rotational motion, avoid the mechanical stresses that produce USURY, compromising the correct use of the joint.

4. - Intrinsic peculiarities to the roto-translational dynamics

Before presenting some works that have been undertaken to try to determine the possible benefits attributable to the device at the variable center of rotation it seems interesting to describe some “theoretical” aspects that accompany from one side the high parallelism created between the trajectory of the knee and that of the mechanical device and from the other as the "rigidity" of the mechanical system can transmit a beneficial effect on an injured knee.

4.1. - Maintenance of articular distance

The fundamental characteristic of joint with variable center of rotation is to accompany the knee on a roto-translational trajectory, without creating any negative effect on the articular mechanics of knee (Fig. 4.1.a, b, c, d, e)

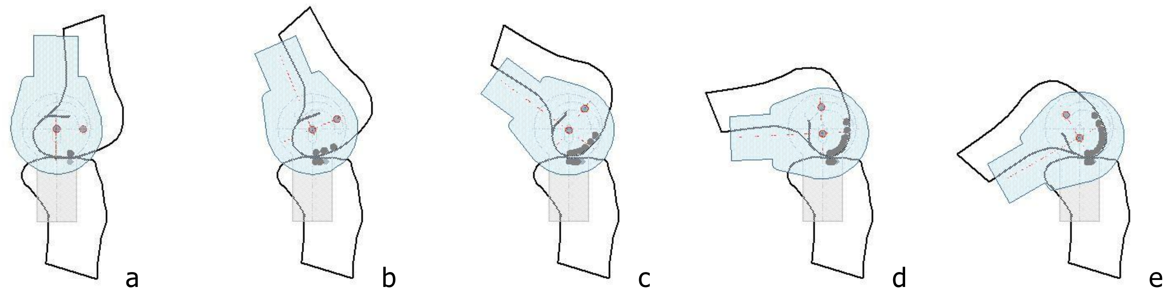


fig. 4.1.

4.2. - Self-centering

The correspondence between the mechanical motion and the physiological one, creates a particularly important condition in practical use of such orthopedic devices that use the variable rotation center.

Based on the mechanical concept for which two bodoes bounded to each other propose a similar motion, in the movement tend to superimpose their trajectories, the device with variable center of rotation tends, during work, to superimpose its mechanical trajectory to the physiological one of the knee under the friction force that is created by the friction between the parts in contact. It is the same frictional force which lets "slipping" the trajectory (fig. 4.2.)of the mechanical device on the physiological one up to disappear

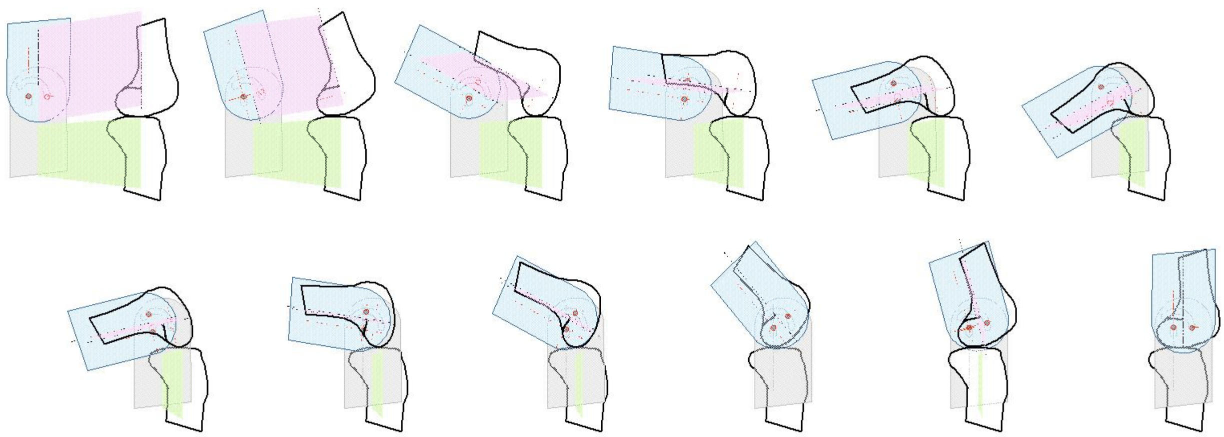


fig. 4.2.

5. - Intrinsic peculiarities to the mechanical constraints

The arrangement of pins located inside the joint, bind between them the movement of individual mechanical elements of the joint itself. If the it is made integral with an injured knee, the mechanical constraints become elements of articular stability.
In that way, a functional compatibility is determinated as a result of a precise anatomical deficiency.

5.1. -Compression - Tolerance of the peak load

In the upright position and in particular when the support lies on a single limb, the transmission of body weight (load P) between the articular heads of the knee occurs by compression on 2 physiological points of contact (Fig. 5.1.1.):

A - Medial Femoral Condyle / Medial Tibial Plateau
B - Lateral Femoral Condyle / Lateral Tibial Plateau

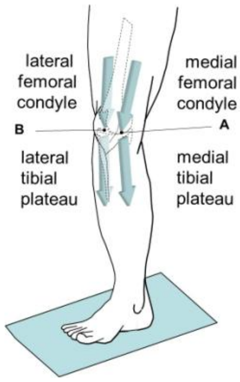


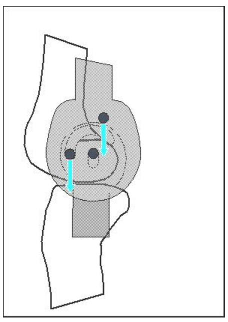
Fig.5.1.1.

In the presence of a trauma that affects the articular cartilage and meniscus, a "discharge" on points of contact can contrast a progressive degeneration of traumatized surfaces.
A cracked or fractured meniscus subjected to continuous compression exerted by the articular heads will tend to progressively reduce its functionality.

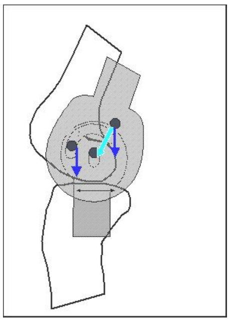
Functional compatibility - meniscal trauma, chondropathy, osteoarthritis, tibial plateau vertical fractures

In this situation, the mechanics of the KTJ joint, joints the knee and by virtue of the geometric positioning of the two peripheral pins (located on the femoral plate which remain the one in contact of the outer profile and the other with the peripheral hole) determines a condition for which the two contact points are joined by the 4 mechanical points with great reduction of compressions.

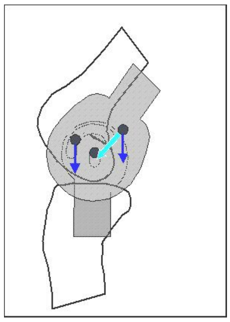
Fig. 5.1.2.



a



b



c

The reduction of the compression between the articular heads and their maintenance at a regular and constant distance and in all phases of movement, is particularly compatible with what is necessary in case of menscal trauma (Fig. 5.1.3.) or articular profiles degeneration (Fig. 5.1.4.)

fig. 5.1.3.

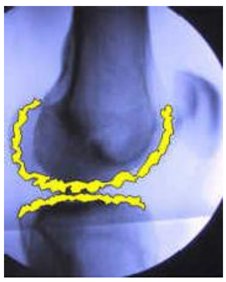


fig. 5.1.4

5.2. - Strength to traction

The central pin is also opposed to traction which distancing of the two plates. After the 30-35 degrees of flexion at the end of the phase of rolling, when the central pin comes off from the upper part of the central opening, the removal is contrasted by the pin placed in the spiral hole (Fig. 5.2.1.).

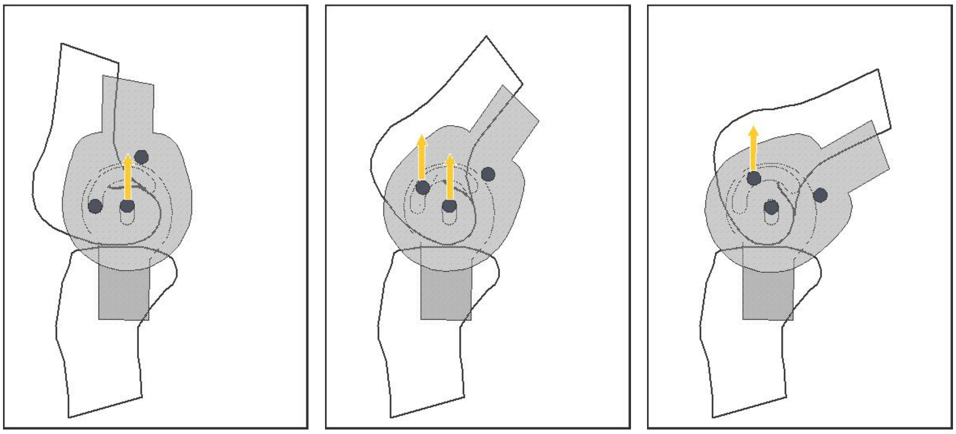


Fig. 5.2.1.

Functional compatibility -Trauma LCL and LCM

The collateral ligaments laxity, destabilizing the knee on the lateral plane (Fig. 5.2.2.b).

In particular, for supporting a knee with a lesion to the lateral collateral ligament LCL is important to stabilize it laterally to prevent a detachment while medially, compression must be avoided.

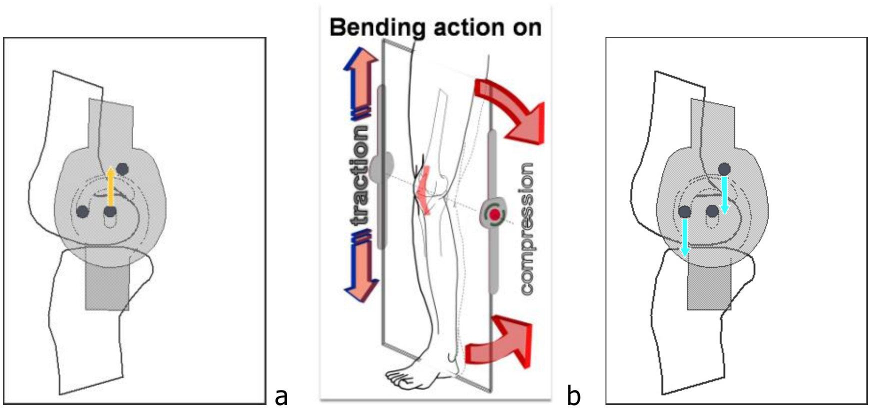


fig 5.2.2. a b c

To support a knee which had a trauma to the medial collateral ligament LCM, instead it is important to stabilize it by ensuring that from the lateral side is prevented compression (Fig. 5.2.2.c), while in the inner or medial part, must be prevented traction (Fig. 5.2.2.a).

5.3. - Opposition to the anterior-posterior displacements

The geometry of the pins placed on the femoral plate and inserted in tibial plate openings, tend to prevent antero-posterior "slipping" (Fig. 5.3.1.).

Fig. 5.3.1.

Functional compatibility - LCA and LCP laxity

This characteristic is particularly indicated in cruciate ligaments traumatology for which is required a marked anterior-posterior stability.

The laxity of the LCA leads to a sliding of the head of the tibia forward (anterior drawer – Fig. 5.3.2.), while the laxity of the PCL to a door or slipping of the head of the tibia in behind (posterior drawer – Fig. 5.3.3.).

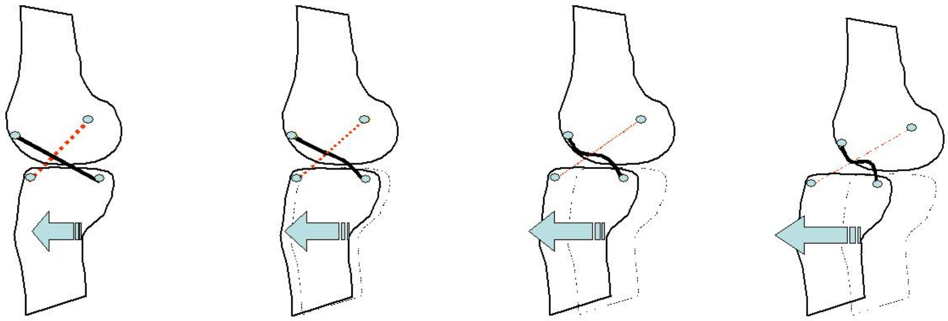


fig. 5.3.2. - LCA Laxity - anterior drawer

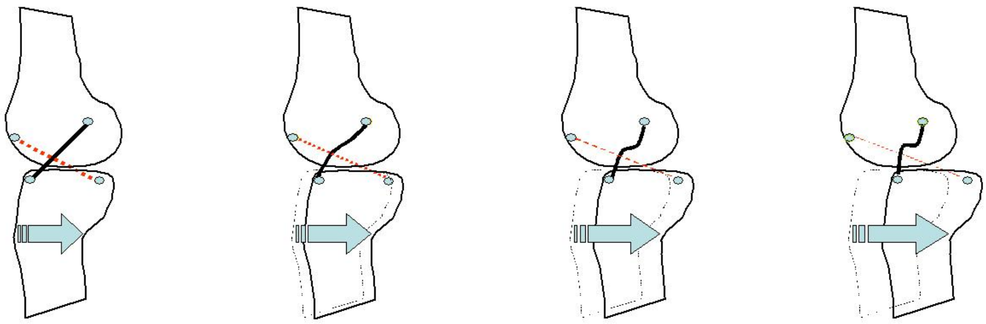


fig.5.3.3. - LCP Laxity - posterior drawer

When the knee is made integral with the joint with variable center of rotation, the joint is opposed to the anterior-posterior slipping soto avoid usury phenomena of the articular surfaces which may lead to important consequences, such as meniscal broken, osteoarthritis, etc. .

5.4. - The perpendicularity and the verticality of the center of rotation

As already mentioned in chapter 2.1., the shape of the device with variable center of rotation tends to ensure that at every stage of flexion-extension the perpendicolarity of the center of rotation is respected (initial and instantaneous), which must always hang, as specified by Insall, on the perpendicular of the articular contact point (fig. 5.4.1.).

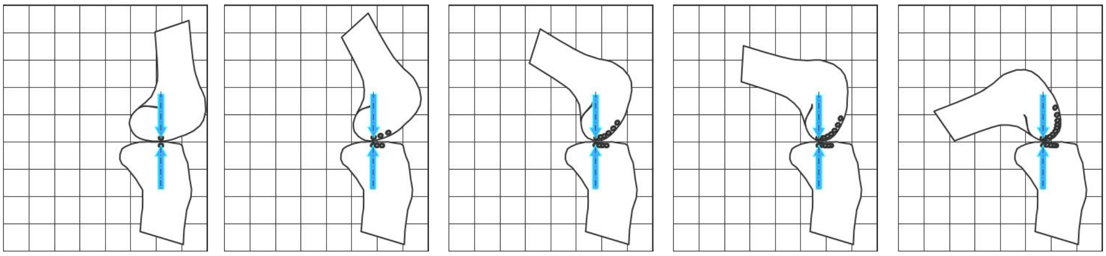


fig. 5.4.1

In practice, for this to happen, the joint is designed with four side arms that, in pairs, should be placed along the midline of the thigh (one internal and one external) and along the midline of the leg (one internal and one external - fig. 5.4.2.).

The side bars tend to support the knee making maintain a correct verticality (fig. 5.4.3.);
to this end the shape of the bars is designed so that it can adapt to the anatomy of the lower limb, also in consideration of the physiological valgus determined by the inclination of the femur.
This adaptation of the shape of the bars, has been proposed to increase the contact between the device and the limb for a better support of the knee even in presence of a compromised verticality (fig. 5.4.4.a, b).

