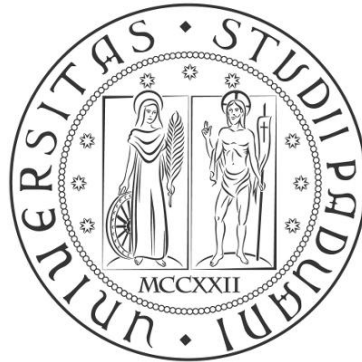


UNIVERSITÀ DEGLI STUDI DI PADOVA

*Department of Industrial Engineering
Master degree course in Mechanical Engineering*



Mathematical models of wear assessment in hip replacement testing methods according to ISO 14242

Supervisor: Prof. Nicola PETRONE
Department of Industrial Engineering
Università degli studi di Padova

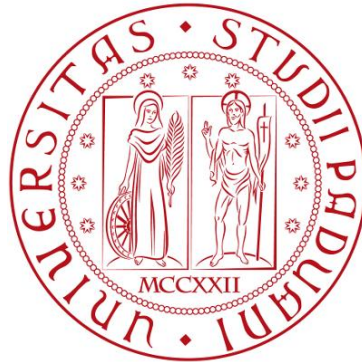
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Technische Universität Chemnitz

Graduate Student:
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*To my mother, to my father,
and to all my beloved grandparents*

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Abstract

This thesis was developed in Germany, in the department of Sports Equipment & Technology (Sportgerätetechnik) of the Technical University of Chemnitz (Technische Universität Chemnitz), in Saxony. It was developed thanks to the program funded by the European Union called “Erasmus Placement”. The study is part of a wider project of the department that aims to start an activity of analysis and testing on hip prostheses.

The first part regarding research and information collection of the thesis – together with modeling and prototyping – was carried out during the first six months at the SGT department in Germany, while the second part (the writing of the thesis) was concluded in Italy.

This work was structured in three phases:

In the first phase wide research was carried out on the state of the art of hip prostheses technology, on ISO norms for testing, and on scientific literature about characteristics of modern prosthesis (strong and weak points, behavior during fatigue tests, wearing process, etc.).

The second phase consisted of developing a mathematical model which could – given the characteristics of the prosthesis, and details about “gait simulation” and loading cycle – evaluate the frictional work dissipated during a cycle and the wear rate of the prosthesis, together with many other useful parameters.

In the third phase, according to the results obtained through the model, some prototypes of hip prostheses testing machines were designed; every single model bears different characteristics that make it suitable for peculiar aspects of testing. For each model characteristics are described and a brief list of strong points and weak points is reported.

The thesis is composed of seven chapters, which are divided in subchapters:

The first chapter is about the hip joint physiology, its axes, all the different kinds of movements it can perform (including active and passive range of motion), the orientation of the femoral head and acetabulum, the structure of the femur, the ligaments and their role, the coaptation of the articular surfaces, the involvement of muscles and bones in hip stability.

The second chapter starts providing information about the bone and the synovial joint capsule. A whole subchapter is dedicated to the critical problem of wear induced osteolysis, follows a short chapter concerning the clinical needs. At the end a brief history of hip joint arthroplasty describes the evolution of prostheses up until modern times, with the technology used nowadays. The last subchapter is about bearings and wear.

The third chapter contains an introduction to ISO norms with description and comments about the motion law and the loading law. The chapter furnishes historical information about the motion law, and how it was studied during the second half of last century. Right after the loading law is described and commented; in particular the chapter bears extensive plots and information about how loads were estimated and measured, until the study that Bergmann conducted in the '90, with the implantation of instrumented prostheses on voluntary patients. At the end of the chapter some

comments explain how the reference frame adopted in the model present in the thesis can benefit from the data acquired according to the reference frame by Bergmann.

The fourth chapter bears the title of the ISO norms concerning the hip prosthesis testing prescriptions (ISO 14242): “Implants for surgery - Wear of total hip-joint prostheses”. The chapter contains all the prescriptions in detail and some author’s personal comments are added.

The fifth chapter is the core of the thesis, it contains the mathematical model for the hip prosthesis wear assessment. At the very beginning a few pages of introduction to the vast chapter describe its structure together with functions, plots and tables. Then, a complete list shows the parameters used by the MatLab[®] code; motion law and loading law follow right after. An important subchapter exposes how trajectories on cup and head were derived, there are comments on the plots and comments of comparison between cup and head tracks. Another subchapter contains the direction vectors that were found starting from the trajectories; some comments on these vectors follow. Then is found the most important subchapter: in this can be read all the useful information coming as output from the direction rose function (`DirRose.m`); conclusions and comments close this section. At the end of the chapter a brief statistical analysis shows that the hypothesis of Normal distribution has to be discarded for the first histogram found.

The sixth chapter is dedicated to possible machine prototypes for hip prostheses tests. After an introduction to the chapter, the machine requirements according to ISO 14242 together with the key points to address (devised by the author of the thesis) for a good machine design are listed. Then the cup-hosting bowl is described with all its features. After this, the first three prototypes (adopting traditional ball bearings) are illustrated, with their weak points and strong points; these prototypes have 1, 2 and 3 degrees of freedom respectively. Concluding the last prototype is presented: this model makes use of a ball joint and a special double Cardan joint; strong and weak points follow. The last subchapter proposes some considerations on the models exposed before comparing and commenting their characteristics.

The seventh and final chapter contains the conclusions of the whole work.

Introduzione

Questa tesi è stata sviluppata in Germania, nel dipartimento di Tecnologia ed Equipaggiamento Sportivo (Sportgerätetechnik) dell'Università Tecnica di Chemnitz (Technische Universität Chemnitz), in Sassonia. È stata sviluppata grazie al programma “Erasmus Placement”, finanziato dall'Unione Europea. Questo studio è parte di un più ampio progetto del dipartimento che mira ad iniziare una attività di analisi e test sulle protesi all'anca.

La prima parte di ricerca e raccoglimento di informazioni della tesi – assieme alla parte di modellazione e concezione di prototipi – è stata condotta durante i primi sei mesi presso il dipartimento SGT in Germania, mentre la seconda parte (la stesura della tesi) è stata conclusa in Italia.

Questo lavoro si è articolato in tre fasi:

Nella prima fase è stata svolta una ampia ricerca sullo stato dell'arte della tecnologia delle protesi all'anca, sulle normative ISO per i test, e sulla letteratura scientifica riguardante le caratteristiche delle moderne protesi (i loro punti forti e i loro punti deboli, il loro comportamento durante i test a fatica, il processo di usura, etc.).

La seconda fase è consistita nello sviluppo di un modello matematico, il quale può valutare – date le caratteristiche della protesi, e i dettagli della simulazione di camminata e ciclo di carico – il lavoro dissipato per attrito durante il ciclo di test e il tasso di usura della protesi, assieme ad altri numerosi parametri utili.

Nella terza fase, secondo i risultati ottenuti tramite il modello, sono stati progettati alcuni prototipi di macchina per test sulle protesi all'anca; ogni modello racchiude caratteristiche diverse che lo rendono adatto per particolari aspetti di test. Per ogni modello sono descritte le caratteristiche ed è riportata una breve lista che riassume i punti forti e deboli di ognuno.

La tesi si articola in sette capitoli che si suddividono in diversi sottocapitoli:

Il primo capitolo riguarda la fisiologia dell'articolazione dell'anca, i suoi assi, i vari movimenti che può riprodurre (inclusi i range di movimento attivi e passivi), l'orientazione della testa del femore e dell'acetabolo, la struttura del femore, i legamenti e il loro ruolo, la coattazione delle superfici articolari, il coinvolgimento dei muscoli e delle ossa nella stabilità dell'articolazione.

Il secondo capitolo comincia fornendo informazioni riguardo le ossa e la capsula sinoviale. Un intero capitolo è dedicato al problema critico dell'osteolisi indotta dal particolato dell'usura, segue un breve capitolo riguardante le necessità cliniche. Alla fine una breve storia sulle protesi all'anca descrive l'evoluzione di queste fino ai tempi attuali, con la tecnologia odierna. L'ultimo sottocapitolo riguarda il giunto artificiale e l'usura.

Il terzo capitolo contiene un'introduzione alle norme ISO con descrizione e commenti circa la legge del moto e la legge di carico. Il capitolo fornisce informazioni storiche riguardanti la legge del moto e come è stata studiata durante la seconda metà dell'ultimo secolo. Subito dopo viene descritta e commentata la legge del moto; in particolare il capitolo porta una vasta gamma di grafici e

informazioni su come i carichi sono stati stimati e misurati, fino a quando lo studio condotto da Bergmann negli anni '90, con l'impianto di protesi strumentate su pazienti che si sono prestati come volontari. Alla fine del capitolo alcuni commenti spiegano come il sistema di riferimento adottato nel modello presente nella tesi possa sfruttare i dati acquisiti secondo il sistema di riferimento adottato da Bergmann.

Il quarto capitolo porta il titolo della normativa ISO riguardante le prescrizioni sui test delle protesi all'anca (ISO 14242): "Implants for surgery – Wear of total hip-joint prostheses". Il capitolo contiene tutte le prescrizioni nel dettaglio e sono stati aggiunti alcuni commenti personali dell'autore.

Il quinto capitolo è il cuore della tesi, contiene il modello matematico per la valutazione dell'usura delle protesi all'anca. Al principio un po' di pagine di introduzione al vasto capitolo descrivono la sua struttura con le varie funzioni, i grafici e le tabelle. Quindi, una completa lista mostra i parametri utilizzati dal codice MatLab[®], la legge del moto e la legge di carico. Un importante sottocapitolo espone come le traiettorie sulla coppetta acetabolare e sulla testa del femore vengono derivate, ci sono commenti sui grafici e commenti di raffronto tra tracciato sulla coppetta e sulla testa del femore. Un altro sottocapitolo contiene i vettori direzionali che sono stati trovati a partire dalle traiettorie; seguono alcuni commenti su questi vettori. Quindi si trova il sottocapitolo più importante: in questo si possono leggere tutte le informazioni utili provenienti come output dalla rosa delle direzioni (DirRose.m); a chiudere questa sezione vi sono conclusioni e commenti. Alla fine del capitolo una breve analisi statistica mostra come l'ipotesi di distribuzione Normale debba essere scartata per il primo istogramma trovato. In conclusione sono stati ottenuti alcuni istogrammi con più alta risoluzione grazie ad una modifica del codice.

Il sesto capitolo è dedicato a possibili proposte di prototipi di macchina per eseguire test su protesi all'anca. Dopo una introduzione al capitolo, le specifiche minime della macchina secondo la normativa ISO 14242 sono elencate assieme ai punti chiave ai quali attenersi (secondo l'autore della tesi) per una buona progettazione. Quindi viene descritta la coppa sulla quale alloggia la coppetta, assieme a tutte le sue caratteristiche. Dopo ciò, i primi tre prototipi (che adottano cuscinetti a sfera) vengono illustrati, assieme ai loro punti di forza e debolezza; questi prototipi hanno rispettivamente 1, 2 e 3 gradi di libertà. Per concludere, l'ultimo prototipo viene presentato: questo modello sfrutta un giunto sferico come sostegno e uno speciale giunto di Cardano doppio; anche qui seguono punti forti e punti deboli. L'ultimo sottocapitolo propone alcune considerazioni sui modelli esposti precedentemente e li sottopone a confronto commentando le loro caratteristiche.

Il settimo e ultimo capitolo contiene le conclusioni dell'intero lavoro.

Chapter 1

An introduction to the physiology of the hip joint

1.1) Introduction

In the hip joint a large amount of incredible characteristics merge together. The hip joint is relatively small, but can withstand a force equivalent to many times the body weight, it has a wide range of motion, but the hard and soft tissues joint action guarantees great stability, even in many critical configurations of the articulation preventing joint dislocation (Fig. 1.1 and 1.2). Surprisingly the hip joint shows good stability and strength when the individual has an erect posture, which was proved not to be the natural physiological position of the hip joint (which is reached when the individual is in the *position on all fours*, the position of our ancestors).

It's stunning how nature and evolution have produced such a high structural and mechanical efficiency.

The information contained in this chapter are mostly derived from “The Physiology of the Joints” by I. A. Kapandji [1] and the material from the course “Sports Engineering and Rehabilitation Devices” kept by professor Nicola Petrone [2].



Fig. 1.1) Nadia Comaneci at the Montreal Olympics, 1976.



Fig. 1.2) Almir Velagic lifting 235 kg at the European Weightlifting Championships, 2010.

1.2) The hip joint

The hip joint is the proximal joint of the inferior limbs; and it's a ball joint (Fig. 1.3). The lower limbs (legs) have a range of motion which is more limited with respect to the upper limbs (arms); this implies that the movements they can reproduce are less complex, but, on the other hand, they can bear much greater loads while holding a specific posture and in the act of walking, running, stair climbing, jumping, etc.

Here follow the elementary movements the lower limbs can perform for each of the three degrees of freedom, including the anatomical planes and axes, with the body motion that can be executed:

- transverse or mediolateral axis: it's the horizontal axis located on the frontal plane, getting across the centre of the articulation. On this axis flexion and extension movements are performed;
- anterior-posterior axis: it's the horizontal axis located on the sagittal plane, getting across the centre of the articulation. On this axis adduction and abduction movements are performed;
- vertical axis: when the hip bone is on its reference position (that is when the person is standing upright on its feet), the vertical axis is very close to the longitudinal axis of the lower limb (axis passing through the femoral head and the centre of the malleoli, when the person is standing upright). This is the axis of reference to describe the internal and external rotation movements.

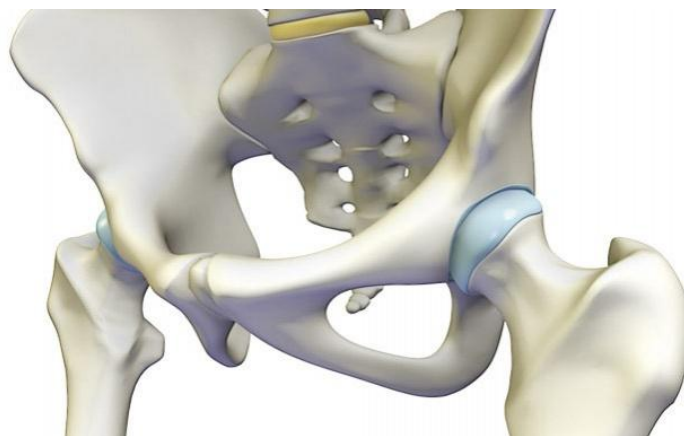


Fig. 1.3) The hip joint

1.3) Hip flexion movements

The flexion movement takes the thigh closer to the abdomen, so that the femur comes to lie before the frontal plane that gets across the joint.

The entity of the flexion can change according to certain conditions:

Active flexion is less wide than passive flexion, and depends on the relative position of the knee joint, in fact the musculo-skeletal system can impede or allow specific movements. To be more specific, while the knee is fully extended the flexion reaches 90° (Fig. 1.4 (2)), with the knee fully flexed, the flexion can reach 120° or more (Fig. 1.4 (3)), depending on the subject.

The *passive flexion* can exceed 120° and, as before, is dependent on the position of the knee. In fact, when the knee is fully extended (Fig. 1.4 (4)), the flexion movement is smaller than in case of flexed knee (Fig. 1.4 (5)). In the case of flexed knee the flexion can be above 140° and the thigh can touch the thorax.

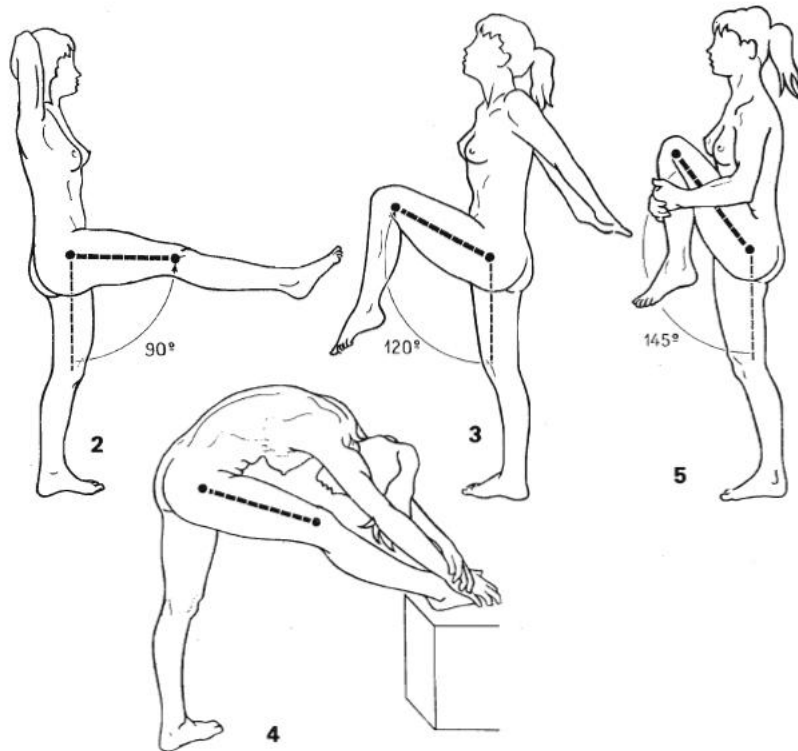


Fig. 1.4) Hip flexion

1.4) Hip extension movements

The extension movement takes the femur behind the frontal plane.

The maximum extension is much lower than the one experienced during flexion, and is arrested by the tension of the iliofemoral ligament.

The *active extension* is smaller than the passive flexion. When the knee is fully extended (Fig. 1.5 (7)), the hip extension can reach the value of 20° which is bigger than in case of flexed knee (Fig. 1.5 (8)); this is due to the fact that the hamstrings don't work well as extensors of the hip, since their contraction has been used to flex the knee.

Passive extension can reach 20° when the subject bends forwards (Fig. 1.5 (9)); while it reaches 30° when the leg is pulled back (Fig. 1.5 (10)).

The various angles given are representative for a “normal” individual, and can easily rise if the subject in question is an athlete.

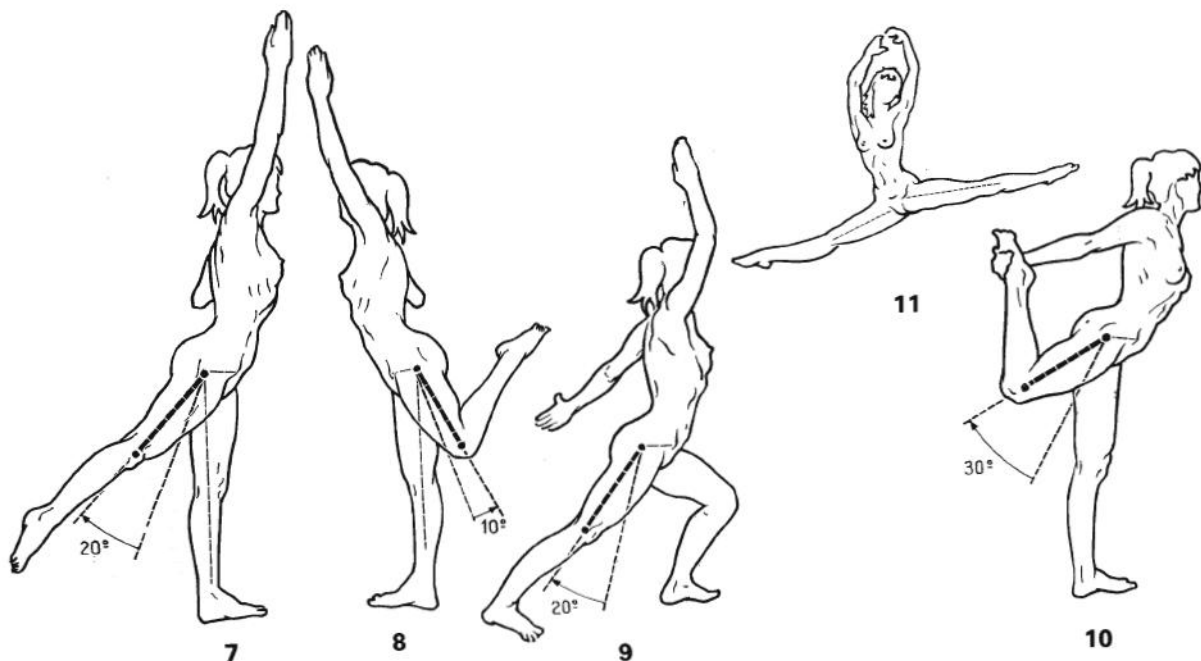


Fig. 1.5) Hip extension

1.5) Hip abduction movements

The abduction movement is directed laterally and takes the femur away from the sagittal plane.

The abduction movement of the femur is generally accompanied by a movement of abduction – of the same extent – of the other lower limb (Fig. 1.6 (12)).

When the maximum abduction is reached (Fig. 1.6 (13)), the angle between the two femurs is 90° ; since abduction develops spontaneously at both limbs, the actual abduction with respect to the hip bone is 45° for every leg. The abduction movement is arrested by the collision of the femoral neck with the acetabular rim, but generally the movement is halted before by the tension of the abductor muscles and the ilio- and pubofemoral ligaments.

Training can increase the maximum abduction angle, and this is particularly evident in ballerinas (Fig. 1.6 (14), (15), (16a) and (16b)).

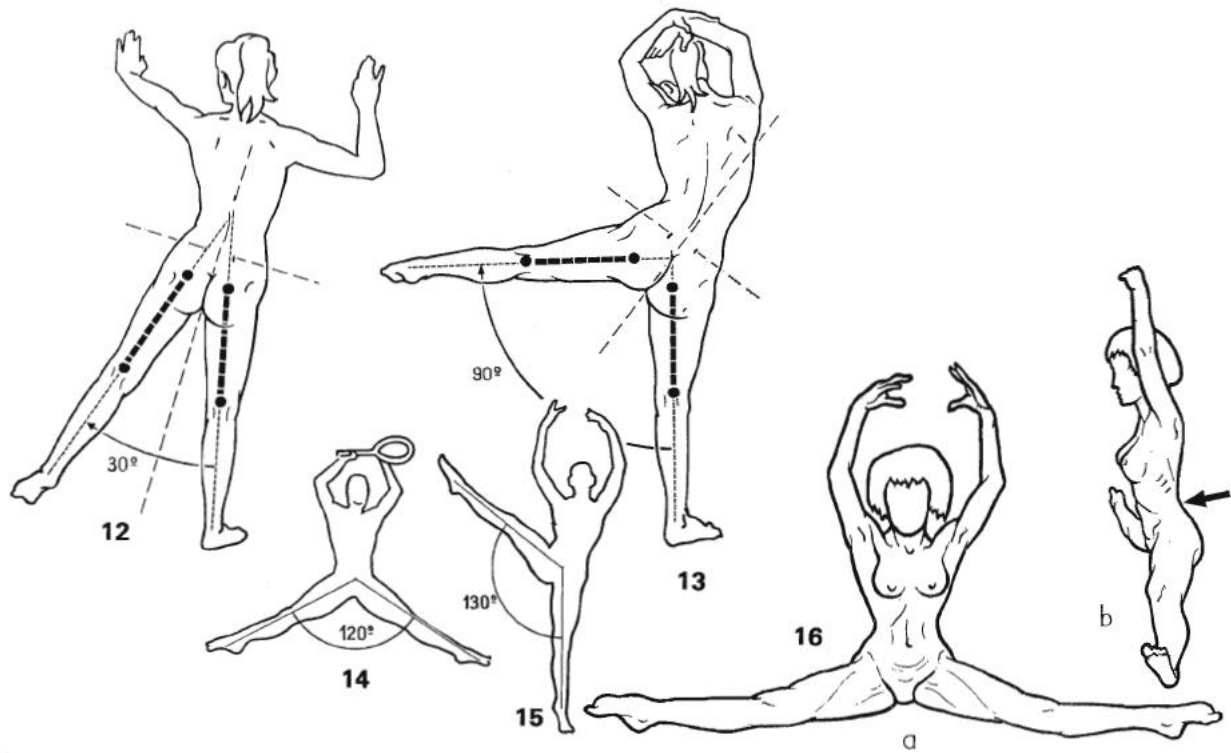


Fig. 1.6) Hip abduction

1.6) Hip adduction movements

The adduction movement is directed medially and takes the femur closer to the sagittal plane.

When an individual is standing upright in the position of reference, both legs are touching, hence pure adduction is not possible. Despite this, *relative adduction* is possible when the femur moves in the medial direction starting from any position of abduction (Fig. 1.7 (17)).

Adduction can occur together with extension (Fig. 1.7 (18)) or flexion (Fig. 1.7 (19)). There can also be adduction at one leg and abduction at the other leg (Fig. 1.7 (20)). The maximum adduction possible is 30°.

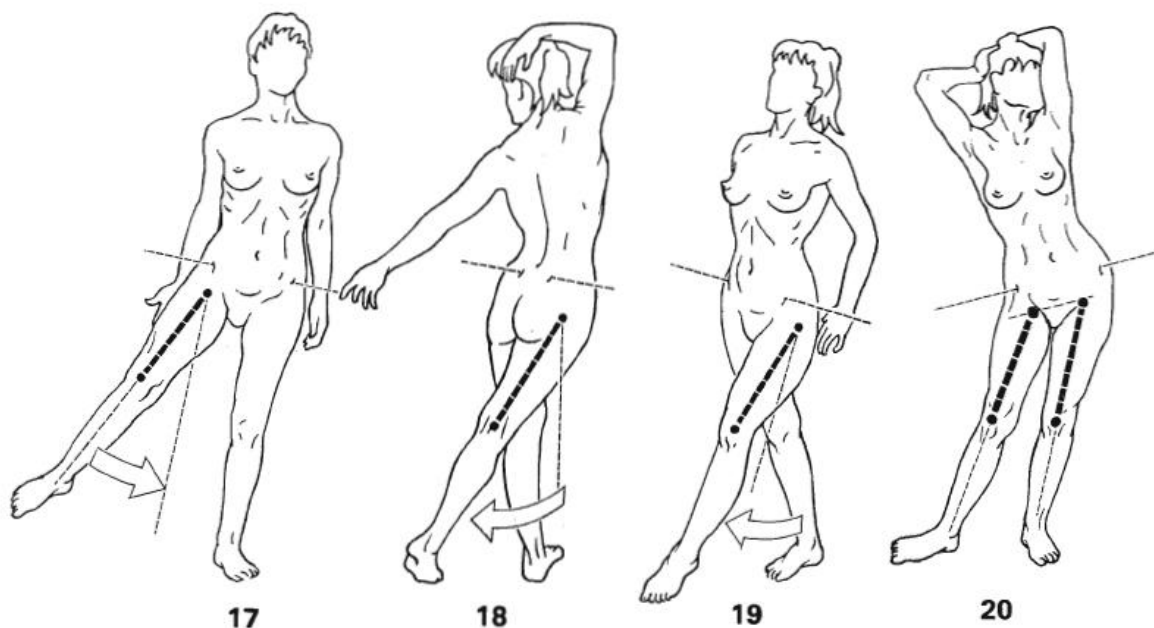


Fig. 1.7) Hip adduction

1.7) Hip internal and external rotation movements

These rotational movements occur on the OR axis (Fig. 1.8 (48) bold dashed line); when the individual is in the reference position the axis lays over the vertical axis of the hip. So when the external rotation occurs, the toes are moving away from the sagittal plane, and when the internal rotation occurs, the toes are moving towards the sagittal plane.

The easiest way to evaluate the range of the movements is when the subject is lying prone, and the position of reference (Fig. 1.8 (23)) is now with the knee at 90° and the tibia vertical with respect to the ground. Starting from this position, when the tibia moves laterally, the femur performs an internal rotation reaching a maximum of 30° or 40° (Fig. 1.8 (24)), and when the tibia moves medially, external rotation occurs, with a maximum value of 60° (Fig. 1.8 (25)). When the subject is sitting on a plane surface, with the feet that are not touching the ground, the tibia which can move freely, and the hip joint and knee joint flexed by an angle of 90° , the range of motion of internal and external rotation is wider (Fig. 1.8 (26) and (27)), because the ilio- and pubofemoral ligaments are much more relaxed.

The range of internal and external rotation of the femur is closely bound to the angle of anteversion of the femoral neck. In children this angle appears to be quite wide, and with aging this angle decreases to average adult values, allowing the individual to walk and run in the fashion of an adult, which is dynamically more efficient and “less clumsy”.

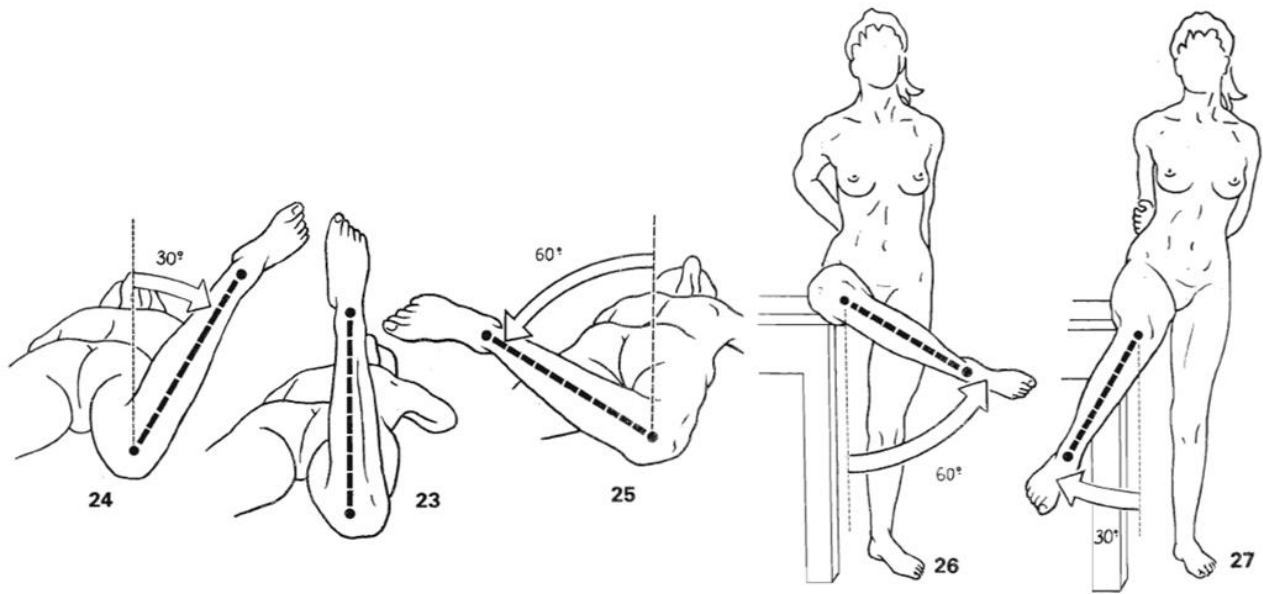


Fig. 1.8) Hip internal and external rotation

1.8) Circumduction of the hip

The movement of circumduction is defined as *the combination of elementary movements occurring simultaneously around the three axes*. When the circumduction reaches its maximal extension the axis of the lower limb generates a conoid with its vertex lying at the centre of the hip, this conoid is called cone of circumduction (Fig. 1.9 (29)).

The conoid is highly asymmetrical since the range of motion of every single movement varies a lot, in addition to this, the range of motion is influenced by the relative position of the limb and by the combination of movements that took the limb in that specific position. For this reason, the extremity of the limb traces a wavy path on a spherical surface concentric with the joint centre, and the path gets across many sectors generated by the intersection of the three planes of reference (sagittal, frontal and horizontal planes).

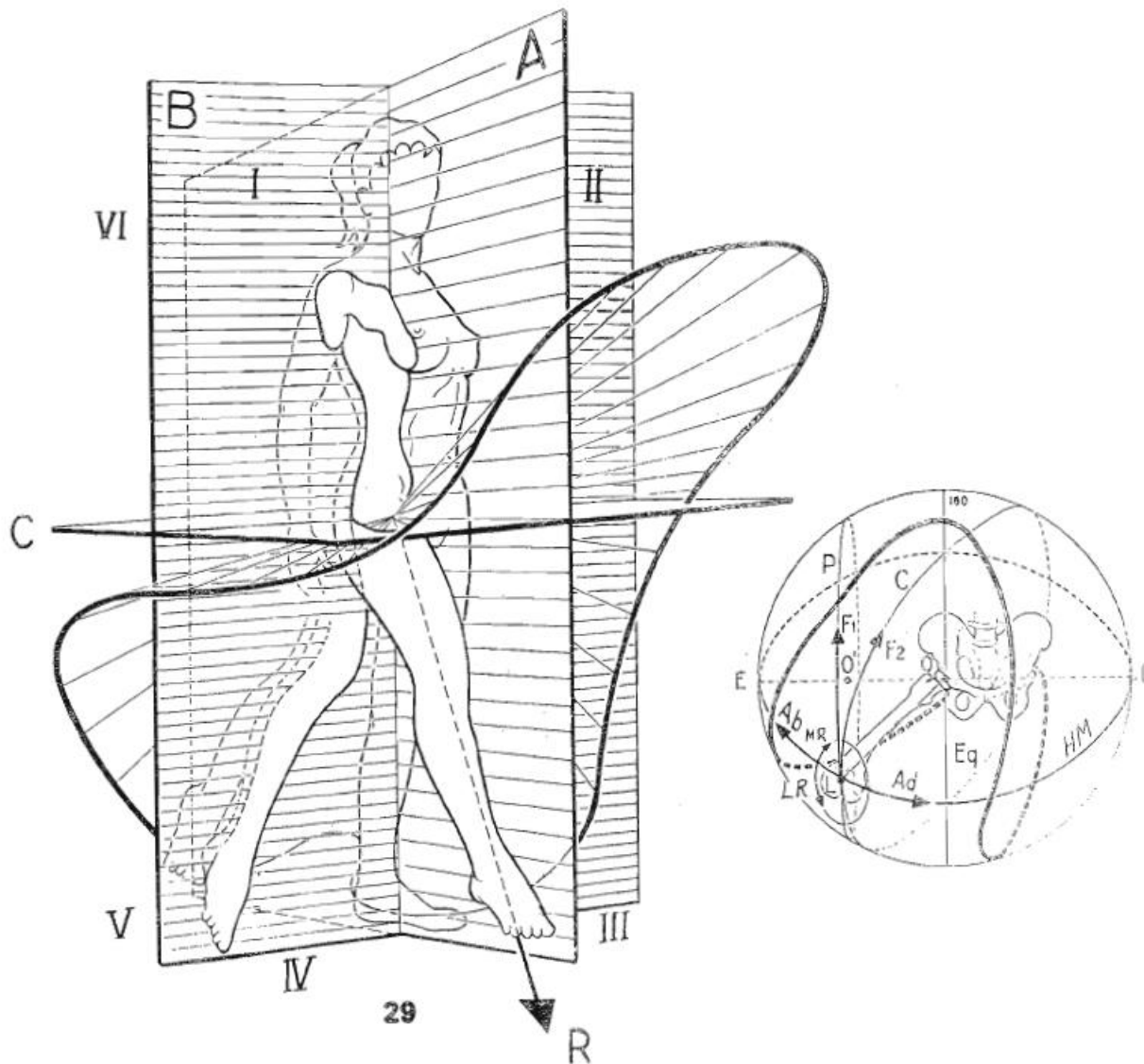


Fig. 1.9) Hip circumduction

1.9) Orientation of the femoral head and acetabulum

The femoral head is about two-thirds of a sphere, and its diameter spans from 40 to 50 mm. The three axes pass right through the centre of this sphere and are: the horizontal axis (1), the vertical axis (2) and the antero-posterior axis (3). The neck of the femur consists of the mechanical support that bears the load down from the head, to the shaft. The axis of the neck (Fig. 1.10 (31)) has a tilt with respect to the three axes of rotation of the femur and, starting from the base of the neck, it's directed *superiorly, medially and anteriorly* (C). In an adult it forms an angle of 125° with the shaft (D) and an angle of 10° to 30° with the frontal plane (Fig. 1.10 (37)), and it's called angle of anteversion.

The coronal plane, which at the same time gets through the centre of the femoral head and contains the axis of the femoral condyles (Fig. 1.10 (34)), lies almost completely anterior to the femoral

shaft; furthermore it contains the mechanical axis MM' of the lower limb and it forms an angle that ranges from 5° to 7° with respect to the axis of the shaft (D).

The shape of the head and neck, and their relative proportions can vary a lot with the individual; and show two different evolutionary strategies (Fig. 1.10 (35a) and (35c)): one slender with a wider range of motion (which favours agility and speed), and one bulky with a smaller range of motion (which favours mechanical resistance and power).

The acetabulum (Fig. 1.10 (32)) is the hollow which hosts the femoral head and is located on the side of the hip bone, where its three bones meet; it's hemispherical and is kept together by the acetabular rim (R). It is lined on the sides by a horseshoe-shaped (Fig. 1.10 (33)) articular cartilage (Ca), with an opening on its lower part where the acetabular notch is located. The central area of the cavity is deeper than the cartilage and is non-articular; it is the acetabular fossa (Af).

The acetabulum (Fig. 1.10 (32)) is directed *inferiorly, laterally and anteriorly* (C'), and this particular orientation allows the femoral neck (which is directed *superiorly, medially and anteriorly*) to perform a wide rotation in the flexion direction. The fact of facing inferiorly generates an optimal resistance to vertical loads and the upper part of the cavity bears the greatest pressure from the femoral head; for this reason the articular cartilage (Ca) is thicker superiorly. The tilt of the acetabulum with respect to the horizontal is 30° - 40° downwards and the upper part of it protrudes from the hip bone (Fig. 1.10 (36)) increasing the surface that wraps the femoral head. The "extent of overhanging" is determined by the *angle of Wiberg* (W) which is typically 30°.

The tilt that directs the acetabulum anteriorly can be quantified as 30° - 40° with respect to the frontal plane (Fig. 1.10 (37)).

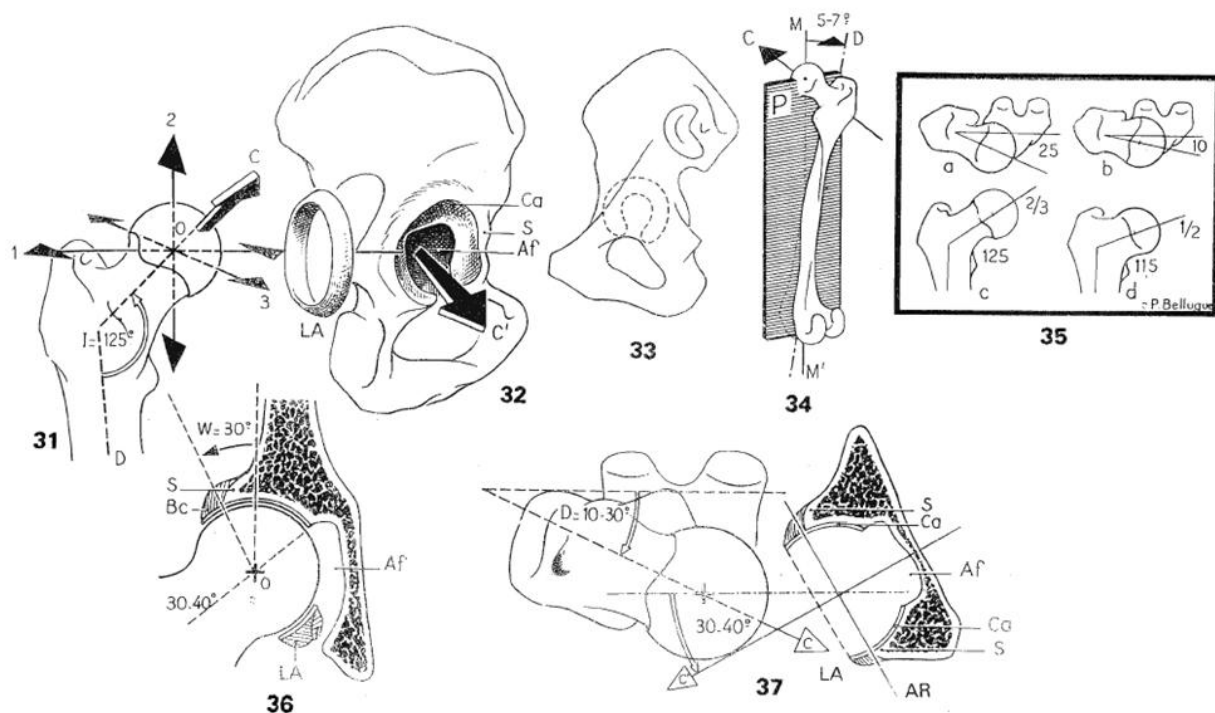


Fig. 1.10) Orientation of femoral head and acetabulum

1.10) Articular surfaces relative orientation

When the subject has an erect posture (Fig. 1.11 (39)), the hip assumes the neutral position and the femoral head appears not to be fully covered by the acetabulum, leaving the cartilage-lined anterosuperior area exposed (Fig. 1.11 (38)). This non-perfect matching of the two surfaces is ascribable to the fact that the axis of the femoral neck is oriented *superiorly, medially and anteriorly*, and so, not in line with the acetabular axis, which is oriented *inferiorly, laterally and anteriorly*.

In Fig. 1.11 (40) a simple mechanical model of the hip highlights the misalignment that occurs in the human erect posture, while in Fig. 1.11 (43) the model is represented in the configuration of perfect alignment.

The perfect coincidence of the two surfaces is possible thanks to three elementary rotations: flexion of about 90°, little abduction and little external rotation.

This perfect match of the two surfaces (Fig. 1.11 (41)) is reached when the individual is in the *position on all fours* (Fig. 1.11 (42)), which is clearly the natural physiological position of the hip joint. Throughout evolution the change from the quadruped to the biped condition has provoked this misalignment on the articular surfaces of the hip joint. On the other hand, this particular coincidence is a strong evidence in favour of the theory that the human beings are descended from quadruped ancestors.

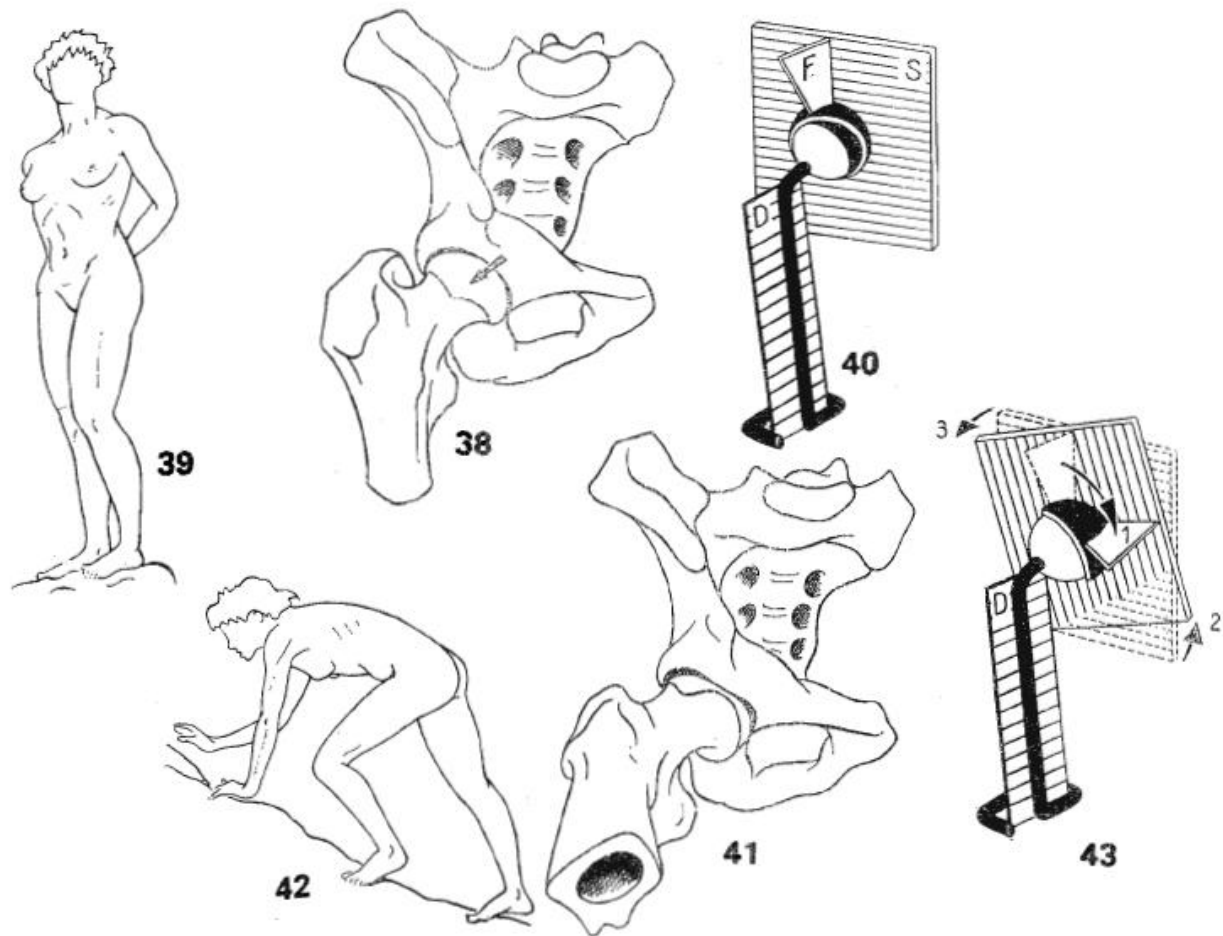


Fig. 1.11) Articular surfaces relative orientation

1.11) The structure of the femur

The upper part of the femur, with its characteristic bend, is similar to the structure known as “the overhang”, and it’s like the “L” structure of a gibbet, with its strut which turns the bending moment into a compressive force (Fig. 1.12 (50)).