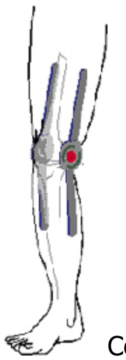
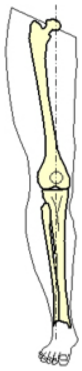
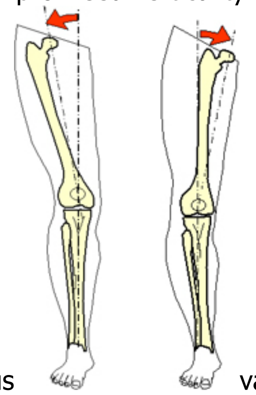


fig. 5.4.2.



Correct verticality

fig. 5.4.3.



valgus varus

fig. 5.4.4. a, b

Functional compatibility – cartilage anisotropy - valgus and varus

The cartilage is a tissue with anisotropic properties which mainly resists to the compression exerted by vertical forces. As explained more in detail below, the cartilage tissue has mechanical properties that depend on the direction along which the forces act; This makes it crucial that the device with variable center of rotation "forces" the center of rotation to the fall on the perpendicular of the tibiofemoral contact point and to respect, therefore, the concept of perpendicularity which is the basis of any functional concept and recovery of the articular motion.

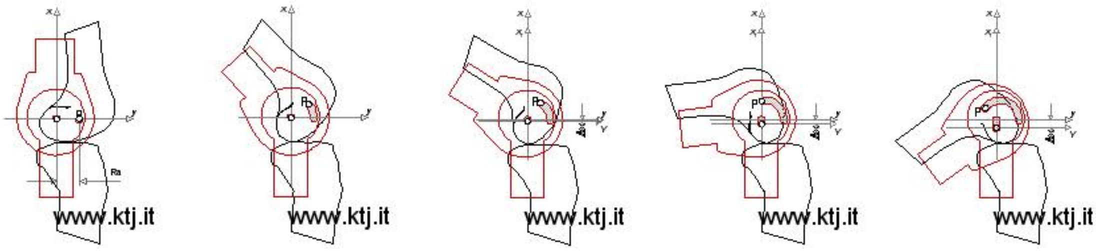


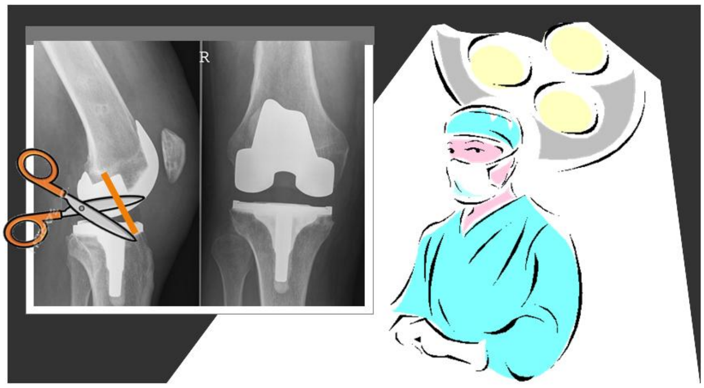
fig. 5.4.5.

In presence of a deviation of the vertical longitudinal axis of the limb (Fig. 5.4.4.a, b), joint with variable center of rotation (KTJ brace) can be proposed as a guide (provided by the side bars) which are opposed to lateral movement.

The deviation of the verticality determines compressive stress that you download only on one compartment of the knee, causing a continued and progressive degeneration of articular profiles.

To try to contrast these degenerative phenomena is important to help knee "supporting" the compartment subject to compression(Fig. 5.4.2.).

5.4.1. - Il mantenimento della perpendicolarità nel ginocchio instabile



In the implant of a complete prothesis at least one of the cruciate ligaments is lifted (Fig. 5.4.1.1.) with resulting aricular instability, partially compensated only after a good proprioceptive recovery.

(fig. 5.4.1.1.)

Such instability during deambulatory stance, may mean that the instantaneous center of rotation does not go to fall on the vertical of the articular point of contact thus determining the moments of force that may be unfavorable for grafting over time (Fig. 5.4.1.2.).

fig.5.4.1.2.

"Driving" the center of rotation on the vertical point of articular contact, the axial load, determined by the weight of the body, is transformed into an homogeneous pressure over the whole surface of contact prosthesis / bone tissue.

Until now, the use of guardians was not indicated because none of them proposed a trajectory that would ensure an axial load distribution.

Today, instead, the use of the KTJ brace in the patient with prothesis, allows to accompany the knee on the right trajectory with the double effect:

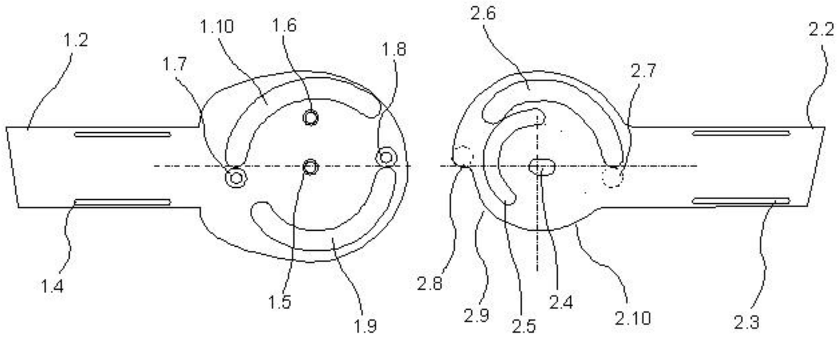
- The perpendicular transmission of the load particularly useful in the process of calcification and
- The lowest friction in movement, which reduces usury of prosthesis itself.

The same concepts are applied to unicompartmental prothesis in which both cruciate ligaments are not sacrificed (Fig. 5.4.1.3.).

fig.5.4.1.3

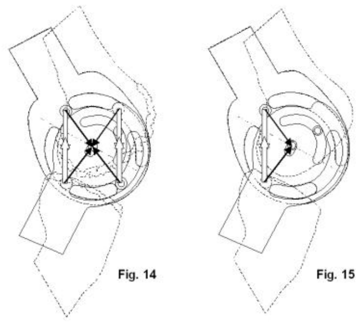
6. - Specific joint-for each pathology

Patent: "Dispositivo per il ginocchio a supporto dei carichi verticali n. GO2008000002 (Italy) , "Knee ergonomic device for resolving the vertical load" (EU) n. 2291149;



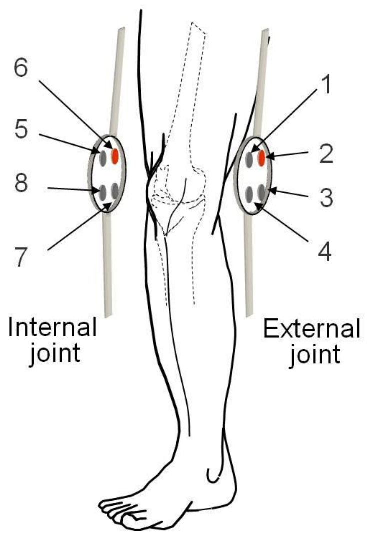
It's a new orthopedic device designed for the specific trauma of the knee and tends to reduce the vertical load (body weight) that weighs on the knee in walking and running.
The roto-traslational dynamic, is assisted by 8 pins (4 inside the joint and the outer 4 in the outside) positioned so as to realize the force components that tend to keep perfectly away each articular heads during the movement.

In this way the load is distributed on the physiological points (femoral and tibial) and on the 8 mechanical points which transmit it directly from the leg to the thigh bypassing the knee itself.



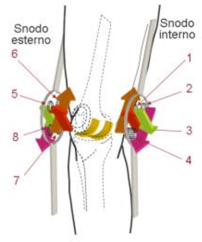
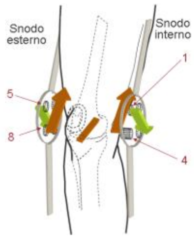
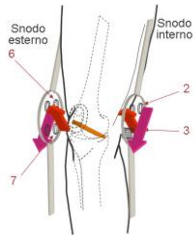
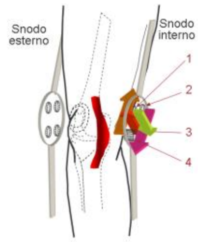
In addition to this, the specific positioning of one or more pins, creates a precise force component which is opposed to a specific laxity determined by a joint failure.

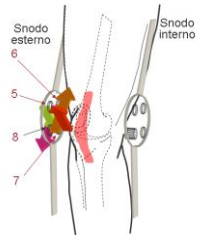
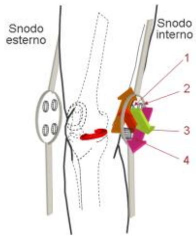
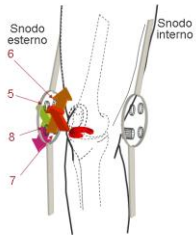
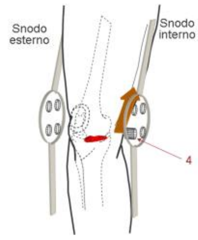
The device so "personalized" is particularly suitable for the most important diseases of the knee.

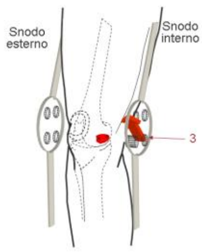
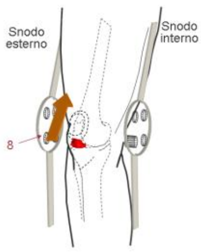
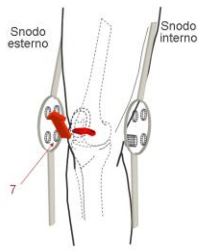
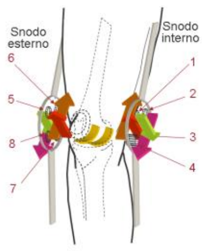


PATOLOGY
Chondropathy
Anterior Cruciate Ligament ACL
Posterior Cruciate Ligament PCL
Medial Collateral Ligament MCL
Lateral Collateral Ligament LCL
Medial Meniscus
Lateral Meniscus
Medial Meniscus Horn Front
Medial Meniscus Posterior Horn
Lateral Meniscus Horn Front
Lateral Meniscus Posterior Horn
ACL + medial meniscus
ACL + lateral meniscus
PCL + lateral meniscus
PCL + medial meniscus
Varo Knee
Valgus Knee
Tibial plateau fracture

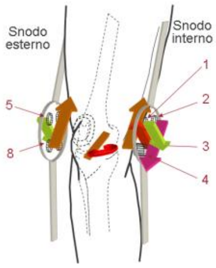
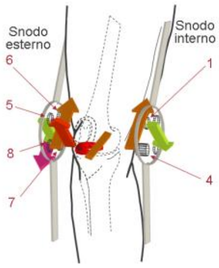
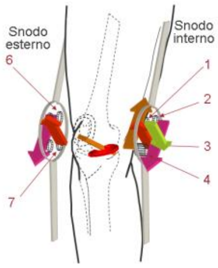
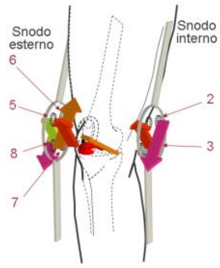
6.1. - Major Diseases

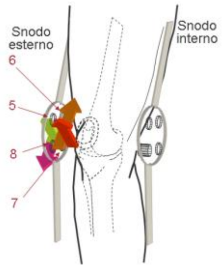
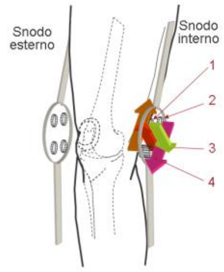
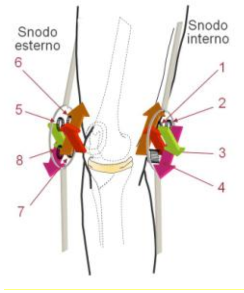
Chondropathy	Anterior Cruciate Ligament ACL	Posterior Cruciate Ligament PCL	Medial Collateral Ligament MCL
			

Lateral Collateral Ligament LCL	Medial Meniscus	Lateral Meniscus	Medial Meniscus Horn Front
			

Medial Meniscus Posterior Horn	Lateral Meniscus Horn Front	Lateral Meniscus Posterior Horn	Tibial plateau fracture
			

6.2. - Other Diseases

ACL + medial meniscus	ACL + lateral meniscus	PCL + lateral meniscus	PCL + medial meniscus
			

Varo Knee	Valgus Knee	Tibial plateau fracture	
			

2nd part

7. - Human studies

Further work has been done to try to determine any benefits attributable to the device with variable rotation center compared to other systems on the market.

7.1. - THE TOLERANCE OF A PROTECTOR WITH AN ARTICULATED JOINT WITH A VARIABLE ROTATION CENTRE DURING THE RE-EDUCATION OF AN UNSTABLE KNEE.

XVI Congresso Internazionale di Riabilitazione e Traumatologia - Milano 2007

Pellis G., Di Cosmo F.:

The aim. To evaluate the tolerance young athletes have to two knee protectors, using different types of articulated joints: the KTJ© articulated joint with a variable rotation centre (Fig. 7.1.1.) and the double centre articulated joint (Fig. 7.1.2.).

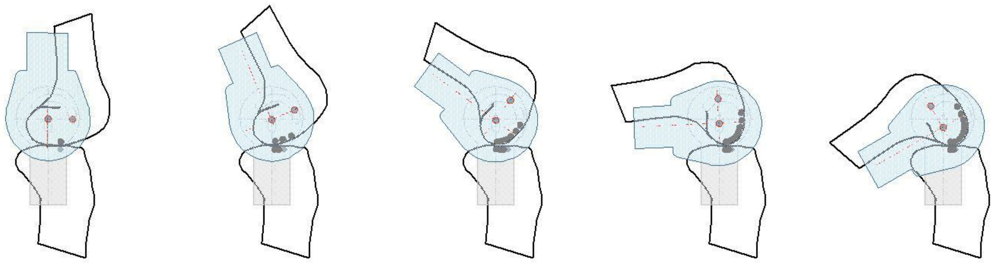


fig.7.1.1.

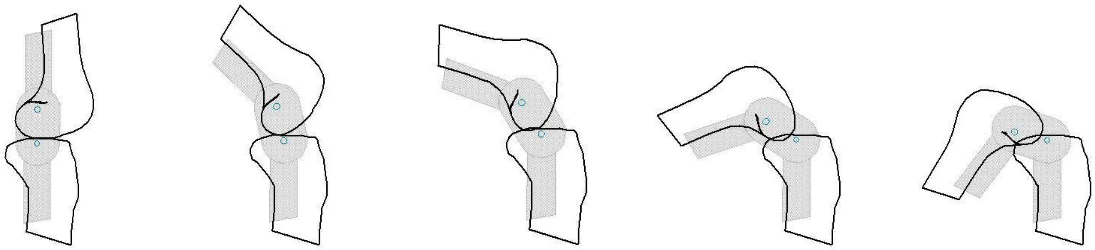


fig. 7.1.2.

The models. 8 males and 2 females (footballers) took the test in two stages: the first stage was carried out with four exercises, where they wore only one knee protector, first one type then the other, choosing randomly; in the second stage they had to complete 10 exercises, with both knee protectors worn at the same time.

The evaluation method. At the end of each exercise, the models were asked to indicate, on a scale of 1 to 10 (Fig. 7.1.3.), any feelings of discomfort they had had, the mobilisation of the protector, any limitations of movement they experienced during the test and how many times they had had to re-position the knee protector manually

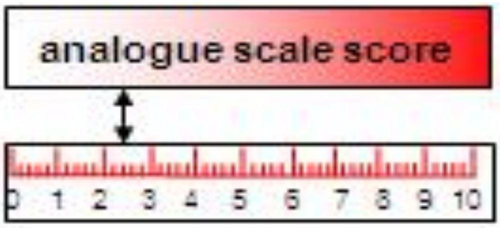


fig. 7.1.3.

RESULTS

First stage

Es.1) walking	5,5 km/h:	- 4,3%
Es.2) running	8,5 km/h:	- 22,3%
Es.3) running	12 km/h:	- 37,5%
Es.4) running	20 km/h:	- 1,9%
Average-		**16,5%**

Second stage

Es.1) walking	5,5 km/h:	+30,7%
Es.2) running	8,5 km/h:	+20,1%
Es.3) running	12 km/h:	+27,2%
Es.4) running	20 km/h:	+29,3%
Es.5) vertical jumps n.15:		+25,2%
Es.6) lateral translocation:		+28,7%
Es.7) running forwards and backwards:		+21,9%
Es.8) running and jumping:		+30,7%
Es.9) cyclette 125 watt:		+27,2%
Es.10) proprioceptive table:		+18,5%
Average:	**+25,9% = comfort KTJ©**	

CONCLUSIONS

The positive tolerance (+25.9%) of the knee pad using a KTJ© articulated knee joint compared to the knee pad using an articulated knee joint with a double centre, reflects on a personal level what has already been found from previous studies. These showed the transmission of minimum and balanced tensions on the cruciate ligaments by the KTJ© articulated joint with variable rotation centre during knee movements and the harmony of the rotational-translatory motion with the real trajectory of the knee which the KTJ© articulated joint gives. This harmony is not verifiable with the double centre articulated joint which is the one found in most protectors on the market.

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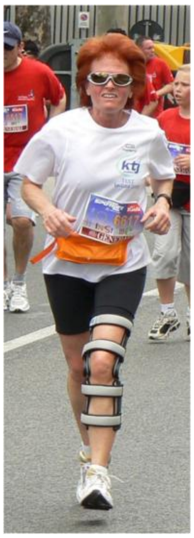

7.2 - Joint with variable center of rotation on guardians.

7.2.1. - The $^1/_2$ Marathon

A subsequent check on comfort found in the study presented in the previous pages, was proposed by making running 4 healthy subjects who wore a KTJ brace, the half marathon (21.097m).

Patients who did this test had instruction that in case of "annoyance" or "impediment in the running", could remove the guardian, at any time, to not give up to finish the race.

The aims, however, was to check the condition of the skin after the finishing line, considering the fact that if this was found red or abraded, this problem would be charged to the conflict between the trajectory of the joint with variable center of rotation and the physiological motion of the knee.

Wanting to underline that in these races, where the repetition of the gesture is proposed without interruption for more than two hours, even a shirt with a seam badly done, can lead to bleeding and abrasions of the most sensitive part of skin.

Results

After the test, all athletes examined showed no sign of redness on the skin.

In addition to the statements on feelings during the race had been very positive.

Almost all were agreed that initially they "felt" the guardian, but just "entered in the race" due to fatigue and for tactical engagement, they did not "feel it anymore".

In addition, the common comment after the race was: "I felt my leg more stable and relaxed"

The following year (2009), given the particularly positive effects on healthy subjects, the research was extended to "injured runners" who could not compete but they did not to give up to a "sgambata". 5 athletes have agreed to participate in a "not competitive" race of 8 km using a KTJ© brace.

All the 5 participating athletes finished the race.

The common comment: "*The brace helped me, I felt the difference, I was able to finish the race without stopping, my knee did not blow*"

In this case too, no one, after the trial, had signs of abrasion or skin irritations due to friction or conflict between the guardian and the skin.

7.3. - The variable rotation centre knee-pad: assessment of gait and ADL in patients with gonarthrosis operated for lower limb arthroprosthesis

8th Mediterranean Congress of Physical and Rehabilitation Medicine – Limassol – Cyprus 29/9 – 2/10 - 2010

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Foreword: the term gonarthrosis is meant as a degenerative process initially involving cartilage and in advanced phases affecting also bones and synovial joints of the knees. Associated symptoms render the rehabilitation program very complex by not allowing proper support to the limb affected by osteoarthritis, making it difficult for the patient to return to a correct gait and slowing down, and sometimes even preventing, a full recovery of autonomy in activities of daily living.

Can a variable rotation centre knee-pad favour the recovery of a good autonomy level in ADL?

Resources and Methods: This testing began in January 2010. Subjects are represented by 20 patients (11 female and 9 male) who underwent surgery of hip or knee arthroprosthesis, who were carriers of gonarthrosis homo-or contralateral. 11 were female and 9 were male.
Minimum age of subjects 65 years, maximum age of subjects 86 years, average age of subjects 76 years. The controls consist of patients who underwent the same kind of operation but without phenomena of gonarthrosis. 11 female 9 male. Minimum age of subjects 67 years, maximum age of subjects 84 years, average age of subjects 77 years.
Subjects were given a variable rotation centre knee-pad, a device designed to follow the fascial and ligamentous structures of the knee.
The two groups were controlled through the WOMAC osteoarthritis index both in terms of level of autonomy in ADL when admitted to our department and on months 1 and 3.
Patients with gonarthrosis using the knee-pad were also evaluated on a stabilometric platform through the Static Test Riva in order to define the oscillation of the body axis and to evaluate the usage time of hands in a precautionary support position. They were also evaluated with the 100 m Walking Test for comparing the travel time of 100 m with and without knee-pad., and finally the pain symptom was avaluated through the VAS scale before and after the application of the knee-pad.

Results: Subjects evaluated so far show have shown a level of autonomy in ADL overlapable to patients without osteoarthritis after the use of the knee-pad.
This can be seen in the chart.
Please remember that higher WOMAC grade correspond to worse clinical conditions.
The assessment of the balance through the stabilometric platform through the Static Test Riva demonstrates that the use of a variable rotation centre knee-pad determines a reduction of the swing in monopodalic support thereby reducing the risk of falling.
As seen in chart 2 the average oscillation of the body axis during monopodalic support passes from 3,0° to 2,4 ° and it decreases its precautionary resting time (see chart 3) from 82,2% to 60,7% in patients using the knee-pad.

The 100 meters walking test shows an improvement of the capacity of dynamic walking. Patients using the variable rotation centre knee-pad show an average reduction in 100 m walking time from 2:45 to 2:25 minutes.

According to VAS scale (Chart 5), pain evaluated before using the knee-pad and a month after its use, outlines a distinctive decrease of the pain symptom with the average VAS grade dropping from 7 to 3.

Conclusions: The employment of a variable rotation centre knee-pad should be one of the main treatments in the management managing of gonarthrosis. Our result confirms the ipotesis assumption that a variable rotation centre knee-pad favours the recovery of a good good quality autonomy level in ADL without exert causing unnecessary stress on the fascial and ligamentous structures.
The variable rotation centre knee-pad also determines a prompt and immediate pain reduction and improved balance and gait thereby reducing the risk of downfalls.

Chart 1 – Grafico 1

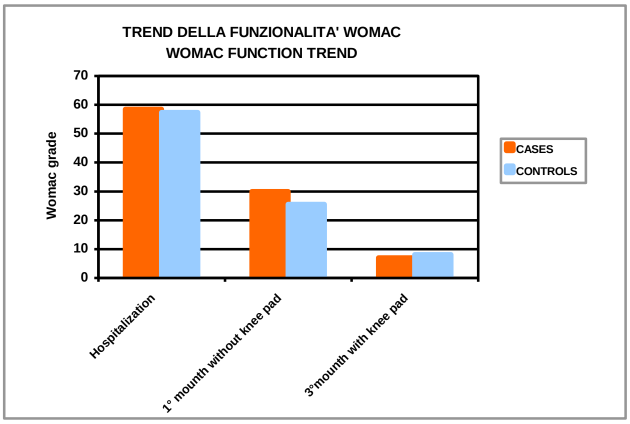


Chart 2 – Grafico 2

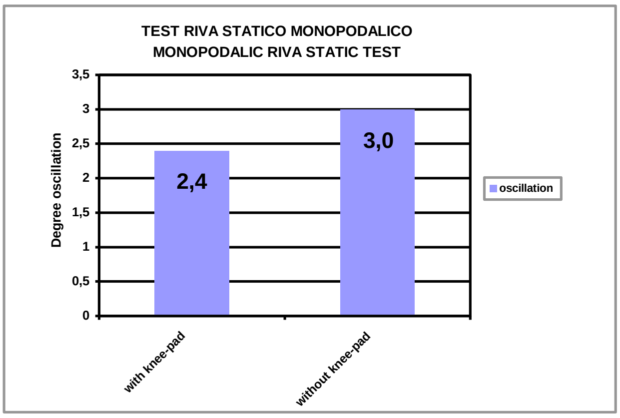


Chart 3 – Grafico 3

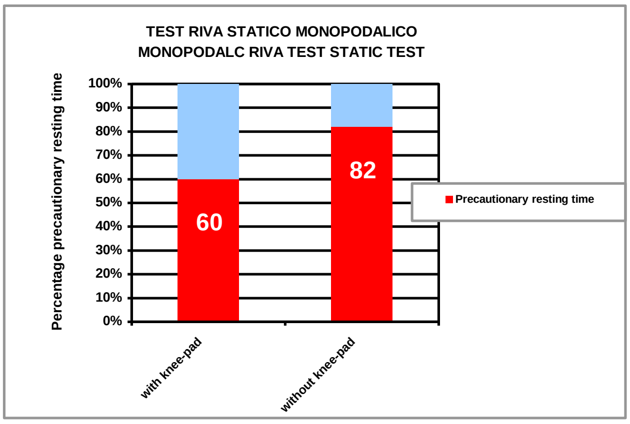


Chart 4 – Grafico 4

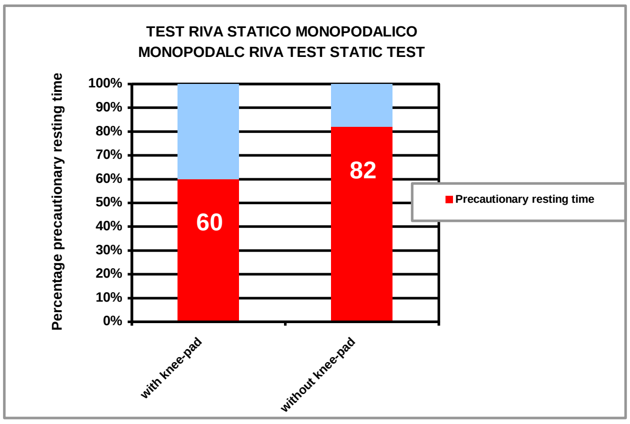
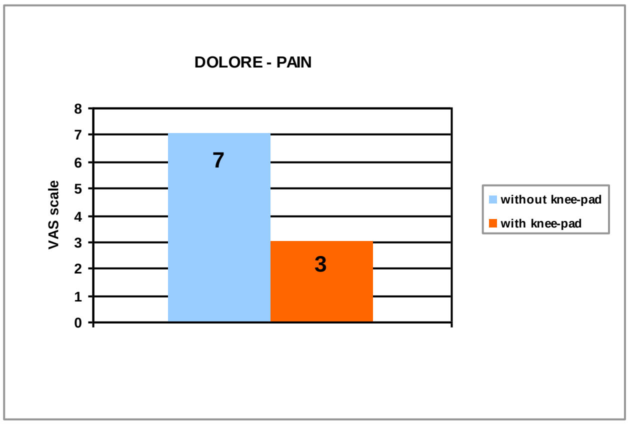


Chart 5



3rd part

8. – Load protected

The primary objective, after an inability period, is the need to recover the full motor functionality that unquestionably passes for a correct recovery of deambulatoon and, subsequently, also the running recovery.

In a general context KTJ devices may, therefore, be used:

in the immediate post-trauma and during any period previous surgery
which can be protracted also for 3-4 months during which it is important
- Maintain a good degree of muscular trophism;
- Prevent further damage to the articular structures;
- Be able to resume autonomy for own professional activity;

in the immediate post operating-physiotherapy
period in which it is necessary to start physiotherapy through passive mobilization and protect what has been surgically reconstructed and resume deambulation in compliance with the concept of protected load;

after physiotherapy.... before gym
period in which, finished the medical care, but still persisting musclular stiffness, swelling, pain and limited possibility to articulate and it is not possible to resume full play-sports activities.

A proper motion programming, with **load protected**, can create the more favorable conditions for a correct sequence of trained stimuli which using the supercompensation principle, made that progressive rehabilitation work that tends to bring the injured to the primitive functionality based on the physiological principles highlighted by the "general adaptation syndrome".

8.1. – The protected load

Nowadays there are many proposal addressed to the recovery of deambulatory activity for patients with desease of knee cartilage.

Even with the awareness that cartilage lesions tend not to heal and to degenerate into osteoarthritis, literature contains a lot of rehabilitative approaches : directed to the development of eccentric strength , to an adequate muscole trophism , to the early mobilization, ecc..

From a careful analysis of existing protocols and in particular of a study on the mechanical characteristics of cartilage tissue with specific reference to the concepts of "anisotropy" and "adaptability" , the **protected load system** has been developed ,based on the use , in motion rehabilitation activity , of a Ktj brace to guarantee the respect of the perpendicular load and of joints in synergy with the deambulatory activity planned depending on the exploitation of physiological laws that regulate the process of organic adaptation (or rehabilitation).

The proposed methodology has been applied for more than 10 years at the Center of Sport Medicine of Trieste on athletes and not, particulary on subjects included in an age range from 40 to 60 years presenting problems resulting from the knee osteoarthritis.

The results were very positive and led to further develop a working protocol that allow to create the best conditions to awake those chain of physiological responses that tend to lead to a repowering of the articular cartilage tissue.

The **protected load system** was structured as a rehabilitation protocol after cartilaginous/articular trauma of the knee with the aim to offer a

mechanical defense with the use of KTJ© brace to ensure the full respect of joints, the vertical load and the load reduction during deambulation (resulting in reduction or disappearance of pain)

defense against stress overload proposing a load quantity programming (understood as speed of deambulation , distance to go and recovery time) organized in accordance with the laws regulating organic adaptation to activity in motion.

8.2. - The cartilage biomechanics

Articular cartilage is a tissue composed of collagen fibers absorbed in a matrix of proteoglycans ; it is not innervated and it has no blood vessels. The only cellular elements are the chondrocytes, specialized to live in a environment continuosly stimulated (Fig. 8.2.1.).

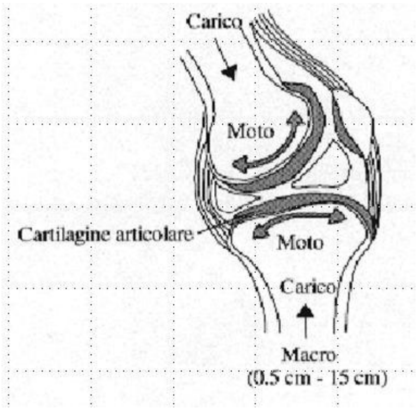


fig. 8.2.1.

Chondrocytes are long - lived and , in normal conditions ,stop to multiply at the end of growth , keeping their numbers unchanged for the rest of life.

The articular cartilage has little intrinsic ability to repair and every defect of the tissue tends not to heal deteriorating over time in arthritis. Exercise can delay this process because chondrocytes are able to respond positively mechanical stimuli even if the response of cartilage cells will be different depending on the intensity of mechanical stimuli administered and on its constitution.

Articular cartilage is mainly composed by water (68 - 85 %), collagen (10 - 20 %) and proteoglycans (5 - 10%) that act together ; In particular the mechanical behavior depends on the amount of collagen and on the arrangment in the thickness of the cartilage itself.

Microscopically the cartilage can be divided in 4 depending on the collagen organization and on the proteoglycans density : the first area (superficial which is equivalent to 10 - 20 % of thickness) has the higest content of collagen (85%) and fibers are parallel oriented to the surface; the fibrillar system assumes overall a multiple arches morphology and the collagen fibers tightly intersect each other to form a three - dimensional network in the interstices of which the liquid component is "retained".