In FIG 48 is clearly shown how the mechanical axis of the lower limb, the axis of the femur and the vertical axis are well distinguished and don’t coincide. This configuration is particularly important, together with the arrangement of the abductor and adductor muscles, to perform abduction and adduction efficiently.

The head is connected to the shaft through a system of lamellae of spongy bone. These lamellae are arranged in two *systems of trabeculae* to bear the stress efficiently according to the lines of force (Fig. 1.12 (46)) in agreement with Culmann’s experiment on the curved beam (Fig. 1.12 (49)).

There are two sets of trabeculae with different roles which constitute the main system: the *arcuate bundle of Gallois and Bosquette* (1) which is subjected to the greatest part of the shearing stress, and the *supporting bundle* (2) which bears the greatest portion of the compressive stress.

The accessory system is composed of two bundles which end up in the greater trochanter: the *trochanteric bundle* which is subjected to the stress generated by the gluteal muscles and the bundle with the trabeculae running parallel to the greater trochanter (which is less important).

There are some important things to note:

- The arcuate bundle (1) and the trochanteric bundle (3) generate a Gothic arch, and its keystone is made of a much denser bone tissue. The “medial pillar” (3) is less strong and gets weak with aging because of osteoporosis.
- Another Gothic arch is generated by the arcuate bundle (1) and the supporting bundle (2) crossing up. The intersection is in the femoral head and is made out of a much denser tissue. This system lies on an extremely strong support: the inferior spur of the neck (SP), even known by the name of the vault of Adams.
- Between the Gothic arch of the trochanter and the supporting bundle there is a cone of weakness (+) which is much more easily subjected to fracture in old age, because of senile osteoporosis. This is the area where the basal fracture of the neck happens (Fig. 1.12 (51)).

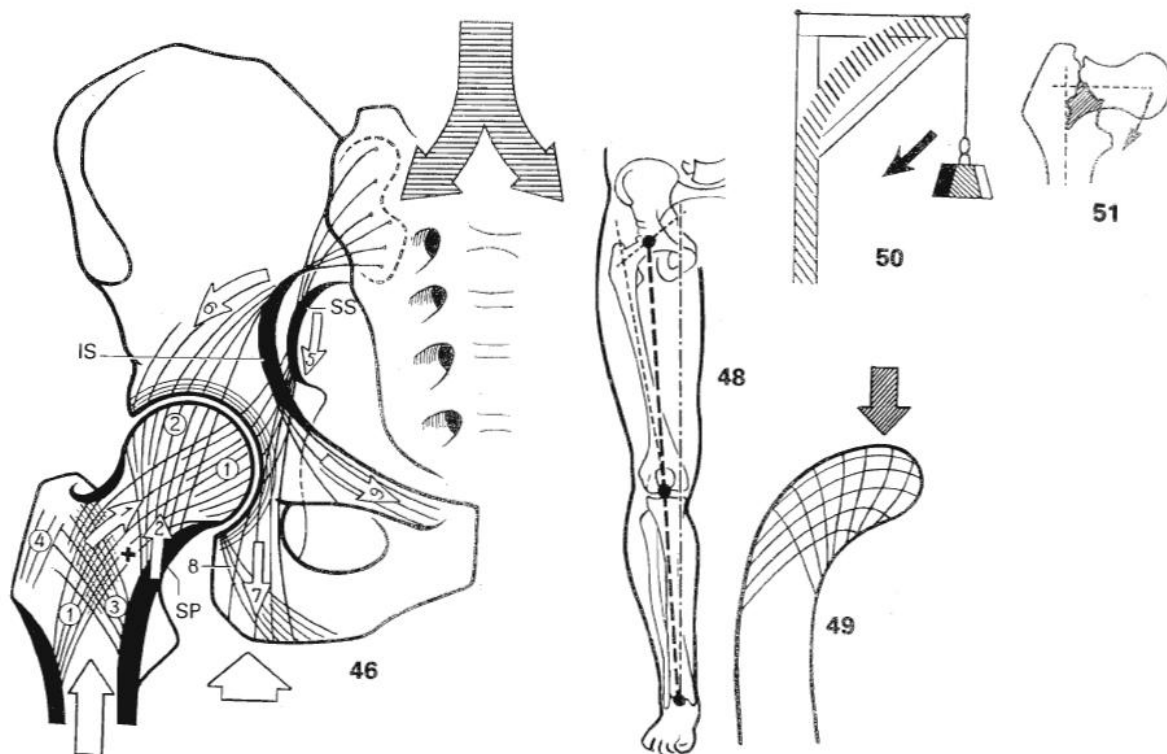


Fig. 1.12) Structure of the femur

1.12) Ligaments of the hip joint and their roles

The ligaments of the hip have as main function: keeping the joint in place, increasing its strength and stability during the movements, and avoiding the luxation of the joint. The *ligamentum teres* (LT) is a fibrous band about 30 – 35 mm long, consisting of three bundles (Fig. 1.13 (56)): *posterior ischial bundle* (pi), *anterior pubic bundle* (ap), *intermediate bundle* (ib). It comes out

from the acetabular notch (Fig. 1.13 (52)) and gets into the fovea femoris capitis (Fig. 1.13 (55)) by running through the gap of the acetabular fossa (Fig. 1.13 (53)). This ligament is surrounded by a fibro-adipose tissue and is lined by synovium (Fig. 1.13 (54)). The ligamentum teres does not undergo a high mechanical stress, despite this, it's very strong (its breaking force reaches the noticeable value of 45 kg weight); a tiny branch of the obturator artery follows the ligament to irrigate the femoral head with blood (6 in Fig. 1.13 (57)).

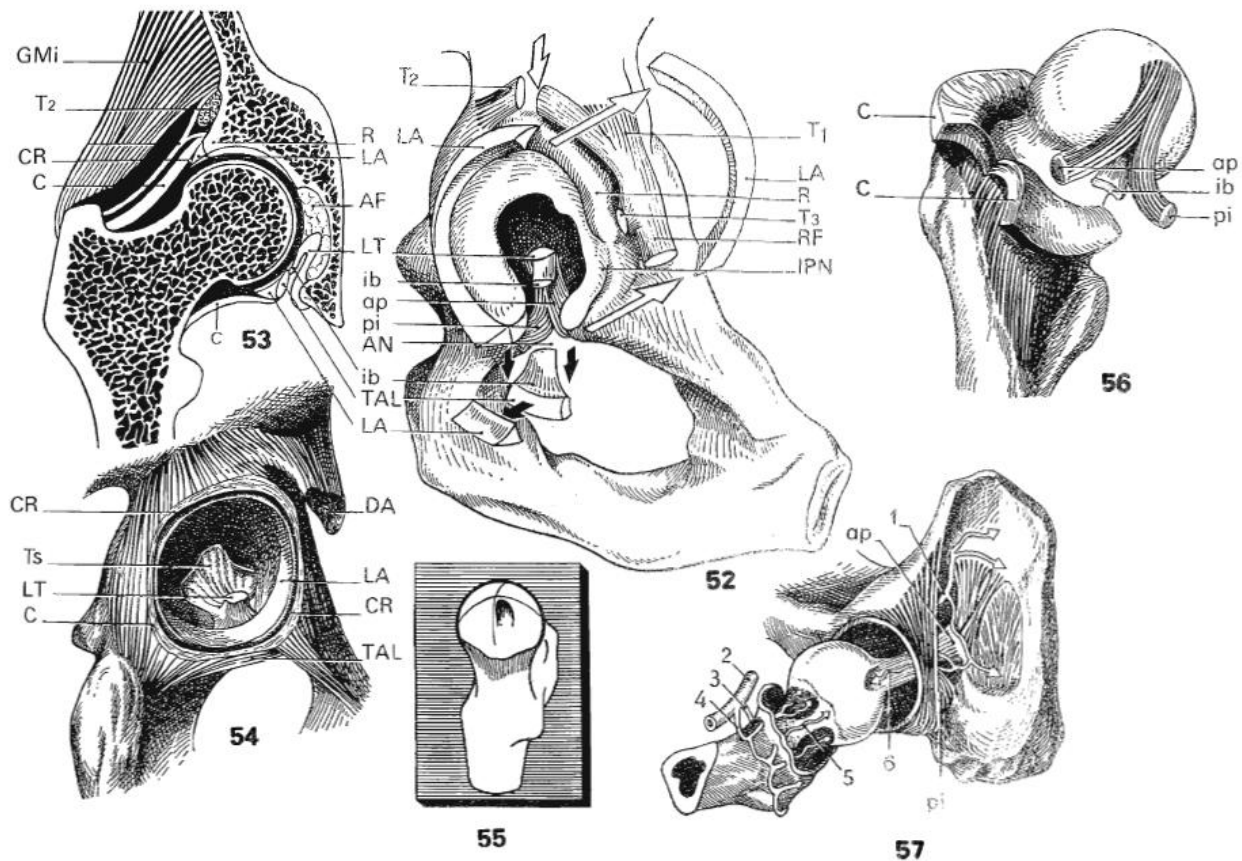


Fig. 1.13) Hip joint ligaments

The capsular ligament has the shape of a sleeve (Fig. 1.14 (58)) connecting the iliac bone to the femur and wrapping around the joint.

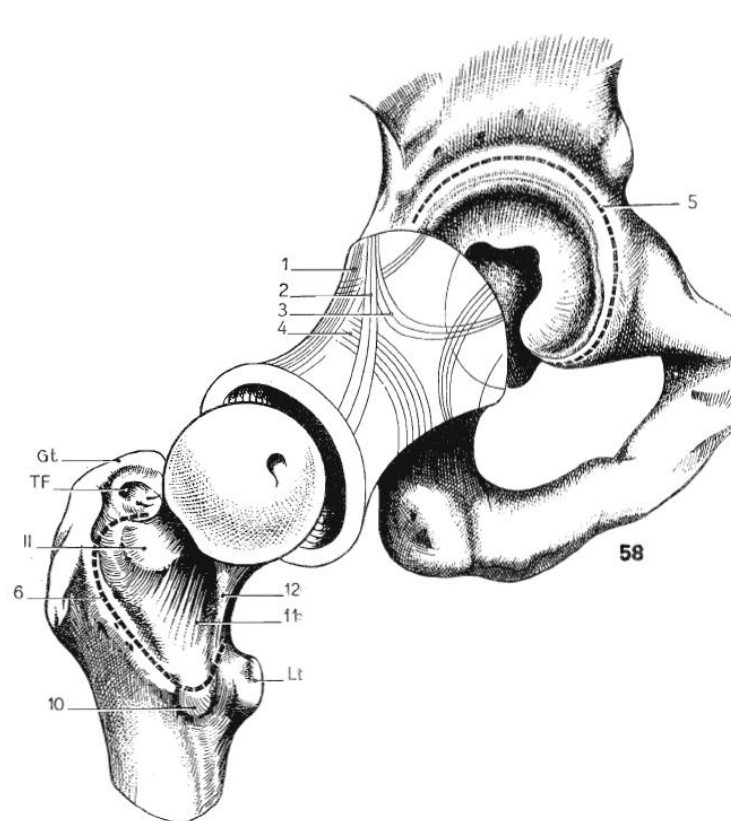


Fig. 1.14) Hip joint capsular ligament

The capsule is reinforced by robust ligaments anteriorly and posteriorly. Anteriorly (Fig. 1.15 (63)) we find the iliofemoral ligament (1), resembling a fan, which is composed of the *iliotrochanteric or superior band* (a) and the inferior band (b). Anteriorly we even find the *pubofemoral ligament* (2). These two ligaments together generate the shape of the letter “Z” (Fig. 1.15 (64)).

Posteriorly (Fig. 1.15 (65)) there is just one ligament, the ischiofemoral ligament (3). In Fig. 1.15 (66) are shown in black the fibres of which it’s composed.

All the ligaments of the hip joint appear to be twisted around the femoral neck (Fig. 1.15 (63) and (65)), all in the same direction; this is due to the fact that the “proper position” of the human being, from the anatomical point of view, should be the one on all fours. So when the man moved from the quadruped position to the erect position, the pelvis got tilted, coiling all the ligaments. For this reason, the movement of flexion tends to unwind the ligaments of the joint.

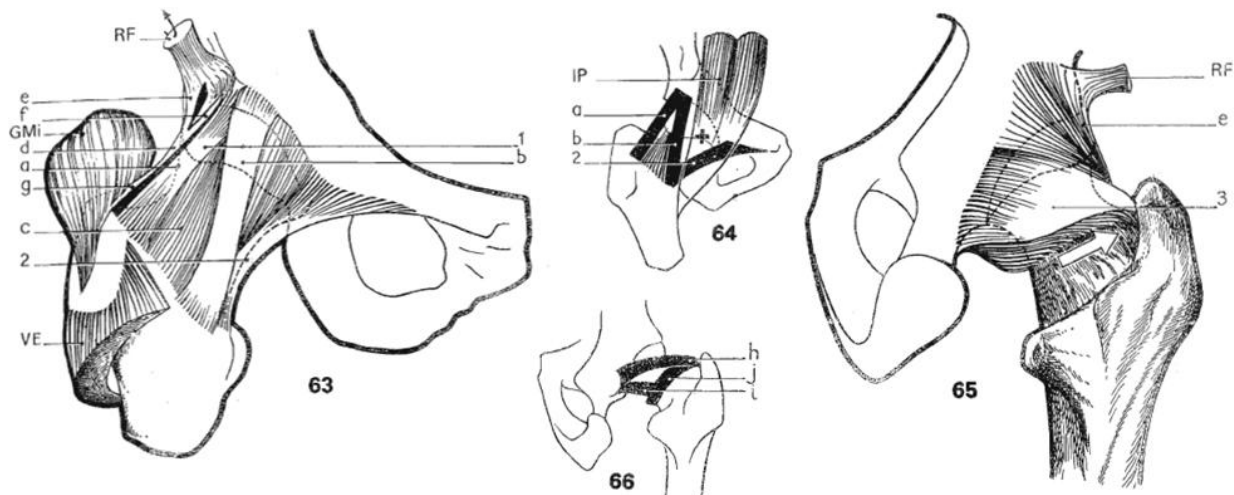


Fig. 1.15) Hip joint ligaments

1.13) Coaptation of the articular surfaces of the hip

The force of gravity tends to keep the femoral head in place, pressing it against the roof of the acetabulum (Fig. 1.16 (92)). The acetabulum alone, is a hemispheric surface, for this reason it can not generate interlocking; anyway the labrum acetabulare extends its surface making the acetabular cavity exciding the hemisphere, and turning it in a ball and socket joint.

The role of the atmospheric pressure is particularly important to the stability of the hip joint. The Weber brothers demonstrated with an experiment, that even after disconnecting all the soft tissue connections between the hip bone and the femur, the dislocation of the joint was hard to obtain even by making use of a great force (Fig. 1.16 (93)); on the contrary, by producing a little hole that by reaching the surface of the acetabulum would have spoiled the air-tight capacity (or fluid-tight capacity, in general) of the joint, the femur could have then fallen down under its own weight (Fig. 1.16 (94)). Basically it works like a suction cup (Fig. 1.16 (95) and (96)).

The presence of both ligaments and periarticular muscles, plays a crucial role in the task of keeping the joint together. In fact in spite of the fact that anteriorly the muscles are very few, while the ligaments are robust, posteriorly the ligaments appear weaker but acting together with powerful muscles (Fig. 1.16 (97)).

Coaptation appears even related to the relative position of the hip joint, in fact while the femur is flexed (Fig. 1.16 (99)), the ligaments appear “unwound”, and so relaxed, on the other hand, when the individual is standing upright, or even better, with the femur extended (Fig. 1.16 (98)), the ligaments wind up producing a strong force that keeps the two parts of the joint together (like in the mechanical model in Fig. 1.16 (100)). The sitting position with crossing legs is therefore the most dangerous for what concerns a possible dislocation event. In fact the leg appears flexed and slightly adducted, which causes the maximum laxity of the ligaments (Fig. 1.16 (101)).

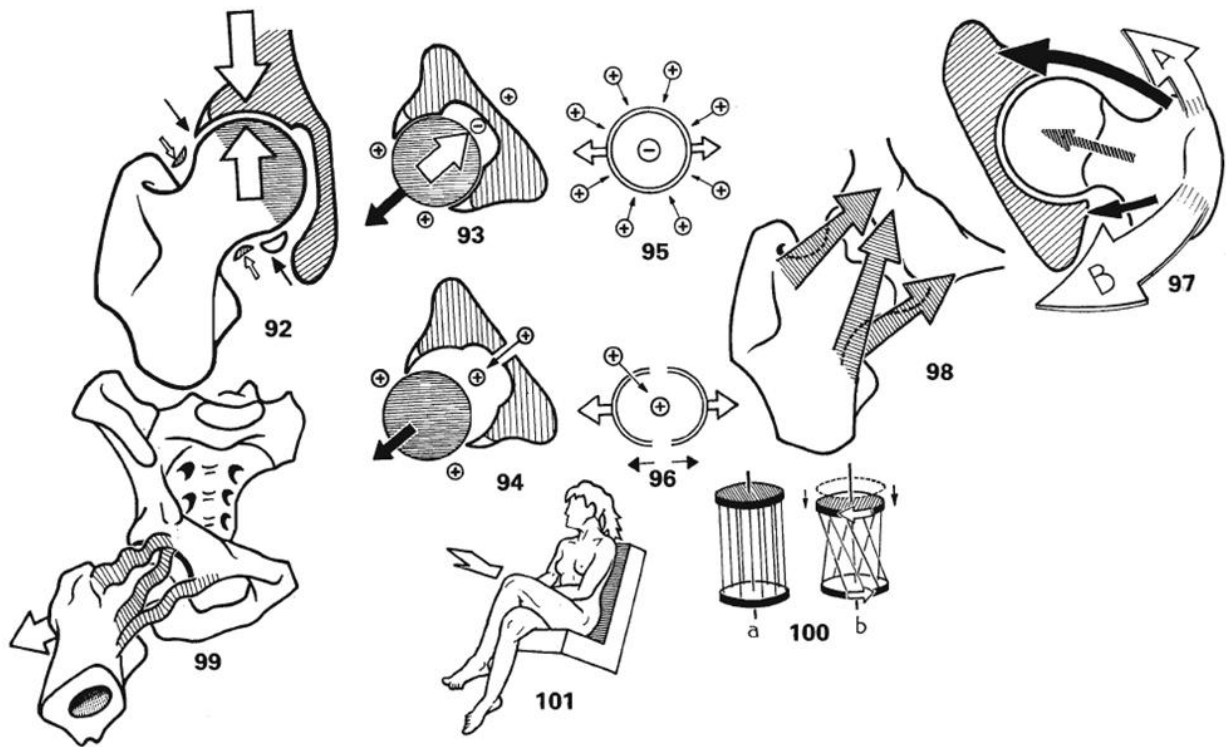


Fig. 1.16) Coaptation of the articular surfaces

1.14) Involvement of muscles and bones in hip stability

The periarticular muscles are crucial for what concerns the stability of the hip.

The muscles that are running parallel (or almost parallel) to the femoral neck, keep the femoral head in place in the acetabulum, like the piriformis and the glutei (which produce a strong coaptation (3)) just to name a few. For this reason these muscles are called muscles of apposition of the hip. Longitudinal muscles, like the adductors, tend to dislocate the femoral head above the acetabulum (Fig. 1.17 (102)), in particular when the roof of the acetabulum is everted. This eversion of the acetabulum is present in case of malformation, where there is a congenital dislocation of the hip (Fig. 1.17 (103)). The angle between the horizontal line running through the cartilages at Y and the line tangent to the acetabular roof is 25° in the infant and becomes 15° after the first year; when the angle is wider than 30° there is a congenital malformation. When this malformation is present, the adductors (4') can produce dislocation, and this is more likely when the femur is adducted (Fig. 1.17 (102)); on the contrary the greater the abduction, the smaller appears the probability of dislocation, in fact in this case the adductors press the femoral head in the acetabulum, increasing the joint stability (Fig. 1.17 (104)).

The direction of the femoral neck is very important in keeping the stability of the hip joint. In a normal individual, the angle between the axis of the shaft and the axis of the neck in the frontal plane is $120^\circ - 125^\circ$ (FIG 105), when this angle is wider, and for example reaches 140° (b), which is about 20° wider than the "normal" one. This condition is called *coxa valga* and it reduces the adduction range (c), in fact in a 30° adduction in a malformed hip (P), corresponds to a 50° adduction in a healthy hip. In case of coxa valga the probability of dislocation is much higher than

in a normal hip, on the contrary the greater the abduction the higher the stabilization (Fig. 1.17 (106)).

As previously exposed, the femoral neck has an angle of anteversion in the horizontal plane (angle between the femoral neck and the frontal plane (Fig. 1.17 (107)); this angle is usually about 20° (a). Since the erect position leaves part of the femoral head out of the acetabular cup, a greater angle of anteversion, 40° for example, makes the femoral neck running more anteriorly increasing the chance of anterior dislocation. This pathology is called *anteversion of the femoral neck*. In fact, in case of lateral rotation (c) the axis of an anteverted neck can collide with the acetabular rim, augmenting the risk of anterior dislocation. On the other hand, as it's easily understandable, the retroversion of the neck and medial rotation (d) promote stability.

Concluding, during the hip replacement, the surgeon must take into account the following facts:

- Reproducing the anteversion of the femoral neck which fits the anatomy of the patient
- Setting an adequate orientation of the acetabular cup, making it facing inferiorly with an angle of 50° or less with respect to the horizontal and slightly anteriorly with an angle less than 15° . It has to be said that sometimes the surgeon changes these angles on purpose according to the anatomy of the patient and the characteristics of the prosthesis (i.e. in some cases the acetabular cup has its axis almost vertical, configuration substantially different from the anatomical one)
- A faithful reproduction of the functional length of the femoral neck to restore the original lever arm of the gluteal muscles that are basic for the prosthesis stability

Nowadays the technology at disposal to the surgeon for this kind of replacement is particularly advanced. In fact a software helps in the phase of the evaluation of the angles and general geometry of the prostheses that are going to be implanted and computerised tools help during the surgical operation to accurately reproduce these angles.

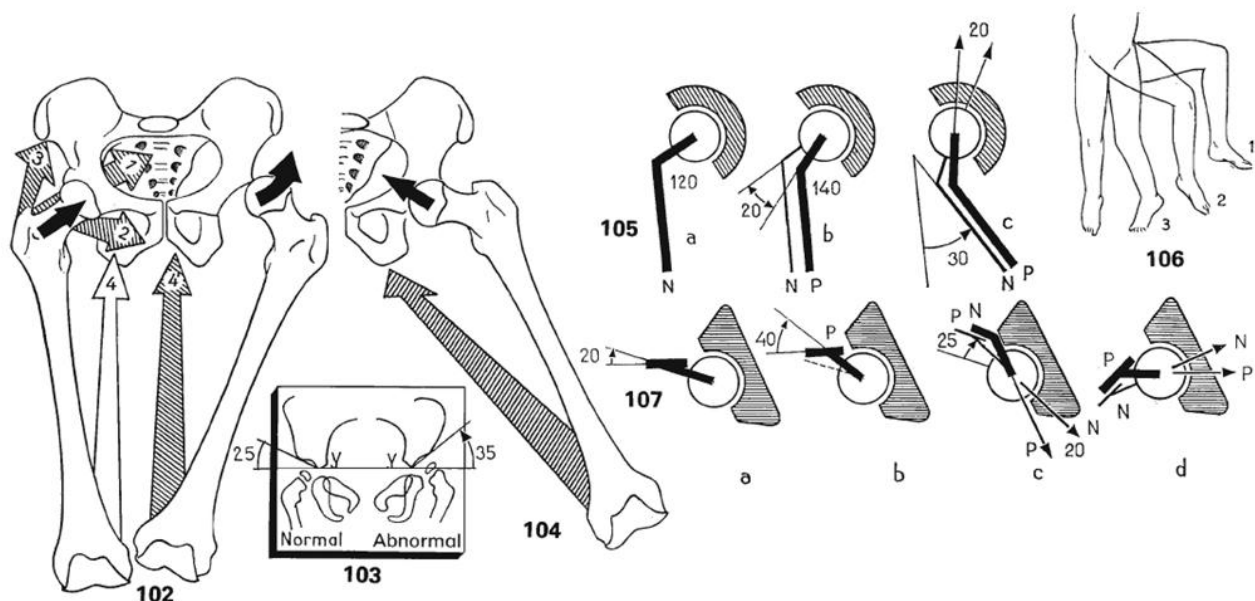


Fig. 1.17) Role of muscles and bones in stability

Chapter 2

The hip, its technical problems and an introduction to the hip joint arthroplasty

2.1) Introduction

This chapter gets through many aspects useful to understand issues related to hip prostheses. At the beginning some anatomical/physiological/biological aspects regarding the bone are examined; for example: details related to microstructure, physical and mechanical characteristics, and role of synovial joint capsule. Then the longstanding problem regarding wear induced osteolysis is exposed; details about its deleterious effects and issues that can arise after implantation are given. Follows a brief subchapter with information about the incidence of health problems based on the population age, gender, ethnicity, etc.

Two subchapters are about the history joint arthroplasty, from the early experiments with wood and porcine tissues, to the most modern technologies adopting special materials and advanced methods.

The final part of the chapter examines in depth wear, the different solutions for implantations, metal on metal prostheses questions (debris, squeaking), different techniques for older and younger patients, and conservative techniques (hip resurfacing).

Much of the information and images contained in this chapter come from “Medical Devices” by Gail D. Baura [3].

2.2) The bone

Collagen fibrils of bones are arranged in piled up sheets which are mineralized by hydroxyapatite that appear as crystals. The mineralized fibrils may be held in place by a nonfibrillar organic matrix that has the role of a glue. When the bone is subjected to a force this “glue” keeps the mineralized collagen fibres together (Fig. 2.2), preventing their relative shift.

The bone tissue can be divided into two different types: *cortical bone* (or *compact bone*: structured in tightly packed layers) and *trabecular bone* (or *cancellous bone*: consisting of a number of “rods” and “plates” within a marrow matrix).

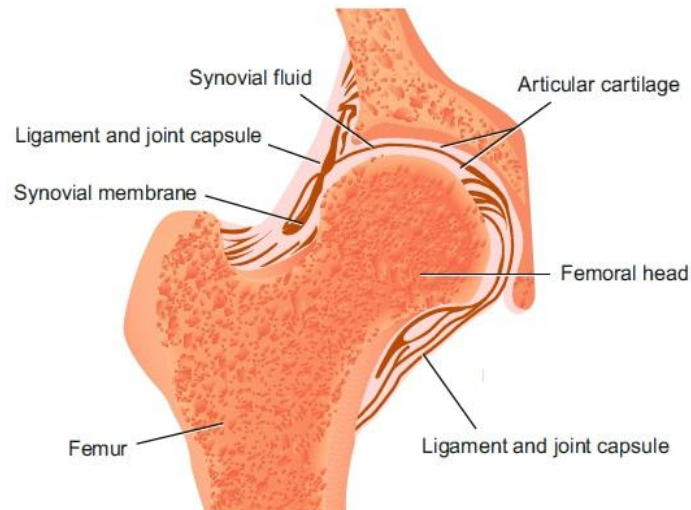


Fig. 2.1) Hip joint capsule

Cortical bone is found on the surface (like a shell) of the greatest part of the bones, and, from the mechanical point of view, consists of structural bone tissue; trabecular bone, on the other hand, is found on the inside of flat or irregular bones, such as sternum, and at the extremities of all long bones (Fig. 2.1). The mechanical properties of the trabecular bone are not evenly distributed (anisotropic nature) and they depend on how trabecular rods and plates are distributed and oriented.

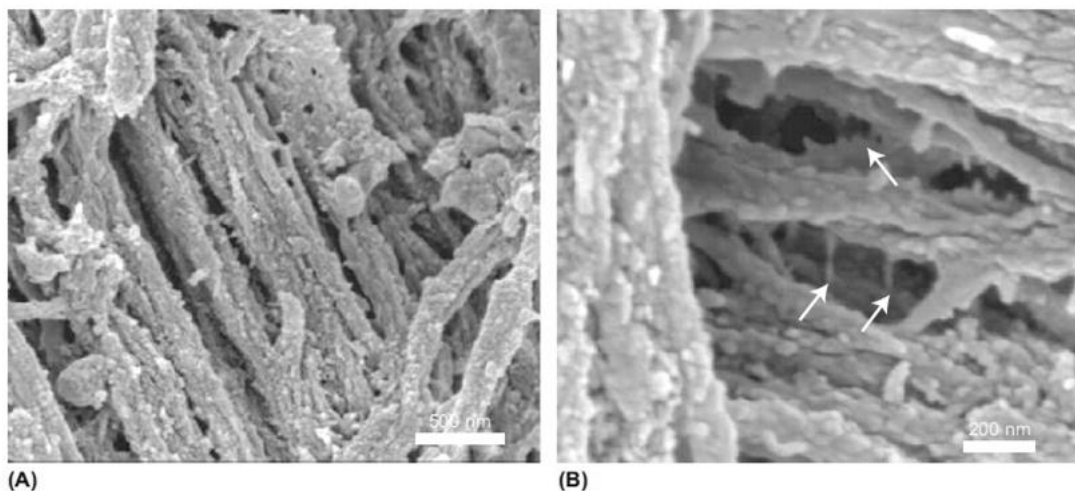


Fig. 2.2) Mineralised collagen fibrils on a fracture surface of human trabecular bone. **(A)** Fracture surface. **(B)** Individual collagen fibrils held together with glue filaments (arrows), which might resist separation of the filaments. Images captured with a scanning electron microscope.

The most important mechanical properties of the bone are: the elastic modulus and ultimate strength. The elastic modulus is the slope close to the origin of the axes, in the supposed linear elastic area. The ultimate strength is the stress at which a complete detachment of the bone occurs, and the bone breaks (Fig. 2.3 and Tab. 2.1).

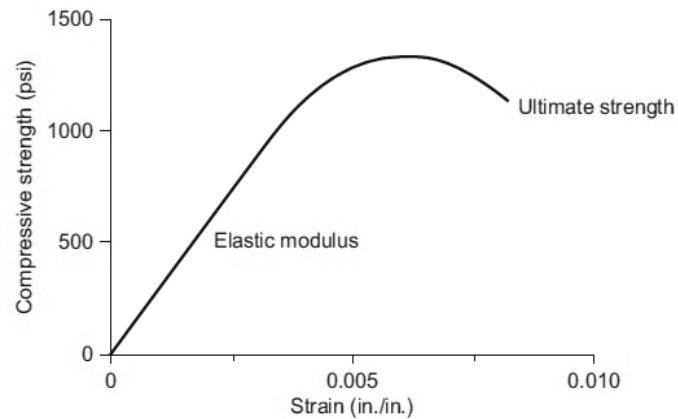


Fig. 2.3) Stress strain diagram for human trabecular bone in femoral head (Anglo-Saxon units).

Material	Elastic Modulus (GPa)	Ultimate Strength (MPa)	Hardness HVN
Human vertebra, 15–87 yr	0.067	2.4	—
Human proximal femur, 58–85 yr	0.441	6.8	—
UHMWPE	0.5–1.3	30–40 <i>t</i>	60–90 MPa
PMMA	1.8–3.3	38–80 <i>t</i>	100–200 MPa
Al ₂ O ₃	366	3790 <i>c</i> /310 <i>t</i>	20–30 GPa
ZrO ₂	201	7500 <i>c</i> /420 <i>t</i>	12 GPa
Co-Cr alloy ASTM F75	210–253	655–1277 <i>t</i>	300–400
Ti alloy Ti-6AL-4V ASTM 136	116	965–1103 <i>t</i>	310

t = tension; *c* = compression.

Source: Keaveny et al. (2001); Hallab et al. (2004b).

Tab. 2.1) Mechanical properties of orthopedic biomaterials

Bone tissue is constantly resorbed, grown and reinforced. This process allows the bone to adapt to the lifestyle of an individual, modifying its overall structural properties when needed. This is particularly important after a partial or total hip replacement.

Osteoclasts are multinucleated cells that selectively destroy bone tissue by secreting an acid. They ingest the debris produced and expel it to the blood stream.

Osteocytes allow the damaged bone tissue to be repaired.

Osteoblasts, located on the surface of the trabecular bone, secrete *osteoid*, the collagenous matrix that forms the basic structure of bones.

2.3) Synovial joint capsule

At the interface between femoral head and acetabulum, cartilage has a double role: friction reduction and shock absorption. Femoral head and acetabulum are wrapped into the synovial joint capsule (Fig. 2.4). This capsule is composed of a dense fibrous connective tissue lined with synovial membrane, in the end it consists of a sleeve around the joint. This capsule secretes and confines the

synovial fluid for joint lubrication. Moreover, accessory ligaments provide a stable and strong connection of the two bones, in order to limit the range of motion, preventing luxation under ordinary loads and protecting the capsule from loading.

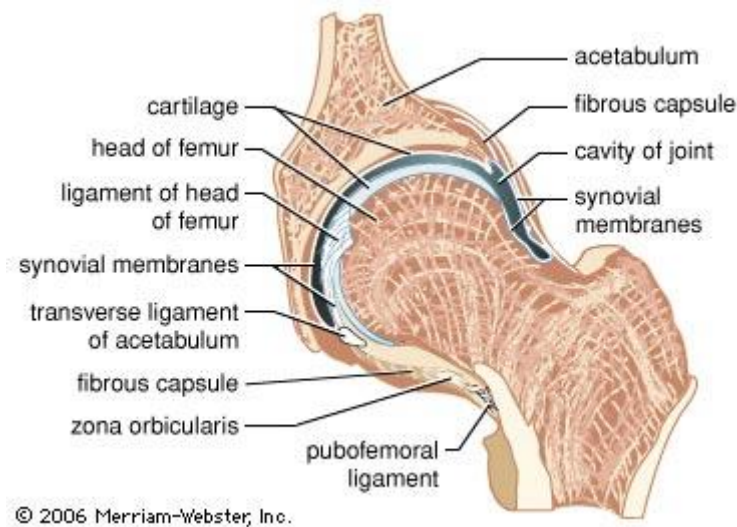


Fig. 2.4) Synovial joint capsule

2.4) Wear induced osteolysis

After numerous cycles, because of the continuous relative motion between the head and cup surfaces, wear particles are produced. The main phenomena causing wear particles are three: *abrasion*, *adhesion* and *fatigue*. Abrasion happens when the harder surface ploughs grooves into the softer surface. Adhesion occurs when asperities that get in contact stick together, causing the tips of the asperities to fracture. Microscopic fatigue happens when cracks underneath surfaces form and propagate because of an alternation in the loading process. This condition, at length, causes delamination and so debris (Fig. 2.5).

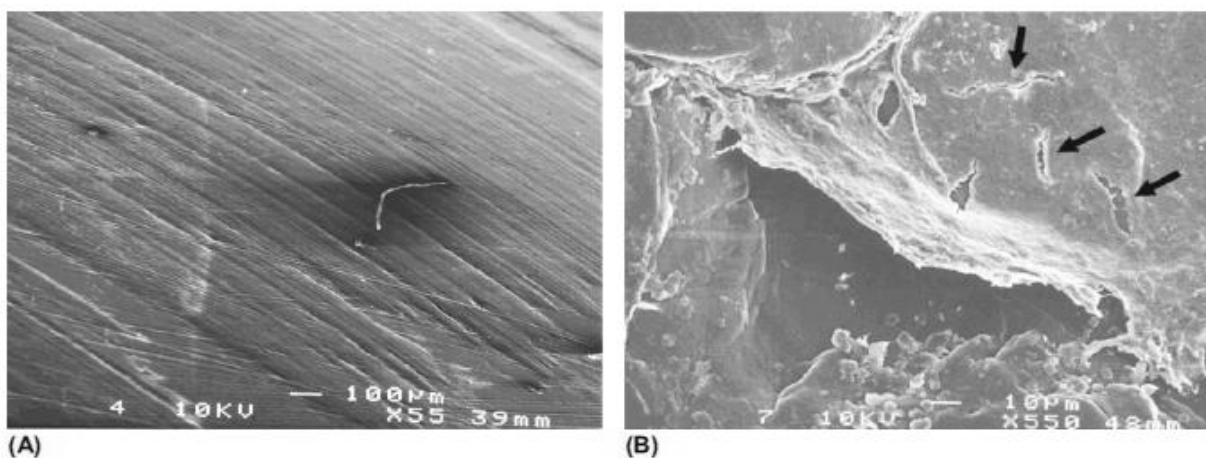


Fig. 2.5) High cross-linked UHMWPE liners, explanted from patients at the time of revision total hip arthroplasty, exhibit wear, as seen under the scanning electron microscope. (A) Adhesion. (B) Fatigue

Many factors come into play in the wearing process. The most important are: prosthesis characteristics, patient conditions, and surgical factors.

Design specifications, like bearing materials, surface finishes, and manufacturing technologies in general are really influential in the wearing process; as well as surgical factors, like prosthesis positioning and orientation during implantation.

Despite assessing wearing rate through mathematical equations is quite complex, with actual technology and proper implantation is possible to estimate, in case of cobalt-chromium (Co-Cr) head on an ultrahigh-molecular-weight-polyethylene (UHMWPE) liner, an average wear rate of about 0.1 mm/year, with a particulate production as high as 1×10^6 particles per gait cycle.

The particulate generated during the prosthesis life causes inflammation, which promotes a foreign-body granulation tissue response that may invade the bone-implant interface. In fibrous membranes close to retrieved prostheses, foreign-body giant cells are associated with wear particles (Fig. 2.6). Biologically active polyethylene wear particles were found to have an average size of about 0,5 μm .

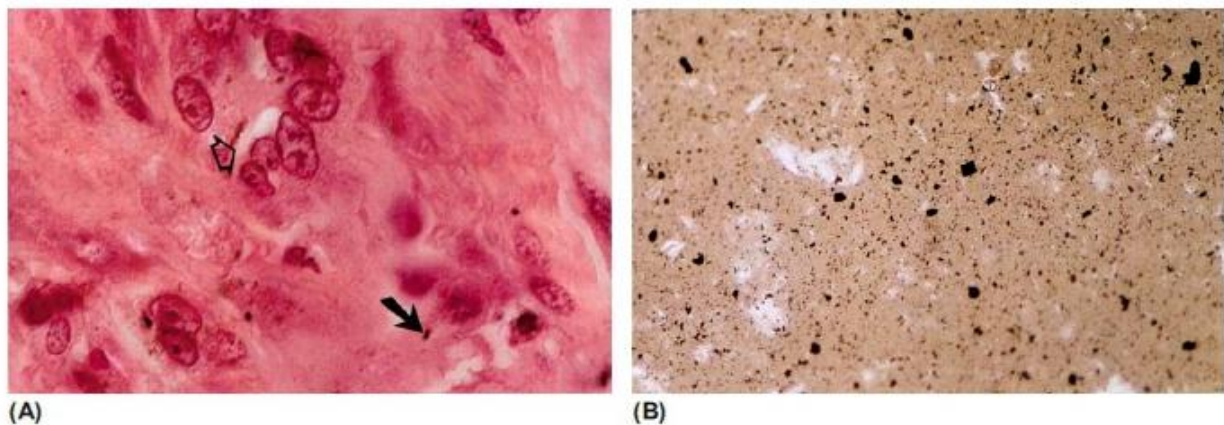


Fig. 2.6) Photomicrograph of the same tissue before and after tissue digestion. **(A)** Before digestion, a foreign-body giant cell is present that contains polarizable material, presumably UHMWPE (void arrow). Small particles of metal are also present (solid arrow) [X1040]. **(B)** After digestion, a photomicrograph was made under partially polarised light. There are many particles of dark metal and polarizable polyethylene [X420].

Foreign-body giant cell phagocytosis of those particles starts the release of cytokines and other inflammatory mediators. Increased cytokine release stimulates the osteoclastic activity, aseptic prosthesis loosening, and *in loco* bone resorption. The resulting bone loss (osteolysis), compromises the structural connection located at the bone-prosthesis interface, known as osteointegration and the durability of the prosthesis, which leads to clinical failure, and so compulsory prosthesis retrieval.

2.5) Clinical needs

Usually hip prosthesis implantation occurs in case of grave arthritis associated to pain and reduced deambulation capability. In particular, one of the most common forms of arthritis is *osteoarthritis* (OA), in which the entire joint experiences focal and continuous articular cartilage loss. Meanwhile,

the bone beneath the cartilage may experience a little protrusion and increased thickness of the bony envelope. The synovium may have inflammatory infiltrates and ligaments laxity may arise.

Many factors influence the incidence of OA on the world population, such as: age, gender (especially over 50-year-old women), ethnicity (African-Americans), bone density estrogen replacement therapy in post menopausal women (lower risk), and genetic factors. In addition, specific case factors can promote or exacerbate OA; in specific: obesity, injury, joint deformity, sport practice and muscle weakness.

Arthroplasty is the artificial reconstruction of a body joint, and it is currently among the most effective solutions to OA problems. After post surgical stabilization, arthroplasty can basically bring back the functionalities of the normal healthy joint.

2.6) Brief hip joint arthroplasty history

The first records of hip joint replacement date back to the beginning of the XIX century, when bones constituting the joints were removed and replaced with materials like wood and porcine tissues.

In 1890, Themistocles Gluck conceived the first prosthetic hip, which consisted in a femoral head crafted from ivory, fixed in the body by pumice and plaster of paris. In 1929, then, Marius Smith-Petersen improved the previous model by using a molded glass cup, which was put in place between the femoral head and the acetabular cup (Fig. 2.7); later the cup was substituted by a Co-Cr alloy cup in 1938.

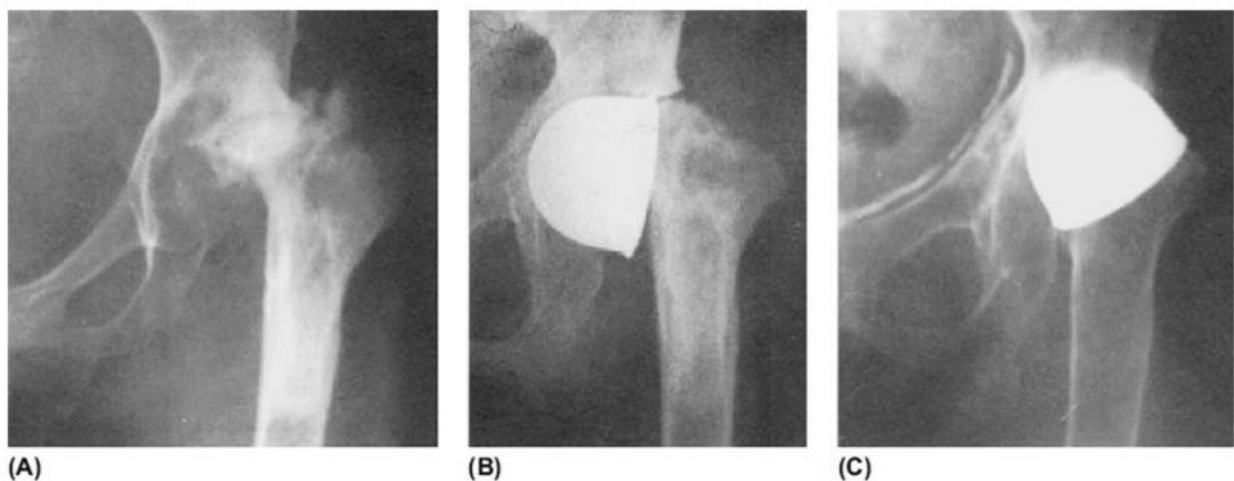


Fig. 2.7) Forty-five year follow-up of a Smith-Petersen Vitallium moulded cup. **(A)** 25 year-old patient in 1949, with severe degenerative hip due to congenital dislocation. **(B)** Same patient after cup implantation in 1949. **(C)** Follow-up in 1995. The patient walked with a limp but was free from pain. Note the resorption of the neck.