When, because of compressive forces , the water contained in the fibrillar system is squeezed out (Fig.8.2.2.) and generates drag forces between the liquid component and the solid matrix that grow with compression increasing and make the exudation more difficult.

So the cartilage becomes stiff when load increases.

The compaction degree of the proteoglycans affects fluids motion during compression and so on the permeability as a resistance of the flow through the cartilage matrix . In particular ,when the cartilage is under compression there is a viscous friction due to the resistance that the interstitial fluid meets in its movement. Under increasing load, the fluid flow decreases and with it the permeability accompanying the compression that is the mechanical stress which acts on articular cartilages of the knee during deambulation that is the main motion action for moving.

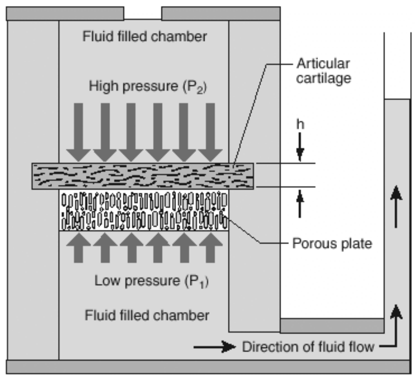


fig. 8.2.2.

The alternate compression

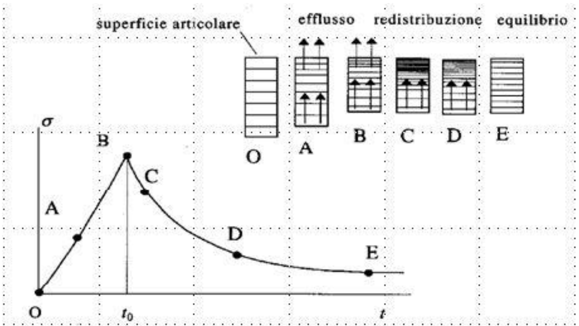


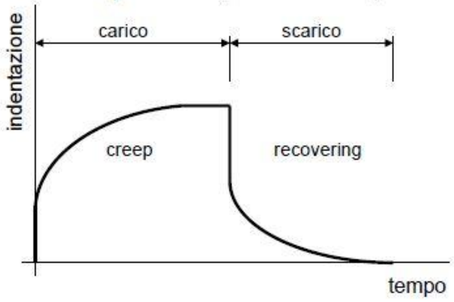
fig. 8.2.3.

MK Barker and BB Seedhom (2000) , have analyzed the cartilage behavior in laboratory subjecting samples of it to **alternate compression** as occurs during deambulation (Fig. 8.2.3.).

From their results it appears initially that , when the cartilage surface is solicited with alternate loads, the water exuded during the load phase is not completely reabsorbed during the recovery phase, it means that the cartilage does not completely compensate the deformation received.

Continuing the number of phases load/recovery , instead, we have a reduction of liquid quantity loss : during compression the cartilage releases a water quantity equal to how much it absorb during unloading (Fig.8.2.4).

So, we have an instantaneous deformation of the solid matrix during loading followed by an instantaneous and equal recovery of form during the unloading phase. During this behavior , defined "elastic" , a minimal deformation is evident which is determined by the exudation and consequent absorption of small and equal volumes of liquids which depend on viscous friction.



So, the "visco - elasticity" determines a "damper" effects made according to the vertical loads alternation acting during deambulation.

fig. 8.2.4.

The anisotropy

Cartilage is a tissue with **anisotropic properties** that mainly resists to compression exercited by vertical forces as studied *by Jurvelin JS, Buschmann MD , Hunziker EB in the work " Mechanical anisotropy of articular cartilage of the humans knee in compression*" 2003.

Recalling that anisotropy is the mechanical property for which a material has characteristics that depend on the direction along which forces act , with specific reference to the knee ,the Authors state that " *anisotropy during compression* (exercited in the orthogonal direction to the point of articular contact) *may be essential for the cartilage function... this property must be considered development of advanced theoretical models for the cartilage biomechanics*."

It seems also relevant to report that MK Barker and BB Seedhom (2000) , on the environment in which cartilages work, stated that : "**the synovial fluid**, especially under condition of static load , allows much better performances".

However, the performances of articular cartilages depend also from the type of synovial liquid there is in the articulation which , composed by blood plasma, hyaluronate and glycoproteins, acts as a lubricant and provides nourishment to the cartilages.

The adaptation to vertical loads

The more relevant concept to the development of a rational rehabilitational protocol , is based on MK Barker and BB Seedhom 's sperimental concept (2000) for which "*all the constituent components of matrix of cartilage **fit** as a function of compression deforming* " in particulary to those forces that are exerted perpendicular to the surface plane (Fig. 8.2.5.).

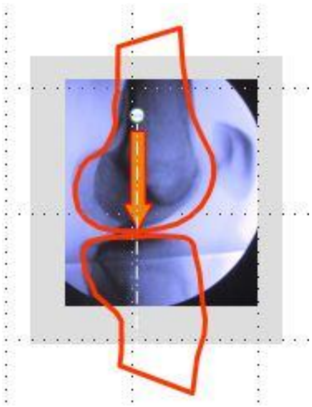


fig. 8.2.5.

In rehabilitational protocol , on the **adaptability concet** , the cartilage is associated to any biological function : in fact ,if cartilage tissue cannot regenerate ,the old one , remained intact if properly stimulated (respecting anisotropy concept) and following principles that regulate the organic adaptation , can readjust to the new situation by increasing its efficiency and functionality

8.3. - Application of organic adaptation laws as theoretical basis of the rehabilitational protocol

The organic adaptation uses that chain of physiological responses, defined by Selye as **General Adaptation Syndrome** ,consequent to a stress situation such as trauma, diseases , strong emotions, work in motion , ecc...

The reactions chain is divided into answers :

- Non specific of short-term and of low - intensity followed by *very pronounced* phenomena with the peculiarity of being always the same , independently from the stressor agent that affects the body: trauma, disease , emotion, work in motion, ecc.;

- Specific tend to increase one or more biological functions *with summation effect* after constant repeability of stress or understood as a repetition of specific working in motion.

The response phenomena "*very pronounced*" and " *summation effect*" , are the basis of adaptation of an organic function that is of the modification of specific structure oriented to bear increasingly heavy situations.

For this to happen mechanical /in motion stimulus must be programmed in a sequential and growing way : in fact if the first exposition was not too severe and the duration of the resting phase was sufficient, the next exposition finds the body already prepared and with a top degree of adaptation from the start , because the body always repays the work done with an higher level than consumed (very pronounced reponse) ; this increase in energy availability is defined "***supercompensation***".

This leads to a subsequent increase in resistance to specific stimulus compared to the initial , provided the time elapsed between the two expositions is not excessive and the body retaining the memory.

In this case ,a new exposition well-dosed even if more intense than the previous , will further increase the adaptation and resistance capacity;

In this way we will have for shelves , an increase in capacity preparing the system to increasingly intense loads (Fig. 8.3.1.).

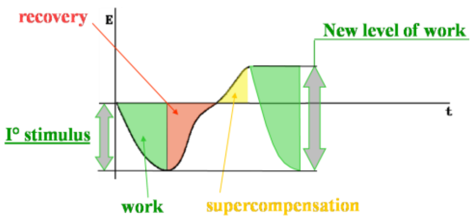


fig.8.3.1.

A proper organization of rehabilitation work , then, should provide a rational and progressive distribution of work loads in between the various sessions that should be gradually and progressively increased, but alternating with specific relief phases (during which load must decrease) and of rest.

In this periods that organic **adaptation** happens, that is the settlement of those mechanisms that repays the work done , increasing and cementing the functional reserves and preparing the biological system to an heavy situation (Fig. 8.3.2.).

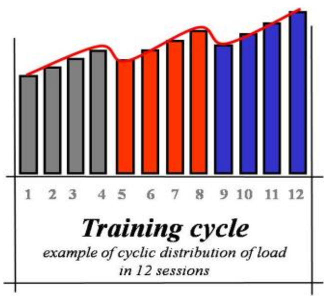


fig. 8.3.2.

Specifically , the programming of activity in motion oriented to the functional recovery of the knee cartilage must provide a precise consequentiality of "pressure" stimulus (alternation compression/recovery) generated by the deambulatory action during which the visco - elastic process of "damping " of cartilage is reactivated and programmable by " deambulation speed distance to go ,recovery time ".

8.3.1. - TOP7.KTJ - Software for Protected load work in motion programming

TOP7.KTJ is oriented to three main functions :

- the deambulation recovery
- the running recovery
- strengthening of lower limb muscles

Specially :

- Programs for the protected load deambulation recovery, have been developed trying to comply with the mechanical properties of cartilage , to restart that visco - elastic process which is the base of mechanical functionality.

For this each program indicates exactly

- deambulation speed to maintain (calculated according to the results on which was calculated the alternation cartilage liquid exudation/absorption during compression) ;

- distance to run (calculated according to the numbers of phases load/recovery during which cartilage mechanical properties remain unchanged) ;

- the recovery periods to be made between series of work so that cartilage totaly rest and recover its characteristics of visco - elasticity.

Between the individual training sessions , **TOP7.KTJ** proposed a moderate increase in workload (understood as speed , distance , recovery time) so that there may be those summation effect which exploits that response very pronounced caused by the previous work session.

Program effectiveness is based on deambulation to specific speed mainteined for specific distance. So, it is very important strictly follow the set schedule evenwhen you feel good and you are convinced "you can do more".

The main characteristic of **TOP.KTJ** Software, however, is the cyclic workload, specifically targeted to the adaptation of articular cartilage of the knee , which must take into account the anthropometric characteristics of the subject and in particular of the body weight that inevitably rests on the knee . More the subject is heavy , more the load should be initially reduced and distributed over time to avoid overloading of the articular structure.

To solve this problem , **TOP7.KTJ** modulates the distribution in function of the Body Mass Index (BMI – Fig. 8.3.4.):

PESO (kg)	45.3	47.6	49.8	52.1	54.4	56.7	58.9	61.2	63.5	65.7	68.0	70.3	72.5	74.8	77.1	79.3	81.6	83.9	86.1	88.4	90.7	92.9	95.2	97.5	99.7	102.0	104.3	106.5	108.8	111.3	113.4
ALTEZZA (cm)	INDICE DI MASSA CORPOREA (BMI)																														
152	20	21	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49
154	19	20	21	22	23	24	25	26	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	43	44	45	46	47
157	18	19	20	21	22	23	24	25	26	27	27	28	29	30	31	32	33	34	35	36	37	37	38	39	40	41	42	43	44	45	46
160	18	19	19	20	21	22	23	24	25	26	27	27	28	29	30	31	32	33	34	35	35	36	37	38	39	40	41	42	43	43	44
162	17	18	19	20	21	21	22	23	24	25	26	27	27	28	29	30	31	32	33	33	34	35	36	37	38	39	39	40	41	42	43
165	17	17	18	19	20	21	22	22	23	24	25	26	27	27	28	29	30	31	32	32	33	34	35	36	37	37	38	39	40	41	42
167	16	17	18	19	19	20	21	22	23	23	24	25	26	27	27	28	29	30	31	31	32	33	34	35	36	36	37	38	39	40	40
170	16	16	17	18	19	20	20	21	22	23	23	24	25	26	27	27	28	29	30	31	31	32	33	34	34	35	36	37	38	38	39
172	15	16	17	17	18	19	20	21	21	22	23	24	24	25	26	27	27	28	29	30	30	31	32	33	33	34	35	36	36	37	38
175	15	16	16	17	18	18	19	20	21	21	22	23	24	24	25	26	27	27	28	29	30	30	31	32	32	33	34	35	35	36	37
177	14	15	16	17	17	18	19	19	20	21	22	22	23	24	24	25	26	27	27	28	29	29	30	31	32	32	33	34	34	35	36
180	14	15	15	16	17	17	18	19	20	20	21	22	22	23	24	24	25	26	26	27	28	29	29	30	31	31	32	33	33	34	35
182	14	14	15	16	16	17	18	18	19	20	20	21	22	22	23	24	24	25	26	26	27	28	28	29	30	31	31	32	33	33	34
185	13	14	15	15	16	16	17	18	18	19	20	20	21	22	22	23	24	24	25	26	26	27	28	28	29	30	30	31	32	32	33
187	13	13	14	15	15	16	17	17	18	19	19	20	21	21	22	22	23	24	24	25	26	26	27	28	28	29	30	30	31	31	32
190	12	13	14	14	15	16	16	17	17	18	19	19	20	21	21	22	22	23	24	24	25	26	26	27	27	28	29	29	30	31	31
193	12	13	13	14	15	15	16	16	17	18	18	19	19	20	21	21	22	23	23	24	24	25	26	26	27	27	28	29	29	30	30

fig. 8.3.4.

the more unfavorable is this index, the more diluited will be workloads over time (Fig. 8.3.5.a, b, c).

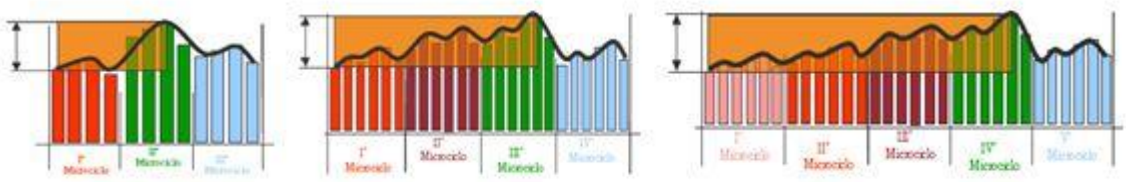


fig. 8.3.5. a. normal weight b. overload c. obesity distribution

8.4. - Protected load deambulatory recovery

The importance of the support foot in deambulatory recovery

A proper deambulatory recovery has as its basis a proper *proprioceptive systems* strengthening that are activated only with the support of the foot on the ground, region of the body that trasmits the most information on the balance as the basis for a correct posture and the consequent control of the relationship between thigh/leg/foot.

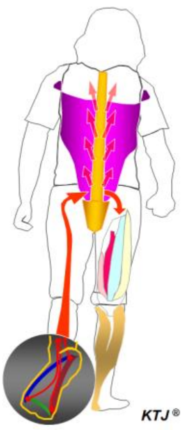


fig. 8.4.1.

We can say that a limb with a stable postural balance , allows the development of an appropriate dynamic activity.

The importance of the support foot

The foot is the region of the body that transmits the largest numbers of proprioceptive information indicating instantaneously movements that the body is making.

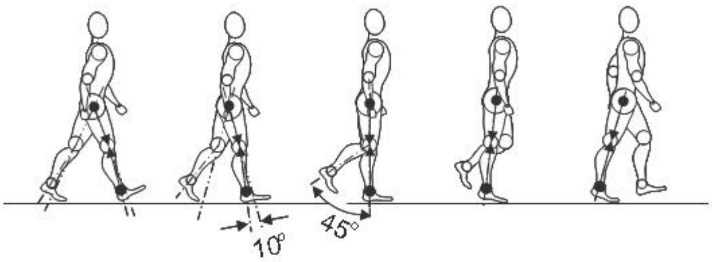
The main proprioceptive receptors are located in the arches of the foot (trasverse lateral and longitudinal) and particulary in the front of the heel, under the head of metatersals , under the big toe and in the eumbrical muscles of the foot and are solicited on the basis of the degree of deformation during the support (Fig. 8.4.1.).

This function is crucial for balance and a proper posture and the consequent control of the reltionship between segments thigh/leg/foot.

The deambulatory dynamic

Analyzing in more detail the step, we can break it down in a dynamic phase of (Fig. 8.4.2.):

- *ground contact,* the thigh is in line with the leg and the body weight loads on the knee;
- *air phase* , instead , the knee is flexed at an angle of 45-50°,



- (fig. 8.4.2.)

Lameness

Also this function tends to avoid onset of pain and as a result the interruption of flexion of the leg on the thigh so lameness ; in the air phase or in the tilting of the injured leg forward (fig. 8.4.3. e., f., g., h.) , the leg itself is unable to bend over 30° to shorten the distance from the ground so that the foot does not impact with it . Instinctively the propre deambulatory action changes : the injured leg remains semifolded if not almost rigid , while the foot of support is forced to extend more to increase the difference in height of the center of gravity from the ground.

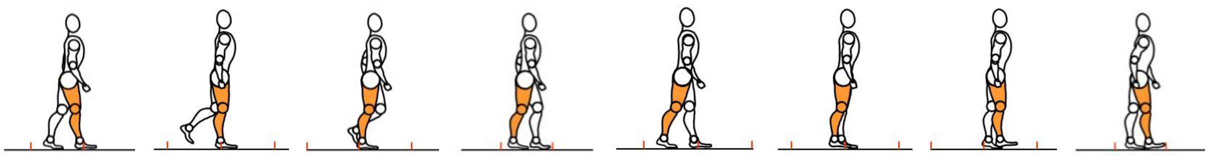


fig. 8.4.3. a) b) c) d) e) f) g) h)

Note: *we want to underline that traditional crutches or the use of the stick, initially allow a discharge of the joint but significant, considering the fact that the support is always carried out on several points, in the recovery of walking does not allow to exploit the "unbalance "base on which the proprioceptive stimulation and recovery of postural balance.*

Fig. 8.4.4.

Feed Foward

Considering that the nervous system is able to perform movements already known (carried out automtically as deambulation) , and to learn new movements to adapt to perform complex gestures, which are "designed " with the creation of brain representations of learning called **engrams** , that allow an **anticipatory decision-making mechanism** (feed- foward) with respect to behavior in motion that is being implemented.

On the basis of the above, we can understand how a wrong movement (lameness) , if repeated over time,may lead to the strengthening of a deambulatory engram changed from the existing, so offsetting the fluidity of the walk bacause **this will be acquired as correct and repeated (proposed)** as reference model.

In the consideration that correcting these movements parasite determined mainly by pain in deambulation,especially in the elderly, is particularly difficult , it is very important avoid their settlement.

Studies of Dr. Zadini focused on the disappearance (or alleviation) of pain ; In her work : "*The variable rotation center knee-pad : assessment of gate and ADL in patient with gonarthrosis operated for lower limb arthroprosthesis",* she concluded saing that:

"the use of a knee brace with variable center of rotation must be between treatments of first choice in the managment of knee arthritis. Our results confirm the hypothesis that a knee brace with variable center of rotation promotes the recovery of a good level of autonomy in activity of daily living without causing unnecessary stress on the ligamentous and facial structures of the knee.

The device also determines immediate pain reduction and an improvement of balance and of deambulation resulting in reduction of the risk of falls.

8.5. - Mechanical Protection of the Knee

The considerations listed above come from observations made on a population of elderly which with various degenerative diseases (chondropathies, arthritis, servevalgus, ecc.) , have immediately realized significant benefits recovering to deambulate quickly.

These benefits are attributable to both the mechanical support offerd by KTJ© brace , and the proprioceptive recovery determined in first place from the support of the foot "safer" and amplified by cutaneous sensory system.

As explained in more detail, proprioceptive system which chairs the postulate equilibrium , has as basis the nerve sensory references present in articular organs (Corpuscle of Ruffini - proximal joint capsule, Corpuscle of Pacini - Capsule, synovium and distal joints, Corpuscle and ligaments) that cooperate synergistically with the skin receptors of which also belong the spinal nerves (Fig. 8.5.1.) that have a dual function : the posterior root (*dermatome*) develop the sensory/proprioceptive action while the front root (miomero) develop in motion action.

In lower limb dermatome and miomero overlap; It follows that a local pressure produces an immediate response of the muscles group beneath the covered area.
When a limb is fixed to a knee brace this overlaps with areas of skin that can be highlighted by the diagram below (Fig.8.5.2.).

Nerviospinali	**Motor muscle**	**Skin areas**	
L3	knee extention (quadriceps)	orange	
L4	dorsal flexion instep (anterior tibialis)	violet	
L5	extension of the big toe	blue	(long extensor of the big toe)
S1	plantar flexion instep	red	(surae triceps)

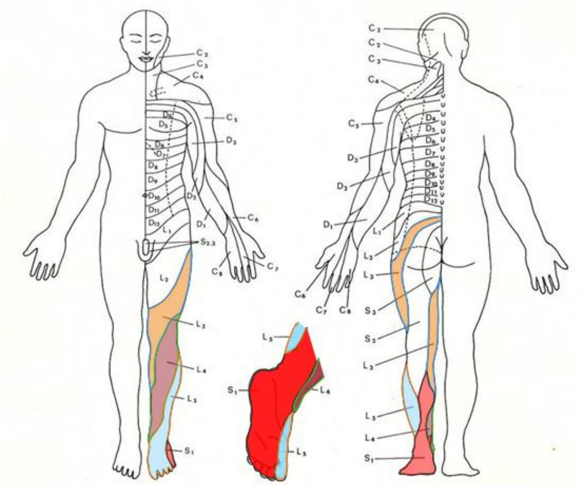


fig. 8.5.1.

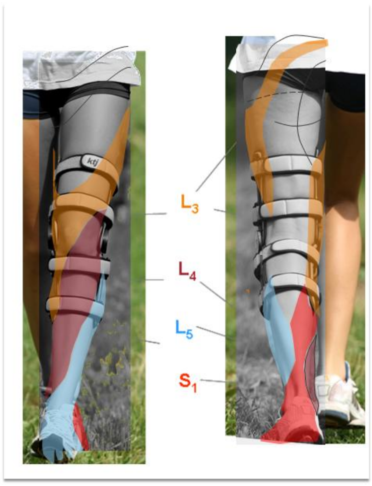


fig. 8.5.2.

So we can understand how a possible imbalance recorded during deambulation inevitably produces pressure on sides that are "transmitted" from sidebars and "felt" by sensitive skin areas.

These pressures are transposed from the *dermatome* and immediately processed for a correction of the movement by the *miomero*.

The special motion of Ktj brace helps the sensitivity of perception of skin to be free from interferences determined by friction between brace and skin, due to the perfect parallelism between the mechanical motion of orthopedic and the roto - translational of the knee (Fig. 8.5.3.).

From the consideration that the use of the brace is recommended in case of injury to a joint (organ), inevitably accompained also by an injury to nervous/proprioceptive references, we can consider sensory/skin stimulation as a "**proprioceptive amplifier**" to replace the torn , to strengthen the possibility of a proper foot support with the subsequent maintenance and improvement of postural balance.

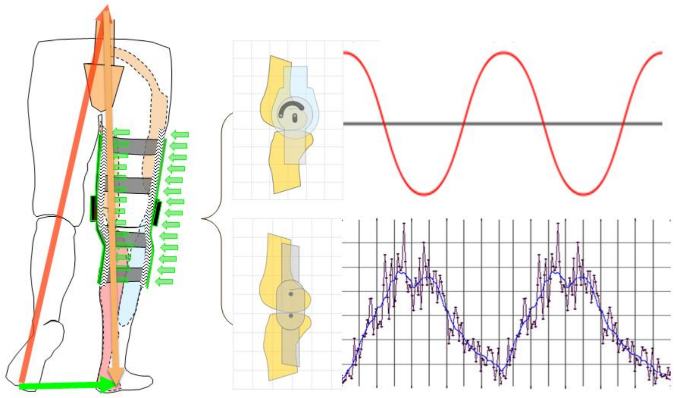


fig. 8.5.3.

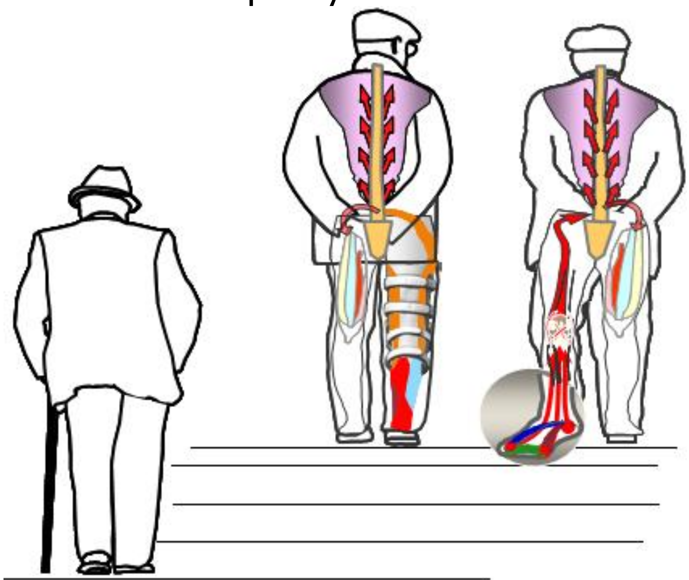
In fig. 8.5.3. it was decided to propose the difference of "signal" which is sent from an orthopedic device that uses a joint with a variable center of rotation and from one that uses a joint with a dual center (see Chapter. 6.1.). The divergence between the trajectory of the mechanical device and knee turns into "rubbing" and then in proprioceptive disorder.

The advantages for the elder

The deambulatory recovery of the elder is not only a form of autonomy , but also one more chance against loneliness and isolation . The possibility to return to deambulate creates a chain of benefits to the articulation itself, which is increasingly intensified when the movement becomes more quantitative.

The deambulatory recovery , in fact, brings benefits on strengthening of proprioceptive controls determined for the recovery of postular stability, on the muscolar system, and on that of major organ system (cardiac, circulatory and respiratory) with a marked improvement in

quality of life.



8.6. - Recovery of the run

In the first phase of recovery oriented to running recovery, it is advisable to use a KTJ© brace to protect the knee at all stages of the running itself.

Proprioceptive or contact phase: begins with the support of the foot to the ground during which are amortized forces determined by the potential energy acquired in sinusoidal lifting of the center of gravity and those pronunced in the spine for the propulsion. In this phase , proprioceptive controls that the foot transmits to the various body segments for the maintenance of postulare balance are activated (Fig. 8.6.1.).

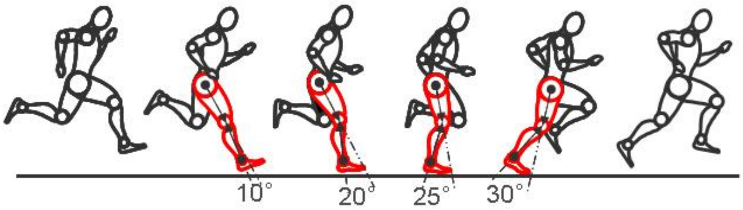


fig. 8.6.1.

Kinesthetic or air phase - When the foot is not in support, the joints of the knee are not controlled by the proprioceptive system but remains subjected to the alternate accelerations on the antero-posterior plane and to the inertia determined by the accelerations to which the mass of the foot is subjected.

Moreover , the angles between thigh and leg reach their maximum closure during which the progressive and predominant slip between joints is expected.

So, in air phase, knee is subjected to kinesthetic control that elaborates stress as : motion direction, angulation between joints, acceleration, progress speed (Fig. 8.6.2.) but excludes articular heads control on the dynamic relationship because they remain free to move in function of the drag determined by the acceleration forces of the peripheral masses especially at the closed angles.

In this phase KTJ© brace can support the unstable knee accompanying it especially in angles of the translation , absorbing tractions determined by the alternation of oscillatory motion of the whole lower limb.

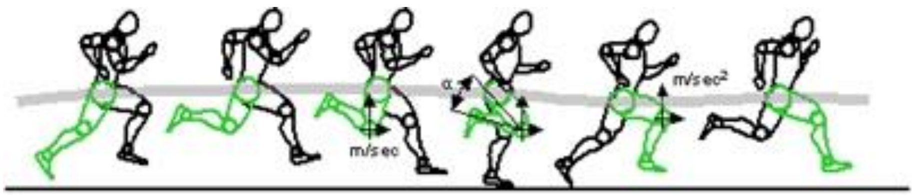


fig. 8.6.2.

Other

8.7. - Pedaling: the alternation compression / traction

In cycling the knee is stressed alternately in compression in the "push" phase (limb extension) and in traction in the "lifting" phase (limb flexion).

It seems relevant to point out that while the compression stress is a "physiological" solicitation, which reflects what was created to counteract the gravity, traction stresses (Fig. 8.7.1.) are particularly "atypical" and contraindicated in unstable knee also due to the repetitive rhythm of pedaling, as mechanically action which tends to the removal of articular heads.

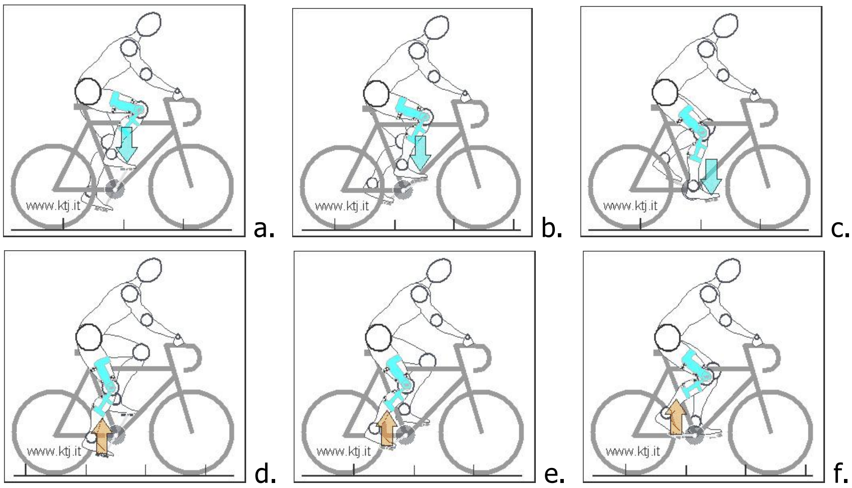


fig. 8.7.1.

Functional compatibility

The KTJ© function objects to those dynamics tending to support the knee in the push phase (Fig. 8.7.1.a., b., c. e Fig. 8.7.2.a., b.), with a function of lightening of the compression and holding it in the phase of "lifting" during the limb flexion (Fig. 8.7.1.d., e., f. e Fig. 8.7.2.c., d.).

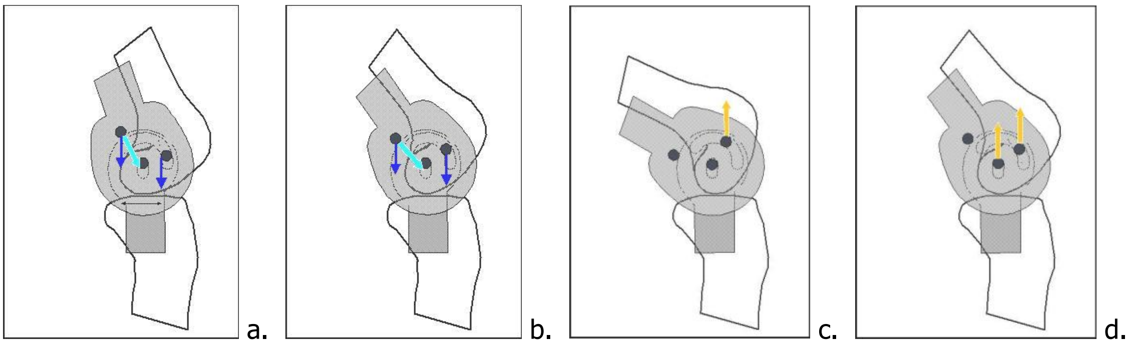
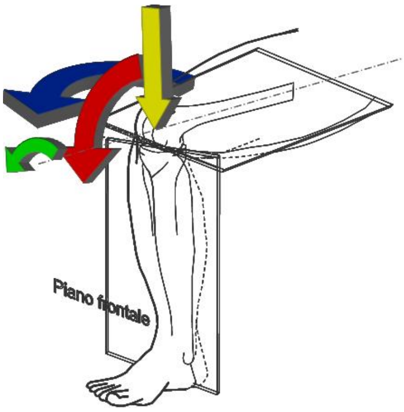


fig. 8.7.2.