The moulded cup eventually included a short stem that was later elongated. In the mid fifties, orthopedic surgeons G. K. McKee and John Watson-Farrar reconceived the prosthesis splitting it into two parts: a Co-Cr spherical femoral head with a long stem and a Co-Cr acetabular cup.

2.7) Hip prostheses modern technology

In 1949, orthopedic surgeon Sir John Charnley started a more accurate investigation focused on the elements of total hip arthroplasty (THA). In his early studies he tried to evaluate friction and lubrication conditions of animal and artificial joints. In 1956, consequently to his experiments and speculations, he conceived an artificial acetabulum made of polytetrafluorethylene (PTFE) as a surrogate for articular cartilage, aiming to reduce friction (Fig. 2.8). After noticing a high wear rate in the PTFE acetabular cups, he took the decision to substitute PTFE with UHMWPE, which has a reasonably higher wear resistance, low friction and high impact strength. In the following radiographs is shown the hip before and after total hip replacement (Fig. 2.9)

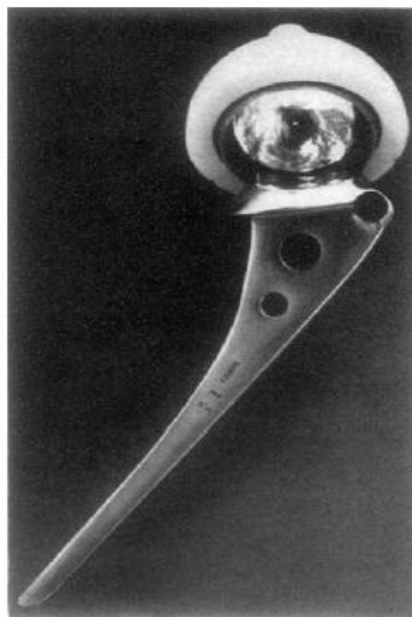


Fig. 2.8) Charnley's stainless steel femoral head prosthesis mated to PTFE

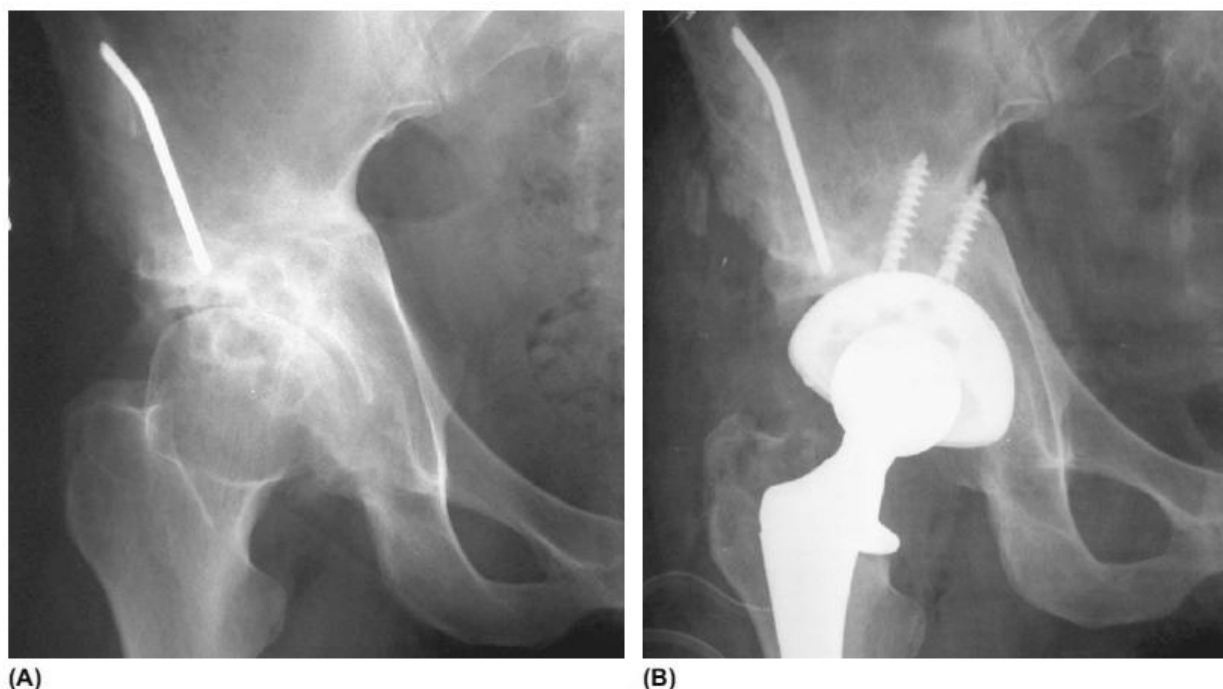


Fig. 2.9) Radiographs before **(A)** and after **(B)** THA. This patient had five previous surgeries for developmental dysplasia of the hip.

Charnley revised the way of gluing the prosthesis into the bone with resin, substituting this process, in 1960, with grouting of polymethylmethacrylate (PMMA) cement. By putting bone cement in the bone hollow, and letting it cement into all the interstices, the prosthesis-bone force transmission capability was increased by 200 times. Because of his contributions to conceptual and technical aspects in the field of total hip joint replacement, which have opened new horizons of research and treatment in arthritis and crippling joint diseases, Charnley received in 1974 the Lasker Clinical Medical Research Award.

The Charnley's low-friction arthroplasty (1960s) can be found even today as a metal femoral component, consisting of stem and ball, articulating against an acetabular component with a metal cup and a inner liner that, most of the times, is made of polyethylene (Fig. 2.11). The femoral stem, which is usually made of titanium (Ti) or Co-Cr alloy, can either be cemented or press fitted in place. In case cement procedure is selected, the procedure implies femoral preparation to diminish interface bleeding, reduced cement porosity by vacuum mixing, stem and polymer preheating, pressurization with a cement gun, stem geometries that increase the intramedullary pressure, and cement intrusion into the cancellous structure of the bone. Ordinarily, over 70-year-old people are implanted the cemented prosthesis, because the necessity of revision after 20 years is little. In case of press fitted stem, the cross-sectional area of the drilled hole is a little smaller than the stem caliber, for this reason, the stem is pressed and stuck in place. Press-fit femoral stems are often proximally coated to promote locally osteointegration.



Fig. 2.10) Hip prosthesis biocompatibility and wear debris

The Ti or Co-Cr alloy acetabular cup is also press fitted in place, and sometimes is provided with additional screws intended to give more stability in the early life of the prosthesis. The external surface of the cup has a rough finish, obtained by grit-blasting or plasma-spraying. It can be either porous- or hydroxyapatite-coated to reach an additional grip at the bone-prosthesis interface. The early polyethylene acetabular cup (also called acetabular shell) evolved to a cross-linked polyethylene liner, that is obtained through UHMWPE gamma irradiation exposure and then undergoes further treatments to reduce residual free radicals. Residual free radicals, such as H_2O_2 , make polyethylene susceptible to degeneration by oxidation.

The major issue that can affect the success in implanting a hip prosthesis is probably osteolysis, which can be triggered by an excessive value of wear rate, and so an abundant production of particulate in time (Fig. 2.10). Wear rate is function of prosthetic, patient, and surgical factors, that can again be subdivided into design and environmental variables.

2.8) Bearings and wear

Minimization of wear particles production during the life of a prosthesis has been one of the main problems tackled by manufacturers for several years. After many laboratory tests that evidenced the positive influence of highly crosslinking in polyethylene, a study was conducted on 230 patients, who received the same DePuy Co-Cr alloy femoral component and cup (Fig. 2.11), with either conventional, or cross-linked UHMWPE liner. This study gave clear evidence of a drastic wear reduction in the highly crosslinked samples. The patients were matched for gender, diagnosis, age at surgery, weight, and body mass index. Half of the patients (116) received the non-crosslinked Enduron UHMWPE liner; half (114) received the crosslinked Marathon UHMWPE liner.

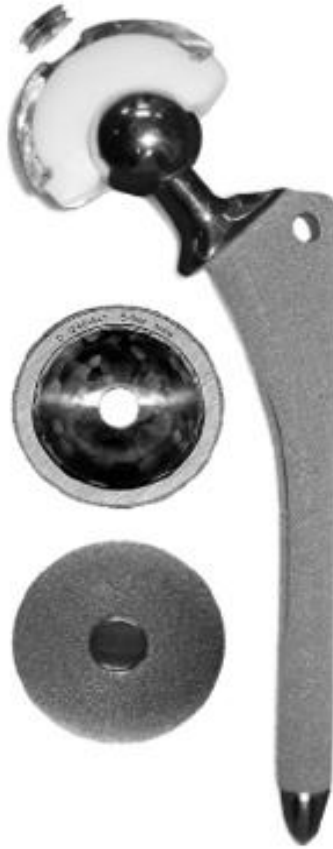


Fig. 2.11) Johnson & Johnson DePuy total hip prosthesis consisting of Duraloc 100 acetabular shell (shown in cross section, middle, and bottom), Marathon liner, and Co-Cr alloy femoral component.

The linear wear rate was calculated as the rate of femoral head penetration per year into the liner, as observed from three pelvic x-rays over a minimum 4-year follow-up. An orthopedic surgeon scrutinized all the x-rays to evaluate osteolysis, not knowing the liner type. As can be noticed in Fig. 2.12, the linear wear rate was significantly smaller in the cross-linked liners: 0.01 ± 0.07 vs. 0.20 ± 0.13 mm/year ($p < 0.001$). The influence of $>1 \text{ cm}^2$ osteolysis was also significantly less: 6.3 vs. 22.2% ($p = 0.002$).

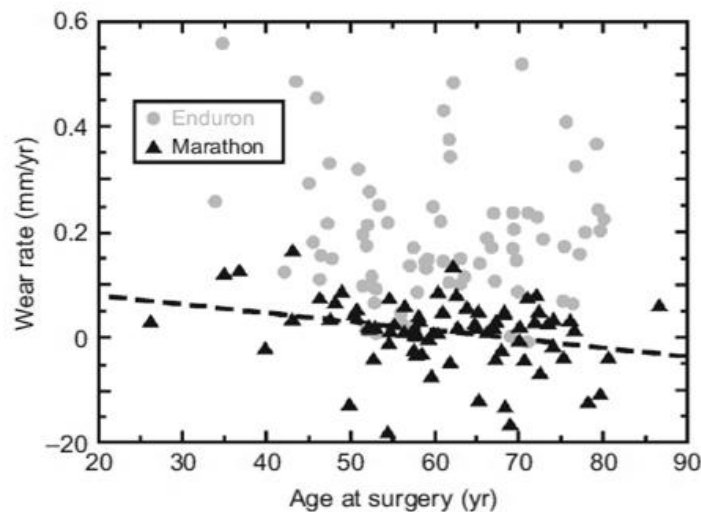


Fig. 2.12) The linear wear data show that the Marathon liners are wearing at substantially lower rate as compared with the non-cross-linked Enduron liners. The dashed black line represents the relationship between Marathon wear rates and age at surgery ($r=0.29$, $p=0.01$). There was no relationship between Enduron wear rates and age at surgery ($p=0.47$).

In the past, in case of polyethylene liners, small femoral heads were used to minimize wear. Heads with larger diameters, which reduce dislocation, are nowadays used with higher modulus metal-on-metal or ceramic-on-ceramic bearing surfaces. For these kinds of joints, linear wear rate was estimated by the Implant Wear Symposium 2007 Engineering Work Group as 5 $\mu\text{m}/\text{year}$ or 0-3 $\mu\text{m}/\text{year}$, respectively. However, clinical wear results vary considerably.

Problems arose after the materials of the bearing surfaces were changed. Metal-on-metal bearings can lead to *metal reactivity*, which is a lymphocyte-dominated reaction that occurs when the joint tissues are exposed to metal ions. Metal reactivity can cause osteolysis, which is being observed earlier and at a higher rate than with other bearing materials. Soft tissues reactions, which have been classified as pseudotumors, have high incidence around metal-on-metal bearings. Systemic effects, like decreased total lymphocyte count in patients and DNA changes induced by synovial fluid, also occur. Even if the potential long-term toxicity of metal-on-metal is unknown, the increasing negative reports led the editors of the *Journal of Arthroplasty* to publish the following notice in 2010:

The lack of clinical advantage with metal bearings and the significant downsides to the use of metal-on-metal mean that, in the authors' opinion, this bearing option should be used with great caution, if at all.

[Crawford et al., 2010]

In recent times, the FDA issued 145 orders of postmarket surveillance studies to 21 metal-on-metal hip prosthesis manufacturers on May 6, 2011. The manufacturers had to submit a research protocol that addressed metal-on-metal adverse events.

Another material frequently used for such bearings is ceramic. Harder ceramic-on-ceramic bearings made of second generation alumina or zirconia materials have shown a small risk of brittle fracture. The most important issue that can come up is squeaking, which is estimated to arise in 0.5 to 20% of implants. It's possible to artificially reproduce the conditions that originate squeaking in the laboratory, this is usually done by generating a wear stripe, this is done by dragging the ceramic head across the rim of a ceramic liner under load (Fig. 2.13). The large variety of *in vivo* squeaking reports, and the uniformity of *in vitro* simulations, suggest that both surgical and biomechanical factors are influential in the process that leads to squeaking.

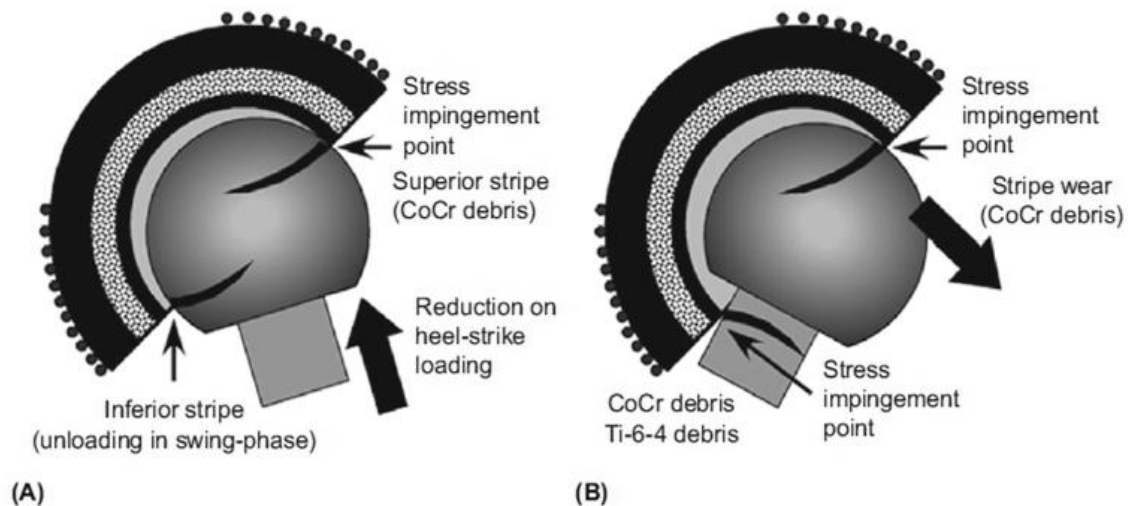


Fig. 2.13) Schematic of stripe wear modes with rigid acetabular component rims wearing on the ball counterface and resulting in a wear stripe on the acetabular component bevel. **(A)** With slight subluxation in the swing phase of the gait, the acetabular component edge will create an inferior and somewhat equatorial ball stripe. During reduction at heel-strike, a superior but equatorial stripe will be created. Both stripes will produce ceramic-on-ceramic debris. **(B)** At any impingement event, the destabilization forces will produce a more polar stripe on the ball, and the neck-cup impingement will produce debris from both the metallic femoral neck and the ceramic ball. Co-Cr (cobalt chromium), Ti-6-4 (grade 5 titanium).

In a sample made out of 999 patients that had 1056 THAs with alumina ceramic bearings implanted in a 12-month time span (January 2002 – December 2004), 28 patients (with 30 artificial hip prostheses implanted), or 2.7%, complained of squeaking. The squeaking arose between 0.6 and 2.7 years after THA; although it was not associated with other symptoms such as pain or instability. In all cases, anyway, both acetabular and femoral components were found to be well fixed, not showing any sign of loosening. Six squeaky hips underwent revision surgery to have the bearings replaced with traditional metal-on-polyethylene bearings. In four of these hips (Fig. 2.14), significant posteroinferior neck-rim impingement was found.

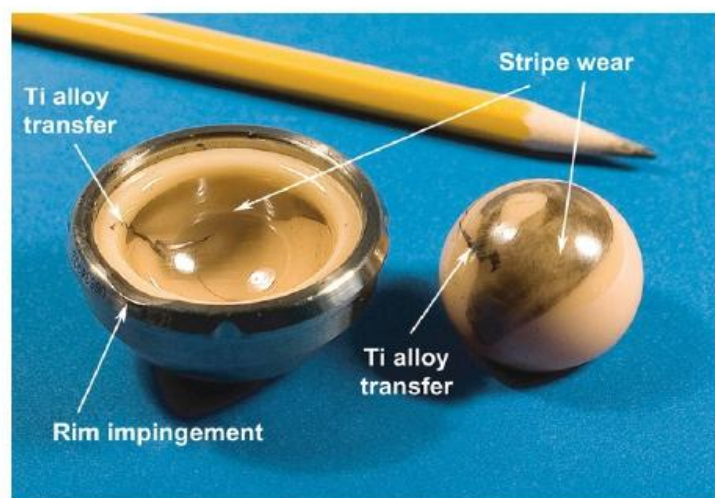


Fig. 2.14) Retrieved acetabular component from a patient with squeaking hip with evidence of impingement. Note the indentation of the metal rim generated by the femoral neck.

In 2006, 71% of the whole hip prosthesis market volume in the USA was covered by the metal-on-polyethylene type, 20% was metal-on-metal, 5% was ceramic-on-ceramic, and 4% was ceramic-on-polyethylene. In the following years, until metal-on-metal bearing problems were acknowledged, the use of metal-on-metal bearings increased dramatically because of the popularity of hip resurfacing techniques.

Hip resurfacing is a technique adopted usually on younger patients; where bone tissue is in good conditions, and so, preserved as much as possible. In this case the femoral head is covered by a metal cap in the shape of a mushroom, which reproduces the round shape of the original head. The alloy used for the cap is Co-Cr; the same alloy is used for the acetabular component on which the head cap slides (Fig. 2.15). As said before, this technique is preferred to THR because it permits to preserve almost the whole bone, intervening only on the very surface of the femoral head. Even the general geometrical aspect is very close to the one of a real bone, and the larger femoral head (with respect to THR) is beneficial to prevent dislocation and the bone preservation gives the possibility to proceed, in the future, with THR [4].

On the other hand, drawbacks for these kinds of surgeries are fractures on the femoral neck, prosthesis loosening, and debris formation due to metal wear [5].



Fig. 2.15) Bilateral hip resurfacing prostheses

Typically, a high risk medical device (Class 3°) must obtain premarket endorsement from FDA before it is released on the USA market. As of May, 2011, a high risk metal-on-metal acetabular component requires only 510(k) clearance (without compulsory clinical testing) before market release because it is a preamendment Class 3° device.

Chapter 3

An introduction to ISO norms and critique

3.1) Introduction

ISO (International Organization for Standardization) is an independent, non-governmental international organization of 162 national standards bodies and 3368 technical bodies. Its story began in 1946 in London, at the Institute of Civil Engineers (Fig. 3.1), where delegates from 25 countries gathered and decided to found an international organization to “facilitate the international coordination and unification of industrial standards”. The organization started operating at the beginning of 1947, and the central headquarter is in Geneva, Switzerland¹.



Fig. 3.1) Founders of ISO, London 1946

The conception and making of ISO norms is carried out through highly specialized world experts of every discipline that together constitute committees. Many international organizations take part in the work too. When drafted, International Standards are sent to the member bodies for voting. To be published as an International Standard, the draft has to receive a positive evaluation by 75% of the member bodies minimum.

¹ Visit: <http://www.iso.org/iso/home/about.htm>

3.2) Motion law and loading law

The ISO 14242, because of the necessity of making the human gait easily reproducible, contains motion law and loading law which are standardised, and that were inspired by previous studies on the human gait, but don't represent any gait in particular.

3.2) Motion law and loading law

For what concerns the motion law, the ISO drew inspiration from previous studies like the one by Johnson and Smidt (1969) (Fig. 3.2 (a)), the HUT-3 simulator (from Saikko, 1996) (Fig. 3.2 (b)) and the BRM simulator (Fig. 3.2 (c)) [6]. In the first case (a), the motion law appears complex, and was obtained by averaging data measured directly on patients. In the second case (b), the motion law was made more regular as it could be easily reproduced by a mechanical machine (the HUT-3 simulator), that is able to imitate all the three degrees of freedom present in the human body; the three wave forms appear smoother than the ones measured in vivo, despite this, the motion appears realistic and relatively similar to the measured one. In the third and last case (c), the testing machine is much simpler than the one mentioned before, and has only two degrees of freedom, with exactly the same motion law, just with the phase shifted by an angle of $\pi/2$. This last machine is very simple but can not reproduce a gait faithful to the human one; despite this, it inspired the criteria adopted in ISO 14242-3.

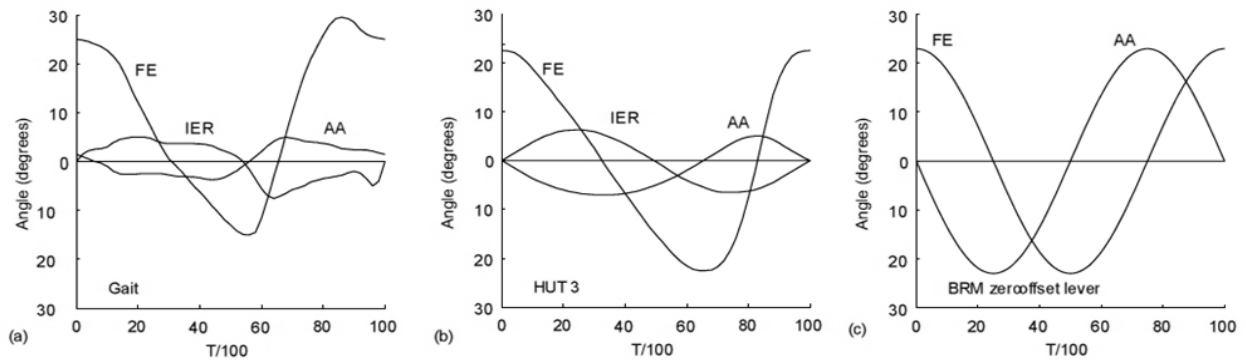


Fig. 3.2) Motion waveforms exploited in the computation of slide tracks: (a) walking (from Johnston and Smidt, 1969), (b) HUT-3 simulator (from Saikko, 1996) and (c) BRM simulator. Positive angle represents flexion, abduction and internal rotation, and negative angle represents extension, adduction and external rotation.

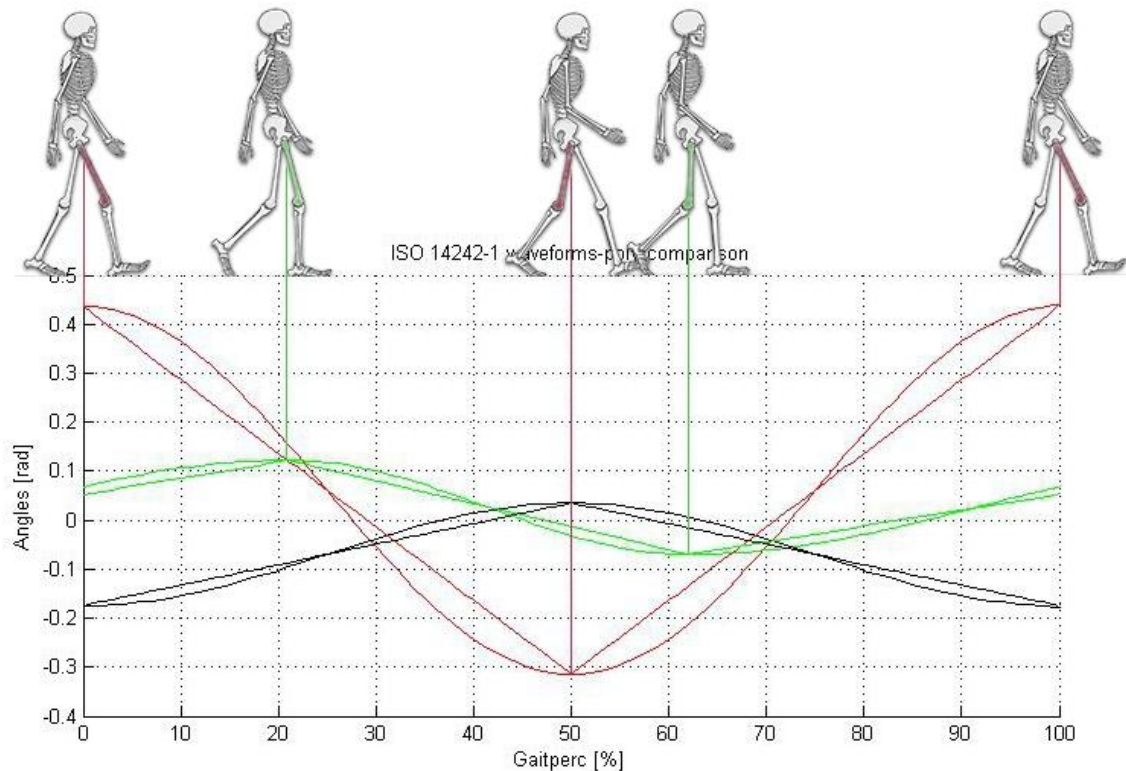


Fig. 3.3) ISO 14242-1 motion law plotted with MatLab. This ISO is the one which is closest to the “real human gait”. On the upper part of the plot a skeleton shows the principal phases encountered throughout the motion law. The motion law refers to the right leg.

3.4) The loading law

The loading law in ISO 14242 was devised by taking into consideration many works of scientists from the second half of the 20th century, like Paul (Fig. 3.4), or Seireg and Arvikar (Fig. 3.5) [6]. But the work which most influenced the scientific committee was the one conducted by the team of Bergmann in nineties (i.e. Hip 98, Bergman study, 1998). In fact in this work Bergmann didn't use speculation or mathematical modelling to determine the forces that come into play; he was able instead, for the first time, to take measurements in vivo and live on patients on which special prostheses were implanted [7].

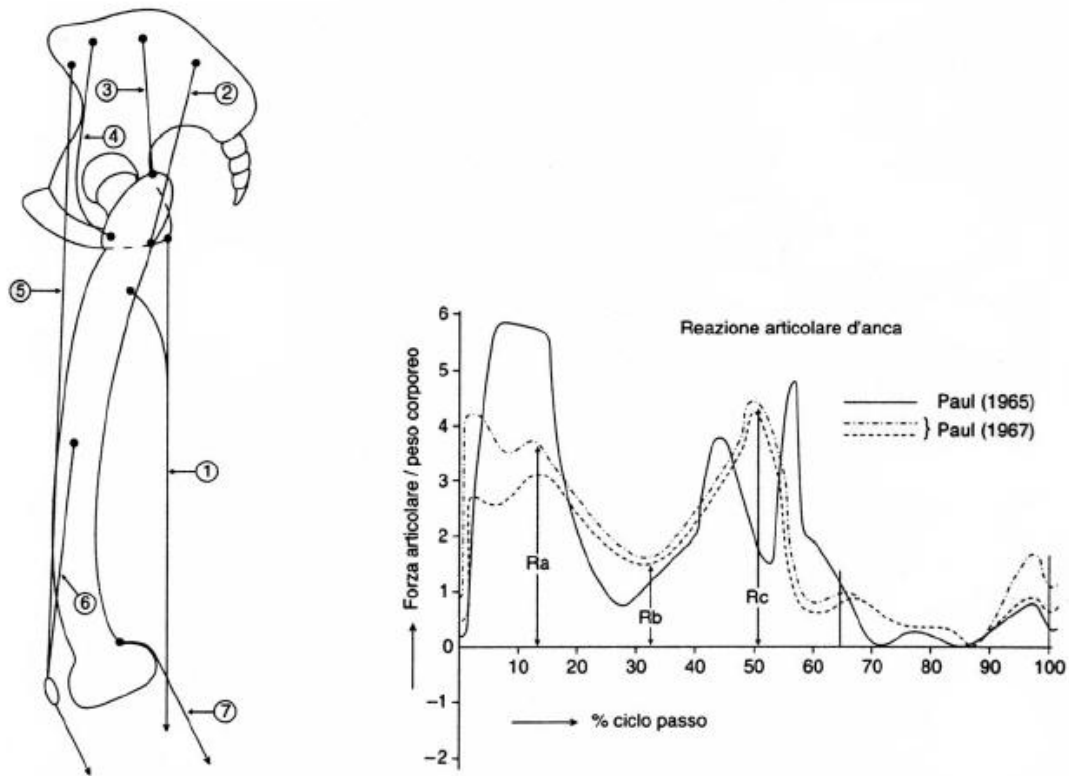


Fig. 3.4) Hip reaction forces (Paul, 1965 and 1967)

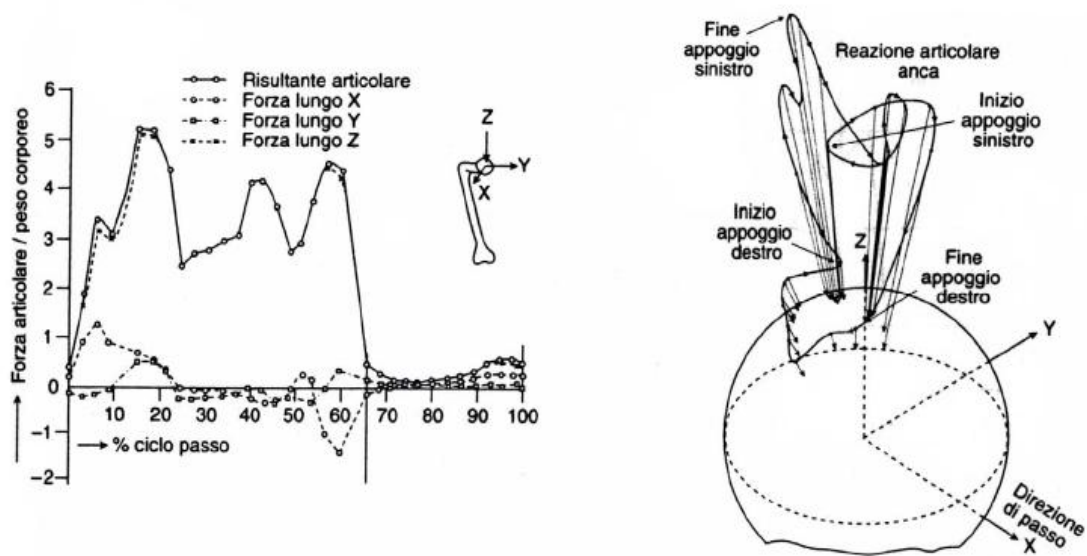


Fig. 3.5) Hip reaction forces (Seireg and Arvikar)

The special prostheses in question were instrumented implants that had three semiconductor strain gauges mounted on the inside of a hollow neck (Fig. 3.6). The neck was sealed by a laser-welded plate bearing an antenna for data transmission. The force data were digitalized by a sampling frequency of 200 Hz and then conveyed via radio to an external receiver; the stated error per sensor was $\pm 1\%$. These live measurements of the musculo-skeletal forces were taken simultaneously to other data acquired with a system of infrared cameras and markers that allowed a 3D reconstruction

of the body movements (Fig. 3.7). Thanks to this technology accurate measurements of forces and limbs' positions could be carried out.

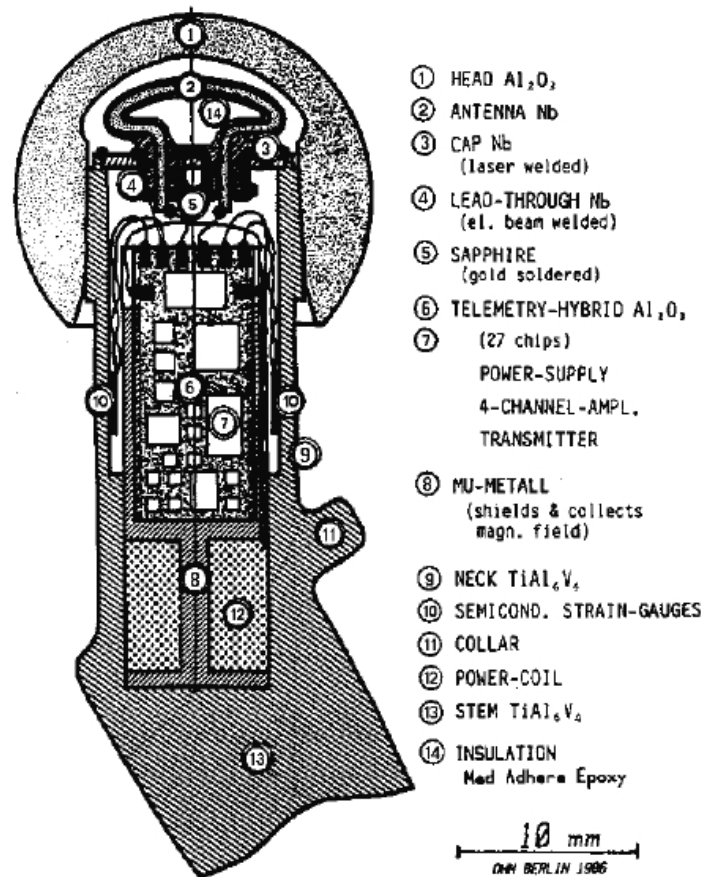


Fig. 3.6) Bergmann study “Hip98”, 2001. Instrumented implant

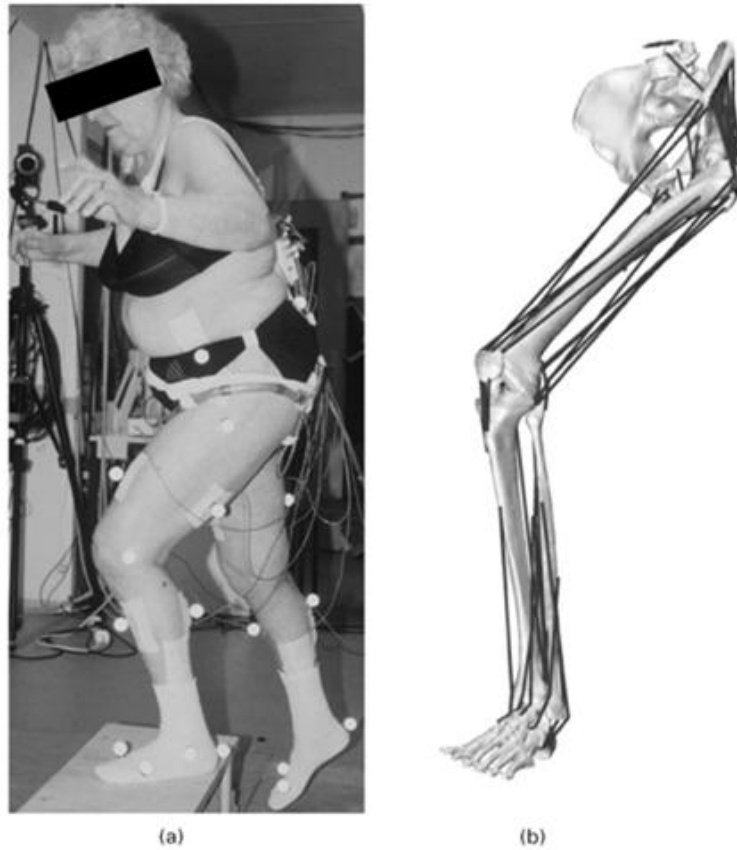


Fig. 3.7) Bergmann study. Patient climbing stairs (a). The markers attached to the skin and a set of six infrared cameras (one visible in the background) were used to obtain the kinematic data. The coil visible around the patient's left hip was used to power the electronics for measurement of the in vivo hip contact forces. (b) The musculo-skeletal model of this patient when going upstairs.

To measure and evaluate the loads, the hip contact force vector F can be decomposed into three linearly independent vectors: F_x , F_y and F_z (Fig. 3.8). The z axis is parallel to the hypothetical femoral main axis, the y axis the medial axis and the x axis is parallel to the dorsal contour of the femoral condyles in the transverse plane. The negative direction points towards the femoral head. The contact force provokes a moment, M_t , around the shaft and neck axes intersection point, called NS. A positive moment induces a rotation on the femoral head inwards. This, is equal to the moment in the negative z' direction, where the z' axis is the prosthesis stem axis. The moment M , can be decomposed into M_x , M_y , M_z (Fig. 3.8).

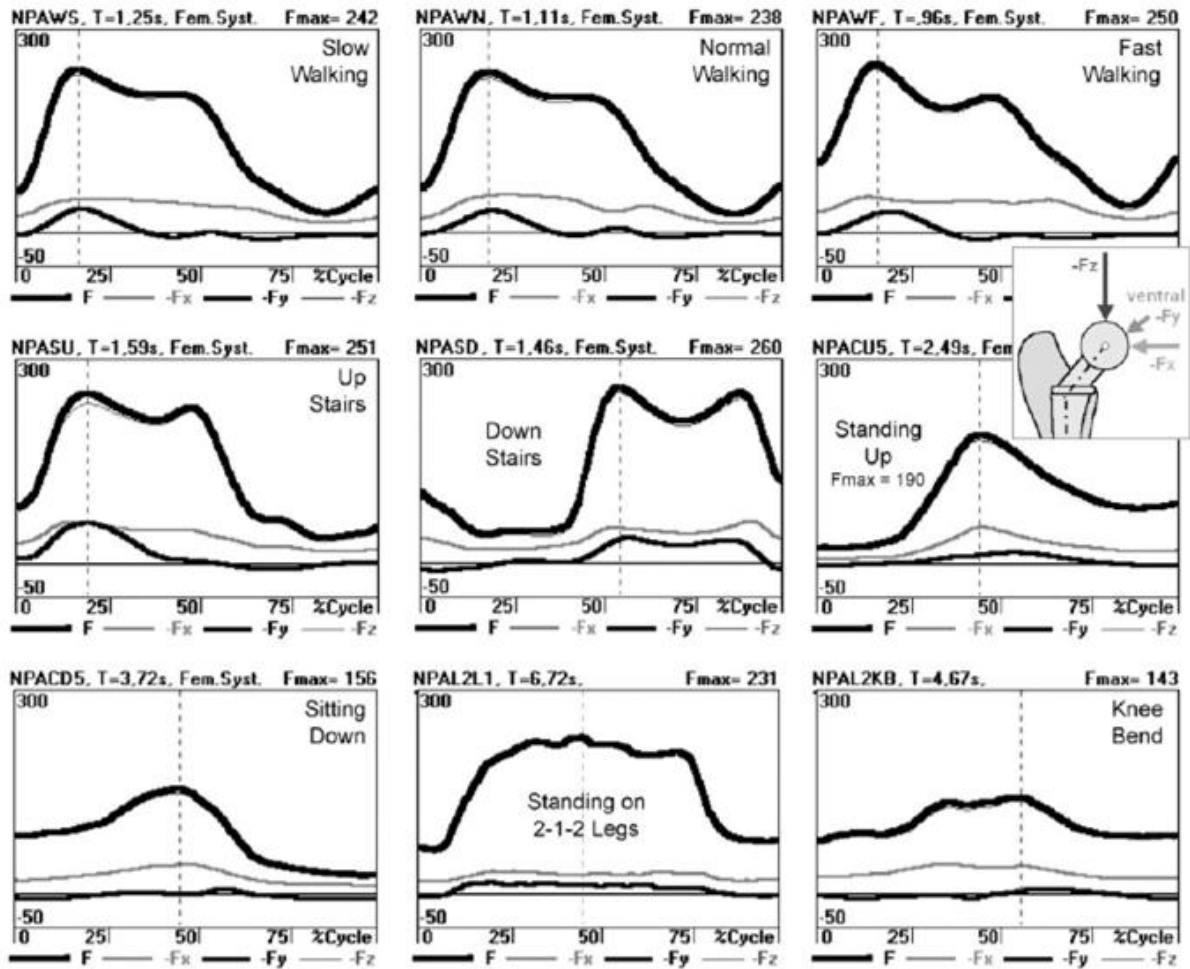


Fig. 3.9) Bergmann study. Contact force F of averaged patient during nine activities. Contact force F and its components $-F_x$, $-F_y$, $-F_z$, F and $-F_z$, are nearly identical. The scale range is -50 to +300% body weight. Cycle duration and peak force $F_p=F_{max}$ are indicated in diagrams.

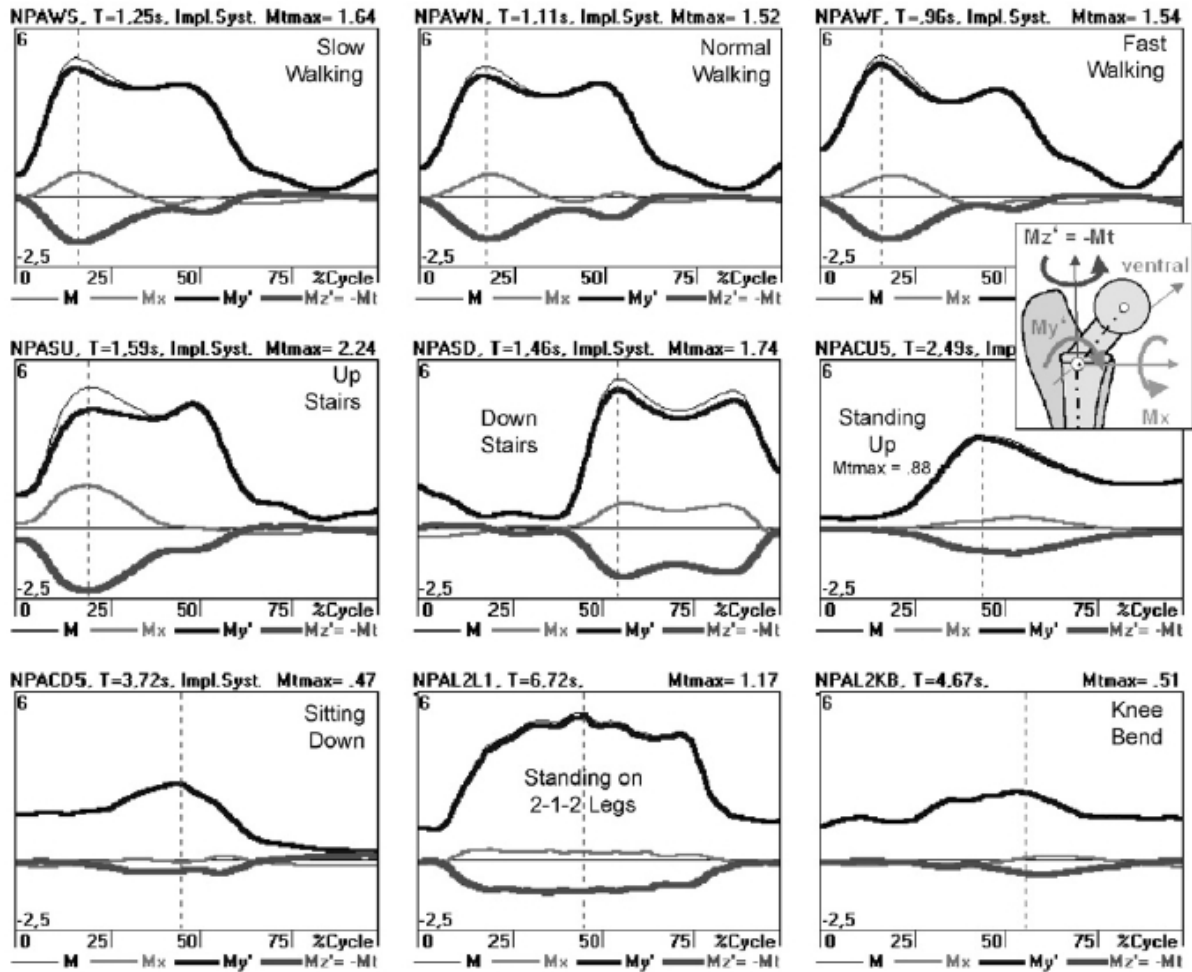


Fig. 3.10) Bergmann study. Moment M of averaged patient during nine activities. Moment M and its components $-M_x$, $-M_y'$, $-M_z'=M_t$. M and $-M_z'$. M and M_z' are nearly identical. The scale range is -2.5 to +6% body weight-meters. Negative M_z causes inward rotation around the femoral stem. Cycle duration T and peak torsional moment $M_{ip}=M_{imax}=-M_{zp}$ are indicated in diagrams.