8.8. - In ski - the twist moment

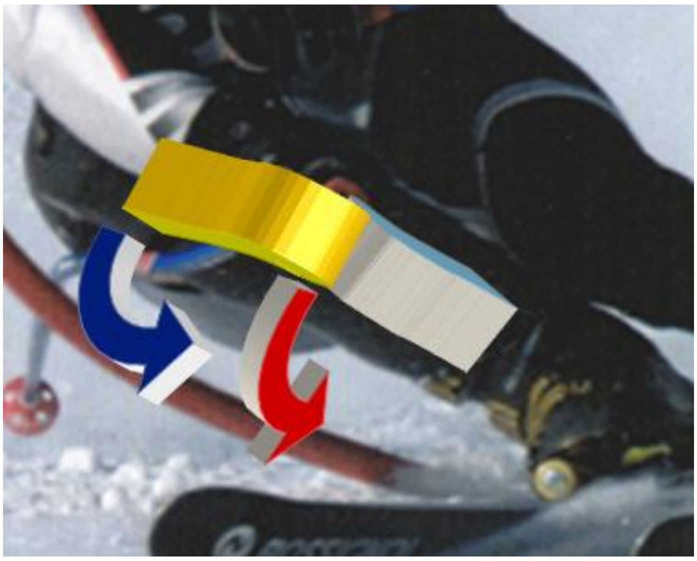
The knee stresses during the technical gestures (curve) which provides a precise attitude between thigh and leg can be individually divided (Fig. 8.8.1.):



(fig. 8.8.1.)

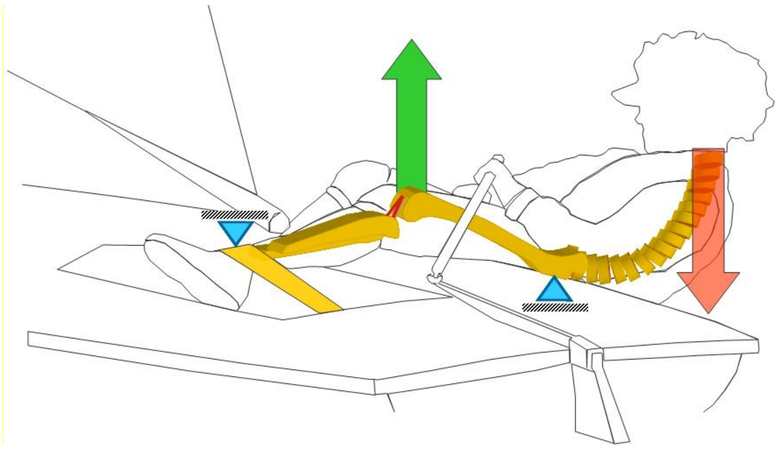
1 - Load vertical distribution (weight of the body and possible overloads derived from gravity - yellow arrow);
2 - flexion moment determined by all the forces acting on the lateral plane and have as arm the distance between the articular profiles and the center of gravity of the skier and are proportional to the side acceleration (red arrow);
3 - the rotations that develop along the longitudinal axis of the thigh and of the leg, which arising from the attitude assumed by the skier (green arrow).
The resultant of these tensions, to various degrees of bending can be understood as a flexion- twist moment (blue arrow) that you can download three-dimensionally on articular organs with an intensity proportional to the degree of bending and at the speed cornering.

Functional compatibility
The KTJ brace tends to support the knee in opposition to this result thanks to the structure of the guardian itself that provides a close link between the operated side arms through the tie-down straps (Fig. 8.8.2.).


(fig. 8.8.2.)

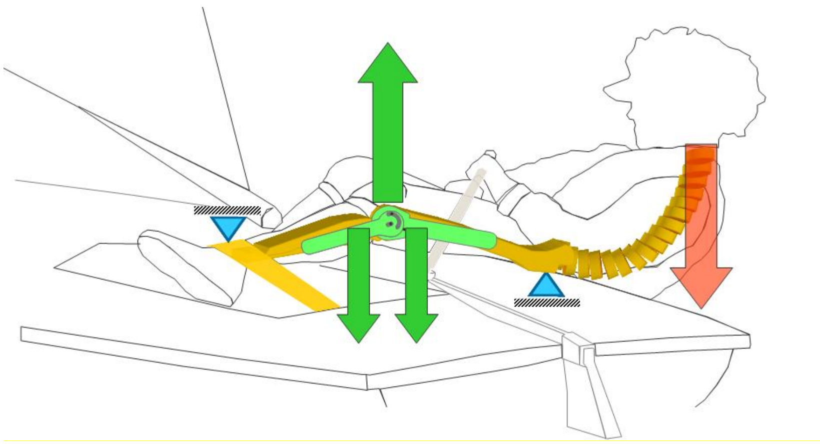
8.9. . The sail (drift) - the anteroposterior moment

In some boats, the sailor needs to attach the feet to the "belt" to be able to lean on a board and better control the layout of the drift. This maneuver, however, creates considerable stress to the knees that are pressured on the antero-posterior plane: the distal part of the femur tends to be removed from the front (anterior drawer) from the head of the tibia with the great suffering of all the ligaments of the knee.



Functional compatibility

Using a KTJ device you can reduce the stress on the ligaments in direct proportion to the degree of the bending between the leg and thigh.



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Mazzuchelli N., Zadini A. e coll.: The variable rotation centre knee-pad: assessment of gait and ADL in patients with gonarthrosis operated for lower limb arthroprosthesis; atti 8th Mediterranean Congress of Physical and Rehabilitation Medicine – Limassol – Cyprus 29/9 – 2/10 – 2010;

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Appendix A

The state of the art

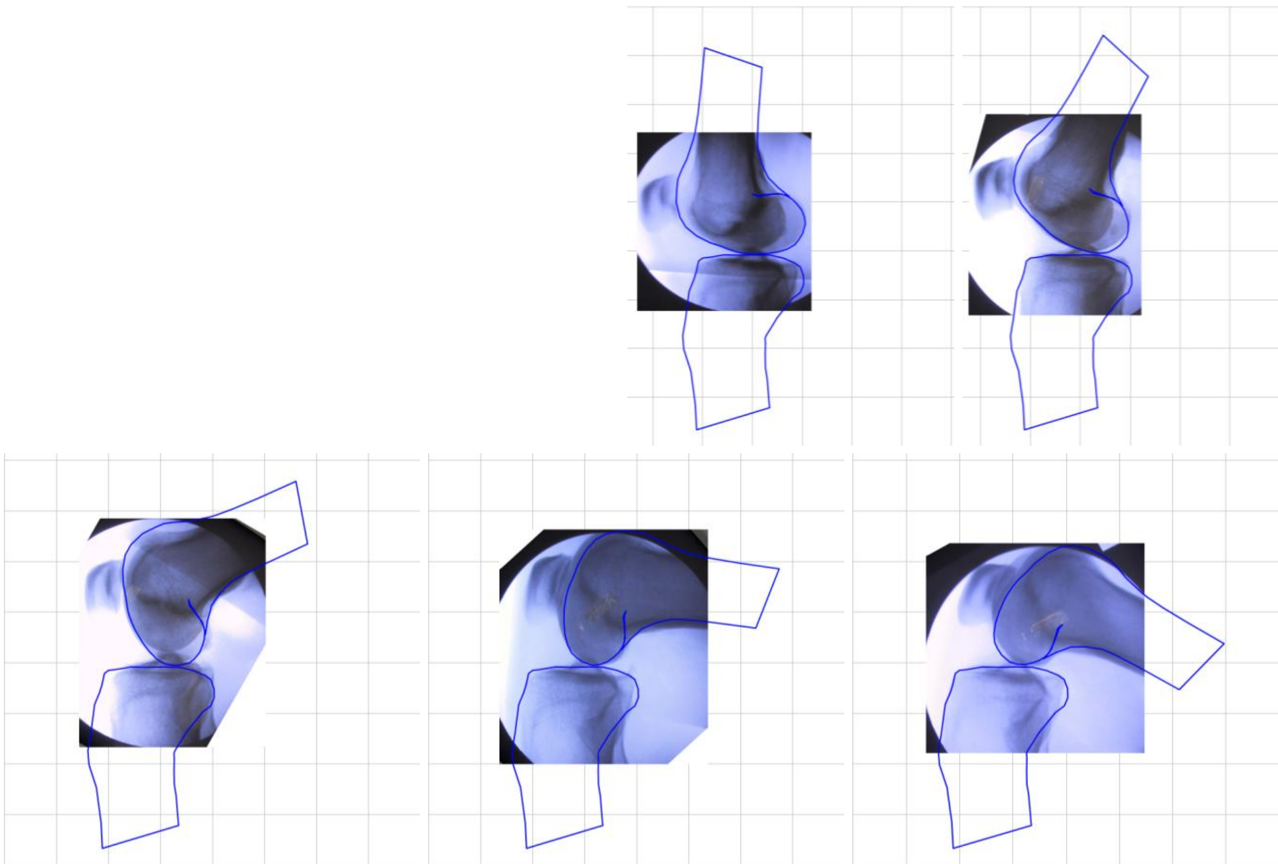
Analysis and comparison of mechanical devices to support the movement of the knee

Analysis of mechanical systems used on most commercially available knee braces

Each of the mechanisms examined, has a different handling and no one comes close to the roto-translational characteristics typical of the knee physiological motion.
Furthermore, for no one device has been found a convincing scientific documentation that would justify the similarity of the trajectory proposal with the physiological movement of the knee itself and in particular the indications that would clarify how to overlay and align the mechanical trajectory with that of the knee.

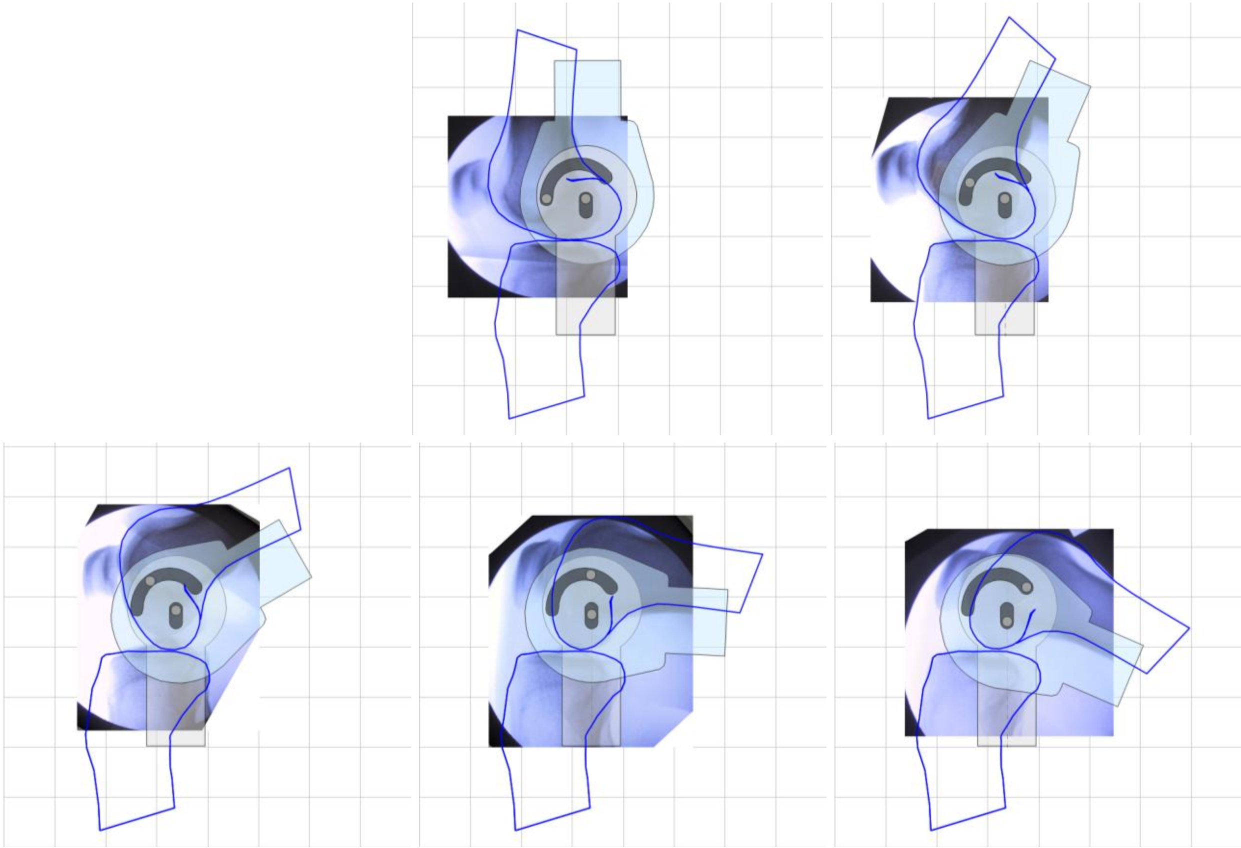
Pathes for comparison

Pathes obtained from the X-ray contours at various degrees of flexion of a healthy knee, were taken as a comparison for each joint tested and replicated in individual designs sketched on a demonstration of the differences observed.



The KTJ overlap

In the opening we report the overlap between the Rx paths and the roto-translational trajectory determined by the KTJ joint.



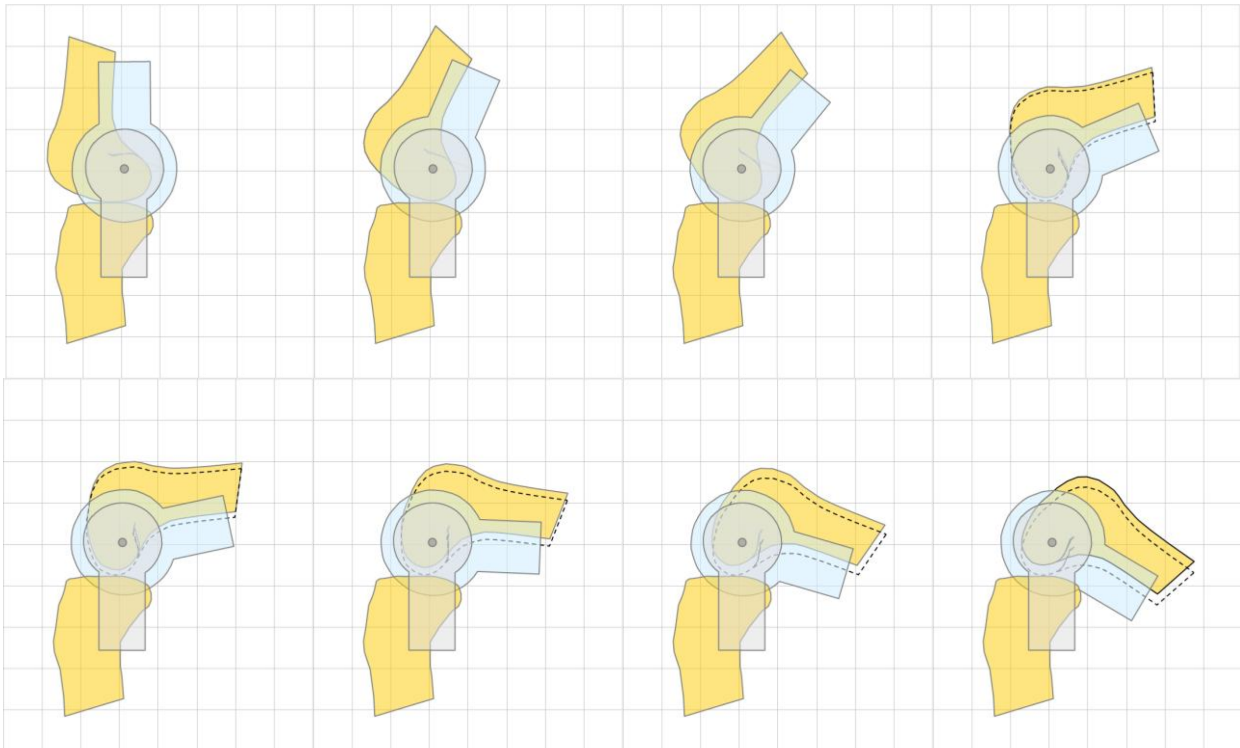
In consideration of the high coincidence between the Rx profiles and determined handling of the KTJ joint, it is considered particularly meaningful to compare the different profiles tracked to the movements of the joints in trade, such as an index of stress that every single mechanical device imposes to the knee.

Fixed center

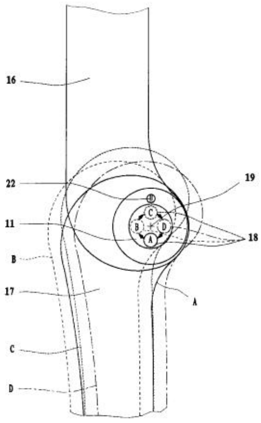
How to recognize

It is predominantly used in post-operative knee braces and is characterized by a single central pivot.

In the first 30 degrees of flexion the trajectory of the joint and those of the knee coincide.
After 30 degrees of flexion, the trajectory tends to distance the two articular heads.



Bauerfeind

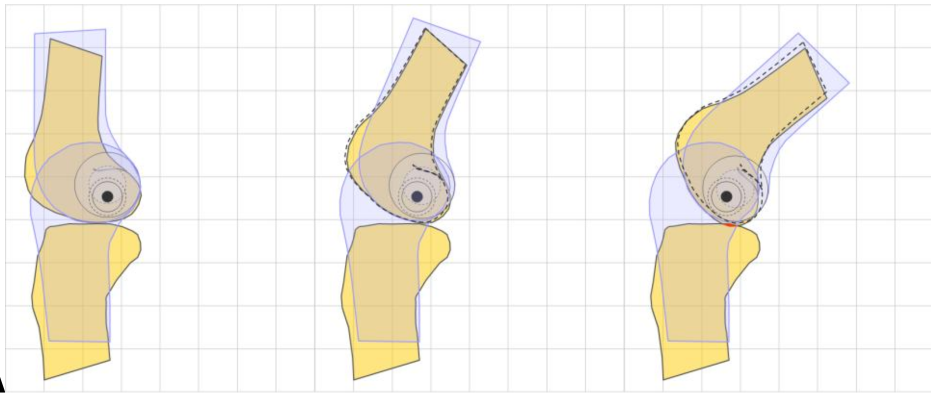


US 6059743 - 09.05.2000

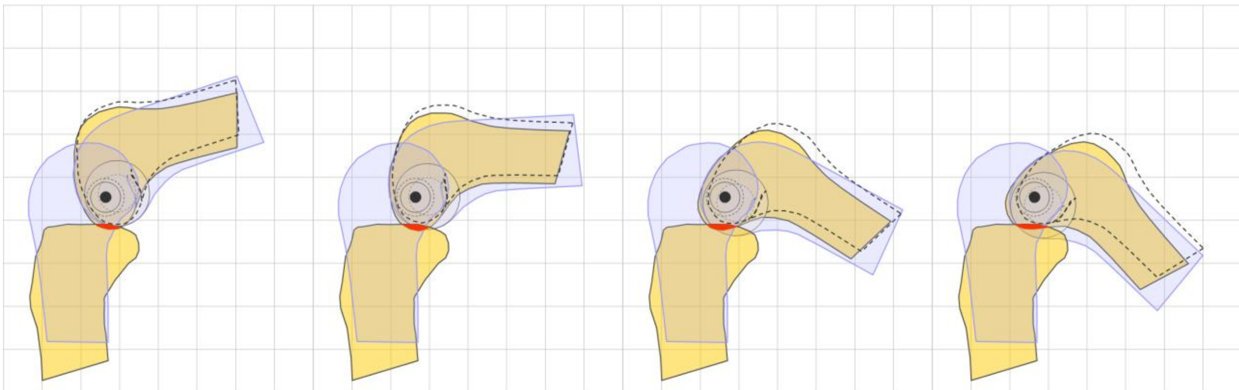
How to recognize

It has a "primitive" system of "personalization" of the center of rotation that can be changed from outside. As can be seen from the drawing patent above, there are four main positions of the center of rotation A, B, C and D.

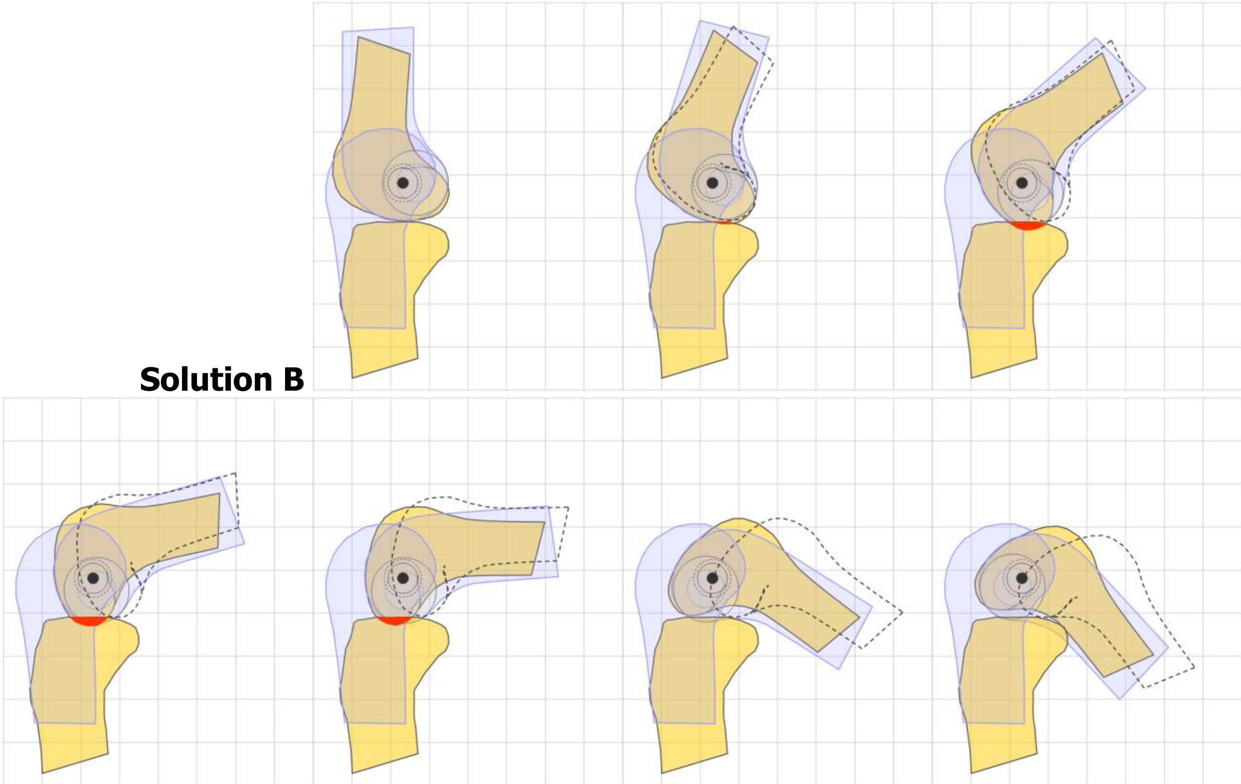
On the basis of this choice we may have the following situations:.



Solution A

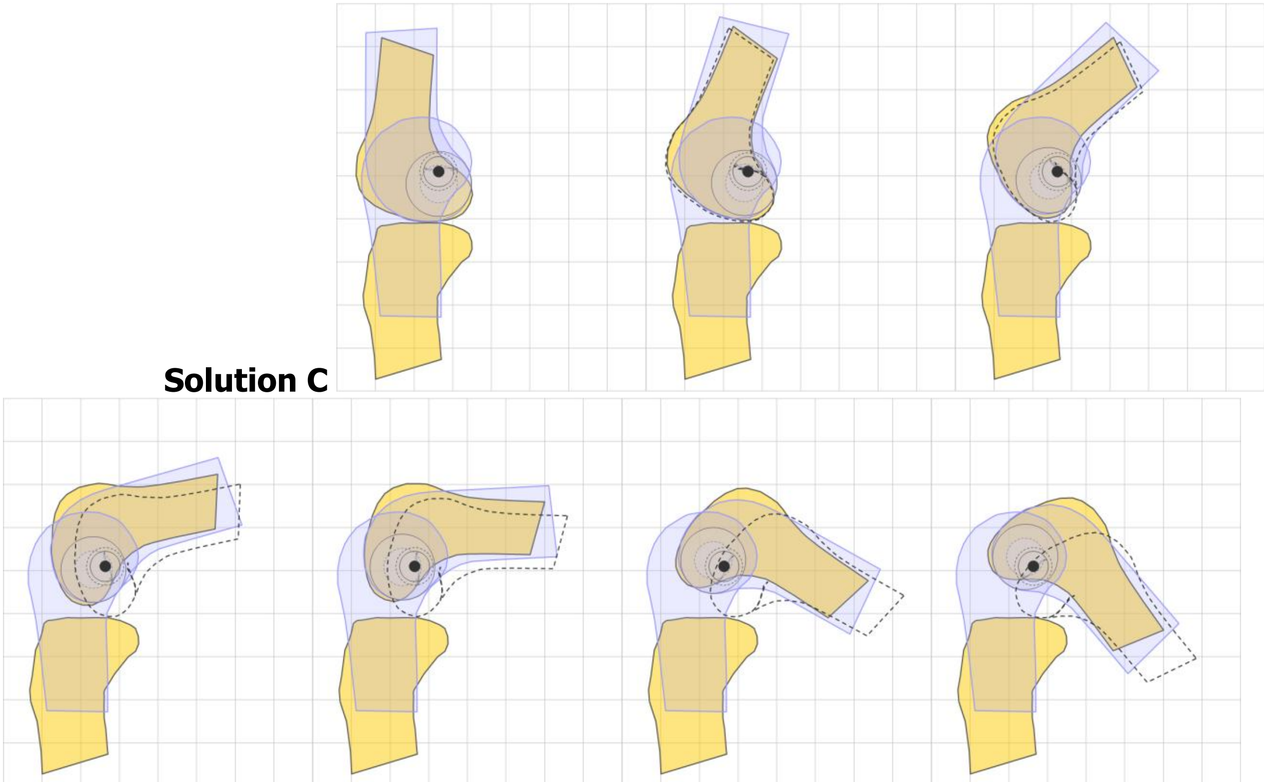


It causes a crash of the femoral condyles on the tibial plateau from 45 degrees onwards



Solution B

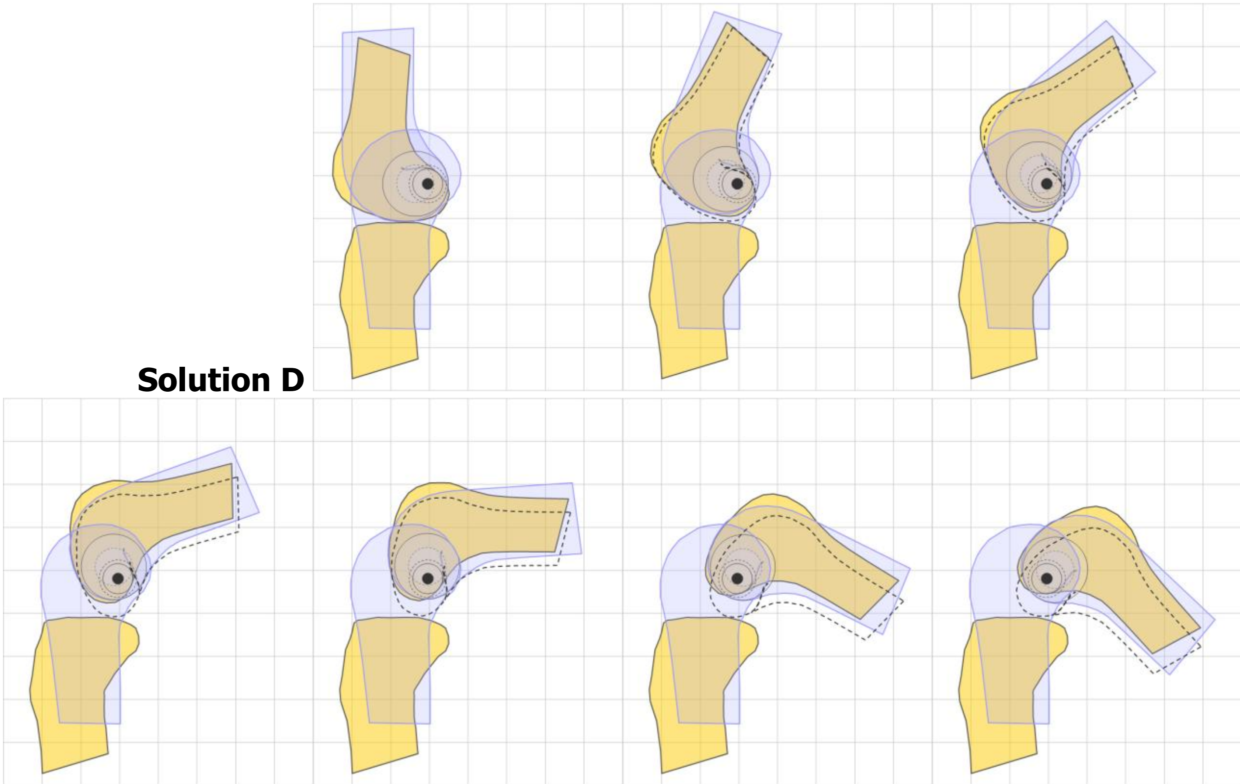
It causes a crash of the femoral condyles on the tibial plateau from 15 degrees to 90 degrees. Subsequently, the femoral condyles tend to be expelled vertically from the tibial plateau.



Solution C

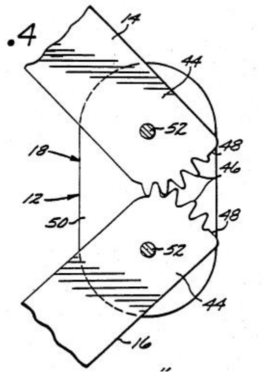
It causes a marked and important departure from the femoral condyles and determines a marked estrangement between the femoral condyles and tibial plateau.

Solution D



It causes a marked departure from the femoral condyles and tibial plateau.