As previously stated, the loading law in ISO is clearly inspired by the one obtained by Bergmann (Fig. 3.11); an important, but not dramatically influential difference, has to be reported: the force on the z axis in the study by Bergmann is referred to the moving frame of reference and is parallel to the axis of the femur, while the force present in the ISO norm is always considered vertical, and so, parallel to the z axis of the fixed frame of reference (parallel to the gravity force vector). The positive side about this is that the maximum angle performed by the femur during the gait is at the moment of maximum flexion, and it is about 30 degrees; if the other two small angles are neglected, and the force is projected on the z axis of the fixed frame of reference, the force becomes about the 87% of the force in the study by Bergmann ($\cos(30^\circ) \sim 0.87$), so the general aspect of the force plot remains the same.

The force plot in the Bergman study shows two peaks during the phase of stance, and a clear decrease in the force during the phase of swing which corresponds to the plateau in the ISO plot (Fig. 3.11).

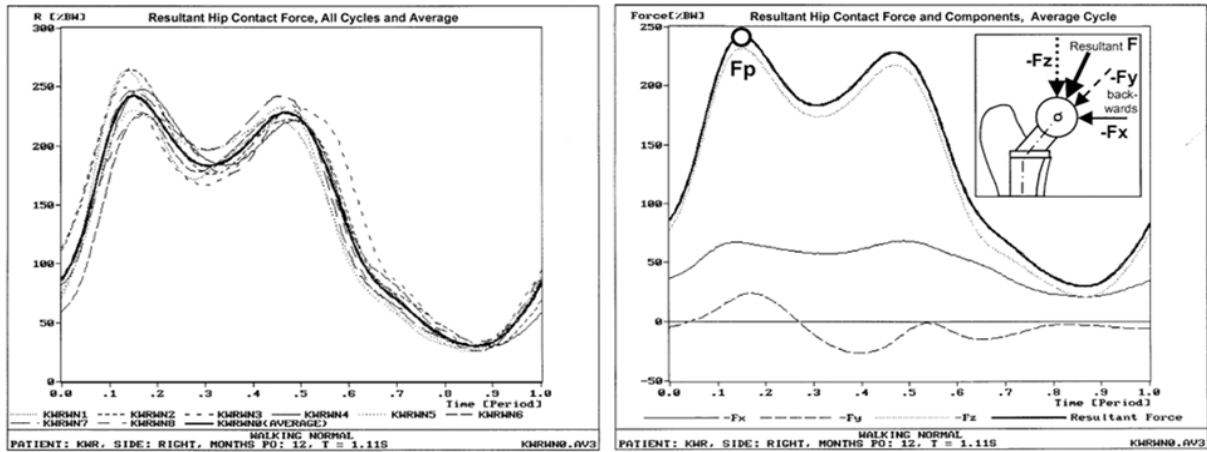


Fig. 3.11) Bergmann study. Contact force F of single trials and individual patient during normal walking. (Left) Hip contact force F in % BW from eight trials of patient KWR (thin lines) and the individual average of this patient (thick line). (Right) Individual average of F from left diagram and its components F_x , $-F_y$, $-F_z$. The highest value is the peak force F_p .

Chapter 4

ISO 14242: Implants for surgery – Wear of total hip-joint prostheses. Description and comments on the three parts that compose the norm

Introduction

This chapter, is composed of three subchapters (Part 1, Part 2, Part 3), which contain information coming from ISO (14242-1, 14242-2, 14242-3 respectively) accompanied by personal comments. To make reference to ISO easier and faster, the numbering of subchapters, sections and figures is exactly the same present in the ISO norms in question.

Part 1 (ISO 14242-1) [9]:

Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

1) Scope

In this ISO norm, relative angular movements between articulating components are specified; furthermore applied force law is stated, together with speed and duration of testing, sample orientation and test environment, all these specifications are to be used for the wear testing of total hip joint prostheses.

2) Normative references

The following contents refer to the first edition of ISO 14242-1 published in 2002 in Geneva.

3) Terms and definitions

Adduction/abduction, flexion/extension and inward/outward rotation are angular movements shown in Fig. 1. The polar axis (Fig. 1, n5) is the axis of the acetabular component which interests the centre of the spherical articulating surface and is perpendicular to the plane of the flange, or, if no flange is present, perpendicular to the plane of the entry diameter.

4) Principle

The femoral and acetabular components of a test specimen are put in position in their normal configuration; the test rig both exerts a specified time-varying force on the components, and

commands the relative angular displacements. In case polymers are object of investigation, a control specimen should be predisposed, and subjected to the same time-varying loading law to determine the creep of the test specimen and the amount of mass change due to fluid absorption. During the test a controlled environment is created for simulating physiological conditions.

5) Reagents and materials

The fluid test medium is calf serum ($25\% \pm 2\%$) diluted with deionized water. The fluid test should be filtered through a filter with pore size $2\ \mu\text{m}$, and should have a protein mass concentration of not less than $17\ \text{g/l}$. Microbial contamination should be prevented by keeping it stored frozen until it is used and an anti-microbial reagent can be added.

Monitoring of the fluid pH may be predisposed and, in case, the recorded values should be transcribed in the final report.

The test specimen is composed of femoral head and acetabular components. The acetabular component shall have the articulating surface fixed by its normal immediate backing (ie. bone cement or a simulacrum of the inner surface of the backing) unless this is not feasible due to the very physical and geometrical features of the prosthesis. In case the component is fixed to the backing by a rim/snap-fit system, the machined replica (simulacrum) shall provide the same fixation conditions.

If the foregoing conditions are not feasible, the support system of the acetabular component should represent normal design features and conditions of use but should allow removal of the component for measurement of wear without damaging or destruction.

The same considerations are to be applied to the control specimen.

6) Apparatus

6.1) Testing machine

The testing machine needs to be capable of replicating the angular displacements and loads specified hereinafter (Fig. 2). The nominal cycle frequency is $1\ \text{Hz} \pm 0.1\ \text{Hz}$.

6.2) Means of mounting and enclosing the test specimen

The specimens have to be mounted on materials resistant to corrosion; the mechanical fixation system's behaviour has to be as close as possible to the anatomical one. A physical barrier to prevent third-body contamination from the test machine and the atmosphere shall be devised. A container or a sack can be fit for purpose.

6.3) Means of aligning and positioning the femoral component of the prosthesis

The femoral component should be put in the inferior position and a proper fastening system may be predisposed to align and position it, and setting its axis at the centre of the testing machine's rotation axes. Furthermore, the same position of the sample has to be reached even after removal for measurements and cleaning when required.

6.4) Means of aligning and positioning the acetabular component of the prosthesis

The acetabular component should be put in the superior position and a proper fastening system may be predisposed to align and position it, setting its axis at the centre of the testing machine's rotation axes. Furthermore, the same position of the sample has to be reached even after removal for measurements and cleaning when required.

6.5) Motion control system

The actuators have to be able to reproduce the stated range of motion with an accuracy of $\pm 3^\circ$ at the maxima and minima and $\pm 1\%$ of the cycle time for phasing.

6.6) Force control system

The force has the direction shown in Fig. 1 and varies with the law shown in Fig. 3. The tolerance accuracy required for the magnitude of the maxima and minima of this force cycle is 3% of the maximum force value, and $\pm 1\%$ of the cycle time for phasing.

6.7) Lubrication system

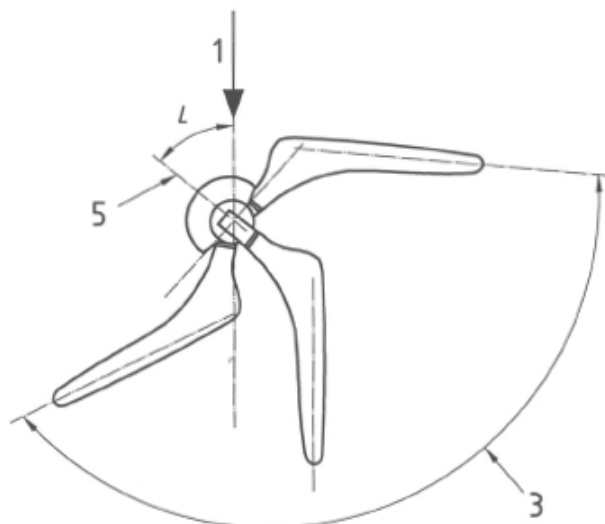
The joint has to be constantly immersed in the lubricating fluid to guarantee lubrication at the sliding surfaces. The use of sealed enclosures is favoured, this to maintain the fluid elements concentration as constant as possible, allowing a better data evaluation afterwards.

6.8) Temperature control system

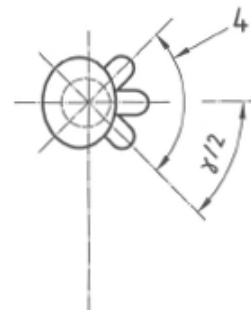
The fluid container may be sensorized for maintaining the temperature at $37 \pm 2^\circ\text{C}$; the characteristic body temperature. The sensor must be positioned in a place where the temperature measured is representative of the bulk fluid temperature.

6.9) Control station/stations

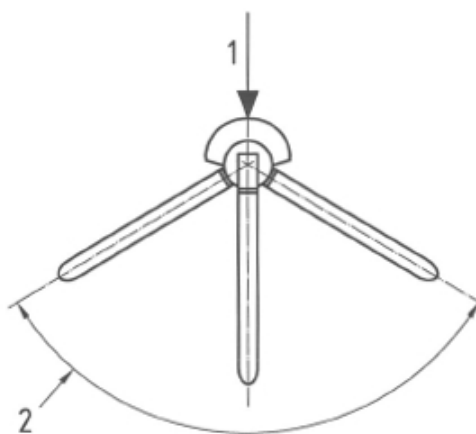
The control stations have to apply the loading law stated in the ISO with all its specifications.



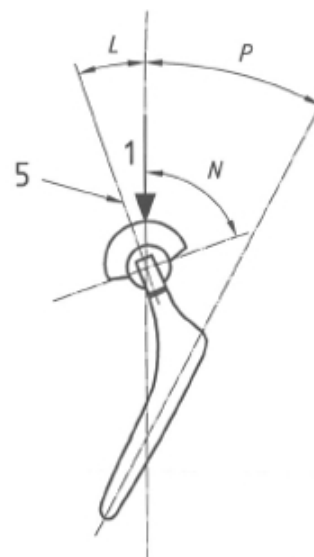
a) Abduction/adduction



c) Inward/outward rotation



b) Flexion/extension



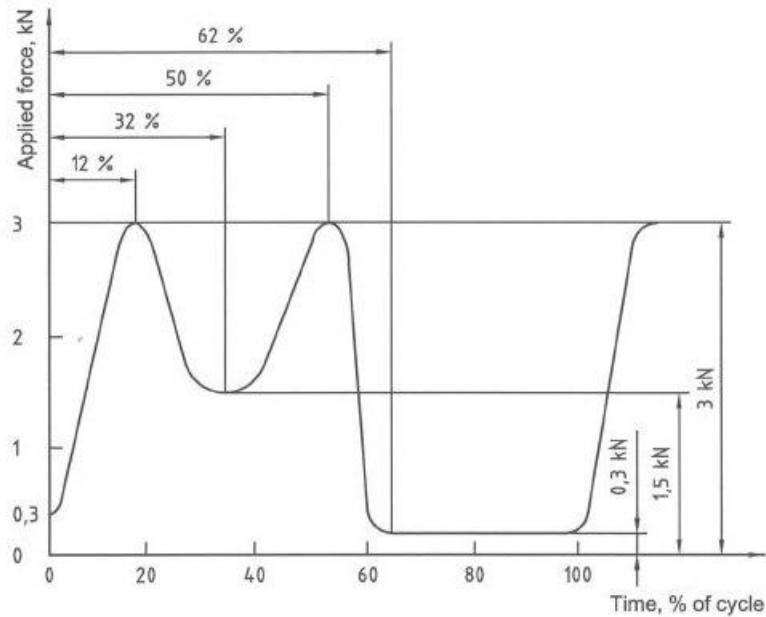
d) Orientation of acetabular component and femoral component in mid-position relative to the load line

Key

- | | |
|--------------------------------------|---|
| 1 Load axis | L Inclination of the polar axis of the acetabular component to the load line |
| 2 Flexion/extension angle | N Inclination of face of acetabular component equal to $60^\circ \pm 3^\circ$ or as specified by the manufacturer |
| 3 Abduction/adduction angle | P Inclination of stem axis to load line in mid-position of abduction/adduction range |
| 4 Inward/outward rotation angle | |
| 5 Polar axis of acetabular component | |

NOTE Angles N , L and P are specified in 7.3 and 7.4.

Figure 1 — Angular movement of femoral component and orientation of components relative to the load line



Time, % of cycle ($\pm 3\%$)	0	12	32	50	62	100
Applied force, kN ($\pm 90\text{ N}$)	0,3	3,0	1,5	3,0	0,3	0,3

Figure 3 — Variation with time of the force to be applied along the loading axis

7) Procedure

7.1) All pre-test measurements have to be carried out to determine, as precisely as possible, the wear amount and/or creep; subsequently each test station has to be calibrated using a load cell.

7.2) After the first measurement session, specimens may be cleaned as specified in ISO 14242-2.

7.3) Mount the femoral component on the machine in the inferior position, with the stem in the adduction/abduction position of $P=10 \pm 3^\circ$ as represented in Fig. 1 and in the inward/outward rotation position $\gamma/2$ as represented in the Fig. 1.

IMPORTANT: depending on the aim and characteristics of the measurements, the stem can be substituted by another support with an identical cone, and assures the same positioning of the head, this to leave the test conditions unaltered².

7.4) The acetabular cup can be mounted in different ways, depending on the aim of the test. A possible choice can be setting the polar axis (the main axis of symmetry) vertical or inclined at an angle L as shown in the Fig. 1; $L = 30 \pm 3^\circ$. In case the manufacturer specifies a particular tilting angle (or angle range), this angle can also be used for testing. If the angle specified is N , then $L = (75-N) \pm 3^\circ$.

² This possibility was taken into account for the prototypes present in chapter 6

7.5) The foregoing procedure may be applied to the control specimen too. For implants with a specific design and same materials, shape and dimensions, control data from previous test may be used.

7.6) Submerge the test specimen with the fluid test medium, so as the surfaces in contact in the joint are completely soaked in liquid. Keep the temperature of the fluid at 37 ± 2 °C.

7.7) Start the testing machine and verify that the loads and displacements are properly applied to the test specimen, and that the same loads are applied to the control specimen. The curves obtained between the maxima and the minima shall be smooth, with no overshoots. Record the displacement and load waveforms at the start-up of the test machine, until the test is over.

7.8) The cycle frequency is 1 ± 0.1 Hz.

7.9) Daily replace the fluid loss due to evaporation by adding de-ionized water. Replace the fluid test medium completely at least every 5×10^5 cycles.

7.10) Interrupt the test measurements at, at least, 5×10^5 or 1×10^6 cycles and at least every 1×10^6 cycles, thereafter until the test is terminated.

7.11) Remove the test specimen and control it; take wear measurements.

7.12) After wear measurements, clean the test specimen and control it as prescribed in ISO 14242-2 and reposition it on the testing machine

7.13) Restart the testing machine with the remounted specimen, repeating the foregoing procedure until one of the following occurs:

- Completion of 5×10^6 cycles (if the party commissioning the test specifies differently, the test can be protracted beyond this limit);
- Failure or delamination of the articulating surfaces;
- Failure of the testing machine to maintain the forces and/or the displacements within the given tolerances.

8) Test report

The report shall include the following information:

- 1) Reference to ISO 14242;
- 2) All possible details about the test specimens, as stated by the specimens supplier, including size, material, type, sterilization and manufacturer;
- 3) A description of the testing machine, including number of stations, types of systems for generating motion and forces, ROMs and forces, type of systems used for measuring motion and forces, arrangement for mounting specimen, arrangement for lubrication of articulating surfaces, arrangement for temperature control, and arrangement for the excursion of contaminant particles;
- 4) Whether control specimens were used, and, if not, the reference to the tests from which the control data were taken;
- 5) A statement of results, including:

1. Total number of cycles applied;
 2. Reason for terminating the test if less than 5×10^6 cycles were applied;
 3. Description of all the surfaces of both components at which relative movement has occurred;
 4. Description of the condition of the interfaces between subcomponents, if the components are of modular construction;
 5. pH values, if routine monitoring was undertaken.
- 6) Details of the method of measurement of wear and the results obtained (ISO 14242), namely:
- a) Method of wear measurement (i.e. gravimetric or dimensional);
 - b) Change in mass for each measurement using the gravimetric method, or change in volume for each measurement using the dimensional method;
 - c) Wear rate (gravimetric or dimensional).

9) Disposal of test specimen

No part of any specimen tested shall be used for clinical purposes.

Part 2 (ISO 14242-2) [10]:

Methods of measurement

1) Scope

In ISO 14242-2 methods for wear assessment are specified. In specific the wear of the acetabular component is estimated by two methods: gravimetric and change in dimensional form.

2) Normative reference

The following contents refer to the first edition of ISO 14242-2 published in 2000 in Geneva.

3) Term and definition

The following term and definition applies:

3.1) Wear: material loss from components of the prosthetic joint due to combined movement and loading.

4) Gravimetric method

4.1) Principle

The test specimen is repeatedly soaked and removed from the lubricant, cleaned, dried and weighted until the amount of fluid sorption is established. The test specimen undergoes then wear testing, and the wear rate is estimated by mass loss. The control specimen undergoes the same

procedure, but is only loaded and the articulating surface does not move; the control specimen constitutes reference to evaluate the changes that occur to the main sample.

4.2) Reagents and materials

4.2.1) Fluid test medium (see ISO 14242-1).

4.2.2) Control specimen (see ISO 14242-1).

4.2.3) Propan-2-ol.

4.3) Apparatus

4.3.1) Scales, with an accuracy of ± 0.1 mg, of sufficient capacity for the mass of the test specimen.

4.3.2) Ultrasonic cleaner.

4.3.3) Vacuum drying system, capable of achieving a vacuum of at least 13.33 Pa.

4.3.4) Filtered inert-gas jet, e.g. nitrogen.

4.4) Preparation of test specimen for gravimetric measurements

4.4.1) Soak both test specimen and control specimen in the fluid test medium (4.2.1) for $48 \text{ h} \pm 4 \text{ h}$.

4.4.2) Remove the test specimen and control specimen from the fluid test medium (4.2.1) and clean in the ultrasonic cleaner (4.3.2).

A typical cleaning procedure in the ultrasonic cleaner is as follows:

- a) Vibrate for 10 min in deionized water;
- b) Rinse in deionized water;
- c) Vibrate for 10 min in a mixture of ultrasonic cleaning detergent in deionized water at the concentration recommended by the detergent manufacturer;
- d) Rinse in deionized water;
- e) Vibrate for 10 min in deionized water;
- f) Rinse in deionized water;
- g) Vibrate for 3 min in deionized water;
- h) Rinse in deionized water;
- i) Dry in vacuum drying chamber (4.3.3).

Care should be taken to avoid abrasion in the ultrasonic cleaner, this could lead to change in mass.

4.4.3) Dry the test specimen and control specimen with a jet of filtered inert gas (4.3.4).

4.4.4) Soak the test specimen and control specimen in propan-2-ol (4.2.3) for $5 \text{ min} \pm 15 \text{ s}$.

4.4.5) Dry the test specimen and control specimen with a jet of filtered inert gas (4.3.4), then dry further in a vacuum of better than $13,3 \text{ Pa} \pm 0.13 \text{ Pa}$ for at least 30 min.

4.4.6) Weigh the test specimen and control specimen on the scales twice in rotation with 90 min of removal from vacuum. If the two readings per specimen are not identical within 100 µg, continue taking readings in rotation until at least two readings per specimen are identical within 100 µg. Store the test specimen and control specimen in a sealed dust-free container between weighings.

4.4.7) Repeat 4.4.2 to 4.4.6 at intervals until the incremental mass change of the specimen over 24 h is less than 10% of the previous cumulative mass change.

4.4.8) Record the average increase in mass S of the control specimen.

4.5) Procedure for gravimetric measurement

4.5.1) Mount the test pieces in the testing machine and conduct the wear test in accordance with ISO 14242-1.

4.5.2) Record the mass of the specimens.

4.5.3) On each occasion when the test specimen and control specimen are removed from the wear-testing machine, repeat the procedures 4.4.2 to 4.4.8, 4.5.1 and 4.5.2.

4.5.4) Calculate the gravimetric wear as follows:

$$W_n = W_{an} + S_n$$

Where

W_n is the net mass loss after n cycles of loading;

W_{an} is the average uncorrected mass loss;

S_n is the average increase in mass of the control specimen over the same period.

4.5.5) Calculate the average wear rate a_G using the equation for the last squares linear fit relationship between W_n and the number of loading cycles n :

$$W_n = a_G \cdot n + b$$

where W_n is the net loss in mass after n cycles and b is a constant.

The zero time point shall not be used in this calculation.

5) Dimensional change method

5.1) Principle

A coordinate measuring machine is used to map the articulating surface of a total hip prosthesis relative to a reference position, direction and plane prior to the start of the wear test and at suitable intervals during the test. From these data the volumetric change between measurements is determined. Loaded non-articulating controls are intended to allow the effects of plastic flow, mainly occurring in the first 5×10^5 cycles, to be separated from material loss.

5.2) Apparatus

5.2.1) Three-dimensional coordinate measuring machine, with maximum axial-position error of measurement D , in micrometers, of:

$$D=4+4l\cdot 10^{-6}$$

where l is the numerical value of the dimension, expressed in meters.

5.2.2) Ultrasonic cleaner

5.3) Procedure for dimensional change measurement

5.3.1) Select point of reference, an origin and a plane on the test specimen. Maintain this reference frame throughout the procedure.

5.3.2) Clean the specimens.

5.3.3) To ensure dimensional stability, retain the test specimen at the measurement temperature ± 2 °C (measured at the normal points of the metrology laboratory) for at least 48 h.

5.3.4) At the beginning of a series of tests, check that relocation of the test specimen does not affect the measured volume by more than 0.05%.

5.3.5) Start the measurement machine and produce a full three-dimensional contour mesh of the articulating surface of the test specimen. Ensure the mesh spacing is no greater than 1 mm in the horizontal plane or along any arc.

5.3.6) Calculate the volume V_n of the acetabular cavity, where n is the number of wear cycles which have been applied.

5.3.7) Express the wear as the volume change after n loading cycles, ΔV_n , as follows:

$$\Delta V_n = V_n - V_o$$

where V_o is the original volume.

5.3.8) Insert the test specimen and any control specimen in the testing machine and conduct the tests in accordance with ISO 14242-1.

5.3.9) On each occasion when the test specimen and the control specimen are removed from the testing machine, repeat procedures 5.3.2 to 5.3.7.

5.3.10) Calculate the wear rate, a_v , using the equation for the least squares linear relationship between ΔV_n and n as:

$$\Delta V_n = a_v \cdot n + b$$

where b is a constant, using a least squares fit.

When controls are provided, the slope of the line, representing the rate of creep, should be calculated including the zero time point. The zero time point shall not be used in the slope calculation for the wear rate a_v .

6) Test report

The test report shall include the following information:

- a) A reference to this part of ISO 14242;
- b) The identity of the test specimens, as stated by the party submitting the specimen for test;
- c) The method of wear measurement (i.e. gravimetric or dimensional change);
- d) The value W_n for each measurement using the gravimetric method, or the value ΔV_n for each measurement using the dimensional change method;
- e) The wear rate, a_G or a_V (gravimetric or dimensional change method);
- f) A reference to the wear test method used from ISO 14242-1.

Part 3 (ISO 14242-3) [11]:

Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test

Introduction

The orbital bearing hip wear simulator (OBM) is commonly used and has produced important and consistent results for the assessment of Total Hip Arthroplasty wear properties. The outcomes from testing have evidenced a good correlation with clinical experience. Since this kind of testing machine is commonly used, it's of fundamental importance that all the testing parameters are standardized to make the results more uniform and comparable between laboratories.

The method here described differs from that in ISO 14242-1 substantially for the overall degrees of freedom that can be simulated on the hip joint prosthesis (basically flexion/extension and adduction/abduction). For this reason the simulation on a OBM machine is simpler and less anatomic than the one described in ISO 14242-1, OBM have been used for more than 30 years for hip prosthesis testing. Despite not reproducing accurately the human gait motion, this machine has shown an excellent correlation between the type and amount of wear produced and the *in vivo* one; this for a large variety of materials, including polyethylene, metals and ceramics. Thanks to the capabilities of this machine, tests have permitted highly accurate projections of the future clinical performance of new materials and designs of prostheses. This even applies to the new crosslinked polyethylenes. Many reports in recent times, with more than five years of follow up, have confirmed the data obtained by testing on OBM simulators.

1) Scope

In this third part of ISO 14242 the following provisions are specified: angular movement between articulating components, the loading law, speed and duration of testing, sample position and

configuration, and test environment to be used for the orbital bearing type wear testing of total hip joint prostheses.

2) Normative references

The following contents refer to the first edition of ISO 14242-3 published in 2009 in Geneva.

3) Terms and definitions

In this document the following terms and definition apply:

3.1) Abduction/adduction

Motion around an axis arranged in an anterior-posterior direction, passing through the centre of the hip joint (Fig. 1).

3.2) Flexion/extension

Motion around a transverse axis, passing through the centre of the hip joint (Fig. 1).

3.3) Internal/external rotation

Component of Internal/external motion.

IMPORTANT NOTE: The OBM was not conceived and designed to induce an inward/outward rotation to the hip. Despite this, Saikko et al. demonstrated that the anti-rotation lever that is part of the OBM machine, induces a component of internal-external rotation to the motion path, turning the OBM into a 3-axis machine. The mechanism of the OBM simulator generates a crossing-path component to the relative motion of the joint surfaces. The overall motion, and in specific the one that occurs during the phases of highest loads, provokes a stress that is comparable to the one that occurs *in vivo* [12].

3.4) Polar axis

The polar axis (Fig. 1, n5) is the axis of the acetabular component which intersects the centre of the spherical articulating surface and is perpendicular to the plane of the flange, or, if no flange is present, perpendicular to the plane of the entry diameter.

4) Principle

The sample orientation, force pattern and control specimen are the same of the ISO 14242 – 1. Only the motion pattern is different, since in this case the machine provides two degrees of freedom, instead of three.

5) Reagents and test specimens

Same as ISO 14242-1.

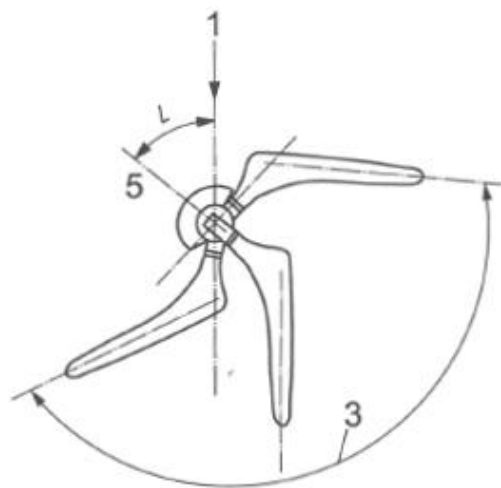
6) Apparatus

6.1) Testing machine

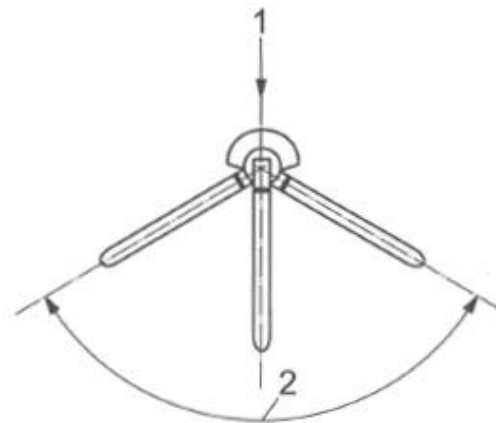
The testing machine needs to be capable of replicating the angular displacements, loads and frequency that are the same found in ISO 14242 – 1, but with a slightly different motion pattern, since the machine is a biaxial one (Fig. 2).

6.7) Lubrication system

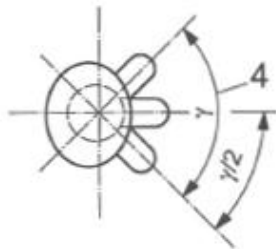
The same prescriptions present in the ISO 14242 -1, but specifying a minimum available lubricant volume of 200 ml.



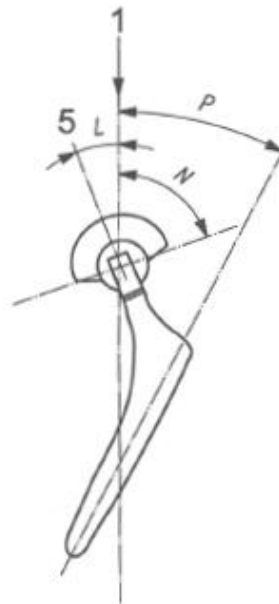
a) Abduction/adduction



b) Flexion/extension



c) Inward/outward rotation



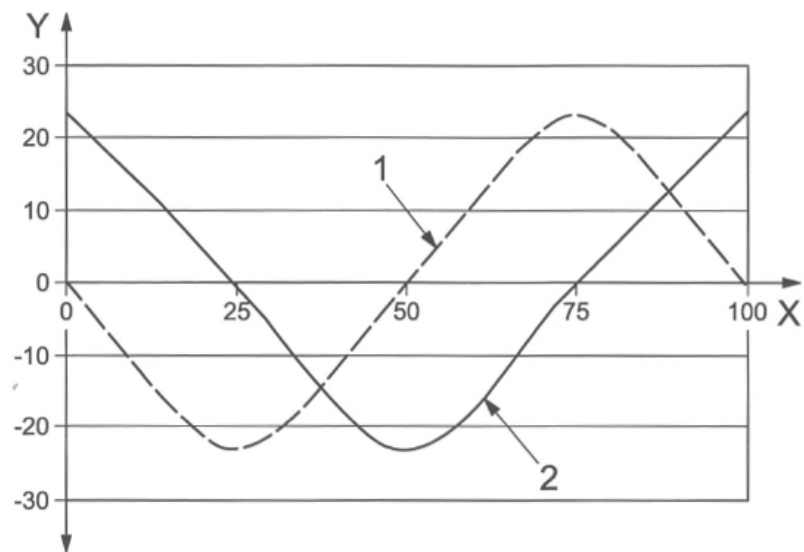
d) Orientation of acetabular component and femoral component in mid position relative to the load line

Key

- | | |
|---------------------------------|---|
| 1 load axis | 5 polar axis of acetabular component |
| 2 flexion/extension angle | L inclination of the polar axis of the acetabular component to the load line |
| 3 abduction/adduction angle | N inclination of face of acetabular component equal to $60^\circ \pm 3^\circ$ or as specified by the manufacturer |
| 4 inward/outward rotation angle | P inclination of stem axis to load line in mid-position of abduction/adduction range |

NOTE Angles N , L and P are defined in 7.4 and 7.5.

Figure 1 — Angular movement of femoral component and orientation of components relative to the load line

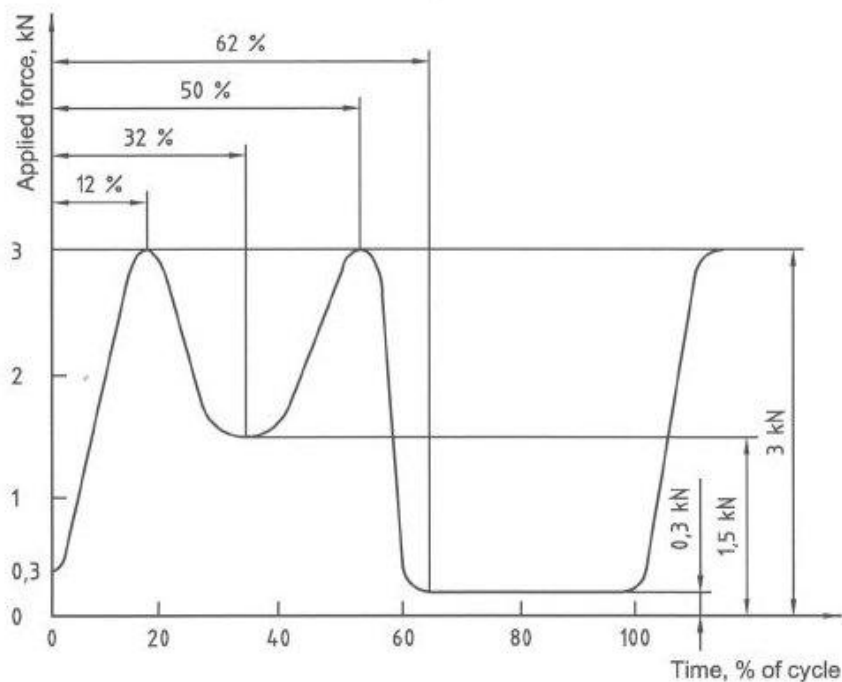


Key

- 1 abduction/adduction
- 2 extension/flexion
- X time in percentage cycle time
- Y angle in degrees

Time % of cycle $\pm 1\%$	0	25	50	75	100
Angle of flexion (+) extension (-) $\pm 3^\circ$	23	0	-23	0	23
Angle of abduction (+) adduction (-) $\pm 3^\circ$	0	-23	0	23	0

Figure 2 — Variation with time of angular movement to be applied to the femoral test specimen



Time, % of cycle ($\pm 3\%$)	0	12	32	50	62	100
Applied force, kN (± 90 N)	0,3	3,0	1,5	3,0	0,3	0,3

Figure 3 — Variation with time of the force to be applied along the loading axis

7) Procedure

7.1) Calibrate every station using a load cell. Execute the calibration while the load is being developer at other stations of the test rig.

7.2) Clean the specimens as prescribed in ISO 14242-2.

7.3) Carry out all the measurement to evaluate, after testing, the amount of wear and/or creep.

NOTE: Methods are widely described in ISO 14242-2.

7.4) Same as 7.3 in ISO 14242-1 (**7.3)** Mount the femoral component on the machine in the inferior position, with the stem in the adduction/abduction position of $P=10 \pm 3^\circ$ as represented in Fig. 1 and in the inward/outward rotation position $\gamma/2$ as represented in the Fig. 1).

NOTE 1: For modular components, the stem can be replaced by a support with an identical cone and that guarantees reproducible positioning of the head.

NOTE 2: For modular components, positioning representative of clinical orientation (Fig. 1) might be useful.

7.5) Same as 7.4 in ISO 14242-1 (**7.4)** The acetabular cup can be mounted in different ways, depending on the aim of the test. A possible choice can be setting the polar axis (the main axis of symmetry) vertical or inclined at an

angle L as shown in the FIGURE; $L = 30 \pm 3^\circ$. In case the manufacturer specifies a particular tilting angle (or angle range), this angle can also be used for testing. If the angle specified is N, then $L = (75 - N) \pm 3^\circ$.

7.6) Same as 7.5 in ISO 14242-1 (7.5) The foregoing procedure may be applied to the control specimen too. For implants with a specific design and same materials, shape and dimensions, control data from previous test may be used).

NOTE: Use data from previous test control can introduce systematic error.

7.7) Same as 7.6 in ISO 14242-1 (7.6) Submerge the test specimen with the fluid test medium, so as the surfaces in contact in the joint are completely soaked in liquid. Keep the temperature of the fluid at $37 \pm 2^\circ\text{C}$).

7.8) Same as 7.7 in ISO 14242-1 (7.7) Start the testing machine and verify that the loads and displacements are properly applied to the test specimen, and that the same loads are applied to the control specimen. The curves obtained between the maxima and the minima shall be smooth, with no overshoots. Record the displacement and load waveforms at the start-up of the test machine, until the test is over).

7.9) Same as 7.8 in ISO 14242-1 (7.8) The cycle frequency is $1 \text{ Hz} \pm 0.1 \text{ Hz}$).

7.10) Same as 7.9 in ISO 14242-1 but with the underlined integration (7.9) Daily replace the fluid loss due to evaporation by adding de-ionized water. Replace the fluid test medium completely at least every 5×10^5 cycles, or every seven days, whichever is shorter).

7.11) Same as 7.10 in ISO 14242-1 (7.10) Interrupt the test measurements at, at least, 5×10^5 or 1×10^6 cycles and at least every 1×10^6 cycles, thereafter until the test is terminated). See 7.15.

NOTE: More frequent measurements might be useful for some materials.

7.12) Same as 7.11 in ISO 14242-1 (7.11) Remove the test specimen and control it; take wear measurements). As prescribed by ISO 14242-2.

7.13) After wear measurements, reposition it in the test machine (see 7.4 and 7.5).

7.14) Same as 7.13 in ISO 14242-1:

(7.13) Restart the testing machine with the remounted specimen, repeating the foregoing procedure until one of the following occurs:

- Completion of 5×10^6 cycles (if the party commissioning the test specifies differently, the test can be protracted beyond this limit);
- Failure or delamination of the articulating surfaces;
- Failure of the testing machine to maintain the forces and/or the displacements within the given tolerances.)

8) Test report

Substantially the same of ISO 14242 – 1 but with the following integrations.

- In 2 the following note is added:
*Note: Lot codes, fabrication history and detailed material treatment conditions should be described if possible.
- Point 4 bears some additional specifications:

*Consideration shall be given to material soak correction or dimensional correction for accurate wear measurement; an explanation of the approach shall be given.

- The following brief additional point was added:

*The bovine serum lubricant used, including type, lot, protein concentration, volume used, replacement interval and steady-state temperature shall be reported; filtering should be described if used.

At the end of this subchapter (subchapter 8) is specified that: method of determination of wear rate, and the statistical analysis (including method and results) have to be added. In conclusion a final note suggests that converting wear rates to volumetric values, using material density (if known), might be useful.

Chapter 5

Mathematical model for hip prosthesis wear assessment

5.1) Introduction

In this introductory subchapter the reader is taken through a brief summary that describes the overall structure of the chapter. Since the mathematical model is encoded in a MatLab[®] program – with tailored subroutines which carry out specific functions – this part shows how the code “unravels throughout the lines” to furnish, at the end, a complete picture of the problem. Plots, and figures in general, constitute a little *sample/example* for the large amount of figures presented along the chapter; for this reason they appear little, incomplete and may be difficult to read.

This script allows to find the trajectory that a hypothetical marker placed on the femoral head (or respectively on the acetabular cup), and solidal to it, traces on the acetabular cup (or respectively on the femoral head). This is possible by setting the marker location in the proper frame of reference, and the characteristic angles that describe the human gait (motion law). This is the starting point to evaluate – after a series of calculations – the performance of a prosthesis under different conditions, like: different system-parameters, different ISO (ISO 14242-1 and ISO 14242-3), and different approaches to ISO plot interpretation.

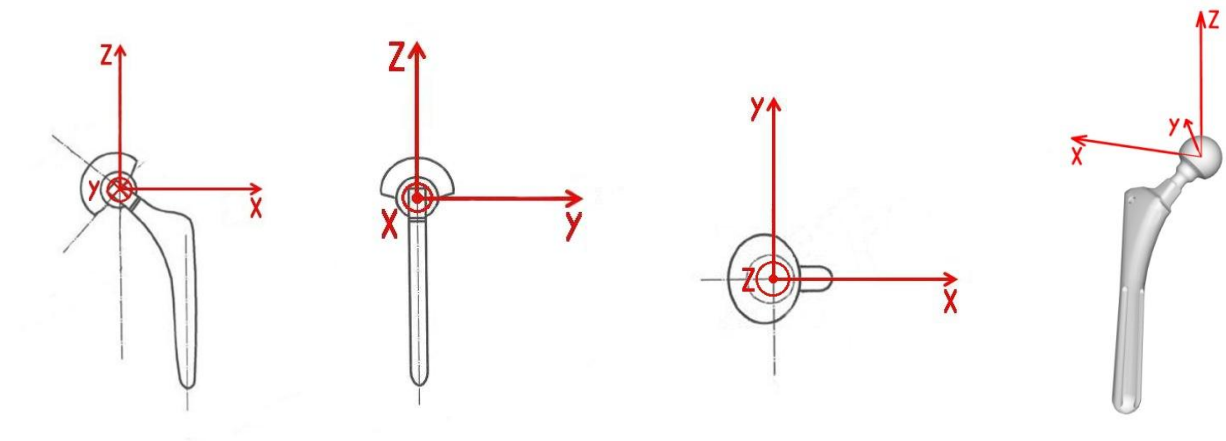


Fig. 5.1) Reference frame of the hip prosthesis (right leg)

At the beginning of the code there is a set of parameters, such as: head radius, friction coefficient, cross-link density, etc. Some are not used, or unknown (default value=1); this is intentionally done to allow a possible further development of the code in the future, broadening its potential. These data are used throughout the code for specific calculations such as: direction of maximum frictional work, work in that direction (assumed as main fibril orientation direction), work in the transverse direction, total work per cycle, etc.

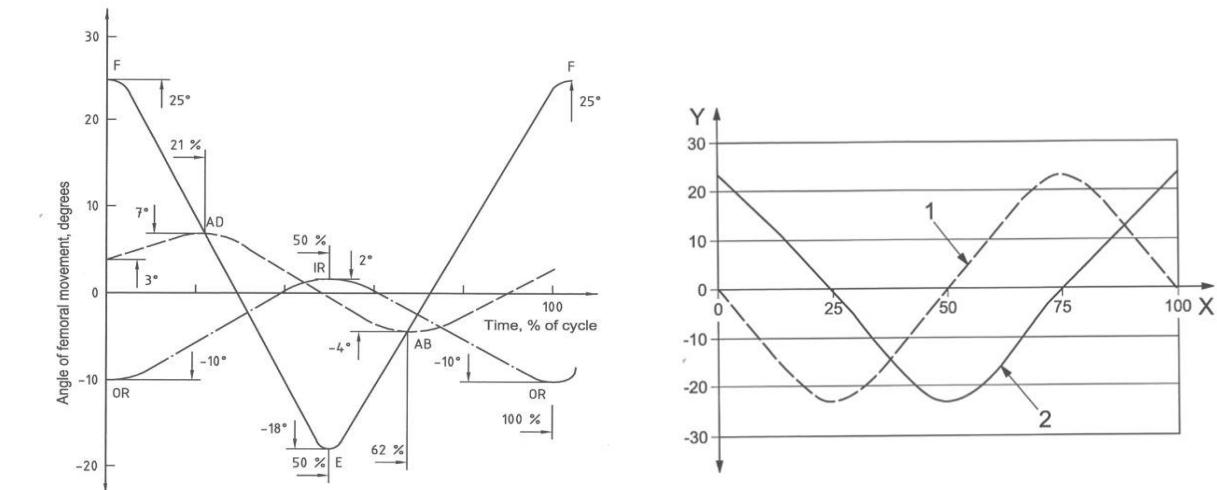


Fig. 5.2) Motion law in ISO 14242-1 (left) and ISO 14242-3 (right)

The motion law of the femoral head was taken from ISO-14242 (Fig. 5.2). Since it's described only by a plot with a few reference points explicitly given, was interpreted in two ways (Fig. 5.3):

- harmonic functions passing through the coordinates explicitly given,
- broken line connecting the coordinates explicitly given.

Furthermore the motion law is represented through two different approaches: the one present in ISO 14242-1, with three degrees of freedom (flexion-extension, adduction-abduction, and internal and external rotation), and the one present in ISO-14242-3, which has only two degrees of freedom (flexion-extension and adduction-abduction).

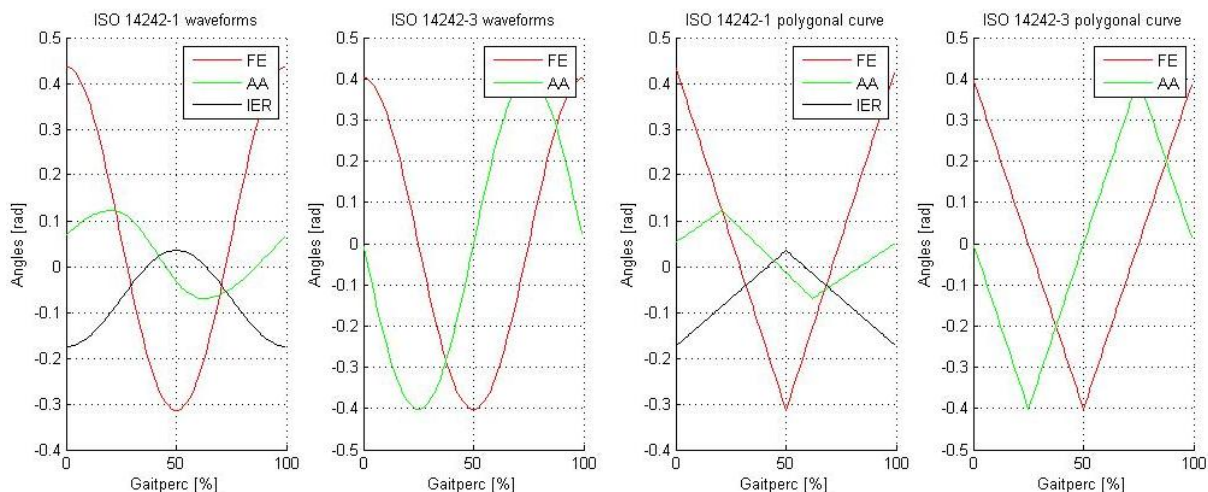


Fig. 5.3) Examples of motion law in ISO 14242-1 and ISO 14242-3 (MatLab model). Harmonic interpretation (left) and polygonal interpretation (right)

ISO-14242, along with the motion law, provides the loading law (Fig. 5.4). Because, even in this case, it's described only by a plot with a set of points, the plot was intended as a broken line connecting the stated coordinates.

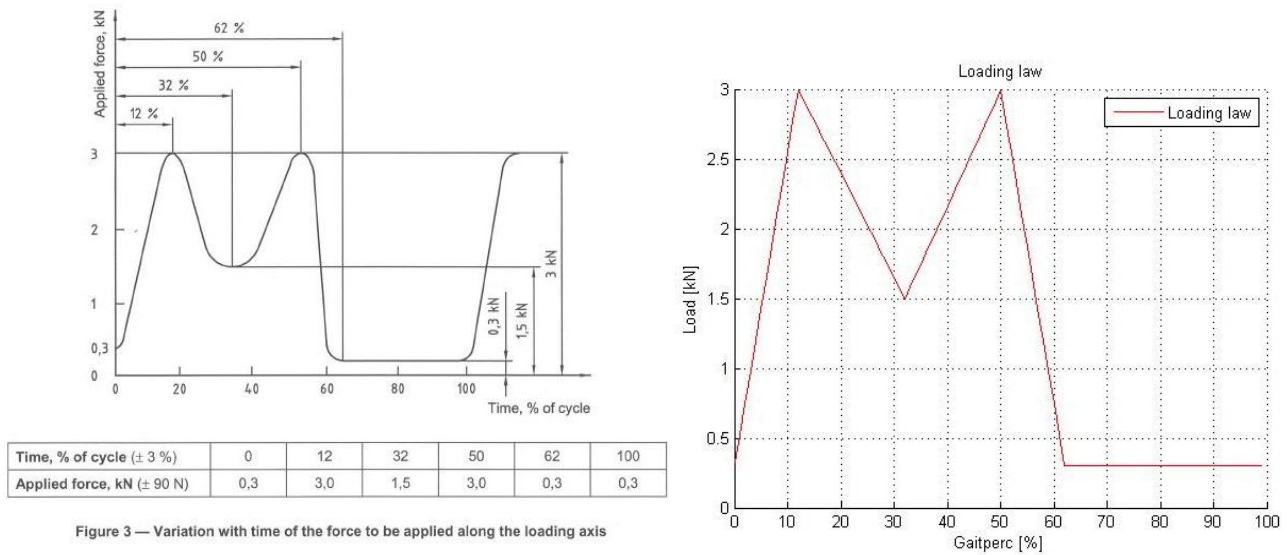


Fig. 5.4) Examples of loading law according to ISO 14242. In ISO publication (left) and in the MatLab model (right)

The trajectories on the spherical surface can be found thanks to `Ematrix.m` (marker path traced on cup, Fig. 5.5) and `EmatrixInv.m` (marker path traced on head, Fig. 5.5). These functions make use of the rotation matrix and the rotation is provided by the three angular functions (`fe`, `aa`, `ier`) present in ISO 14242.

The `EmatrixDirections.m` function is used to find the vectors which compose a rose that represents all the discretised sliding displacements that occur at the inner tip of the cup (Fig. 5.6). These displacements can be exploited for further calculations.

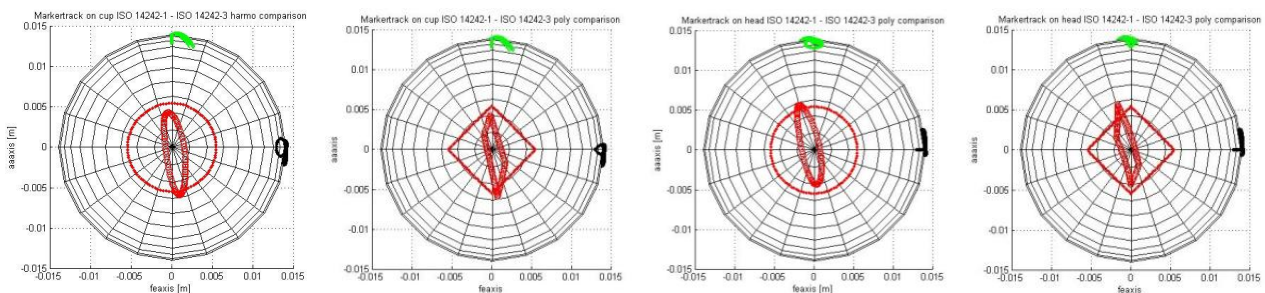


Fig. 5.5) Examples of cup (two on the left) and head (two on the right) trajectories

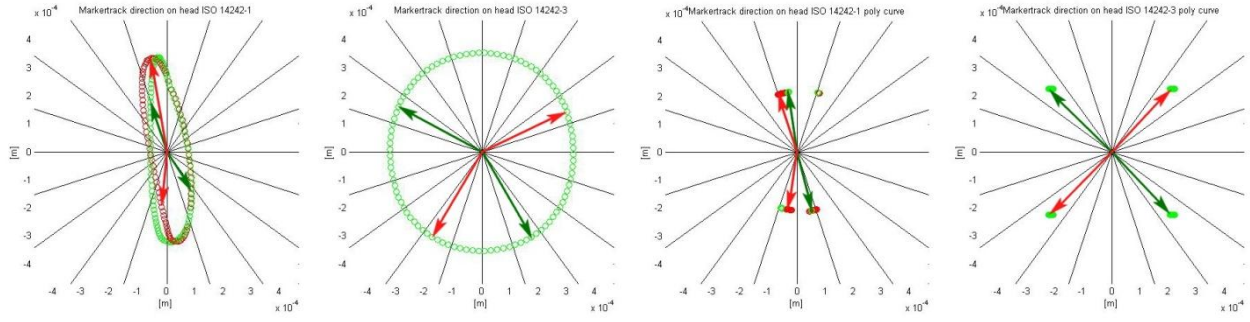


Fig. 5.6) Examples of discretised sliding displacements in ISO 14242. From harmonic interpretation (left) and polygonal interpretation (right)

The `DirRose.m` function is built to count the vectors which are present in a specific circle sector of the vector roses elaborated into this function. Furthermore, by using this information, it outputs useful data to produce histograms representing:

- how many times vectors are inside a specific sector (using `nvec`);
- how much distance is run inside a specific sector (using `mvec`);
- how much frictional work is dissipated inside a specific sector (using `qvec`).

The function in question contains important data (Fig. 5.7 and 5.8) – such as the fibril main orientation vector, and the total work – that are shown in a table.

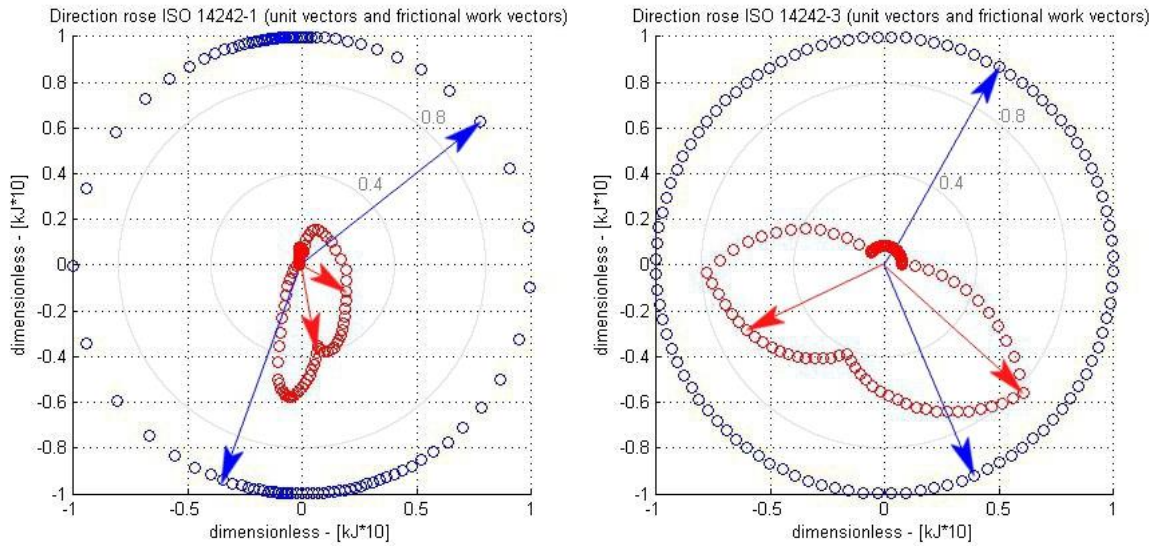


Fig. 5.7) Examples of direction rose with unit vectors (blue) and frictional work-weighted vectors (red) for ISO 14242-1 (left) and ISO 14242-3 (right)

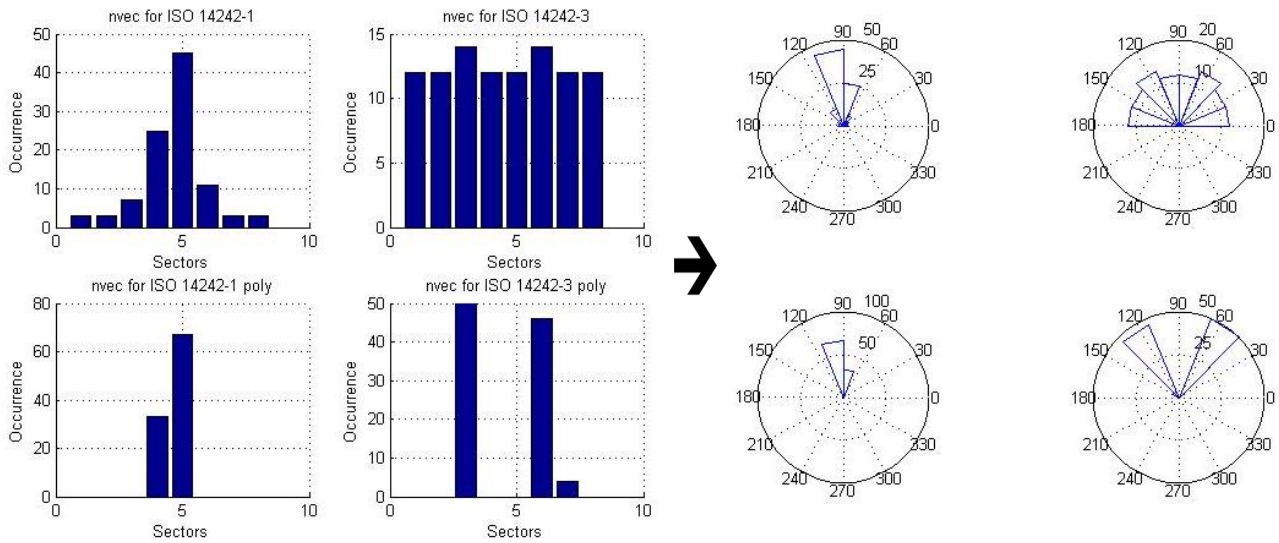


Fig. 5.8) Examples of traditional histograms and rose histograms summarising the directions distribution during one cycle. All combinations are shown: ISO 14242-1 (left column) and ISO 14242-3 (right column), and harmonic (upper row) and polygonal (lower row) interpretation.

The last subchapter proposes a statistical analysis on the distribution of the discretised sliding directions of ISO 14242-1, with harmonic interpretation (Fig. 5.9 and 5.10).

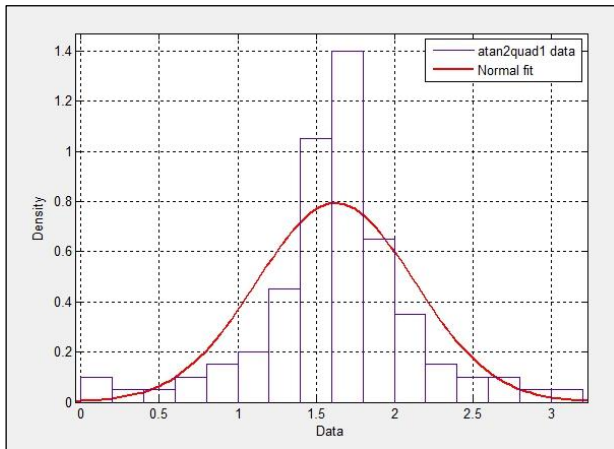


Fig. 5.9) Example of probability density function (PDF) of the data atan2quad1, with the associated Normal distribution fit.

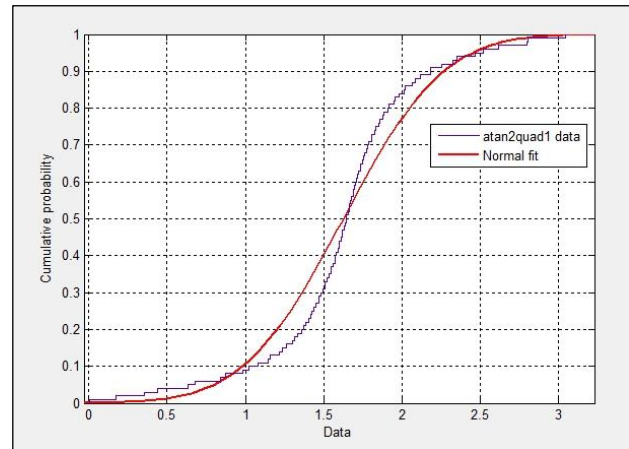


Fig. 5.10) Example of cumulative density function (CDF) of the data atan2quad1, with the associated Normal distribution fit.

The chapter features a large variety of plots derived from the outputs of the functions.

5.2) Code and plots description and comments

5.2.1) Parameters setting

At the beginning of the code the parameters of the system are set.

The known parameters are:

- `gaitperc=0:1:99;`
which stands for “gait percentage”, it’s the vector containing all the parts into which the standard human gate (according to ISO) is divided. In this case it’s divided in 100 parts (100 columns).
- `gaitrad=gaitperc*2*pi/100;`
which stands for “gait radians”, it’s the same vector, but expressed in radians.
- `r=0.028/2;`
it’s half diameter of the femoral head (expressed in meters [m]), that is it’s radius. The radius is expressed as half diameter since in the prostheses’ technical files the diameter is stated. It has to be said that for simplicity reasons the head diameter is the same of the cup; no clearance effect is taken into account in this model.
- `a=pi*r^2;`
is the supposed contact area (expressed in meters [m]).
- `freq=1; T=1/freq;`
are respectively the frequency [1/s] and the period [s].
- `deltat=T/(length(gaitperc)-1);`
is the time lapse between the points.
- `mu=0.08;`
it’s the friction coefficient.
- `Xc=0.00025;`
it’s the cross-link density [mole/g] (see Fig. 7 in A. Wang, 2001 [12]).
- `v1=[ 0; 0; r ]; v2=[ 0; r; 0 ]; v3=[ r; 0; 0 ];`
Radius-vectors that lie on the three axes of moving reference frame.

The unknown parameters are (arbitrary set value=1):

- `kprime=1;`
it’s a proportionality constant (see Eq. 6 in A.Wang, 2001 [12]).
- `gammac=1;`
it’s the C-C bond energy [J].
- `d=1;`
it’s the average cross sectional width of UHMWPE fibrils [mm] (Fig. 5.2.22)

The parameters are divided in two big categories: the ones which are known and the unknown ones (default value=1). The unknown ones are intentionally left in the code to allow a possible further development in the future.

5.2.2) Motion law and loading law

The motion law of the femoral head is expressed throughout the Euler angles. These angles represent the femur motion (moving reference frame) with respect to the acetabular cup (fixed reference frame).

The Euler angles are three:

- flexion and extension ("fe" in the code). This angle represents the femur motion in the sagittal plane (Fig. 5.2.1);
- adduction and abduction ("aa" in the code). This angle represents the femur motion in the frontal plane (Fig. 5.2.1);
- internal and external rotation ("ier" in the code). This angle represents the femur motion around its axis (Fig. 5.2.1).

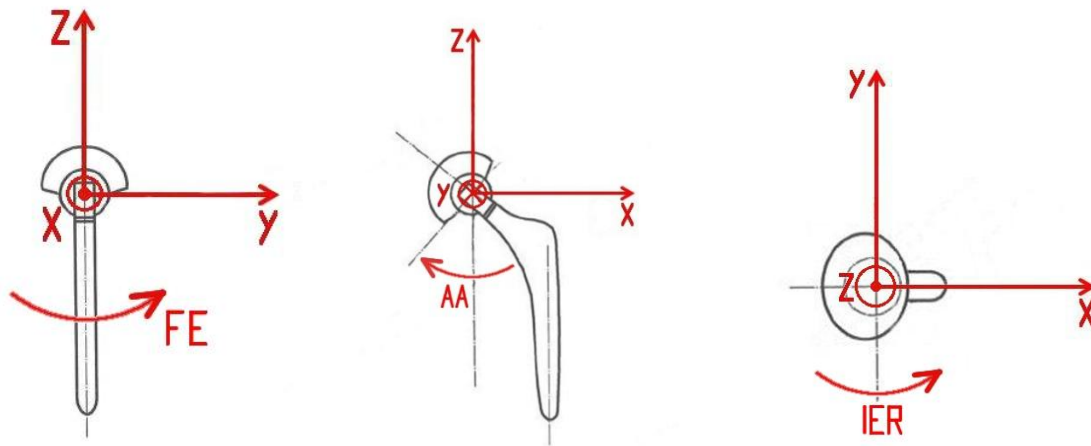


Fig. 5.2.1) Reference frame of the hip prosthesis (right leg)

The rotation is performed through the rotation matrix, which makes use of the Euler angles. The rotation sequence is: $fe \rightarrow aa \rightarrow ier$.

This motion is described in ISO-14242 only by a plot with a few reference points explicitly given (FIG 1, in chapter 4), and not through a specific mathematical function. For this reason it was interpreted in two ways:

- harmonic functions passing through the coordinates explicitly given (Fig. 5.2.2);
- broken line connecting the points specifically given (Fig. 5.2.3).

Anyway, according to the common understanding of these plots by the scientific community, the plots appear to be interpreted in the majority of the cases as harmonic functions passing through the well stated coordinates.

The angles are expressed in degrees and are plotted against the time percentage of the cycle. The two different perspectives will give different results in the simulations.

Furthermore the motion law is represented through two different approaches: the one present in ISO 14242-1 (three dof), and the one present in ISO-14242-3 (two dof).

The ISO 14242-1, which has three degrees of freedom: flexion and extension, adduction and abduction and internal and external rotation (Fig. 5.2.2 and 5.2.3).

The ISO 14242-3, which has two degrees of freedom: flexion and extension, and adduction and abduction (Fig. 5.2.2 and 5.2.3).

All the angular functions are represented by a row vector with 100 columns, each value in each column is the angular value at a specific instant (n^{th} column: angular value at n^{th} instant)

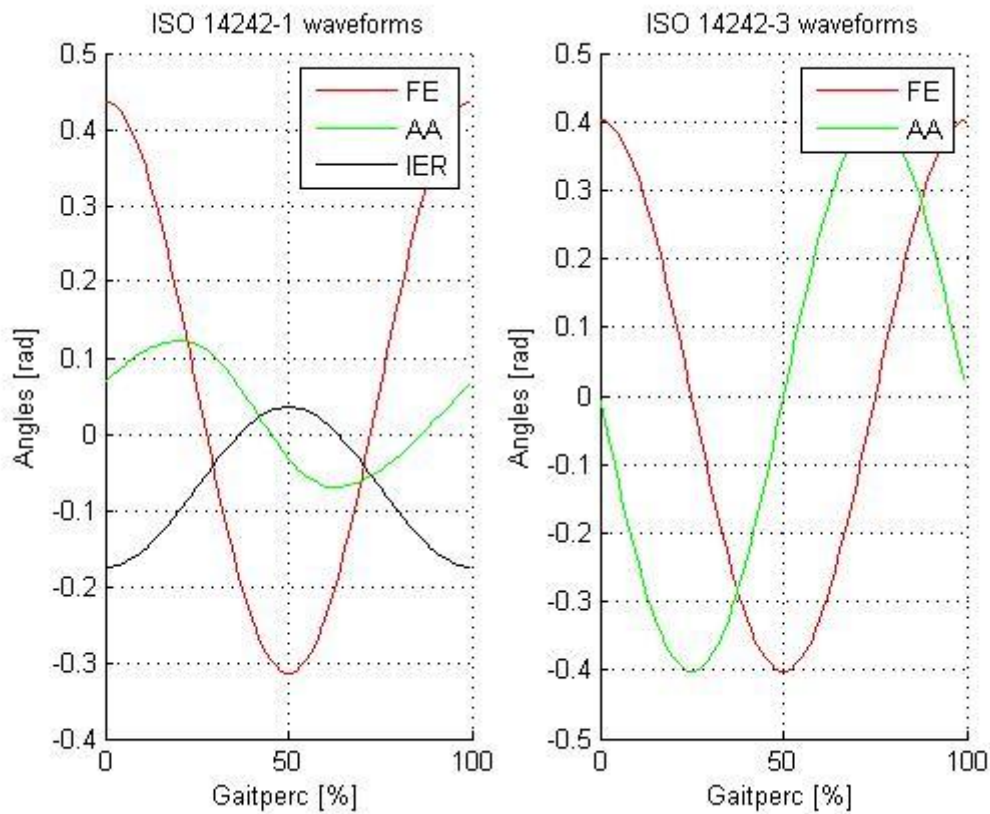


Fig. 5.2.2) Motion law in ISO 14242-1 and ISO 14242-3 (MatLab model). Harmonic interpretation.

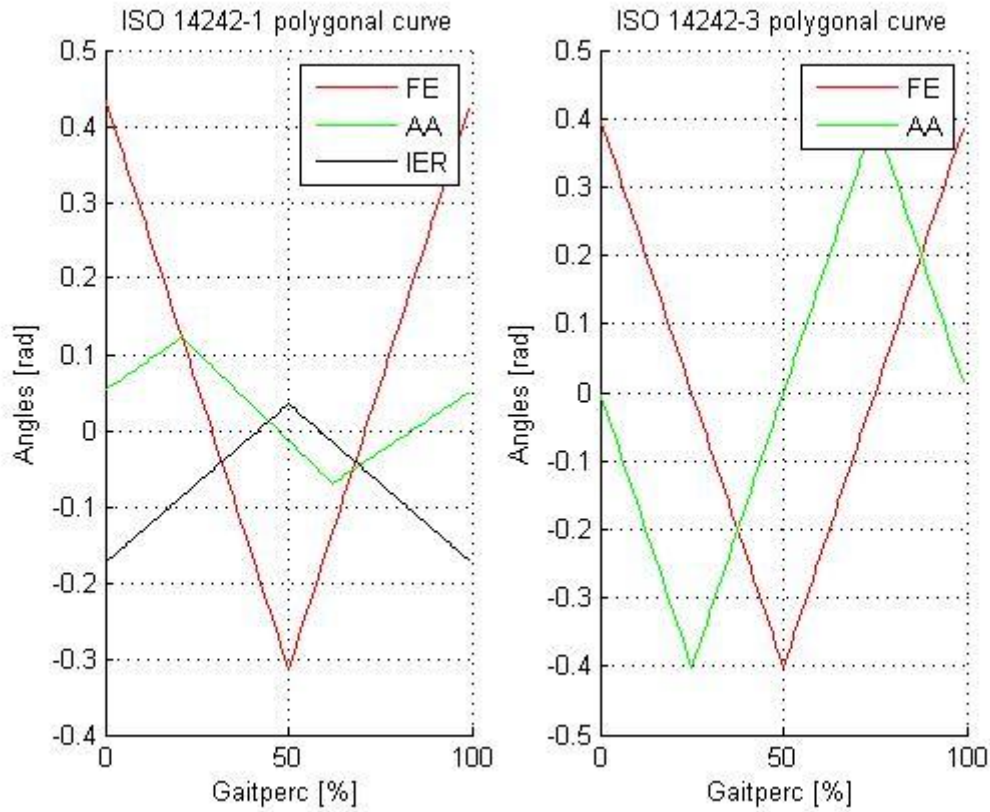


Fig. 5.2.3) Motion law in ISO 14242-1 and ISO 14242-3 (MatLab model). Polygonal interpretation.

ISO-14242 provides the loading law, with the force expressed in newton plotted against the time percentage of the cycle. A set of points of the function are given; by using these points, and connecting them through a broken line, the load-time percentage plot is obtained (Fig. 5.2.5).

All the loading functions are represented by a row vector with 100 columns, each value in each column represents the load value at a specific instant (n^{th} column: load value at n^{th} instant)

In the code, the variable $\mathbf{L}$ indicates the load vector, while the variable $\mathbf{F}$ indicates the frictional force vector ($\mathbf{L}$ values multiplied by μ , which is the friction coefficient, and is equal to 0,08).

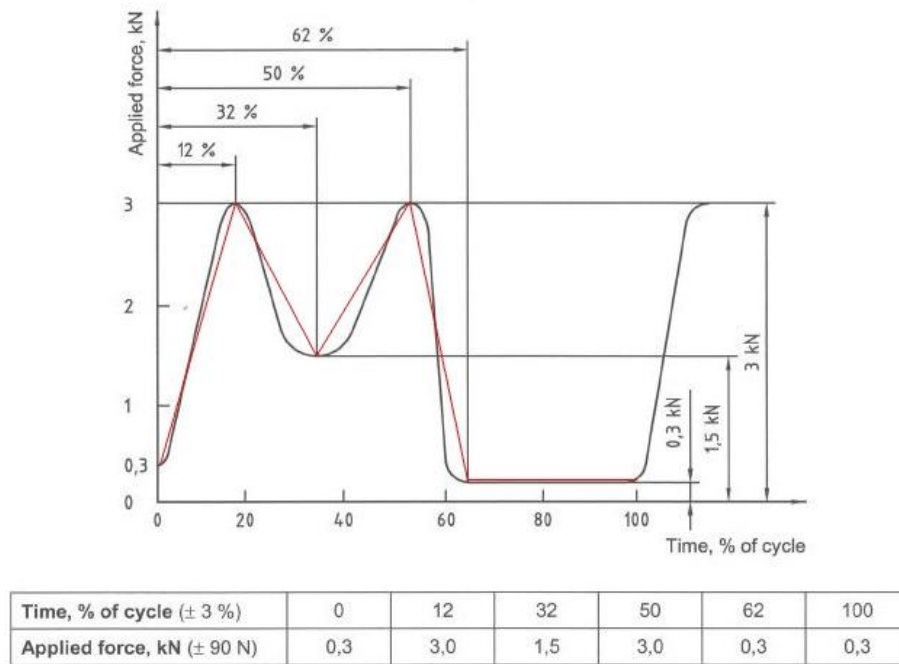


Figure 3 — Variation with time of the force to be applied along the loading axis

Fig. 5.2.4) Loading law in ISO norms

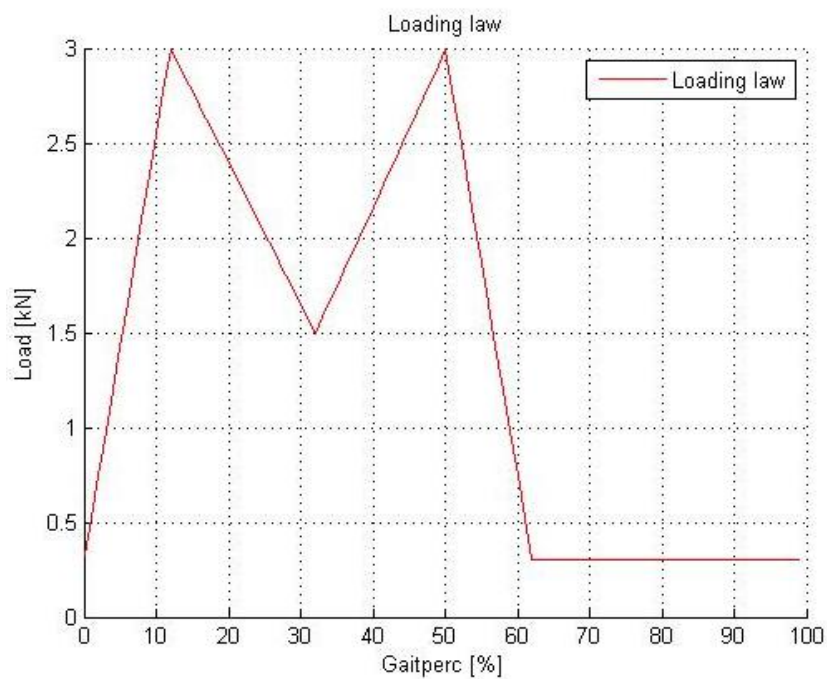


Fig. 5.2.5) ISO loading law implemented in MatLab model

5.2.3) Cup trajectories

```
function [ vmark ] = Ematrix ( v, gaitperc, fe, aa, ier )
```

This function, given a vector indicating a point on the femoral head, and three vectors containing the angular values of the discretised motion law of the femoral head, allows the calculation of the path generated by a hypothetical marker located by the first vector mentioned, drawing its trace on the liner of the acetabular cup (Fig. 5.2.6). The code is preset to calculate the paths of the three markers located at the intersections of the x, y and z axes with the sphere (respectively x=black, y=green and z=red), this to give an idea of the motion of the sphere. In the end only the top marker trajectory will be used to perform the calculations of interest.

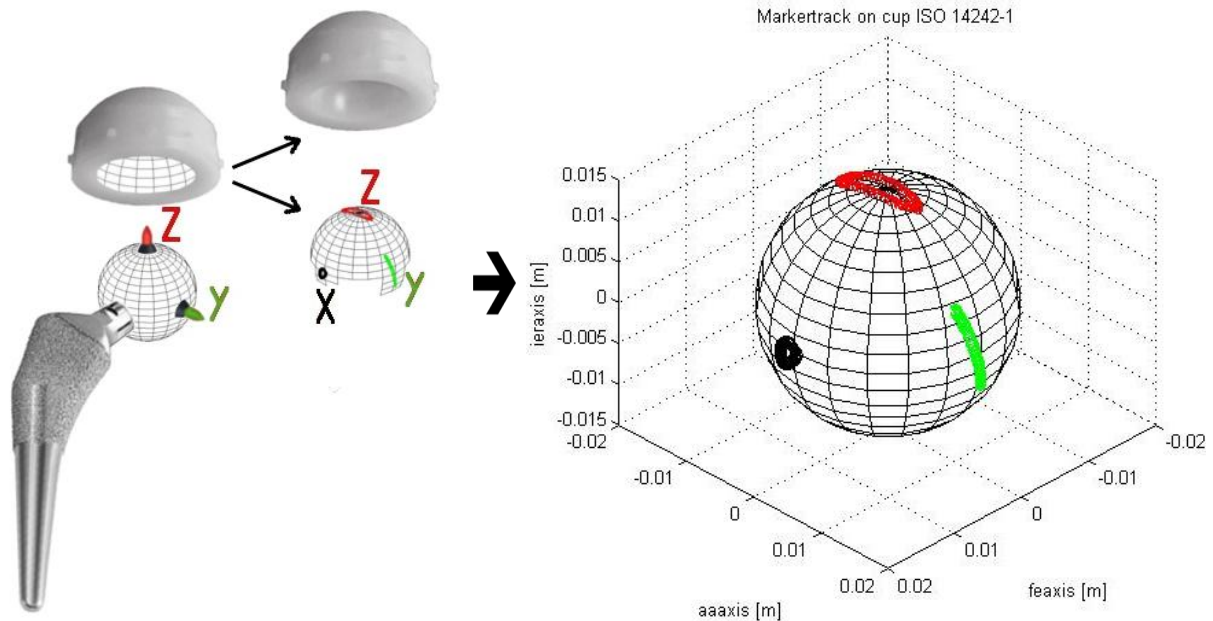


Fig. 5.2.6) Theoretical marker location on femoral head with trajectories from ISO 14242-1, harmonic interpretation

It's worth remembering that the rotation is performed through the rotation matrix, and the rotation sequence is: $fe \rightarrow aa \rightarrow ier$.

In literature this is commonly referred to as “cup track” (Fig. 5.2.7).

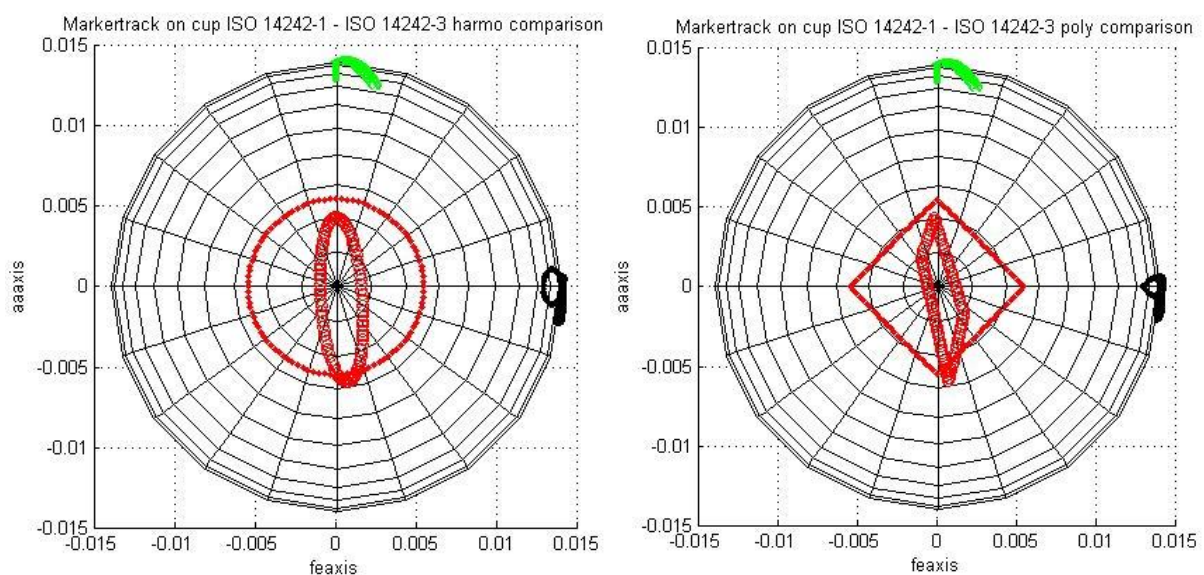


Fig. 5.2.7) Cup trajectories comparison in ISO 14242-1 and ISO 14242-3. Harmonic interpretation (left) and polygonal interpretation (right).

5.2.4) Comments on plots

For what concerns the paths on the cup, ISO 14242-1 and ISO 14242-3 produce respectively an oval path and a circular path (Fig. 5.2.8).

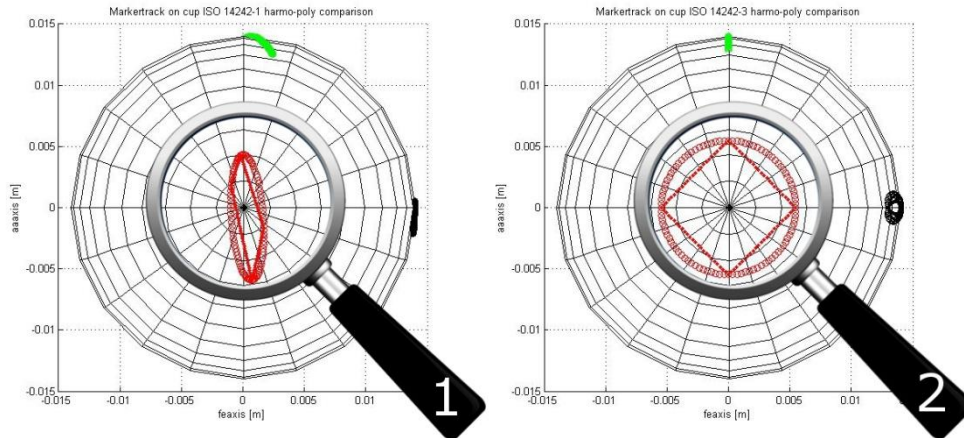


Fig. 5.2.8) Cup trajectories comparison in ISO 14242-1 and ISO 14242-3. Magnified trajectories follow.

The oval path (Fig. 5.2.9, 1) is due to the large difference in amplitude between the fe motion (flexion-extension) and the aa motion (adduction-abduction) during the gait. The oval path is off-centred with respect to the vertical axis and slightly rotated counter-clockwise; this happens since the fe and aa wave forms are both out of phase by a non-notable angle, and they don't oscillate around the same ordinate.

On the contrary, the circular path (Fig. 5.2.9, 2) is generated by the same extent of motion in the fe motion and the aa motion. In fact the two wave forms representing the motions are exactly the same, just out of phase by an angle of $\pi/2$.

In the case of broken lines, the oval path turns into an irregular quadrilateral shape inscribable in the oval shape (Fig. 5.2.9, 1), in which the corners represent an instantaneous change in direction during the motion of the prosthesis. This happens on the peaks and valleys of the wave forms, since those are the only instants in which the harmonic and broken line models match, we see that the path obtained from the two models overlap.

Finally, applying the broken line motion law, the circular path turns basically into a square inscribed into the circle (Fig. 5.2.9, 2) that was obtained with the harmonic motion law.

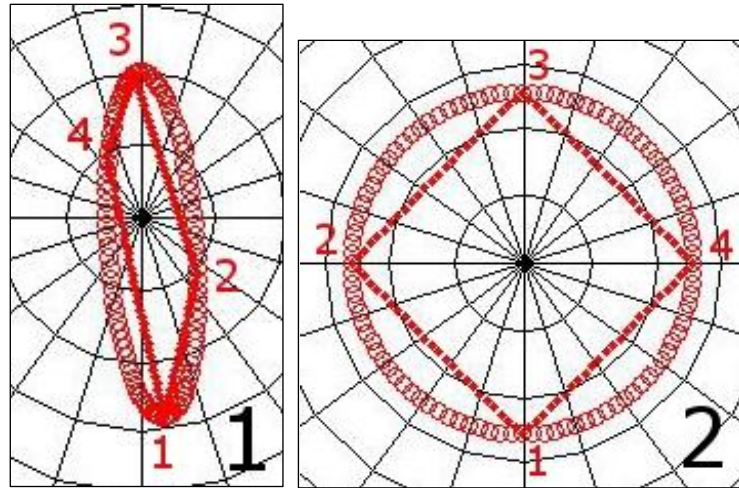


Fig. 5.2.9) Cup trajectories comparison of harmonic and polygonal interpretation. ISO 14242-1 (left) and ISO 14242-3 (right).

It is worth noting that here, in the cup trajectories, ISO 14242-1 generates a counter clockwise motion (Fig. 5.2.9, 1), while ISO 14242-3 generates a clockwise motion (Fig. 5.2.9, 2). This is due to the fact that in ISO 14242-1 the aa waveform succeeds the fe waveform by a phase of $\pi/2$ (Fig. 5.2.10, 1), on the contrary in ISO 14242-3 the aa waveform precedes the fe waveform by a phase of $\pi/2$ (Fig. 5.2.10, 2).

Fig. 5.2.9, 2 even shows how distant from reality is a test conducted by following ISO 14242-3: points 2, 3 and 4 represent a combination of angles that widely overshoot the angles of a possible human gait. Furthermore, points 3 and 4 represent angles that exceed the correspondent physiological ones (even under passive movements, when another person is manipulating the limb!), in fact passive extension reaches a maximum of 30° and adduction can reach a maximum of 30° only under particular conditions; they are both less than 40° . Concluding, ISO 14242-3 depicts an impossible super-wide circumduction of the lower limb.

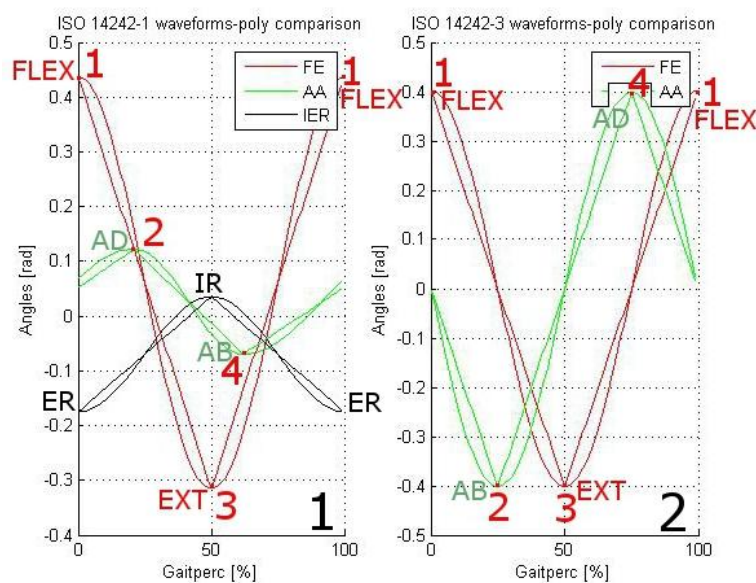


Fig. 5.2.10) Motion law comparison of harmonic and polygonal interpretation. ISO 14242-1 (left) and ISO 14242-3 (right).

5.2.5) Head trajectories

`function [ vmark ] = EmatrixInv ( v, gaitperc, fe, aa, ier )`

This function, given a vector indicating a point on the acetabular cup, and three vectors containing the angular values of the discretised motion law of the femoral head, permits the calculation of the path generated by a hypothetical marker located by the first vector mentioned, drawing its trace on the femoral head (Fig. 5.2.11).