Don Joy



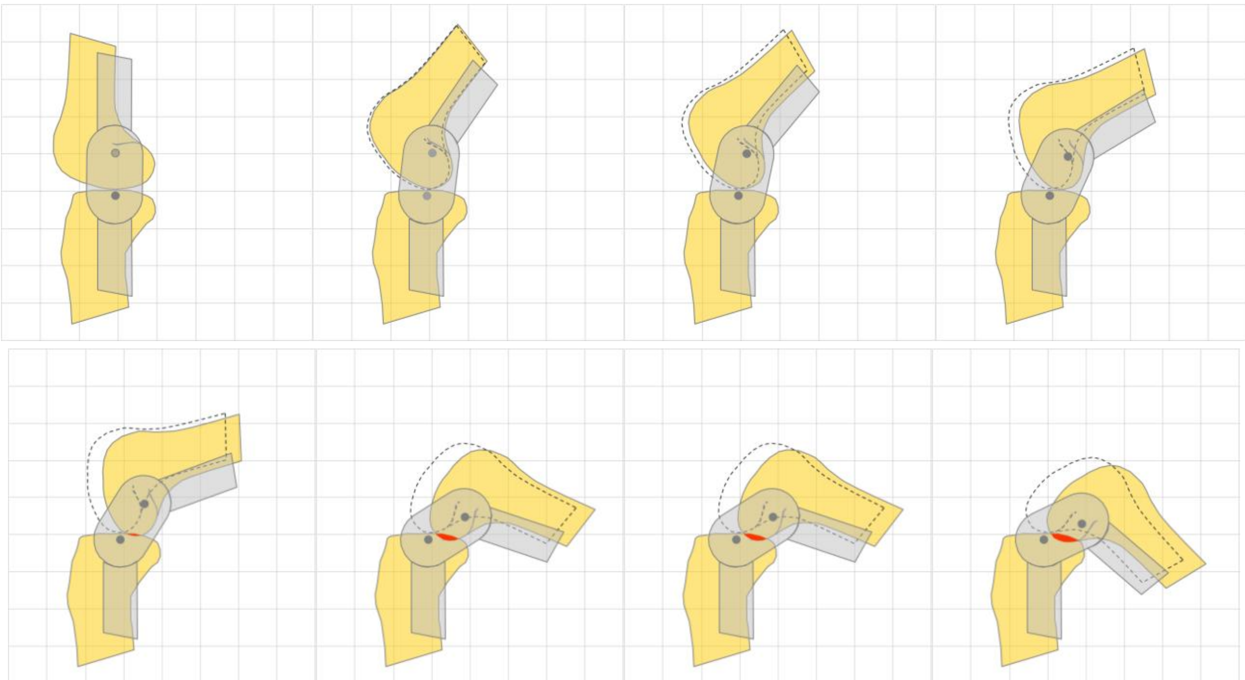
Patent US 4 643 176 A1

How to recognize

It is the joint most used by manufacturers of knee braces.

It has a typical shape elongated rectangle with the short sides rounded in a semicircle the center of which, in many joints are recognizable the two pins of rotation without any cover.

With its motion to reverse cycloid, since the early degrees of flexion tends to place back the femoral condyles that after the 45-60 degrees are also included (in an ever more important way) on the rear edges of the tibial plateau.



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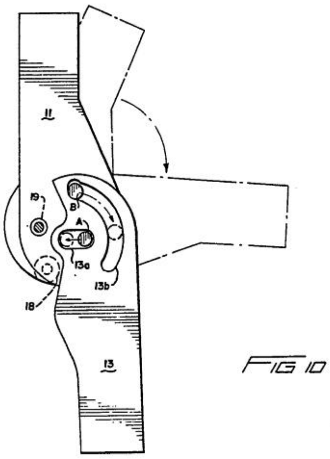
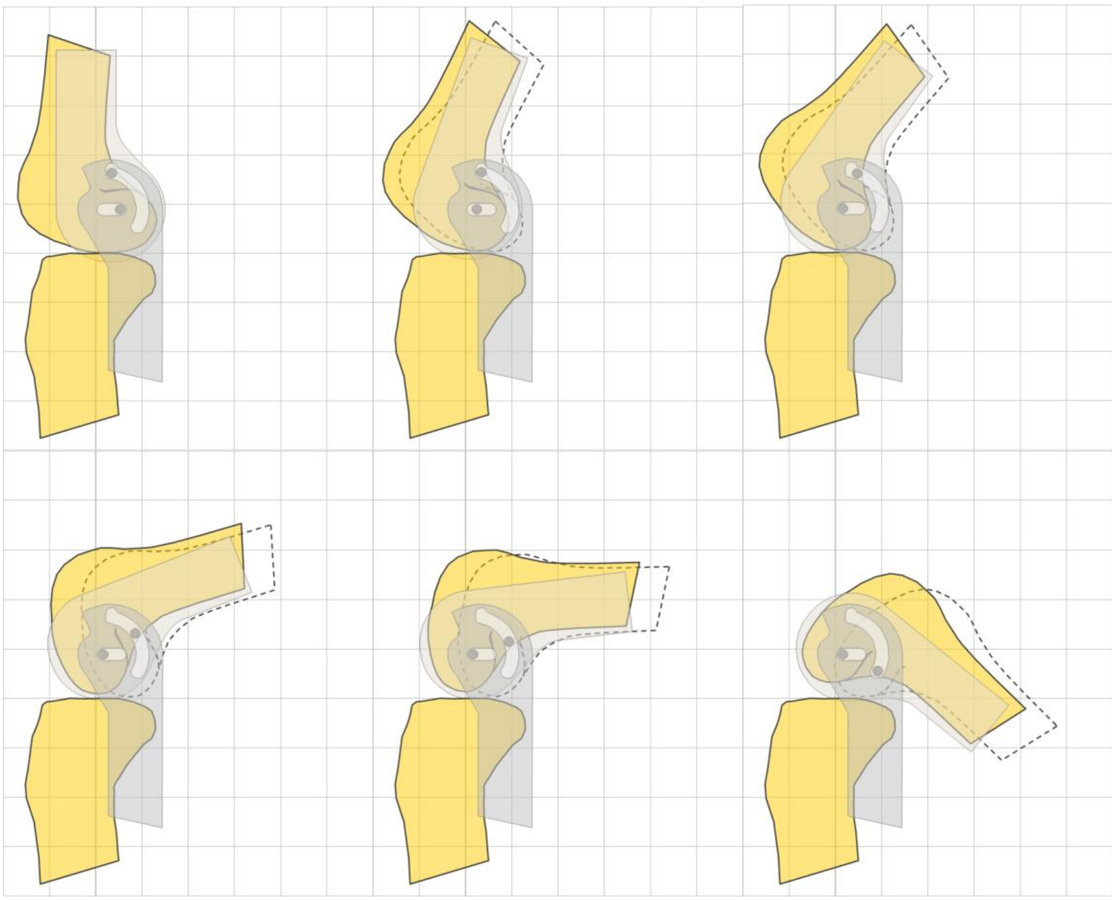


Patent **EPT 0361 405**

How to recognize

The handling and TRANSLA-ROTATORY
In section "THE OPPOSITE THEORY" this movement is discussed in detail.

For the first 20 degrees the femoral condyles are dragged before for 8-9 mm; in the remaining range of motion the same femoral condyles were removed vertically of the tibial plateau.



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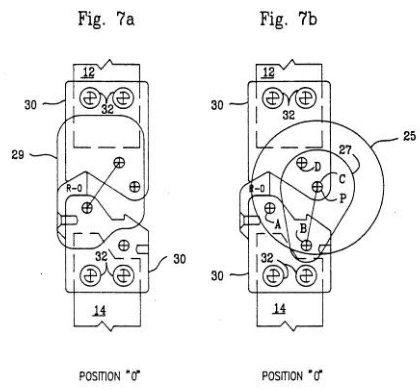
PCT WO 92/15264



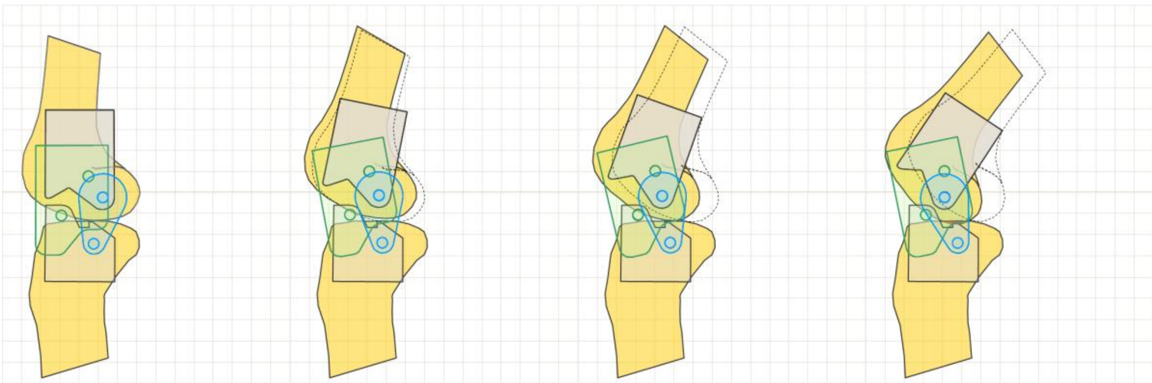
Joint consisting of 4 plates each with 2 holes

We can distinguish 4 plates: a femoral plate (upper), a tibial plate (lower) and two central plates

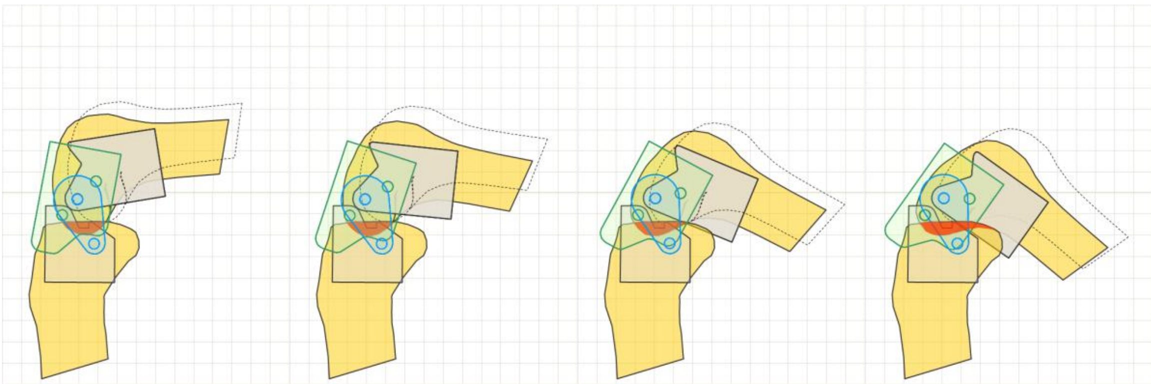
The movement between the plates is pantograph one.
Connecting the upper and lower arms to two plastic models that reproduce a femur and a tibia, according to the position of the pins inserted in the holes, a trasla-rotatory movement is produced

How to recognize

The movement is A TRASLA-ROTATORY

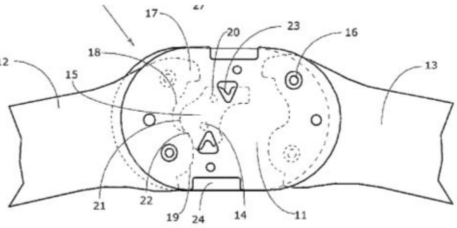


for the first 20 degrees the femoral condyles crawl forwards p the tibial plateau.



From 20 degrees onwards the femoral condyle has a conflict overcoming in an ever more important way the tibial plateau untill a complete and alarming overlap

FGP Physioglide®
PCT – WO 2004/078078 A1



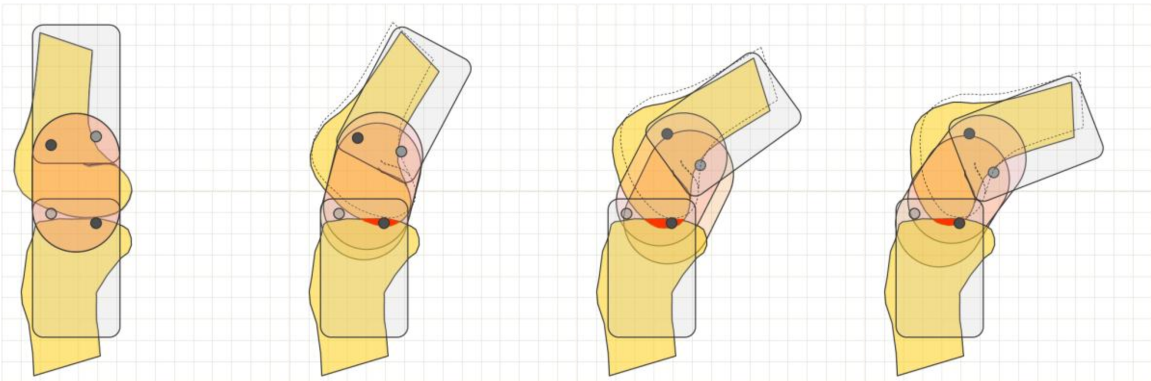
Joint consists of 4 plates each with 2 holes.

a femoral plate(upper)
a tibia plate(lower)
two central plates.
The movement between the plates (only characteristic that distinguishes the innovation from the plagiarism) is similar to the PCT WO 92/15264 of TOWNSEND (1992) with the only variation of the displacement of the pins.
The change consists in the positioning of the hole of the pins, avoiding the crossing of the wheelbase of connection. This, however, produces a trasla-rotatory movement.

How to recognize

The **TRASLA-ROTATORY** movement was highlighted by connecting the upper and lower arms with two plastic models that reproduce a femur and a tibia.

In particular, for the first 90 degrees the femoral condyles crawl forwards lowering in a more important way untillq 45 degrees and they have a conflict with tibial plateau.



From 90 degrees onwards the femoral condyle is backing away from the tibial plateau.

4. - Prof. Antonio Dal Monte's opinion

The joint with variable center of rotation was presented to Prof. Antonio Dal Monte as advisor in the Area Science Park of Trieste in the domotics field, who is expressed in this terms:

"The approach taken by the biomechanical point of view is appropriate."

AREA

SCHEDA CONTATTO

Luogo TRIESTE **Data** 09.10.08 **h inizio** 09.00 **h fine** 10.15

Azienda o Esperto KTJ SISTEMI

Oggetto Incontro (n° 1) ERGONOMIA E BIOMECCANICA NELLA REALIZZAZIONE DI UN TUTORE DELL'ARTICOLAZIONE DEL GINOCCHIO

Referente AREA ZANCHIELLO **Codice Interno**

2. Partecipanti incontro

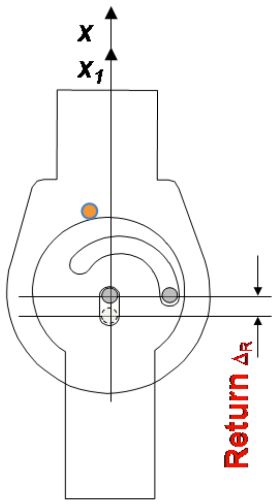
NOME E COGNOME	ENTE	FIRMA *
ZANCHIELLO	AREA	
DAL MONTE	AREA	
PELLIS	KTJ SISTEMI	

3. Argomenti trattati – Note e Commenti

- L'impostazione data dal punto di vista biomeccanico risulta corretta.

5. - The "technical data" of KTJ[1]

All the most significant scientific results, collected in the studies done, were grouped in the "Technical data" table to ensure that all mechanical devices made with KTJ mechanics, correspond to the experimentally obtained.



	KTJ hinge – variable center of rotation				
Amplitude knee movement	0° ÷ 135°				
Return instantaneous center of rotation	cm. 0.36				
Maximum tension on ACL - PCL	Kg. 0.20				
Motion proposed	Roto-traslation				
Breakdown arc movement	arc	Return cm	kg ACL	Kg PCL	Motion
	30°	0	0,12	0,11	rotary
	45°	0,003	0,05	0,04	Roto-trasl.
	90°	0,125	0,06	0,12	Roto-trasl.
	135°	0,36	0,20	0,19	Roto-trasl.
Alignment knee-hinge	self centring				

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