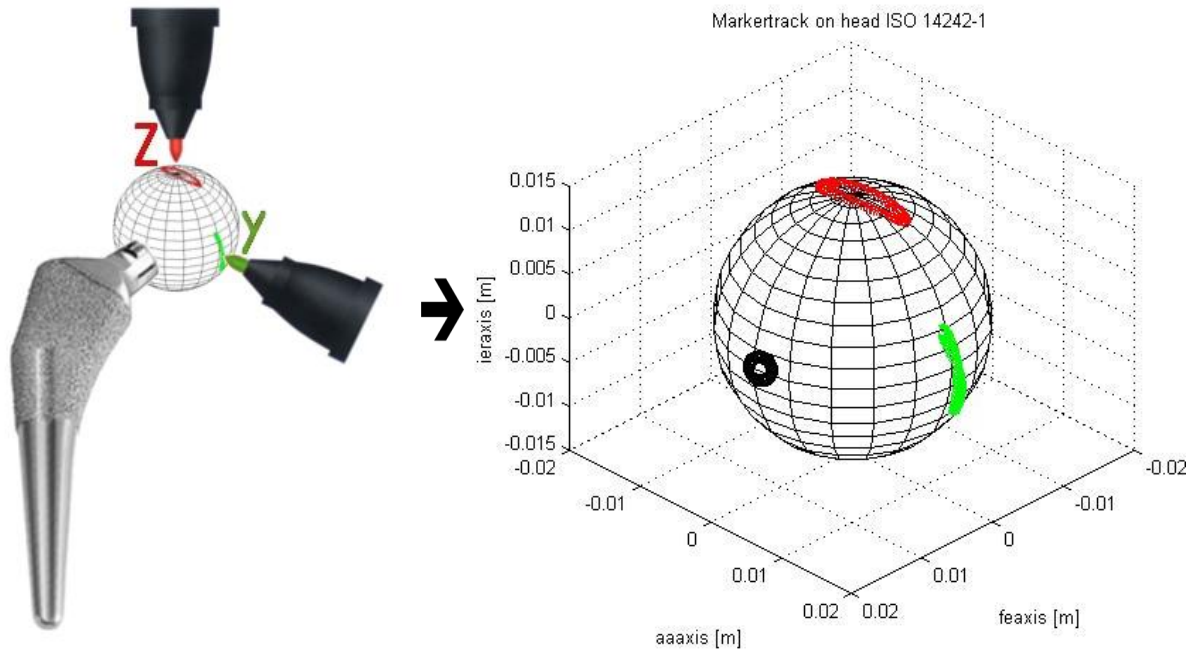


Fig. 5.2.11) Theoretical marker location on acetabular cup with trajectories from ISO 14242-1, harmonic interpretation

Again, the rotation is performed through the rotation matrix, and the rotation sequence is: $fe \rightarrow aa \rightarrow ier$.

In literature this is commonly referred to as "head track" (Fig. 5.2.12).

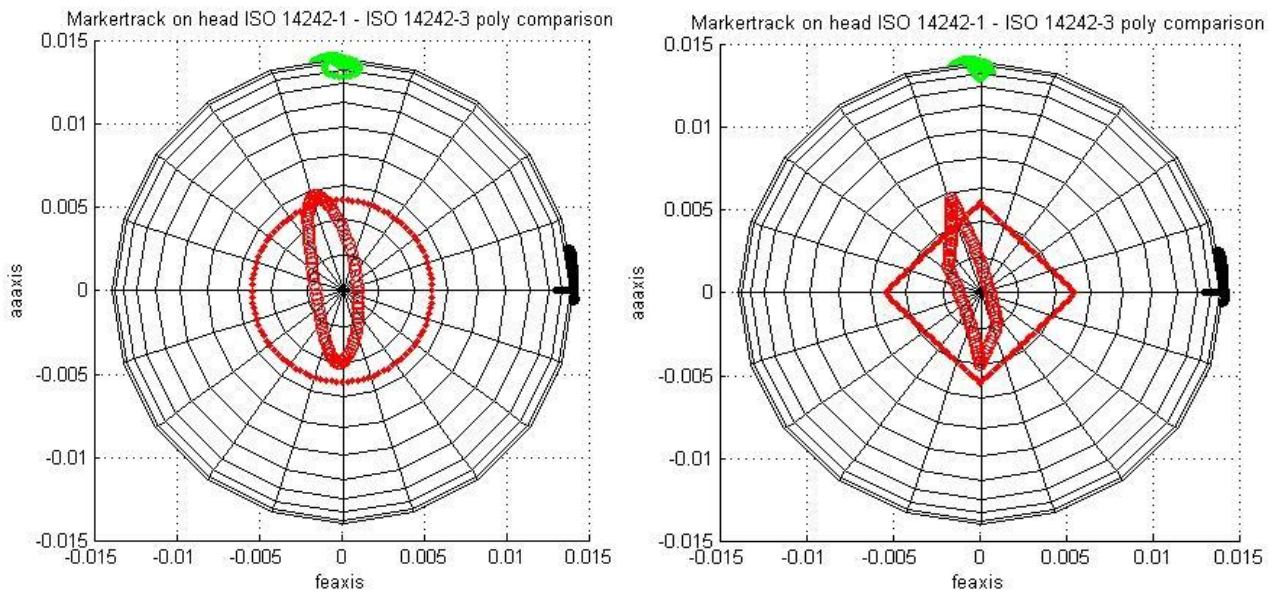


Fig. 5.2.12) Head trajectories comparison in ISO 14242-1 and ISO 14242-3. Harmonic interpretation (left) and polygonal interpretation (right).

5.2.6) Comments on plots

For what concerns the paths on the head, ISO 14242-1 and ISO 14242-3 produce – again – respectively, an oval path and a circular path (Fig. 5.2.13).

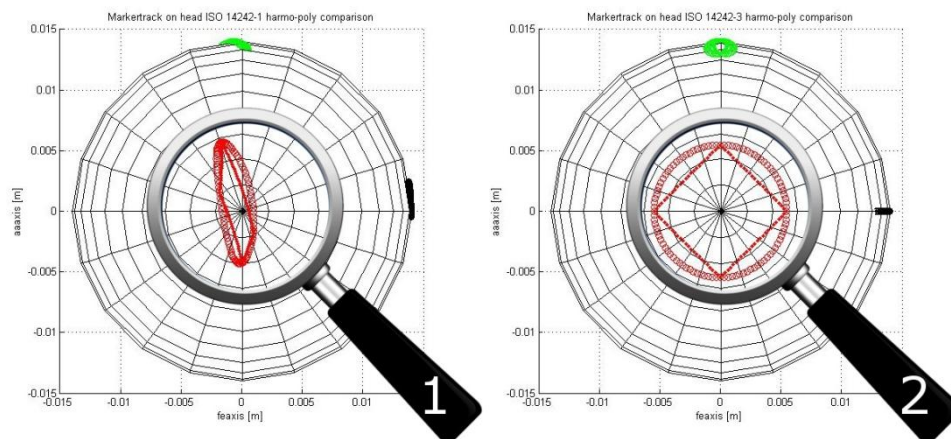


Fig. 5.2.13) Head trajectories comparison in ISO 14242-1 and ISO 14242-3. Magnified trajectories follow.

This oval path (Fig. 5.2.14, 1) has similar characteristics with respect to the cup path; the oblong shape is due to the large difference in amplitude between the fe motion and the aa motion during the gait. As before, the oval path is off-centred with respect to the vertical axis and slightly rotated counter-clockwise; this happens since the fe and aa wave forms are both out of phase by a non-notable angle and they don't oscillate around the same ordinate. What is substantially different is the slight bow-shape of the oval track: this distortion is ascribable to the ier motion, in fact it

appears when we put the marker on the cup, tracing it's path on the sphere. The distance between the marking point location on the cup and the ier axis on the head generates a radius; this radius makes the ier motion influential on the path. This doesn't appear on the cup track because the marking point location is at the tip of the head, exactly on the ier axis, and so whichever ier rotation does not move the marker.

The circular path (Fig. 5.2.14, 2) is generated by the same extent of motion of the fe motion and the aa motion. In fact the two wave forms representing the motions are exactly the same, just out of phase by an angle of $\pi/2$. Here no ier is provided (ier is constant and null), so the track is the same as the cup track.

In the case of broken lines, the oval path turns into an irregular quadrilateral shape inscribed in the oval shape (Fig. 5.2.14, 1); the corners represent an instantaneous change in direction during the motion of the prosthesis. If compared with the respective cup track, we see the slight bow-shape, as expected.

In the end, applying the broken line motion law, the circular path turns basically into a square inscribed into the circle (Fig. 5.2.14, 2) that was obtained with the harmonic motion law.

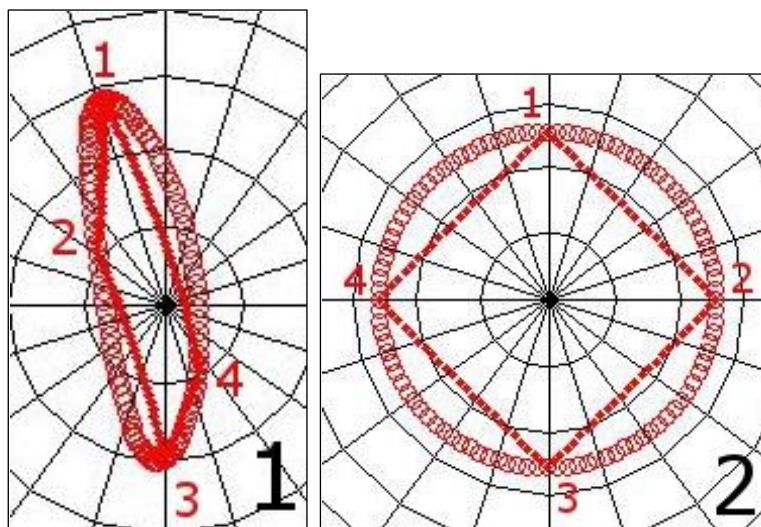


Fig. 5.2.14) Head trajectories comparison of harmonic and polygonal interpretation. ISO 14242-1 (left) and ISO 14242-3 (right).

Like in the cup trajectories, here in the head trajectories, ISO 14242-1 generates a counter clockwise motion (Fig. 5.2.14, 1), while ISO 14242-3 generates a clockwise motion (Fig. 5.2.14, 2). This because in ISO 14242-1 the aa waveform follows the fe waveform with a phase shift of $\pi/2$ (Fig. 5.2.15, 1), conversely, in ISO 14242-3 the aa waveform anticipates the fe waveform with a phase shift of $\pi/2$ (Fig. 5.2.15, 2).

Here the same considerations drawn at the end of subchapter 5.2.3 apply. In conclusion, ISO 14242-3 proposes a circumduction far from being realistic.

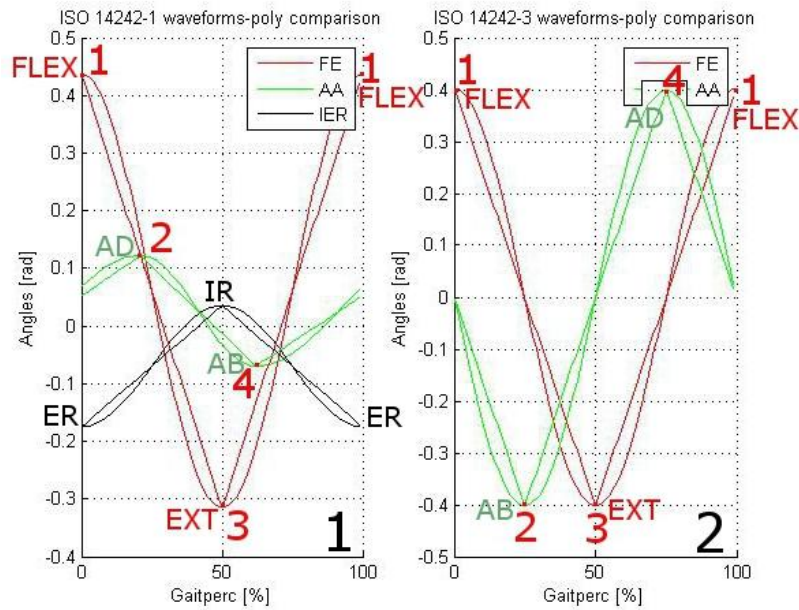


Fig. 5.2.15) Motion law comparison of harmonic and polygonal interpretation. ISO 14242-1 (left) and ISO 14242-3 (right).

5.2.7) Comments of comparison between cup tracks and head tracks

Cup tracks and head tracks bear interesting similarities and symmetrical characteristics. If it wasn't for the ier motion the paths would have been exactly the same, just "mirrored" by a point symmetry.

In fact, by comparing the paths generated by ISO 14242-3, where the ier motion is absent, the path is perfectly mirrored. The number-sequence remains counter clockwise (ISO 14242-3) and clockwise (ISO 14242-1) for both cup tracks and head tracks; this because the head tracks are naturally traced on the spherical surface of the head, while the cup tracks are like "seen from the outside of a transparent cup" (Fig. 5.2.6), and not seen on the actual hemispherical hollow surface where they were drawn. The cup tracks, seen by looking inside the concave surface of the cup, would appear reversed.

In the ISO 14242-1 plots, where the ier motion is present, and so influential, the head track shows a slight bend (or bow shape) due to a non-coincidence of the marker location and the ier axis of the femoral head (Fig. 5.2.16, on the left). It's maybe easier to understand this peculiarity starting from an opposite consideration: the absence of this bend in the cup track case (Fig. 5.2.16, on the right). In fact, in this latter case, the "physical" marker location is at the tip of the sphere (the "north pole" of the head), that is exactly the point where the ier axis and the spherical surface intersect; for this reason the ier motion has no influence on the cup track.

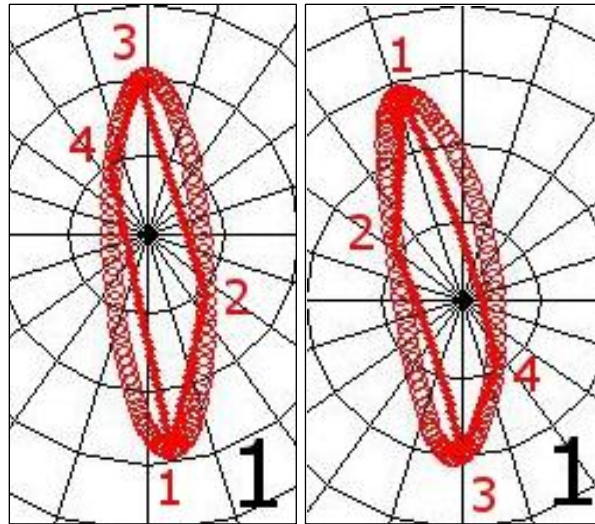


Fig. 5.2.16) Cup (left) and head (right) trajectories comparison in ISO 14242-1. Point symmetry and bend.

5.2.8) Direction vectors

```
function [ vmarkdir, truevmarkdir ] = EmatrixDirections ( vmark,
gaitperc, fe, aa, ier )
```

This function has as inputs: a matrix containing the x, y and z coordinates of a discretised path on the spherical surface (`vmark`), the discretised gait percentage (`gaitperc`), and three vectors containing the angular values of the motion law of the femoral head (`fe`, `aa`, `ier`, the same through which the path was obtained). The function permits the calculation of a new set of vectors, the modulus of which is the distance between the contiguous points that generate the path, and the corresponding direction is the direction that the trajectory instantly assumes in the path.

The outputs are:

- `vmarkdir`, which represents the delta vectors between a mark and the following one;
- `truevmarkdir`, which is a modification of `vmarkdir`, in this output the directions of the vectors are fixed by a rotation.

The rotation is performed thanks to the rotation matrix, and the rotation sequence is: $fe \rightarrow aa \rightarrow ier$.

Here the rotation matrix is used to find the direction vectors by "rotating back" every coordinate present in `vmark` by exactly the opposite rotation applied to find the location of the mark on the sphere, but with a substantial difference: every anti-rotation is applied to the mark that stands – according to the increasing sequence – right after the mark that was obtained by the corresponding rotation. That is to say that the n^{th} mark on the sphere, which was located by the n^{th} set of rotations (`fe`, `aa`, `ier`), is now rotated back by the $n^{\text{th}}-1$ rotation. If this particular process wouldn't be applied, by simply rotating back the n^{th} point we would get back the starting vector (i.e. $v=(0\ 0\ r)$).

When plotted, this new array of coordinates returns a characteristic direction rose that represents all the discretised sliding directions that occur at the head-cup top interface. The direction rose is

composed of vectors that are placed with all their tails at the tip of the inner surface of the cup. Basically the plot represents the motion seen under the Eulerian frame of reference (Fig. 5.2.17).

To obtain the "true" `vmarkdir`, the one that expresses the relative sliding occurring at the head-cup interface at the top of the cup, observed from the top of the cup (where the resultant force of the pressure distribution is concentrated), all the directions recorded in `vmarkdir` must be compensated by the opposite of the `ier` angle. This angle is distorting the true "direction rose" that will eventually be exploited for the precise calculation of the "shear stress rose" located at the tip of the cup during the gait. The new set of vectors is stored in `truevmarkdir`.

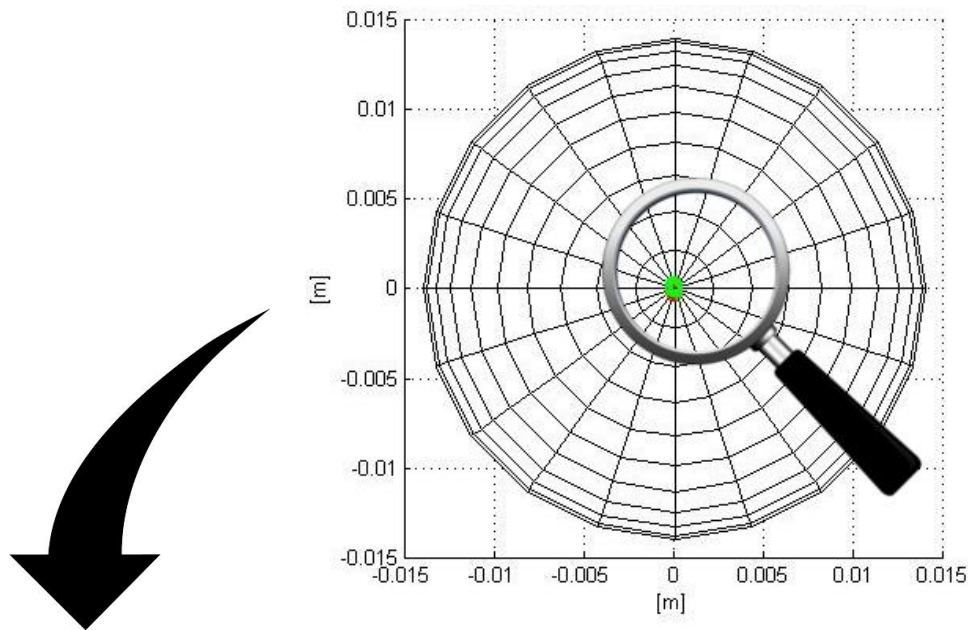


Fig. 5.2.17) Example of plot from `EmatrixDirections` output. Magnified directions follow.

5.2.9) Comments on plots

The previous plot (Fig. 5.2.17), represents the direction vectors in question. The figure with the magnifying glass, depicts a generic result obtained through the mere application of the function; in this case, since the markers appear gathering too closely one another, the scale was changed for every single case.

NOTE: The colours **red** and **green** in the plots refer to the results obtained through `vmarkdir` and `truevmarkdir` respectively. Both transformations are presented to give the reader the possibility to observe the slight difference between the two results. In the plots referring to ISO 14242-3, the green marks perfectly overlap the red marks. This is easily comprehensible since in this ISO norm there is no `ier` motion, and so, there is no correction in the directions with `truevmarkdir`.

The following plots represent: on the left, the directions, and on the right, the velocities.

In the first case (Fig. 5.2.18), representing ISO 14242-1 with harmonic motion law, the longest vectors are heading mainly forward and backwards since the maximum speed occurs during the wide flexion/extension movement; the others, oriented mostly to the right and left, are due to the

adduction/abduction motion. Given a gait frequency equal to 1 Hz and 100 samples per gait equally spaced in time (1 sample every 1/100 s), as it is in this case, since the scale unit is m, it's evident from the plot on the left that the maximum speed is about 0,00035 m per 1/100 s, that is 35 mm/s. By the same reasoning, the minimum speed is less than 10 mm/s. On the right is located the corresponding velocity rose.

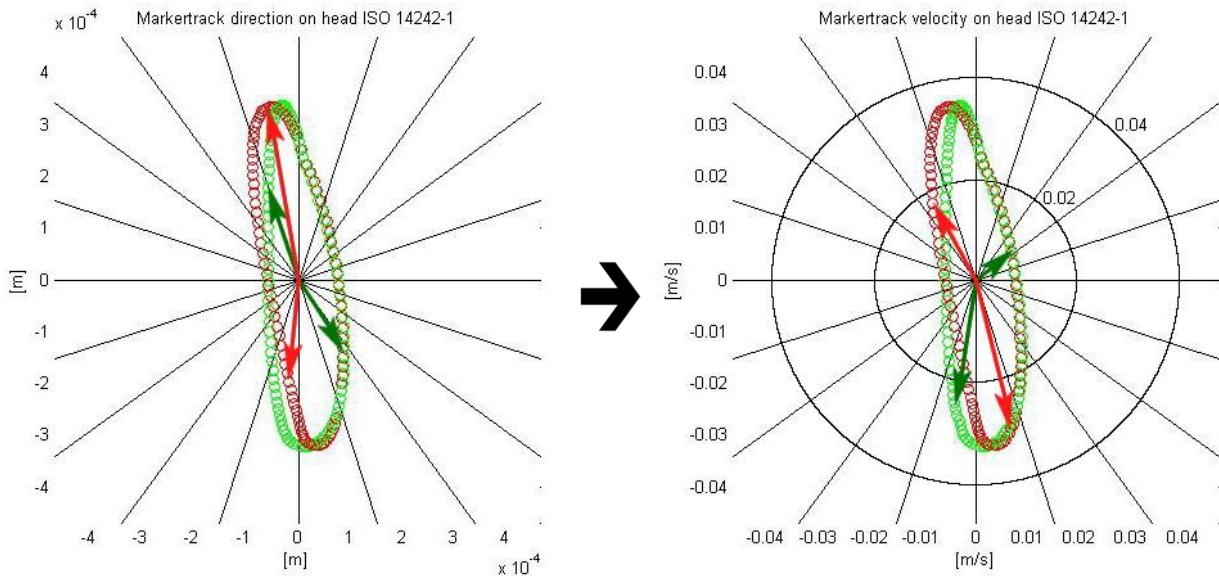


Fig. 5.2.18) Direction (left) and velocity (right) vectors in ISO 14242-1. vmarkdir (red) and truevmarkdir (green) outputs. Harmonic interpretation.

In the second case (Fig. 5.2.19), representing ISO 14242-3 with harmonic motion law, the vectors mark a circular rose, because of the particular conditions given by the motion law (with flexion/extension and adduction/abduction expressed by the same harmonic function out of phase by an angle of $\pi/2$). Here the speed is constant and it is about 35mm/s in every direction.

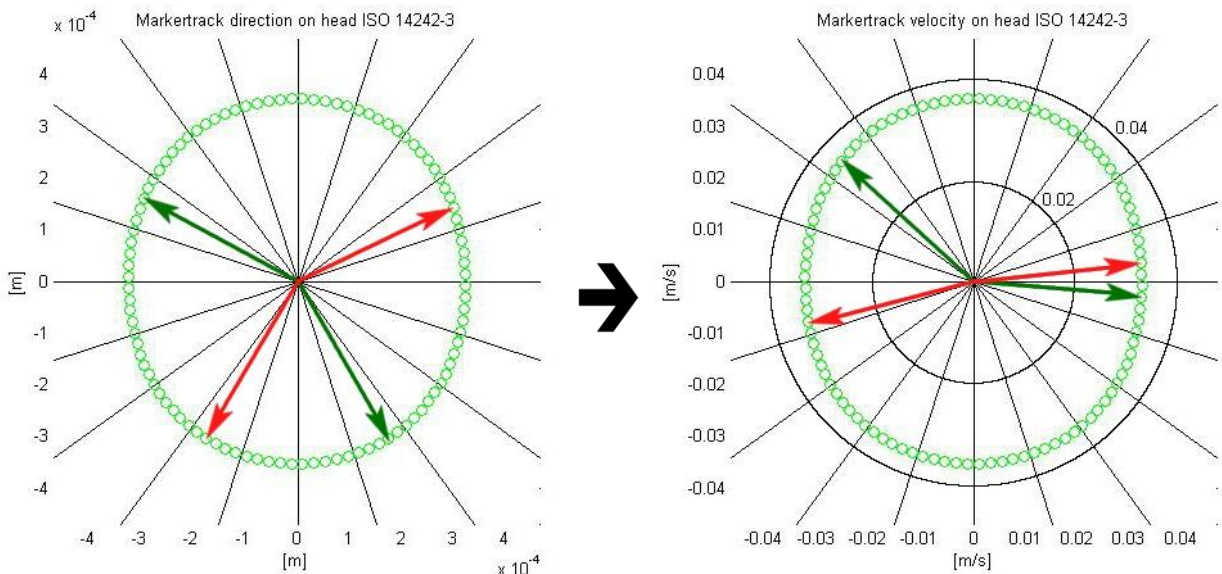


Fig. 5.2.19) Direction (left) and velocity (right) vectors in ISO 14242-3. vmarkdir (red) and truevmarkdir (green) outputs. Harmonic interpretation. The green marks perfectly overlap the red marks.

In the third case (Fig. 5.2.20), representing ISO 14242-1 with polygonal motion law, there are basically four points to which the vectors aim, and these are easily comprehensible by thinking about all the combinations that can occur using the broken line functions as motion law. In fact the four points correspond to: ext-ad (III quadrant), ext+ab (IV quadrant), flex-ab (I quadrant), flex-ad (II quadrant). It may be interesting noticing that the speed value is always about the same, that is just above 20 mm/s; moreover the four directions are sharply defined and always the same. This happens since the motion function is composed of straight lines with almost the same derivative modulus (in fact this is not true for the aa motion, which varies a little); in the first case the harmonic functions produced a velocity that varied continuously, and so this yielded a wider range of speeds and directions.

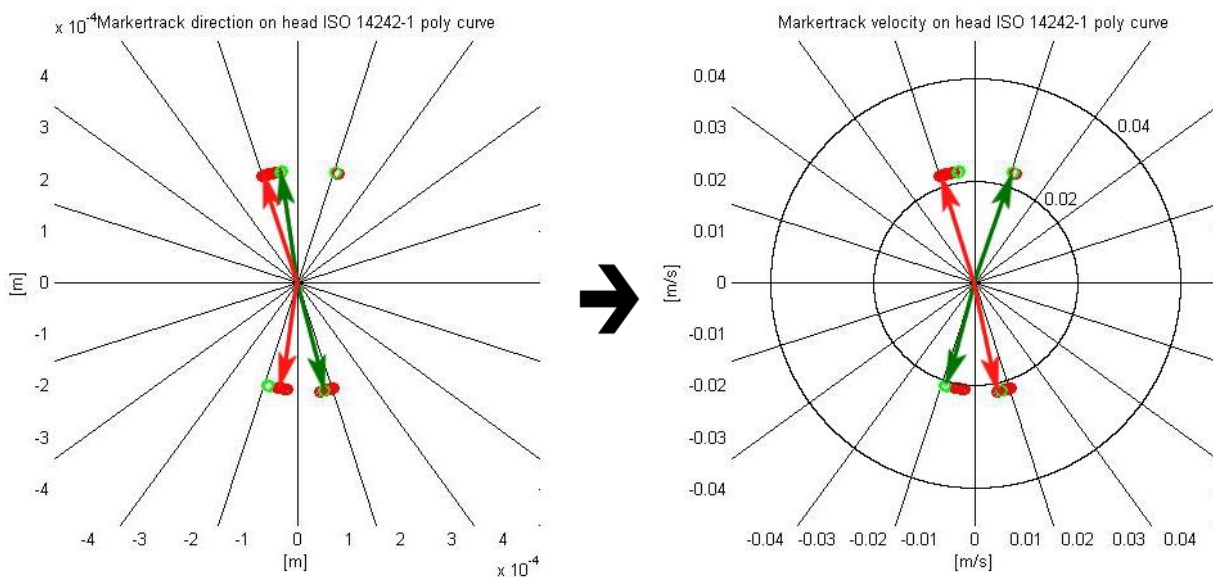


Fig. 5.2.20) Direction (left) and velocity (right) vectors in ISO 14242-1. vmarkdir (red) and truevmarkdir (green) outputs. Polygonal interpretation.

In the fourth case (Fig. 5.2.21), representing ISO 14242-3 with polygonal motion law, the vectors show four different directions, indicating four points generating a square. The speed modulus values are the same in all the directions and their value is just above 30 mm/s.

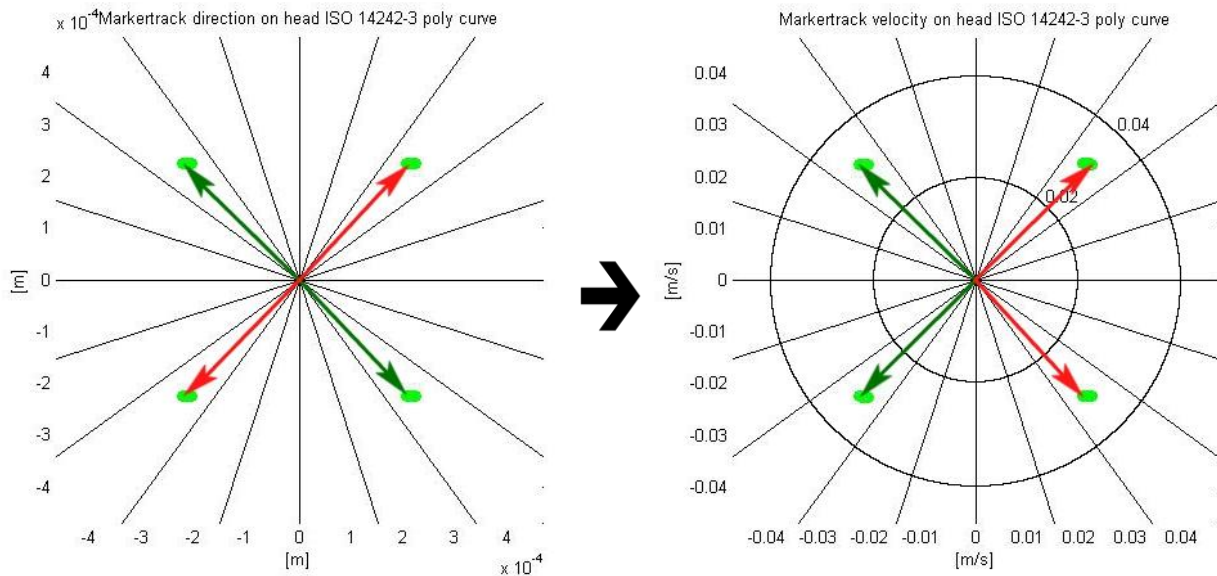


Fig. 5.2.21) Direction (left) and velocity (right) vectors in ISO 14242-3. `vmarkdir` (red) and `truevmarkdir` (green) outputs. Polygonal interpretation. The green marks perfectly overlap the red marks.

5.2.10) The direction rose and all its useful output parameters

```
function [ vmarkdir2d, vmarkdir2dload, pythagoras, nvec, max_numn,
sectorn, mvec, max_numm, sectorm, qvec, max_numq, sectorq,
directiondegn, directiondegm, directiondegq, FMOvec, ORTvec, Wf,
Wo, w, W, Co, k] = DirRose ( kprime, mu, d, a, Xc, gammac, L,
vmarkdir, gaitperc )
```

This function has the following inputs: `kprime`, `mu`, `d`, `a`, `Xc`, `gammac` and `gaitperc` which are parameters set at the beginning of the code (see subchapter 5.2.1, Parameters setting). The remaining inputs are: `L` (the loading law) and `vmarkdir` (which contains the direction rose).

The function, which is the most extensive among all the tailor-made functions part of this project, outputs numerous parameters useful for the assessment of the hip prosthesis performance. Here follows a complete list of the outputs; right after this list will follow one containing only the most important ones.

The outputs are:

- `vmarkdir2d`, which is the direction rose obtained by projecting on the x-y plane the vectors coming from `EmatrixDirections`; the vectors in question were then divided by their modulus, producing a round direction rose (or unit direction rose) made of unit vectors. This new rose loses information concerning the distance run in a specific direction, but is still telling about the direction distribution that occurs in the gait
- `vmarkdir2dload`, derives from the previous output (`vmarkdir2d`). The modulus of the vectors is the load multiplied by the distance run in that specific direction at that specific instant of the gait, in $\text{kN}\cdot\text{mm}$ (that is equal to $\text{Nm}=\text{J}$).

- `pythagoras`, contains all the moduli of the non-normalised vectors contained in `vmarkdir2d` (the direction rose), they were calculated by using the Pythagoras' theorem
- `nvec`, is a row vector containing how much times a direction occurs in a specific sector
- `max_numn`, is the maximum value present in `nvec`
- `sectorn`, is the sector in which the maximum value was found
- `mvec`, is a row vector containing the total distance run in a specific sector
- `max_numm`, is the maximum value present in `mvec`
- `sectorm`, is the sector in which the maximum value was found
- `qvec`, is a row vector containing the frictional work dissipated in a specific sector
- `max_numq`, is the maximum value present in `qvec`
- `sectorq`, is the sector in which the maximum value was found
- `directiondegn`, is the direction (degrees) of `sectorn`
- `directiondegm`, is the direction (degrees) of `sectorm`
- `directiondegq`, is the direction (degrees) of `sectorq`
- `FMOvec`, is the vector indicating the Fibril Main Orientation (FMO) of the UHMWPE
- `ORTvec`, is the vector indicating the orthogonal direction with respect to the fibril main orientation of the UHMWPE
- `Wf`, is the total frictional work dissipated in the fibril main orientation direction
- `Wo`, is the total frictional work dissipated orthogonally to the fibril main orientation direction
- `w`, vector containing the work dissipated on every discretised sliding
- `W`, total work dissipated on one gait
- `Co` coefficient (Eq. 5.1)
- `k`, is the wear factor (Eq. 5.2 and 5.5) [12]

In this long list of parameters some are very important for determining the characteristics of a prosthesis. For this reason, they are put in a table which allows a fast and easy comparison between the different cases. The most important ones can be found in the following list:

- Sector in which much of the work is dissipated (`sectorq`), with corresponding angle of the sector (`directiondegq`)
- Work dissipated both along the fibril main orientation (`Wf`) and the orthogonal orientation (`Wo`); and the total work per cycle (`W`)
- `Co` coefficient (Eq. 5.1)
- `k` factor (Eq. 5.2 and 5.5) [12]

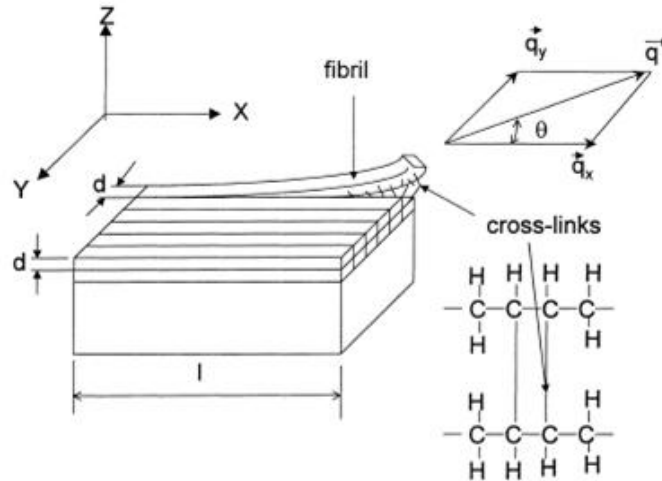


Fig. 5.2.22) Inter-fibril rupture model of an oriented UHMWPE surface by an off-axis force vector $\vec{q}$

In this function most of the final calculations of the whole code are performed.

After projecting the direction rose on the x-y plane (`vmarkdir2dtruelength`), and calculating the length of every single vector (`pythagoras`), the “round rose” is obtained. After this, the vectors of the rose that are located in the 3rd and 4th quadrant are rotated by an angle of π , this because they represent the same stretching direction of the polymer (just performed in the opposite direction). Then, the 1st and 2nd quadrants, which now contain all the vectors, are – on the whole – divided into 8 circle sectors, to be more figurative, a kind of “half cake with 8 slices $\pi/8$ wide”.

By exploiting a simple function called `Counter`, three important calculations can be carried out:

- how much times a direction occurs in every specific sector (row vector `nvec`), the maximum value among the ones that are in all the sectors (`max_numn`), and the sector in which the maximum value was found (`sectorn`), and so, the corresponding angle.
- the total distance run in every specific sector (row vector `mvec`), the maximum value among the ones that are in all the sectors (`max_numm`), the sector in which the maximum value was found (`sectorm`), and so, the corresponding angle.
- the frictional work dissipated in a specific sector (row vector `qvec`), the maximum value among the ones that are in all the sectors (`max_numq`), the sector in which the maximum value was found (`sectorq`), and so, the corresponding angle.

The work per single discretised motion and the total work dissipated in a cycle is calculated right after (`W` in the code).

Another useful parameter is `vmarkdir2dload`. It is necessary to calculate the frictional work rose (*frictional force-distance* vector), and it’s described in the outputs list.

The fibril main orientation (FMO) is the theoretical direction that the UHMWPE fibrils assume when stretched repeatedly in a specific direction [12]; therefore, the fibrils – and so the polymer chains – are stretched along the direction of maximum frictional work, which is the direction subjected to the maximum shear stress.

Subsequently, since the work dissipated in every direction present in the direction rose is known, the work dissipated in the fibril main orientation, and the one dissipated orthogonally with respect to the fibril main orientation, are calculated. Is then possible to calculate the Co coefficient.

$$Co = \frac{W - W_f}{W} = \frac{W_o}{W} \quad (5.1)$$

where W is the total frictional work, W_f is the frictional work dissipated in the FMO direction, and W_o is the frictional work dissipated in the orthogonal direction with respect to the FMO direction.

Finally the wear factor k can be calculated:

$$k = \frac{\Delta V}{PL} \quad (5.2)$$

where ΔV [mm³/cycle] is the volume loss, P [kN] is the normal load, and L [mm] is the sliding distance³ [12].

ΔV is obtained through the equation:

$$\Delta V = k' \frac{\Delta W_o}{(\delta\omega)/(\delta V)} \quad (5.3)$$

where k' is a proportionality constant, ΔW_o [J] is the frictional work released in the orthogonal direction with respect to the fibrils, and $\delta\omega/\delta V$ [J/mm³] is the work required to produce a unit volume of debris.

$\delta\omega/\delta V$ is obtained through the equation:

$$\frac{\delta\omega}{\delta V} = \frac{2dlX_c\gamma_c}{ld^2} = \frac{2dlX_c\gamma_c}{d} \quad (5.4)$$

where d [mm] is the fibril diameter, l [mm] is the fibril length, X_c is the C-C bond density (number of bonds per area), γ_c is the C-C bond energy.

In conclusion, the equation used in the code to calculate k is:

$$k = k' \frac{\Delta W_o}{2X_c\gamma_c/d} \quad (5.5)$$

It's important remembering that some parameters that can be found in the formulae are unknown (k' , γ_c and d have arbitrary set value=1; see subchapter 5.2.1, Parameters setting), for this reason the various values of k in the following chapter are meaningful only when compared one another, and lose their meaning when considered as single values.

As said at the beginning of subchapter 5.2.1, the unknown parameters are intentionally left in the code to allow a possible further development in the future.

³ In the article by A. Wang: P is in N and L in m, hence PL is in Nm. Here P is in kN and L is in mm, so PL is again in Nm

5.2.11) Comments on final plots and tables

These plots are strictly linked to the plots located in subchapters 5.2.8 and 5.2.9. In fact, in those subchapters, all the directions and velocities of the marker tracks generated in the four cases studied are treated in-depth. The plots shown in this subchapter, on the other hand, highlight the directions distribution through unit vectors (blue vectors) and the frictional force distribution (*frictional force-direction* vectors; red vectors).

By analyzing the first two plots (Fig. 5.2.23), treating ISO 14242-1 and ISO 14242-3 with the harmonic motion approach, there is a clear concentration in the directions for what concerns the ISO 14242-1 case (Fig. 5.2.23, left). In this plot the blue marks appear gathering at the top and at the bottom of the plot; this behaviour is due to the predominance of the *fe* movement (the flexion-extension movement) on the *aa* movement (adduction-abduction movement), in fact, vectors directed laterally are very sparse. A fast look at the ISO 14242-3 plot (Fig. 5.2.23, right) shows a high uniformity in the blue vectors distribution, this phenomenon is quite easy to interpret: the high regularity of the motion law generates the circular trajectory, which has direction vectors evenly distributed in space (and time).

The red rose of vectors, finally, furnishes cardinal information on how the frictional work is distributed, and so, on the FMO (fibril main orientation). In Fig. 5.2.23 (left), depicting ISO 14242-1, the two peaks of the loading law are barely visible, but the highest peak is clearly located at about -100° ; this last peak mentioned is decisive in setting the FMO in the 4th sector of the corresponding histogram (Fig. 5.2.27, upper left), in fact the 4th sector represents a theoretical direction of 78.75° that is about 180° away from the peak (about -100°), in fact they lie almost on the same straight line.

The red rose in ISO 14242-3 is much easier to interpret: given the high regularity of the direction distribution, the “friction law” – which would be exactly like the ISO loading law, just scaled by the friction coefficient ($\mu=0.08$) – wraps perfectly around the centre of the plot, generating a kind of loading law polar plot. The two peaks appear now like two “pointed petals”, while the plateau is now turned into a small arch composed of a high density of red marks. The lower right petal generates a little peak at the 6th sector in the corresponding histogram (Fig. 5.2.27, upper right) which would theoretically identify the FMO direction (123.75°), and the V-shaped valley between the two petals generates the minimum, that is located at the 4th sector of the histogram (Fig. 5.2.27, upper right), with a direction of 78.75° .

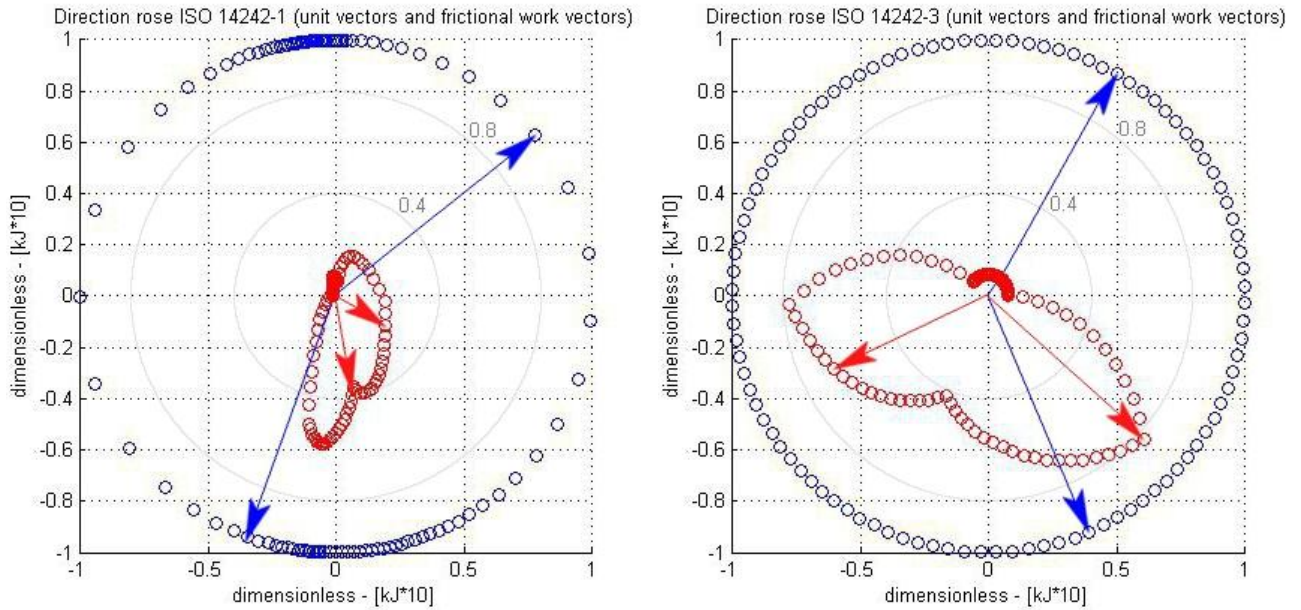


Fig. 5.2.23) Unit vectors (blue) and frictional work vectors (red) in ISO 14242-1 (left) and ISO 14242-3 (right). Harmonic interpretation.

Considering now the two plots referring to ISO 14242-1 and ISO 14242-3 (Fig. 5.2.24) with the polygonal interpretation, the directions shown by the blue unit vectors are only four in both cases. In ISO 14242-1 (Fig. 5.2.24, left) the vectors are pointing mainly “forward and backwards” since the widest movement is *fe*, which is about 3 times wide the *aa* motion. The fact that the *aa* motion changes a little its phase, and because of the presence of the *ier* motion, there is a distortion in the perfect rectangle that some may expect; the quadrilateral shape appears slightly leaning to the right. There is a perfect parallel between this distortion and the one in the elliptical shape of the Fig. 5.2.18. The almost perfect square that the blue vectors generate in ISO 14242-3 (Fig. 5.2.24, right) don’t need extensive explanation: they are the obvious consequence of the regularity of the polygonal motion law of this ISO.

Let’s consider now the red rose of vectors. As for the first two plots of the subchapter, the interpretation of this plot is pivotal to the whole work; this arrangement of red vectors shows how the frictional work is distributed and gives information about the FMO. In ISO 14242-1 (Fig. 5.2.24, left) the two peaks are spread basically on three directions: lower left, lower right, upper right. The corresponding histogram (Fig. 5.2.27, lower left) shows the two peaks placed before and after 90° ; in Tab. 5.2.1 the highest peak is at 101.25° (5th sector), setting here the theoretical FMO.

The last red rose is the one concerning ISO 14242-3 (Fig. 5.2.24, right), which is shaped like a “rotated Greek cross, with a smaller arm”. Here the two peaks can be found on three of the four directions, namely: lower right, lower left, and upper left. The plateau is located on the “smaller arm” of the cross. On the corresponding histogram (Fig. 5.2.27, lower right) the two bars show the 90° angle between the two direction of maximum frictional work; these are located at the 3rd and 6th sector. Here no clear FMO can be found, since the frictional work is almost equally distributed on these two directions 90° apart (123.75° and 56.25°).

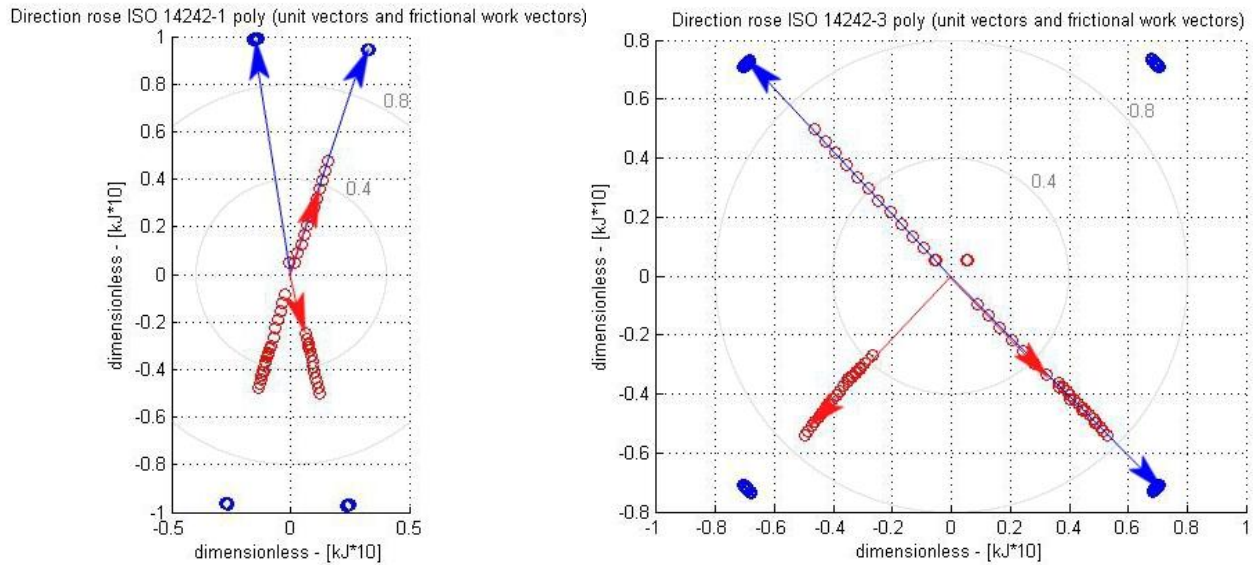


Fig. 5.2.24) Unit vectors (blue) and frictional work vectors (red) in ISO 14242-1 (left) and ISO 14242-3 (right). Polygonal interpretation.

The following table (Tab. 5.2.1) contains all the important data for the wear assessment of a hip prosthesis that undergoes wear testing. It's immediately clear from the table and from the plots (Fig. 5.2.25, 5.2.26 and 5.2.27) that an evident and consistent peak appears only in case ISO 14242-1 is adopted for the motion law: when the harmonic motion is used, this peak is a “real/continuous peak”, since it's preceded and followed by lower values that gradually increase and decrease respectively (Fig. 5.2.25, 5.2.26 and 5.2.27, upper left). On the other hand, when the motion law is generated by a polygonal curve (“poly” in the plot), the peaks are in fact single columns towering in the histogram, and are surrounded by blank spaces (Fig. 5.2.25, 5.2.26 and 5.2.27, lower left); this is due to the fact that with the polygonal curves the plots appear like discretised, due to the monotonic (and even monotonous to a certain extent!) shape of the segments of the broken lines. The most important histogram, in the light of the fact that represents the frictional work distribution in case of ISO 14242-1 harmonic motion (the one with 3 dof which is closer to the real life case), is the upper left one in Fig. 5.2.27: it shows a clear maximum of the peak occurring in the 4th sector (sectorq of ISO1 in the table) that corresponds to an angle of about 79° (directiondegq of ISO1 in the table). A more accurate evaluation could place the peak between the 4th and the 5th sector.

	sectorn	sectorm	sectorq	directiondegn	directiondegm	directiondegq
ISO1	5	5	4	101.2500	101.2500	78.7500
ISO3	3	3	6	56.2500	56.2500	123.7500
ISO1poly	5	5	5	101.2500	101.2500	101.2500
ISO3poly	3	3	6	56.2500	56.2500	123.7500

	Wf [J]	Wo [J]	Co	k	Wcycle [J]
ISO1	0.0019	3.6926e-04	0.1627	26.0299	0.0023
ISO3	0.0020	0.0018	0.4703	75.2485	0.0037
ISO1poly	0.0021	2.4023e-04	0.1028	16.4476	0.0023
ISO3poly	0.0019	0.0015	0.4433	70.9266	0.0034

Tab. 5.2.1) Table containing: *sectorn* (sector in which the maximum quantity of discretised sliding directions occur), *sectorm* (sector in which the maximum distance is run), *sectorq* (sector in which the maximum frictional work is dissipated), *directiondegn* (is the direction (degrees) of *sectorn*), *directiondegm* (is the direction (degrees) of *sectorm*), *directiondegq* (is the direction (degrees) of *sectorq*), *Wf* [J] (is the total frictional work dissipated in the fibril main orientation direction), *Wo* [J] (is the total frictional work dissipated orthogonally to the fibril main orientation direction), *Co* (see Eq. 5.1), *k* (is the wear factor; see Eq. 5.2 and 5.5), *Wcycle* [j] (is the total work dissipated on one gait, $Wf+Wo=Wcycle$).

The histograms located at the lower and upper right of Fig. 5.2.25, 5.2.26 and 5.2.27, represent ISO 14242-3 interpreted through both harmonic curves (upper right) and polygonal curves (lower right), due to their intrinsic nature they cannot give as interesting information as the plots referring to ISO 14242-1. In fact no precise and consistent peak is present; this because ISO 14242-3 was conceived for testing on a biaxial rocking motion testing machine (BRM machine): this machine spreads almost uniformly the frictional work in case of harmonic interpretation, while returns two “tiny bumps” (90° apart) in case of polygonal curves interpretation. For this reason the orientation of the fibres is fictitious according to the model output, and on a real test would probably appear unclear. The only useful conclusion that can be drawn is that the friction work is almost uniformly distributed (harmonic case) or sharply concentrated in directions that are oriented with an angle of 90° one another (polygonal case).

For what concerns the *Co* coefficient it's easy to note that in the two cases of ISO3 the values are close to 50% (0.4703 and 0.4433, in Tab. 5.2.1) given the nature of the motion (uniformity of the distribution of the frictional work). On the other hand the two cases of ISO1 present a minor fraction of frictional work orthogonal to the FMO direction (0.1627 and 0.1028 respectively, see Tab. 5.2.1). Under these circumstances the cross shear effect is less strong than the two precedent cases of ISO 3, so for the prosthesis a longer life is predicted.

When considered, *k* (the wear factor) returns the same response: higher values for ISO 3, and much lower values for ISO 1 (75.2485 and 70.9266 compared to 26.0299 and 16.4476, see Tab. 5.2.1).

As last the work-per-cycle shall be considered: as expected, again, ISO 3 produces 0.0037 J/cycle and 0.0034 J/cycle while ISO 1 generates 0.0023 J/cycle in both cases.

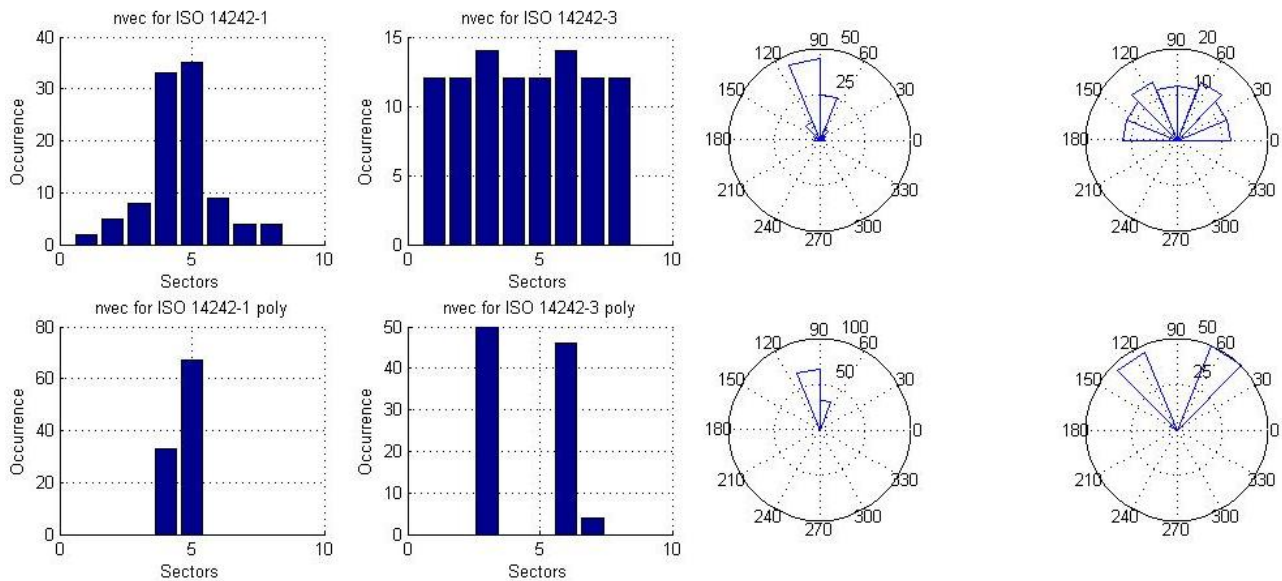


Fig. 5.2.25) Traditional histograms and polar histograms, showing the distribution of discretised sliding directions in the following cases: ISO 14242-1 with harmonic interpretation (upper left), ISO 14242-3 with harmonic interpretation (upper right), ISO 14242-1 with polygonal interpretation (lower left), and ISO 14242-3 with polygonal interpretation (lower right). NOTE: in the traditional histograms the sectors are put in order from the first (1st column) to the last (8th column), while in the polar histograms the sectors are reversed since they follow the convention of the *unit circle*, with an array of angles spanning from 0° to 180°: the first sector is lying on the right and hinged to the centre, and the last sector (8th sector) is lying on the left and hinged to the centre.

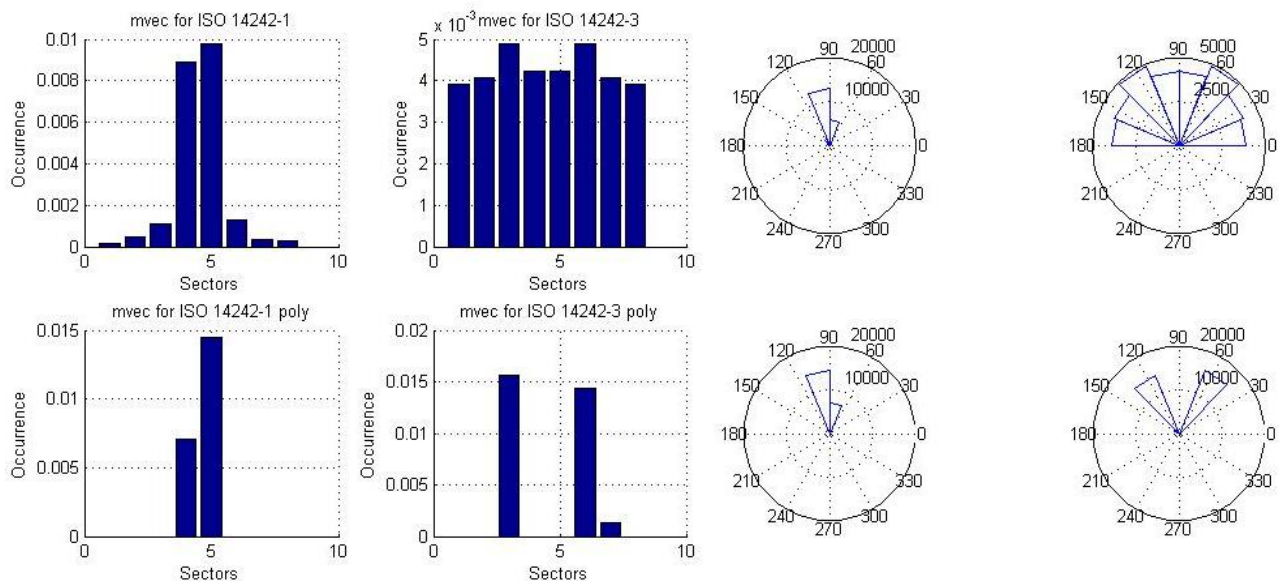


Fig. 5.2.26) Traditional histograms and polar histograms, showing the distribution of distance run in the following cases: ISO 14242-1 with harmonic interpretation (upper left), ISO 14242-3 with harmonic interpretation (upper right), ISO 14242-1 with polygonal interpretation (lower left), and ISO 14242-3 with polygonal interpretation (lower right). NOTE: see note of Fig. 5.2.25.

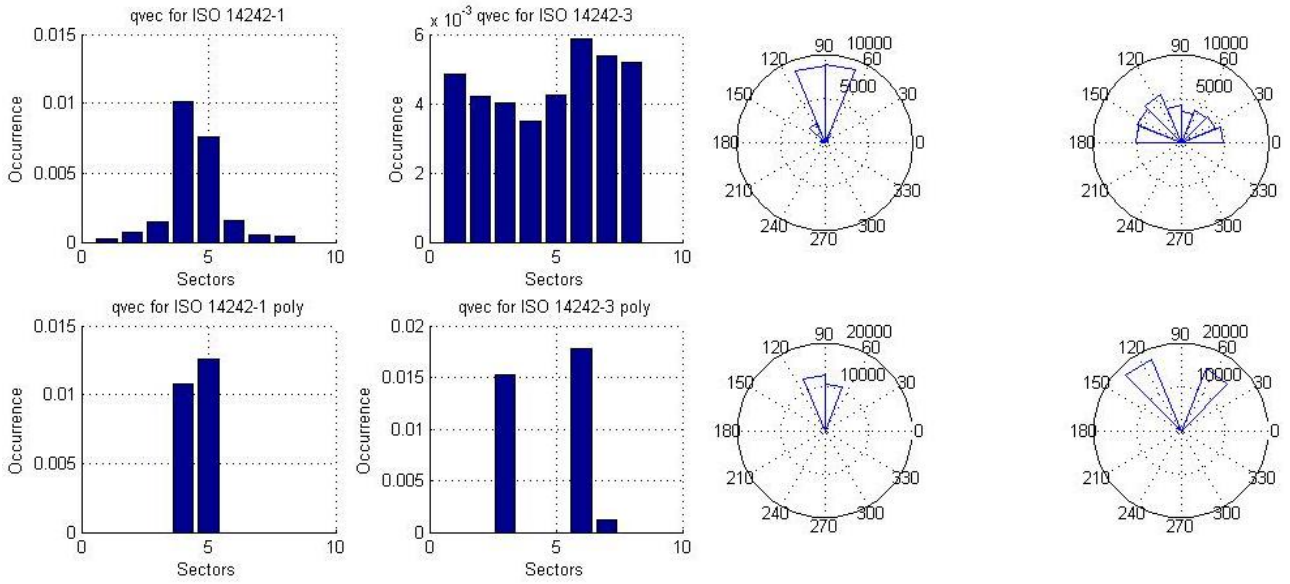


Fig. 5.2.27) Traditional histograms and polar histograms, showing the distribution of frictional work dissipated in the following cases: ISO 14242-1 with harmonic interpretation (upper left), ISO 14242-3 with harmonic interpretation (upper right), ISO 14242-1 with polygonal interpretation (lower left), and ISO 14242-3 with polygonal interpretation (lower right). NOTE: see note of Fig. 5.2.25.

5.2.12) Jarque-Bera test on *nvec* data set

Since all the histograms (traditional and circular) are obtained by a circular distribution of slide trajectories/path run/energy dissipated on a range 2π wide; and because this distribution derives from a well known motion law and loading law, a traditional statistical analysis can not be performed. Anyway, since the direction distribution of the ISO 14242 – 1 motion law (the one interpreted as a harmonic motion) may resemble a Gaussian curve in the vicinity of the central peak, it may be curious and interesting analysing the data as if it was obtained by a phenomenon of which little is known.

By using the Matlab function `atan2` it was possible to obtain all the angular values (expressed in radians) of the directions that occur during the path. Then, since the direction distribution appears like “mirrored” by a point symmetry, showing these two kinds of Gaussian curves, the plot present in the 3rd and 4th quadrant was rotated by an angle of π to “coincide” with the upper “Gaussian”. This rotation was performed thanks to the function `pi_rotation` which was tailor-made for the purpose.

To get to know the characteristics of the distribution, the Jarque-Bera test was used. This test calculates *skewness* and *kurtosis* and checks how well they fit a normal distribution. In Matlab can be found a function that performs the Jarque-Bera test, and, given as input the vector containing the values that generate the distribution, it outputs 1 in case the null hypothesis at the 5% significance level is rejected, on the contrary, the function output is 0. The second output is the percentage (p-value) that has to be compared to the 5% significance level (if this percentage is less than 95% the test is negative, if it exceeds 95% the test is positive).

The first two columns of Tab. 5.2.1 bear the two outputs of the Matlab function that performs the Jarque-Bera test (`jbtest`); furthermore four other parameters were explicitly calculated and put in the table (Tab. 5.2.1), these parameters are: mean and standard deviation, which give the possibility of drawing the hypothetical normal distribution, and skewness and kurtosis, which are implicitly used by the `jbtest` function, which give information about the symmetry and shape of the tails of the distribution.

	I-O <code>jbtest</code>	probability <code>jbtest</code>	mean [rad]	standad deviation	skewness	kurtosis
values	1	0.0056	1.6256	0.5030	-0.3683	4.8269

Tab. 5.2.1) Table containing: I-O `jbtest` (output of a Jarque-Bera test of the null hypothesis that the sample in question comes from a normal distribution with unknown mean and variance), probability `jbtest` (*p-value* of the null hypothesis of the Jarque-Bera test), mean [rad] (estimated mean value in radians), standard deviation (estimated standard deviation of the distribution), skewness (estimated skewness of the distribution), kurtosis (estimated kurtosis of the distribution).

To furnish further evidence to the fact that the distribution fits quite bad the normal distribution, the corresponding Gaussian was drawn by using the tool `dfittool` in Matlab. The result is shown in Fig. 5.2.28 where is clear that the corresponding Gaussian built with the mean and the standard deviation deriving from the data fits the data distribution quite poorly.

The output 1 indicates that the Jarque-Bera test rejects the null hypothesis at the 5% significance level; in fact the second output returns a *p-value* equal to 0.0056 (that is far minor than 0.95). In other words, the data fail the test.

The value of the mean is 1,6256 rad, and the theoretical standard deviation is 0.5030 rad. The skewness is -0.3683, which indicates that there is an asymmetry in the probability distribution, and this asymmetry consists of “fatter” or “longer tails” to the left of the mean; the skewness in a normal distribution is zero (symmetrical distribution). Kurtosis in the distribution is equal to 4.8269 and represents the “fat tails” case (also called *leptokurtic distribution*). The kurtosis of reference is the one calculated from the normal distribution, the kurtosis in this case is 3; for this reason is common to find the parameter *excess of kurtosis*, in our distribution the excess of kurtosis is $4.8269-3=1.8269$, which makes the distribution undoubtedly not a normal distribution.

Here follow the probability density function (PDF) plot (Fig. 5.2.28) and the cumulative distribution function (CDF) plot (Fig. 5.2.29).

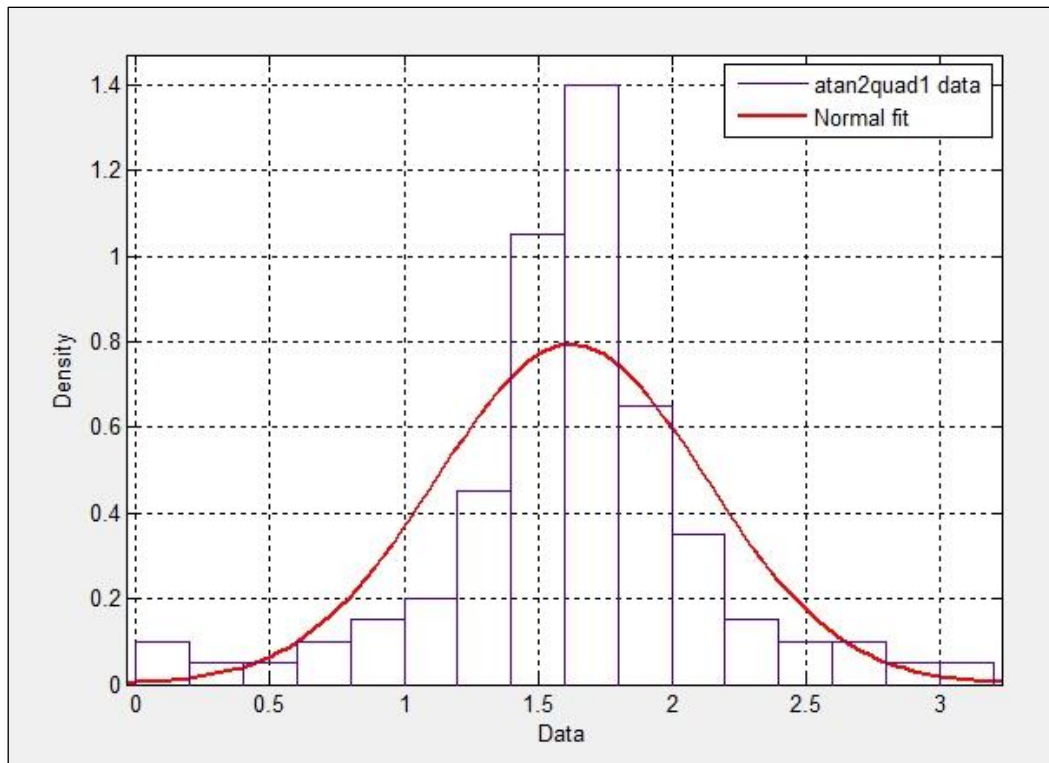


Fig. 5.2.28) Probability density function (PDF) of the data `atan2quad1`, with the associated normal distribution fit.

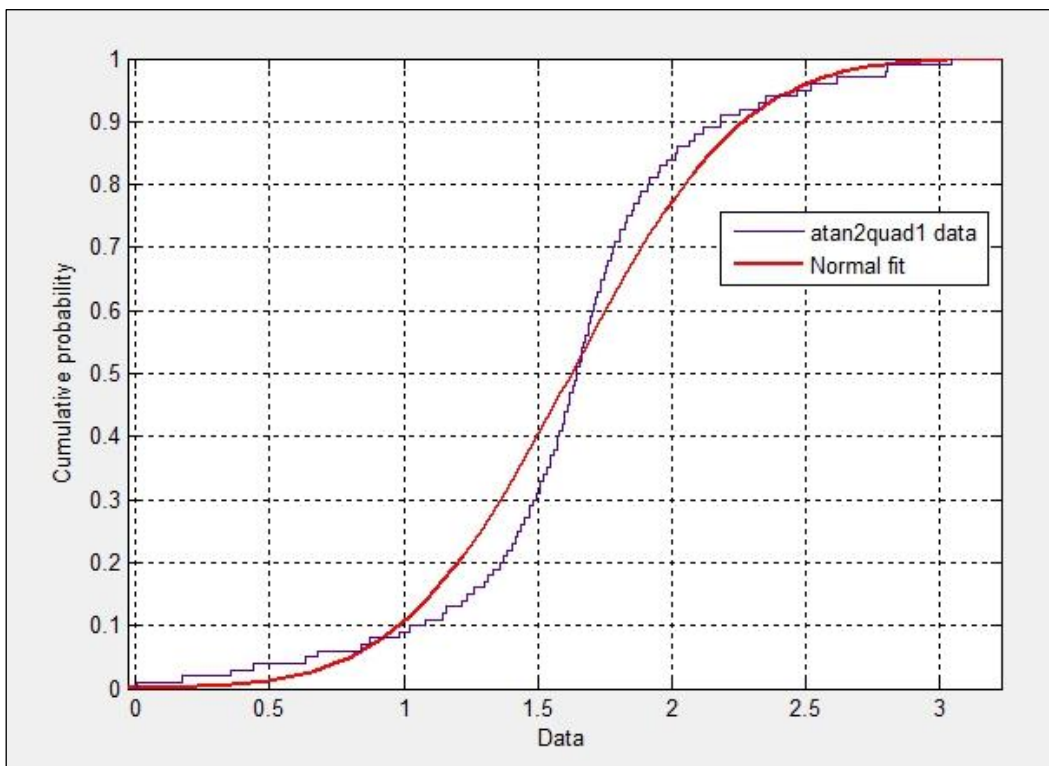


Fig. 5.2.28) Cumulative density function (CDF) of the data `atan2quad1`, with the associated normal distribution fit.

Chapter 6

Prototypes for hip prostheses tests

6.1) Introduction

In this chapter some machines that can address the specifics of ISO 14242 are proposed along with a detailed description of their capabilities, strong points and weak points. The prototypes' design was stopped at an early stage, no precise information is given about dimensions, mechanical resistance, fatigue resistance, etc. The prototypes can only give an idea of the space taken up by the machine, its proportions, the degrees of freedom and range of motion of all the parts.

6.2) Machine requirements according to ISO 14242

ISO 14242 prescribes the details of motion, force, cycle frequency and serum temperature; in addition, every physical magnitude bears its degree of uncertainty. Here follow maximum amplitudes and values of all the parameters that characterise the machine.

- Flexion/Extension: $+25^{\circ}/-18^{\circ} \pm 3^{\circ}$ (1% for phasing)
- Adduction/Abduction: $+7^{\circ}/-4^{\circ} \pm 3^{\circ}$ (1% for phasing)
- Internal/external rotation: $+2^{\circ}/-10^{\circ} \pm 3^{\circ}$ (1% for phasing)
- Force system: $3 \text{ kN} \pm 3\%$ (1% for phasing)
- Cycle frequency: $1 \text{ Hz} \pm 0,1 \text{ Hz}$
- Serum temperature: $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- Acetabular component: angles as specified by the manufacturer

6.3) Key points to address for a good machine design

- Proper angles width per degree of freedom
- Highest overall stiffness possible

Possibly at least one order of magnitude more than the prosthesis' stiffness; this to permit a sharp measurement of the prosthesis' stiffness.

- Particular attention to bearings choice and coupling

Especially for combined loads: radial-axial loads. Even here the maximum stiffness is desirable.

- Possibility to reach a relatively high frequency to accelerate the simulation

It has to be said that the ISO prescribes 1 Hz. Anyway if one would like to increase the test speed or simulate running conditions, 2 Hz maybe a good choice. Attention has to be paid in these cases, because of higher dynamic forces, different friction and temperature conditions, etc.

- Safety switches to prevent impingement and wirings tearing-off

Because of the periodic motion, the electric motor, must move the mechanical parts within a precise range of motion. Exiting these boundaries could cause impingement with severe damage to the whole structure, including the prosthesis and the electric motors.

- Room to place the plastic bag for the serum

There must be enough room for the serum bag, its installation and removal, and it must not interfere with the whole system during the machine operation.

- Cup-hosting bowl features

To hold the cup in place properly and to make the cup extraction easy, the bowl needs some peculiar characteristics: internal surface smoothness and crossing grooves, uniform cement thickness, extracting anchors, proper greasing.

6.4) Cup-hosting bowl

This component is common to all the prototypes and its function is to hold the cup and the liner in place with the proper orientation, and allow the load to be applied to the prosthesis.

It is composed of two main components: the bowl in which the metal cup is cemented, and the stem that allows the loading machine to be connected to the bowl.

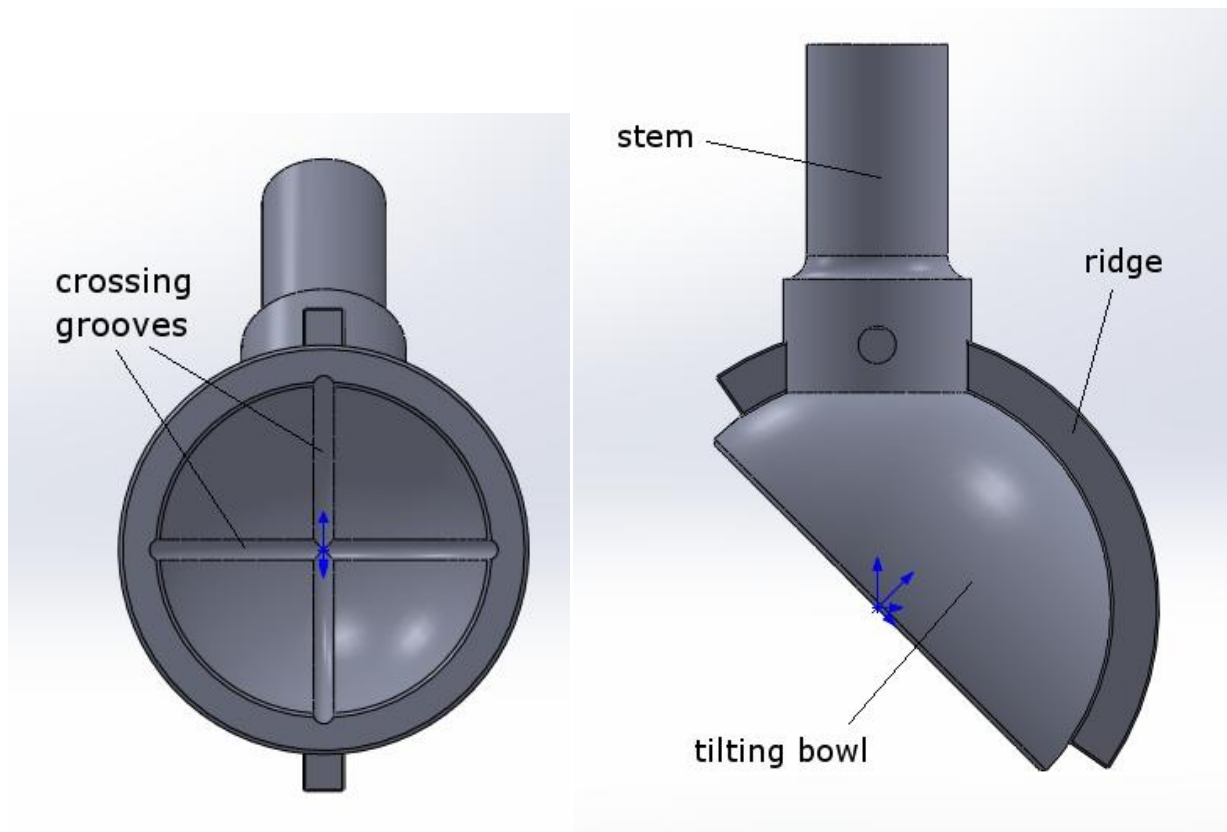


Fig. 6.1) Cup-hosting bowl

The bowl has a ridge on the outside that works like a rail which slides in the stem slot, this to make the bowl rock on the stem and to give the possibility to hold it on a specific tilt. In fact the acetabular cup is installed on patients with different orientations according to the patient's condition and the evaluations made by the surgeon.

The cups' general geometry is hemispherical, and hemispherical is the hollow in the bowl. This condition generates a layer of cement with constant thickness between cup and bowl; this is meant to keep properties as isotropic as possible. Furthermore, the diameter of the hemispherical hollow is large enough (diameter: 80 mm) to host substantially all the cups that are on the market today (LINK[®] company provides the biggest cups on the market, with a nominal diameter of 68 mm and an external rim of 71 mm (LINK catalogue: Acetabular Cup Systems, 2012); the smallest cups are produced by Smith and nephews[®], and have an external diameter of 40 mm (Smith and nephews catalogue: Reflection – Surgical Technique, 2006).



Fig. 6.2) Cup-hosting bowl. Exploded view.

The inner surface is smooth, with crossing grooves that prevent the cement from sliding and help to centre the cement back in place when removed. The anchors lock the cement in place and help during the phase of extraction of the cement block. Greasing the inner surface of the bowl can make the extraction phase easier; furthermore, if the bowl is provided with little through holes it can help extracting the solid block of cement by blowing air into them or by using ejector pins. Even leaving the bowl in hot water and using a rubber mallet could be a solution.

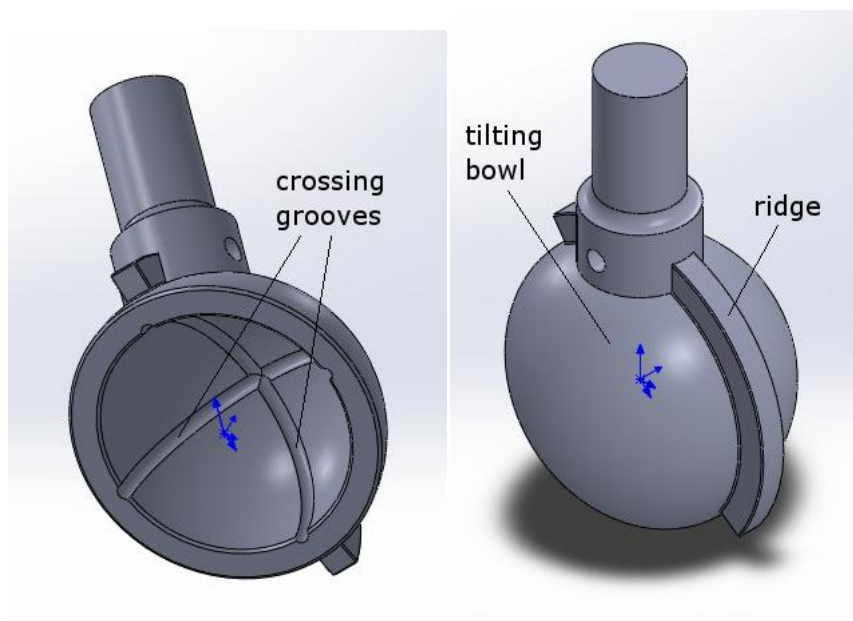


Fig. 6.3) Cup-hosting bowl. Details on crossing grooves and ridge.

Since the natural abduction angle of acetabular cup should be about 60° , but this wide angle would even easily cause dislocation of the femoral head, an angle of 40° is recommended to prevent dislocation⁴.

⁴ Smith and nephew catalogue: Reflection – Surgical Technique, 2006

To guarantee a good centering and a constant cement thickness, the acetabular cup could be centred by using a tool or frame; four marks on the acetabular cup and four on the bowl could permit the collimation of the reference lines. The frame would even prevent the cup from floating for the Archimedes' principle while the cement is hardening.

6.5) 1st prototype with traditional bearings - 1 degree of freedom

This machine is basically composed of a rocking component, which simulates the flexion-extension movement of the leg, and its pillars, with which is connected through roll bearings. The rocking component has the shape of a half-moon, and at the middle of the half-moon there is a rod (or a bolt, according to the head height-regulating system) protruding, which permits to fasten the femoral head component. The rolling bodies of the roll bearings are cylindrical, because they need to bear heavy loads and they must be as stiff as possible; moreover they are not subjected to axial loads.

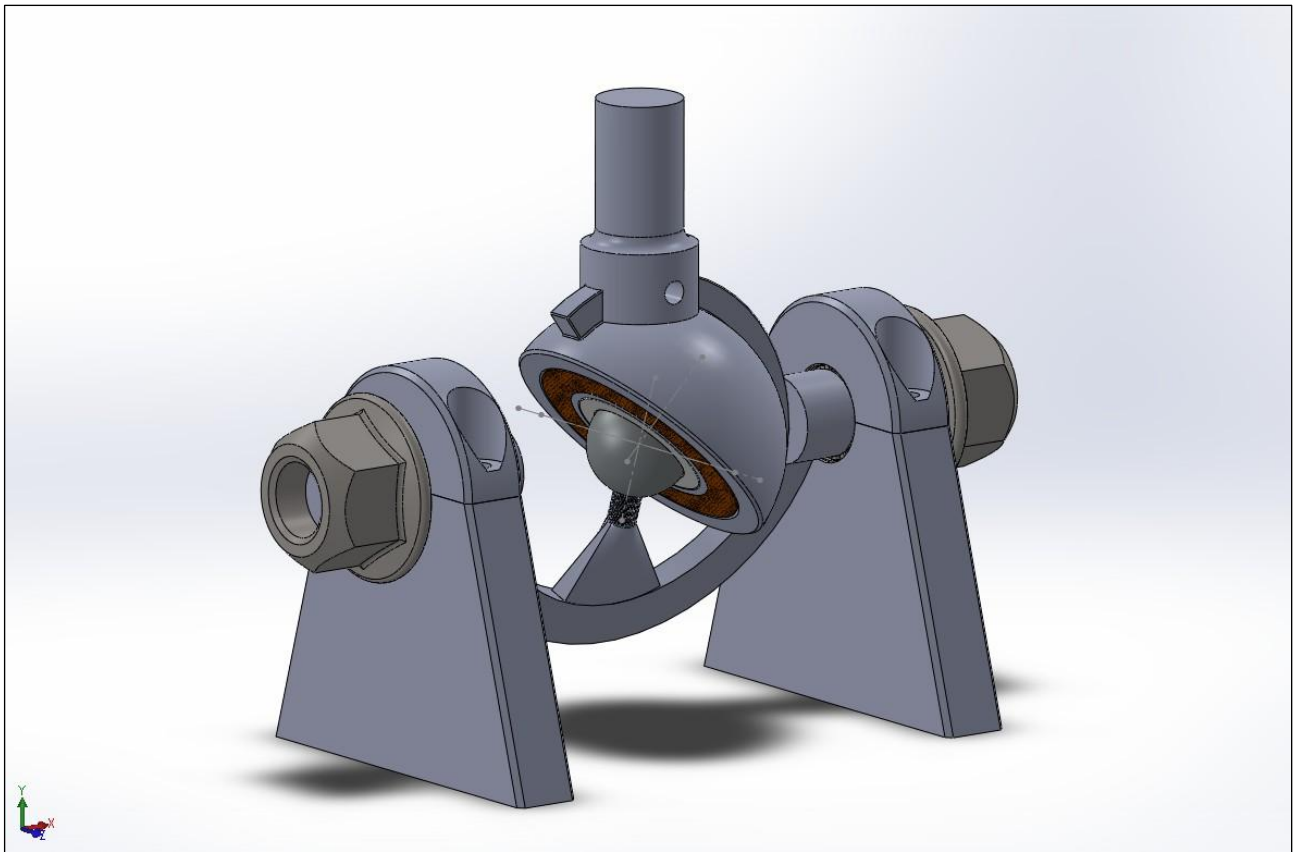


Fig. 6.4) 1st prototype with traditional bearings - 1 degree of freedom.

Strong points

- Easy design
- Very good stiffness
- Cheap

- Easily servo-controlled

Weak points

- Non realistic behavior
- No cross-shear effect (lesser debris production than expected)
- Doesn't match the ISO requirements

6.6) 2nd prototype with traditional bearings - 2 degrees of freedom

The second prototype is an implementation of the first proposed. In this case the inner rocking component, that is identical to the previous one and simulates the flexion-extension movement, is connected to a rocking ring. The rocking ring can oscillate around an axis orthogonal to the axis of the inner component, and, in this case, simulates the adduction-abduction movement. The outer ring is hinged to the two pillars on the two sides. This setting generates a kind of two-axis gimbal set.

In this case the roll bearings of the outer rocking component have cylindrical rolling bodies, since they are not subjected to axial loads, while the roll bearings of the inner rocking component are subjected to both radial and axial loads, and so there must be roll bearings that bear these kind of loads. For example radial and axial roll bearings (simple and strong solution; recommended), or roll bearings that can sustain both radial and axial loads, like tapered roller thrust bearings (another good solution).

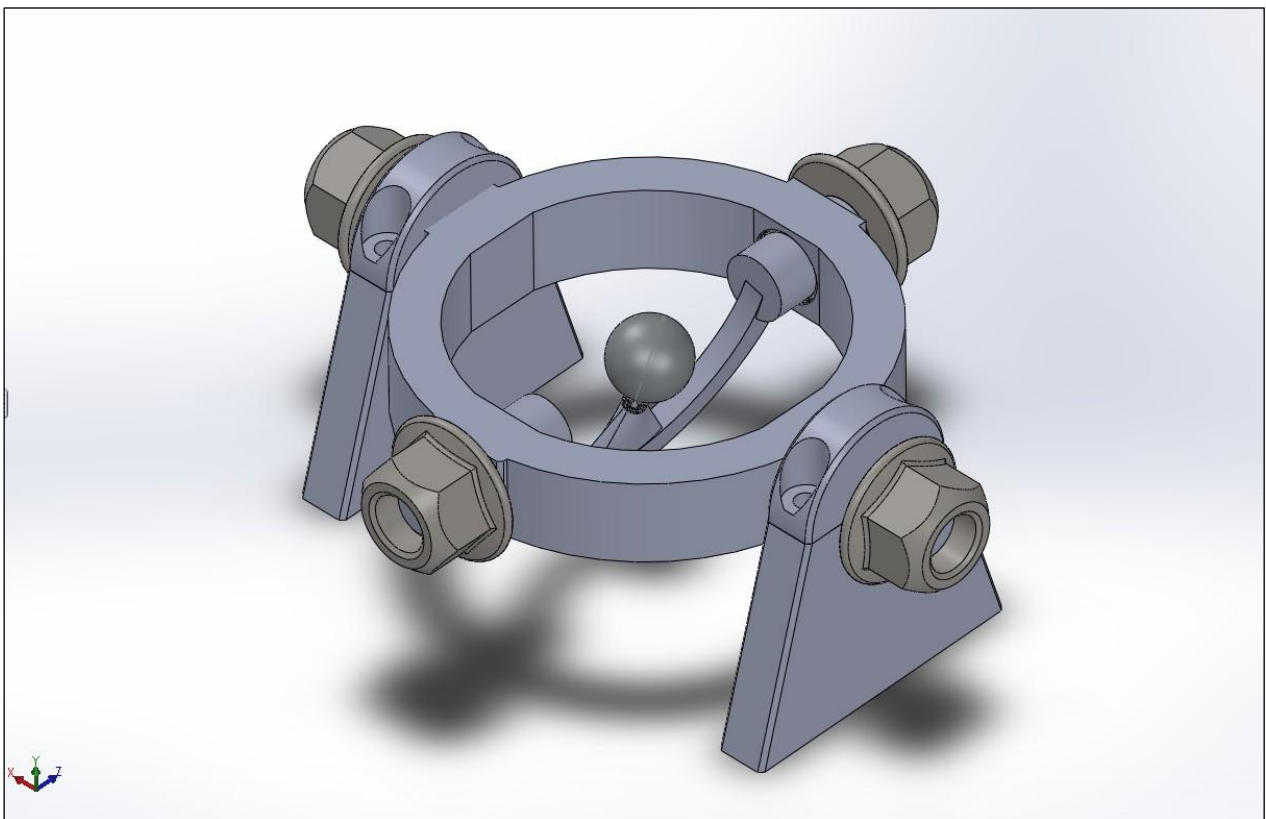


Fig. 6.5) 2nd prototype with traditional bearings - 2 degrees of freedom.

Strong points

- Matches the ISO 14242-3 requirements (quasi-realistic behavior)
- Good stiffness
- Easily servo-controlled

Weak points

- Non fully realistic behavior (can't reproduce ISO 14242-1 conditions)
- Middle-expensive (motors, bearings, machining,...)
- Manufacturing and keeping tight tolerances complicated (many reorientation required)

6.7) 3rd prototype with traditional bearings - 3 degrees of freedom

The third and last prototype of this series has an additional degree of freedom. Is composed of the same two rocking components present in the previous prototype, and so, the considerations made before are still valid and some have to be added. The rocking ring is hinged on a fork that can rotate on its vertical axis which completes a three-axis gimbal set. Now the system has three degrees of freedom and the third degree of freedom simulates the internal-external rotation. The fork has a hinge at its base which generates a vertical-axis hinge joint; here a tapered roller thrust bearing is needed, possibly wide, to distribute the load on a broad surface and make the system stable. The peculiar geometry of the tapered rolling bodies is accurately calculated to allow the roller bodies to roll smoothly on the grooves of the rings without unwanted sliding; cylindrical geometry or miscalculation of the taper would make the bearings work with more friction and more heating, accelerating the wearing process.

One last thing has to be said regarding the outer fork: the internal-external rotation movement that it performs is not the correct one, since the rotation order is $fe \rightarrow aa \rightarrow ier$, and so, the ier is performed on the fixed reference frame rather than the moving reference frame.

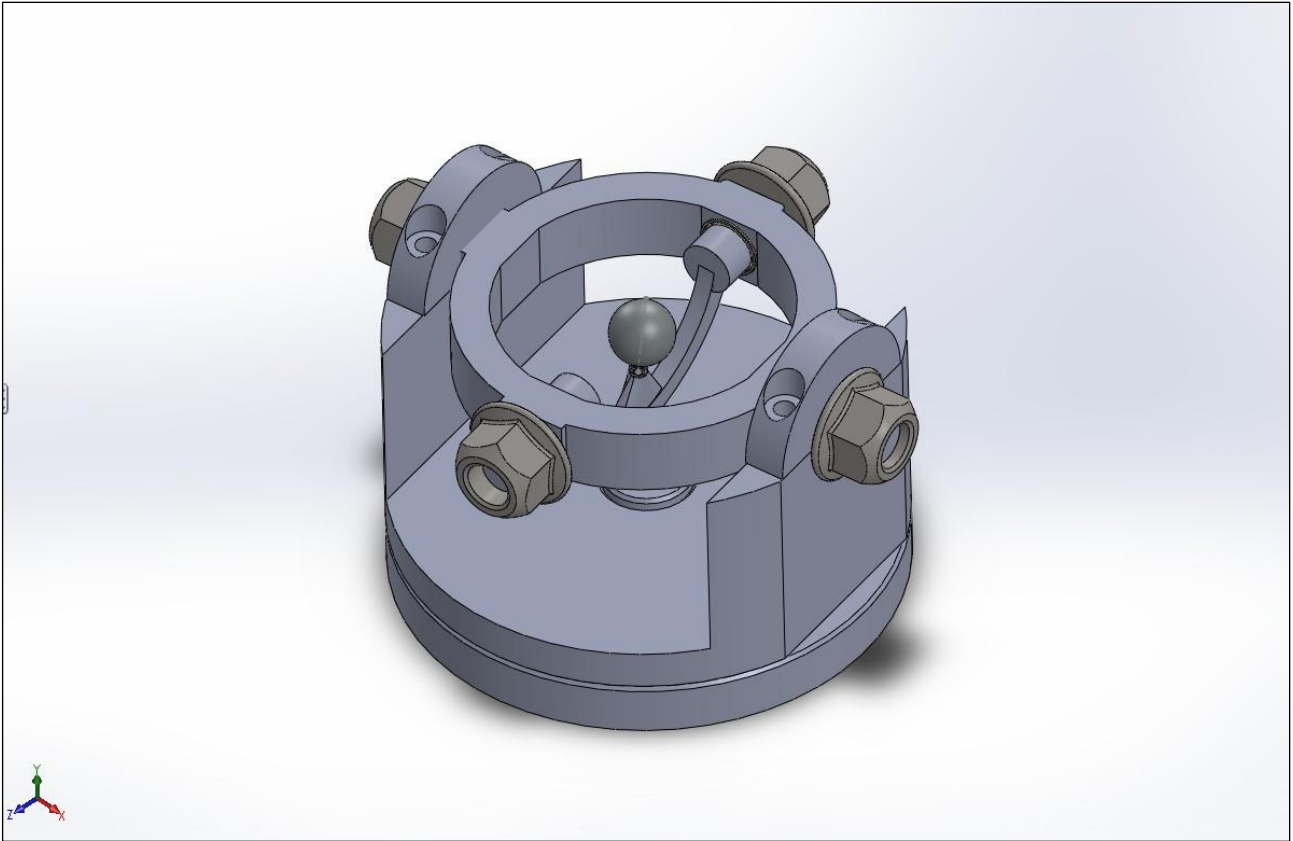


Fig. 6.6) 3rd prototype with traditional bearings - 3 degrees of freedom.

Strong points

- Realistic behavior (matches both ISO 14242-1 and ISO 14242-3⁵)
- Good stiffness
- Easily servo-controlled

Weak points

- Expensive
- Complicated
- Manufacturing and keeping tight tolerances complicated (many reorientations required)

6.8) Prototype with ball joint and Cardan joints

This prototype was conceived starting from the idea that the femoral head should have been placed on a big ball joint (Fig. 6.7) that would have permitted to distribute the load on a very wide surface, giving the structure an extraordinary stiffness and allowing it to move freely on its three axes of rotation. The highest stiffness possible is important because it would give the possibility to observe the change in stiffness and dimension of the prosthesis *in itinere*, while the machine is operating. In fact the stem of the loading machine, which transmits the load to the prosthesis, is provided with a gauge displacement transducer that can check the variations in height.

• ⁵ The vertical axis (int/ext rotation), is related to the fixed frame of reference and not to the moving frame of reference, as it should be.

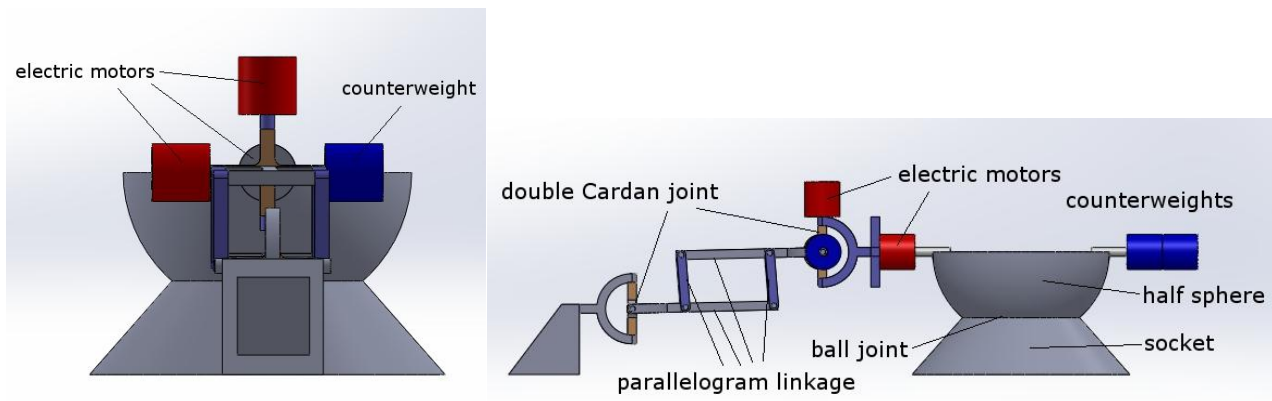


Fig. 6.7) Prototype with ball joint and Cardan joints. Side view (left) and front view (right).

The critical point of the machine now is moving the ball joint accurately, reproducing the motion law with the correct order of the angular displacements ($fe \rightarrow aa \rightarrow ier$) given by the rotation matrix. Solving the problem of moving the ball joint through actuators and linkages is complex and can lead to a large variety of solutions. Since every actuator is necessarily connected through a linkage both to the moving body and the static framework of the structure (i.e. the base of the machine), every movement can interfere with the motion commanded to the other actuators, making the control of the actuators complex with risks of singular configuration, collisions and damage. In fact the actuators have to impose a certain motion law, and, at the same time, must not interfere with the motion imposed by the other actuators.

For this reason here is proposed a motorised linkage (Fig. 6.10) that allows every single actuator to control a single degree of freedom of the system; moreover the actuators are moving together with the moving reference frame and so there is a linear relationship between the input of the actuator and its output (simple application of the rotation matrix: inputs are proportional to the angles of the motion law).

To reach the goal of keeping the actuators moving with the moving reference frame, and, at the same time, being somehow connected to the fixed framework, the design concept started from the idea of making use of the double Cardan joint (Fig. 6.8 and 6.9). Doing so, it is possible to transfer a torque to the system, even if the system would be changing orientation. Yet a problem remains: how can the double Cardan joint fully adapt to the movements of the ball joint? It should be able to elongate the middle shaft (using a prismatic joint). For this reason, since the extent of the elongation would not be conspicuous, the middle shaft is replaced by a parallelagram linkage (Fig. 6.8); the shaft can now perform little elongations and is still capable of transmitting torque between the two Cardan joints.

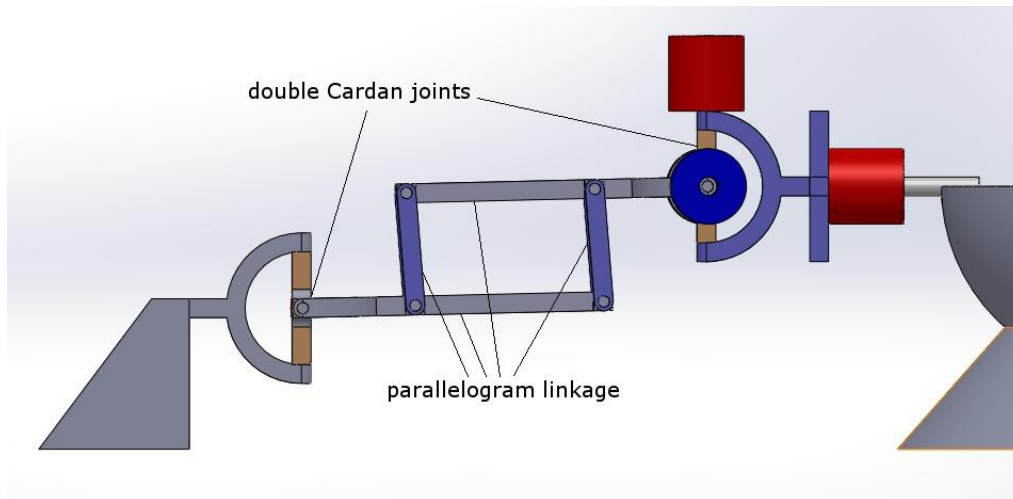


Fig. 6.8) Detail on double Cardan joint. Front view. Detail on parallelogram linkage.

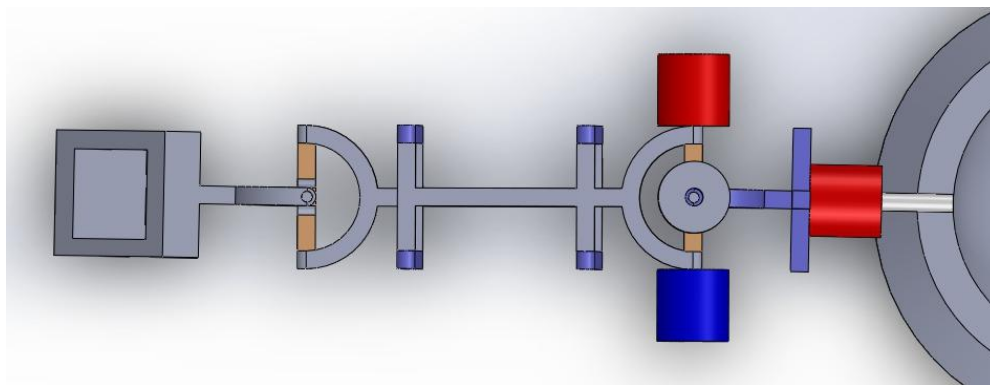


Fig. 6.9) Detail on double Cardan joint. Top view.

The three actuators (electric motors in this case, Fig. 6.10) are placed on the Cardan joint which is closer to the ball joint and they are represented by a red cylinder. The blue cylinders are counterweights (Fig. 6.10) and their aim is to balance the system, keeping the centre of gravity as close as possible to the centre of rotation of the ball joint.

A delicate problem that has to be addressed is the geometric tolerancing and surface finishing, since the ball joint needs to have a good match between the sliding bowl and its support to allow the joint to work smoothly, without affecting the testing session accuracy.

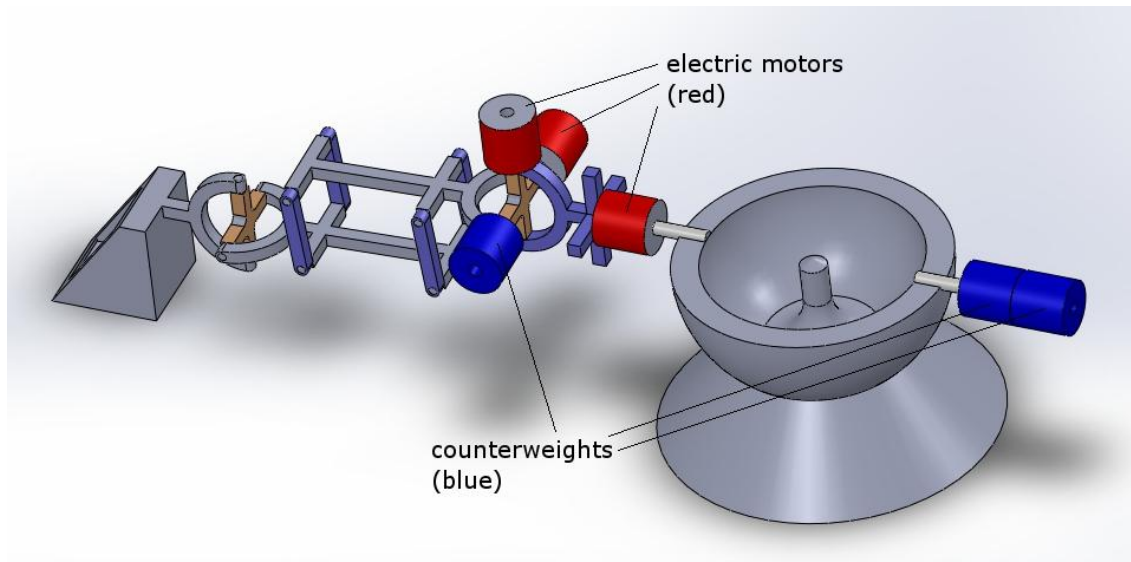


Fig. 6.10) Prototype with ball joint and Cardan joints. θ_e , α_a , θ_{ier} angles set to zero. Details on electric motors (red) and counterweights (blue).

Another problem is linked to the ball joint lubrication, here is proposed a simple solution that may be improved in the future. The base of the joint, where the socket is located, has a channel drilled on its axis; this channel (Fig. 6.11) is meant to take the pressurised lubricant (pump needed) to the bottom of the sphere, where it will spread thanks to the relative sliding motion of the two surfaces. The aim of this solution is not to produce the hydrostatic lubrication conditions, but to simply furnishing the joint interface with lubricant to keep it always in a good lubrication condition.

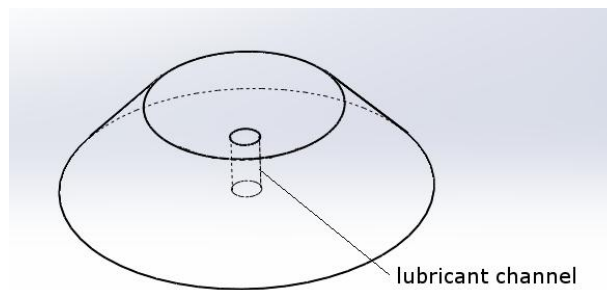


Fig. 6.11) Prototype with ball joint and Cardan joints. The base. Detail on lubricant channel.

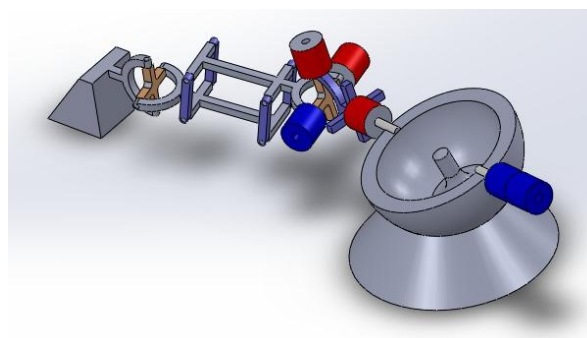


Fig. 6.12) Prototype with ball joint and Cardan joints. θ_e , α_a , θ_{ier} angles different than zero.

Strong points

- Extraordinary stiffness
- Extraordinary realistic behavior thanks to precise angles control (matches both ISO 14242-1 and ISO 14242-3)
- No complicated and expensive bearings combination
- Easier to control
- Bowl machined completely on the turning machine without changing position (reached very high accuracy)

Weak points

- Tight tolerances on the ball joint (spherical surfaces matching)
- Dynamic study on extendible Cardan joints system
- Non-traditional design

6.9) Wear test machine prototypes comparison and comments

The machines are put in order of complexity and potential of performance. In particular in the first three series there is an increment for what concerns the degrees of freedom and the capability to make the motion as realistic as possible. Unfortunately this leads to an increment in the complexity of the machine, making it more expensive, more fragile and less stiff; furthermore the machine becomes even more expensive. One big problem is that in the third machine the rotation around the vertical axis doesn't reproduce exactly the internal-external rotation motion as widely explained in the chapter dedicated to this machine. For this reason the third model is the least desirable, it's the most complex and expensive, the less stiff and doesn't reproduce the motion it is supposed to.

For this reason the best of the first three is the second one, since it's relatively simple and able to fully abide by the specifications of ISO 14242-3. Then a good option may be the first model since it's the simplest and less expensive, it's able to simulate the flexion-extension motion of the gait for simple tests; the problem is that it's not able to fulfil the requirements of any ISO. Then, least, comes the third model.

The fourth and last model stands in a separate category since the design is not comparable to the three which precede it; the bearings are substituted by a big ball joint and the actuators are located on a double Cardan joint modified with a parallelogram linkage in the middle. This model requires a more accurate design and tolerancing, but with an adequate funding can produce performances that are much better than the other models, making this machine the most suitable for a reliable testing and accurate measurements (even during the machine operation).

Chapter 7

Conclusions

Mathematical model

The chapter concerning the mathematical model gave interesting information. First is worth mentioning that the four cases ISO 14242-1 (harmonic and polygonal) and ISO 14242-3 (harmonic and polygonal) shown different shapes in the distribution of directions, directions of distance run and directions of dissipated frictional work. ISO 14242-1 shown a clear peak, while ISO 14242-3 shown a more uniform distribution (harmonic case) or two well defined peaks (polygonal case).

The most important histogram, in the light of the fact that represents the frictional work distribution when ISO 14242 harmonic motion is taken into account (the 3 dof case, which is an excellent approximation of real life conditions), is the upper left one in Fig. 5.2.27: it shows an evident maximum of the peak occurring in the 4th sector (*sectorq* of ISO1 in the table) which is located at an angle of about 79° (*directiondegq* of ISO1 in the table). If interpolation is applied to the histogram the peak appears between the 4th and the 5th sector, which is a more accurate interpretation.

The histograms located at the lower and upper right of Fig. 5.2.25, 5.2.26, 5.2.27, represent ISO 14242-3 seen as both harmonic curves (upper right) and polygonal curves (lower right), they cannot furnish information as noteworthy as the histograms representing ISO 14242-1; this because they don't show any single/sharp peak; in fact in ISO 14242-3 the motion law has only two degrees of freedom and can be reproduced by a simple biaxial rocking motion machine (BRM machine). Frictional work, in this particular case, is uniformly spread on all directions in case of harmonic interpretation, and shows two peaks 90° distant in case of polygonal curves interpretation. For what concerns this situation the orientation of the fibres is totally fictitious and the only conclusion that can be conceived is that the frictional work is either almost uniformly distributed (harmonic case) or "focussed" in directions that are oriented with an angle of 90° one another (polygonal case).

The Co coefficient shows two main trends: for ISO 14242-3 is about 50% (with exact values equal to 0.4703 and 0.4433 respectively); while for ISO 14242-1 the percentage drops to about 10% or 15% (0.1627 and 0.1028 respectively) showing that a minor fraction of the frictional work is orthogonal to the fibril main orientation (FMO). This is crucial for the cross shear effect, in fact in the two latter cases is much less than the other two; for this reason the predicted life of the prosthesis is longer for the two latter cases (Tab. 5.2.1).

The wear factor (*k*) confirms what was found before, in fact for what concerns ISO 14242-3 it shows higher values (75.2485 and 70.9266), and for ISO 14242-1 the values are much lower (26.0299 and 16.4476).

Lastly the work-per-cycle endorses all the considerations made: ISO 14242-3 dissipates 0.0037 J/cycle and 0.0034 J/cycle respectively, and ISO 14242-1dissipates 0.0023 J/cycle in both cases.

The prototypes

The first three prototypes are presented starting from the less expensive (ball bearing type with 1 degree of freedom: the less realistic) and reaching the most expensive (ball bearing type with 3 degrees of freedom: the most realistic). The increment in performance is naturally accompanied by a greater complexity, making the machine more fragile and less stiff.

A decisive issue that makes the third prototype (Fig. 6.6) the least desirable, is due to the fact that the extra-feature (the rotation about the vertical axis) that would theoretically give the machine all the three degrees of freedom necessary for a faithful reproduction of the human gait, does not follow the correct succession of the Euler angles ($fe \rightarrow aa \rightarrow ier$) applying the *ier* first ($ier \rightarrow fe \rightarrow aa$). This generates a different sliding path caused by the “wrong” internal-external rotation motion. Concluding: since this model appears complex, expensive, the less stiff and doesn’t reproduce accurately the motion, is the first discarded.

The first model (Fig. 6.4), despite being the less expensive and less complex can’t reproduce the cross shear effect, which is crucial in determining the life of a prosthesis; furthermore it can’t respect the requirements of any ISO.

For this reason, the best of the three is the second model (Fig. 6.5), which has two degrees of freedom. Thanks to its peculiar characteristics it can easily reproduce the prescriptions of ISO 14242-3.

The fourth prototype (Fig. 6.7) must be considered separately from the previous ones, since its particular design make it completely different from the other three. The big ball joint substitutes the gimbal system and the electric actuators are located on a double Cardan joint modified with a parallelogram linkage in the middle. This model needs a very accurate design and tolerancing, and with a proper investment can produce incredible performances compared to the first three designs. For this reason this model is theoretically the best for reliability and accuracy of measurements, even during the machine operation.

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Sincere thanks to all my aunts and uncles. You really taught me a lot in my life! Starting from my aunt Mariolina to which I owe much of the math I know. My uncle Beppino for being crazy (and engineer!). My aunt Anna for being her only pupillo (or “pupil”). My aunt Betta for her positive thinking and her Christmas cookies. My uncle (and ing!) Marco who kindly proposed to print this thesis. My uncle Giovanni for his being fun and generous. My uncle Carlo for his precious counsels and for being source for reflections.

5 tiny thanks to my 5 tiny (?) cousins... but a special tiny thank *you* to my special tiny Martina.

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Thank you Poland for being so Polish!

Appendix

The MatLab code

Counter.m

```
function [ n, m, q ] = Counter ( vmarkdiraux, gaitperc, pythagoras, L, mu )
%This is a counter

n=0;
for i=1:length(gaitperc)
    if vmarkdiraux(i)>=0
        n=n+1;
    end
end

m=0;
for i=1:length(gaitperc)
    if vmarkdiraux(i)>=0
        m=m+pythagoras(i);
    end
end

q=0;
for i=1:length(gaitperc)
    if vmarkdiraux(i)>=0
        q=q+pythagoras(i).*L(i)*mu*10;
    end
end

end
```

DirRose_final.m

```
function [ vmarkdir2d, vmarkdir2dload, pythagoras,...
    nvec, max_numn, sectorn, mvec, max_numm, sectorm, qvec, max_numq,
    sectorq,...
    directiondegn, directiondegm, directiondegq, FMOvec, ORTvec, Wf, Wo, w, W,
    Co, k]...
    = DirRose_final ( kprime, mu, d, a, Xc, gammac, L, vmarkdir, gaitperc )
%DirRose_final:
%Outputs the sectors vectors with their maximum value, the value's sector and
%the direction values

%3d vector projection on plane
%Elimination of third row: since the angle between the vectors and
%the projection plane is very small, the vector's modulus after the
%projection is imperceptibly shortened
vmarkdir2dtruelength=vmarkdir(~ismember(1:size(vmarkdir,1),3),:);
%Vectors modulus by Pythagoras' theorem
pythagoras=sqrt(vmarkdir2dtruelength(1,:).^2+vmarkdir2dtruelength(2,:).^2);
%"Round rose" (directions given by unit vectors)
vmarkdir2d1=vmarkdir2dtruelength(1,:)./pythagoras;
vmarkdir2d2=vmarkdir2dtruelength(2,:)./pythagoras;
vmarkdir2d=[ vmarkdir2d1; vmarkdir2d2 ];

%Analysis of quantity of directional vectors in circular sector:
```

```

vmarkdiraux=(vmarkdir2d(1,:).*sign(vmarkdir2d(2,:)));
%in each vmarkdir#
phi=[pi/8 pi*2/8 pi*3/8 pi*4/8 pi*5/8 pi*6/8 pi*7/8 pi*8/8]; cosphi=cos(phi);
vmarkdiraux1=vmarkdiraux-cosphi(1);
vmarkdiraux2=vmarkdiraux-cosphi(2);
vmarkdiraux3=vmarkdiraux-cosphi(3);
vmarkdiraux4=vmarkdiraux-cosphi(4);
vmarkdiraux5=vmarkdiraux-cosphi(5);
vmarkdiraux6=vmarkdiraux-cosphi(6);
vmarkdiraux7=vmarkdiraux-cosphi(7);
vmarkdiraux8=vmarkdiraux-cosphi(8);

%Vectors number that are "right" with respect to the stated angle
[ n1, m1, q1 ] = Counter ( vmarkdiraux1, gaitperc, pythagoras, L, mu );
[ n2, m2, q2 ] = Counter ( vmarkdiraux2, gaitperc, pythagoras, L, mu );
[ n3, m3, q3 ] = Counter ( vmarkdiraux3, gaitperc, pythagoras, L, mu );
[ n4, m4, q4 ] = Counter ( vmarkdiraux4, gaitperc, pythagoras, L, mu );
[ n5, m5, q5 ] = Counter ( vmarkdiraux5, gaitperc, pythagoras, L, mu );
[ n6, m6, q6 ] = Counter ( vmarkdiraux6, gaitperc, pythagoras, L, mu );
[ n7, m7, q7 ] = Counter ( vmarkdiraux7, gaitperc, pythagoras, L, mu );
[ n8, m8, q8 ] = Counter ( vmarkdiraux8, gaitperc, pythagoras, L, mu );

%Vectors number that are in the specified circular sector
n8=n8-n7; m8=m8-m7; q8=q8-q7;
n7=n7-n6; m7=m7-m6; q7=q7-q6;
n6=n6-n5; m6=m6-m5; q6=q6-q5;
n5=n5-n4; m5=m5-m4; q5=q5-q4;
n4=n4-n3; m4=m4-m3; q4=q4-q3;
n3=n3-n2; m3=m3-m2; q3=q3-q2;
n2=n2-n1; m2=m2-m1; q2=q2-q1;

%Vectors containing the amount of directions found per sector (8 sectors, pi/8
wide each)
%(The eight cells of this vector represent the eight parts in which the
%first and second quadrants - representing a 180° wide circular sector of
%possible directions - were divided. This to evaluate how many times the
%directions of a complete path are present in a specific sector. I.e. the
%first cell is the sector located within 0 and pi/8, the second, within
%pi/8 and 2*pi/8... and so on. As a simple verification, the sum of all the
%cells should give back the number by which the path was discretised)
%nvec:
%Outputs a value equal to the number of times a direction of the path
%occurs to be inside of a specific sector pi/8 wide
%mvec:
%Outputs a value proportional to the distance run inside of a specific
%sector pi/8 wide
%qvec:
%Outputs a value proportional to the frictional work inside of a specific
%sector pi/8 wide
fprintf(2,'n° times a direction of the path occurs in specific sector'),
nvec=[n1 n2 n3 n4 n5 n6 n7 n8],
fprintf(2,'proportional to distance run in specific sector'),
mvec=[m1 m2 m3 m4 m5 m6 m7 m8],
fprintf(2,'proportional to frictional work in specific sector'),
qvec=[q1 q2 q3 q4 q5 q6 q7 q8],
%Outputs maximum value present in the vector and cell where it was found
[max_numn,sectorn]=max(nvec);
[max_numm,sectorm]=max(mvec);
[max_numq,sectorq]=max(qvec);

```

```

%Total work per cycle calculation
w=mu*L.*pythagoras
W=sum(w)

%vector modulus is the load multiplied by the distance run in a specific
%direction at that instant in kN*mm
vmarkdir2dload1=vmarkdir2d1.*L.*pythagoras*1000;
vmarkdir2dload2=vmarkdir2d2.*L.*pythagoras*1000;
vmarkdir2dload=[ vmarkdir2dload1; vmarkdir2dload2 ];

directionradn=pi/16+pi/8*(sectorn-1); directiondegn=directionradn/pi*180;
directionradm=pi/16+pi/8*(sectorm-1); directiondegm=directionradm/pi*180;
directionradq=pi/16+pi/8*(sectorq-1); directiondegq=directionradq/pi*180;

fprintf(2,'FibrilMainOrientation vector'),
FMOvec=[cos(directionradq) -sin(directionradq)
        sin(directionradq) cos(directionradq)]*[1; 0];

fprintf(2,'FibrilMainOrientation ortogonal vector'),
ORTvec=[cos(directionradq) -sin(directionradq)
        sin(directionradq) cos(directionradq)]*[0; 1];

%projections of vmarkdir2dtruelength on main (cos) and ortogonal (sin)
direction:
%the components are squared because both vectors friction force and
%displacement (which generate friction work)are projected.

vmarkdir2datan2=atan2(vmarkdir2d2,vmarkdir2d1);
angles=vmarkdir2datan2-(ones(1,length(vmarkdir2d1))*directionradq);

deltaSprojFMO=pythagoras.*(cos(angles)).^2
deltaSprojORT=pythagoras.*(sin(angles)).^2

fprintf(2,'main and ortogonal orientation vector work and total work'),

wf=mu*L.*deltaSprojFMO; Wf=sum(wf);
wo=mu*L.*deltaSprojORT; Wo=sum(wo);

%SPECIFY THE ARTICLE FROM WHICH CHE Co COEFFICIENT WAS TAKEN
fprintf(2,'orthogonal wear on total wear ratio'),
Co=Wo/(Wo+Wf);

%----WEAR FACTOR (mm^3/Nm)----
fprintf(2,'WEAR FACTOR k (mm^3/Nm)');
deltaV=kprime*Wo/(2*Xc*gammac/d)
k=deltaV/(pythagoras*L')

end

```

Ematrix,m

```

function [ vmark ] = Ematrix ( v, gaitperc, fe, aa, ier )
%Ematrix (cup track):
%This function, given a vector indicating a point on the femoral head, and
%three vectors containing the angular values of the discretized motion law
%of the femoral head, allows the calculation of the path generated by a
%hypothetical marker located by the first vector mentioned, drawing its
%trace on the liner of the acetabular cup.

```

```

%The rotation is performed through the Eulerian Matrix, and the rotation
%sequence is: fe->aa->ier.
%In literature this is commonly referred to as "cup track".

vmark=zeros(3,length(gaitperc));
for i=1:length(gaitperc)
    emat=[ cos(aa(i))*cos(ier(i))          -
           cos(aa(i))*sin(ier(i))          sin(aa(i))
           sin(fe(i))*sin(aa(i))*cos(ier(i))+cos(fe(i))*sin(ier(i))    -
           sin(fe(i))*sin(aa(i))*sin(ier(i))+cos(fe(i))*cos(ier(i))    -sin(fe(i))*cos(aa(i))
           -cos(fe(i))*sin(aa(i))*cos(ier(i))+sin(fe(i))*sin(ier(i))
           cos(fe(i))*sin(aa(i))*sin(ier(i))+sin(fe(i))*cos(ier(i))    cos(fe(i))*cos(aa(i))
    ];
    vmark(:,i)=emat*v;
end

end

```

EmatrixDirections.m

```

function [ vmarkdir, truevmarkdir ] = EmatrixDirections ( vmark, gaitperc, fe,
aa, ier )
%EmatrixDirections:
%This function, given a matrix indicating a path on the spherical surface, and
%three vectors containing the angular values of the discretized motion law
%of the femoral head, allows the calculation of both distance and direction
%between the contiguous points that generate the path.
%The outputs are:
%*vmarkdir, which represents the delta vectors between a mark and the
%following one;
%*truevmarkdir, which is a modification of vmarkdir, in which the direction
%vectors are rotated
%The rotation is performed through the Eulerian Matrix, and the rotation
%sequence is: fe->aa->ier.

%Here the Euler matrix is used to find the direction vectors by "rotating back"
%every coordinate present in vmark by exactly the opposite rotation applied
%to find the location of the mark on the sphere. Every anti-rotation is applied
%to the mark that stands right before the mark that was obtained by the
%corresponding rotation.
%When plotted, this new array of coordinates returns a characteristic
%direction rose that represents all the discretised sliding directions that
%occur at the head-cup top interface.
%(The true rose will be obtained right after in this function)
vmarkdir=zeros(3,length(gaitperc));
i=length(gaitperc);
emat=[ cos(aa(i))*cos(ier(i))          -cos(aa(i))*sin(ier(i))
       sin(aa(i))
       sin(fe(i))*sin(aa(i))*cos(ier(i))+cos(fe(i))*sin(ier(i))    -
       sin(fe(i))*sin(aa(i))*sin(ier(i))+cos(fe(i))*cos(ier(i))    -sin(fe(i))*cos(aa(i))
       -cos(fe(i))*sin(aa(i))*cos(ier(i))+sin(fe(i))*sin(ier(i))
       cos(fe(i))*sin(aa(i))*sin(ier(i))+sin(fe(i))*cos(ier(i))    cos(fe(i))*cos(aa(i))
    ];
vmarkdir(:,1)=emat*vmark(:,1);

for i=1:length(gaitperc)-1
    emat=[ cos(aa(i))*cos(ier(i))          -
           cos(aa(i))*sin(ier(i))          sin(aa(i))

```

```

sin(fe(i))*sin(aa(i))*cos(ier(i))+cos(fe(i))*sin(ier(i))    -
sin(fe(i))*sin(aa(i))*sin(ier(i))+cos(fe(i))*cos(ier(i))    -sin(fe(i))*cos(aa(i))
-cos(fe(i))*sin(aa(i))*cos(ier(i))+sin(fe(i))*sin(ier(i))
cos(fe(i))*sin(aa(i))*sin(ier(i))+sin(fe(i))*cos(ier(i))    cos(fe(i))*cos(aa(i))
];
vmarkdir(:,i+1)=emat*vmark(:,i+1);
end

%To obtain the "true" vmarkdir, the one that expresses the relative sliding
%occurring at the head-cup interface, at the top of the cup, observed from
%the top of the cup - where the resultant force of the pressure
%distribution is concentrated - all the directions recorded in vmarkdir
%must be compensated by the opposite of the ier angle, which is distorting
%the true "direction rose" that will eventually allow a precise calculation
%of the "shear stress rose" that is present at the tip of the cup during the
%gait.

truevmarkdir=zeros(3,length(gaitperc));
i=length(gaitperc);
rmat= [ cos(ier(i))  -sin(ier(i))  0
        sin(ier(i))   cos(ier(i))  0
        0              0           1 ];
truevmarkdir(:,1)=rmat*vmarkdir(:,1);

for i=1:length(gaitperc)-1
    rmat= [ cos(ier(i))  -sin(ier(i))  0
            sin(ier(i))   cos(ier(i))  0
            0              0           1 ];
    truevmarkdir(:,i+1)=rmat*vmarkdir(:,i+1);
end

end

```

EmatrixInv.m

```

function [ vmark ] = EmatrixInv ( v, gaitperc, fe, aa, ier )
%EmatrixInv (head track):
%This function, given a vector indicating a point on the acetabular cup,
%and three vectors containing the angular values of the discretized motion
%law of the femoral head, allows the calculation of the path generated by a
%hypothetical marker located by the first vector mentioned, drawing its
%trace on the femoral head.
%The rotation is performed through the Eulerian Matrix, and the rotation
%sequence is: fe->aa->ier.
%In literature this is commonly referred to as "head track".

vmark=zeros(3,length(gaitperc));
for i=1:length(gaitperc)
    emat=[ cos(aa(i))*cos(ier(i))    -
           cos(aa(i))*sin(ier(i))     sin(aa(i))
           sin(fe(i))*sin(aa(i))*cos(ier(i))+cos(fe(i))*sin(ier(i))    -
           sin(fe(i))*sin(aa(i))*sin(ier(i))+cos(fe(i))*cos(ier(i))    -sin(fe(i))*cos(aa(i))
           -cos(fe(i))*sin(aa(i))*cos(ier(i))+sin(fe(i))*sin(ier(i))
           cos(fe(i))*sin(aa(i))*sin(ier(i))+sin(fe(i))*cos(ier(i))    cos(fe(i))*cos(aa(i))
    ];
    %inverted matrix application by using "\"
    vmark(:,i)=emat\v;
end

```

end

Hip_prosthesis_release_2final.m

```
%This script allows to find the trajectory that a hypothetical marker
%placed on the femural head (or on the acetabular cup), and soldal to it,
%traces on the acetabular cup (or on the femural head). This is possible by
%setting the marker location, and the characteristic angles that describe
%the human gait (motion law).
%The trajectories can be found thanks to Ematrix.m and EmatrixInv.m
%functions.
%EmatrixDirections.m function is used to find the vectors that connect the
%points of the discretised trajectory on the head; their direction is
%adjusted by subtracting the ier angle (internal and external rotation
%angle) and they are placed with all their tails at the tip of the inner
%surface of the cup. These vectors compose a rose that can be exploited for
%further calculations.
%The DirRose_final.m function is built to count the vectors which are present in
%a specific circle sector of the vector rose. This function, outputs useful
%data to produce a histogram representing:
%How many times a vector is inside of a specific sector (using nvec)
%How much distance was run inside of a specific sector (using mvec)
%How much frictional work was dissipated inside of a specific sector (using
qvec)
%The function in question contains important data - such as the fibril main
%orientation vector, and the total work - that are shown in a table
%which allows a fast and easy comparison between the different approaches.
%In Distmatrix.m, by the simple application of Pythagoras' theorem, the
%Distmatrixvector is generated; this vector contains the distances between
%the marks composing the trajectory of a marker during the gait.

%The motion law of the femural head, which is described in ISO-14242 only
%by a plot with a few reference points explicitly given, and not through a
%specific mathematical function, was interpreted in two ways:
%- harmonic functions passing through the coordinates explicitly given
%- broken line connecting the points specifically given
%The angles are expressed in degrees and plotted against the time
%percentage of the cycle.
%The two different perspectives will give different results.

%Furthermore the motion law is represented trough two different approaches:
%the one present in ISO-14242-1 (three dof), and the one present in
%ISO-14242-3 (two dof).
%The ISO-14242-1, which has three degrees of freedom: flexion and
%extension ("fe" in the code), abduction and adduction ("aa" in the code)
%and internal and external rotation ("ier" in the code).
%The ISO-14242-3, which has two degrees of freedom: flexion and extension
%("fe" in the code), and abduction and adduction ("aa" in the code).

%The ISO-14242 norm provides the loading law, with the force expressed in
%Newton plotted against the time percentage of the cycle. A set of points
%of the function are given; by using these points, and connecting them
%through a broken line, the Load-time percentage plot is obtained.

%XXXXXXXXXXXXXXXXXXXXX

%note: the data section contains much more parameters than those which
%are actually used, this to allow a possible further developement of the
%code in the future, broadening it's potential.
```

```

clear all
close all
clc

%Main data:
gaitperc=0:1:99;           %gait vector (percentage)
gaitrad=gaitperc*2*pi/100; %gait vector (radiants)
r=0.028/2;                %sphere radius [m]
a=pi*r^2;                 %supposed contact area
freq=1; T=1/freq;         %gait frequency and period
deltat=T/(length(gaitperc)-1); %deltat between points
mu=0.08;                  %friction coefficeint
%From Fig. 7 of "A unified theory of wear for ultra-high molecular weight
%polyethylene in multi-directional sliding", [A. Wang] 2000:
Xc=0.00025; %cross-link density (mole/g)
%Unknown data. Arbitrary set value: 1
kprime=1; %constant
gammac=1; %C-C bond energy (Joule)
d=1;      %average cross sectional width of UHMWPE fibrils (mm)
%Most of these data will be used to calculate k:
%k=kprime*(mu*d/(2*Xc*gammac))*(1-sin(2*alpha)/(2*alpha))

%Radius-vectors corresponding to the three axes of moving reference system
v1=[ 0; 0; r ]; v2=[ 0; r; 0 ]; v3=[ r; 0; 0 ];

%----ANGULAR VECTORS FROM FUNCTIONS-----

%ISO 14242-1 waveforms (radians)
feISO1=(21.5*cos(gaitrad)+3.5)*pi/180;
aaISO1I=(5.5*cos((50/59)*gaitrad-(50/59)*(21/100)*2*pi)+1.5)*pi/180;
aaISO1II=(5.5*cos((50/41)*gaitrad-(50/41)*(21/100)*2*pi)+1.5)*pi/180;
aaISO1III=(-5.5*cos((50/59)*gaitrad-(50/59)*(62/100)*2*pi)+1.5)*pi/180;
aaISO1=[aaISO1I(1:22), aaISO1II(23:63), aaISO1III(64:100)];
%aaISO1=(5.5*cos(gaitrad-1.3195)+1.5)*pi/180;
ierISO1=(-6*cos(gaitrad)-4)*pi/180;

%ISO 14242-3 waveforms (radians)
feISO3=(23*pi/180)*cos(gaitrad);
aaISO3=-(23*pi/180)*sin(gaitrad);
ierISO3=zeros(1, length(gaitperc)); %ISO 14242-3 has no ier motion

%ISO 14242-1 polygonal curves (straight lines generating poligonal curves)
y1feISO1=(-0.86*gaitperc+25)*pi/180;
y2feISO1=(0.86*gaitperc-61)*pi/180;
y1aaISO1=(0.190*gaitperc+3)*pi/180;
y2aaISO1=(-0.268*gaitperc+12.63)*pi/180;
y3aaISO1=(0.184*gaitperc-15.41)*pi/180;
y1ierISO1=(0.24*gaitperc-10)*pi/180;
y2ierISO1=(-0.24*gaitperc+14)*pi/180;
%actual vectors containing polygonal curves
fepolyISO1=[y1feISO1(1:51), y2feISO1(52:100)];
aapolyISO1=[y1aaISO1(1:22), y2aaISO1(23:63), y3aaISO1(64:100)];
ierpolyISO1=[y1ierISO1(1:51), y2ierISO1(52:100)];

%ISO 14242-3 polygonal curves (straight lines generating poligonal curves)
y1feISO3=(-0.92*gaitperc+23)*pi/180;
y2feISO3=(0.92*gaitperc-69)*pi/180;
y1aaISO3=(-0.92*gaitperc)*pi/180;
y2aaISO3=(0.92*gaitperc-46)*pi/180;

```

```

y3aaISO3=(-0.92*gaitperc+92)*pi/180;
%actual vectors containing polygonal curves
fepolyISO3=[y1feISO3(1:51), y2feISO3(52:100)];
aapolyISO3=[y1aaISO3(1:26), y2aaISO3(27:76), y3aaISO3(77:100)];
ierpolyISO3=zeros(1, length(gaitperc)); %ISO 14242-3 has no ier motion

%----LOADING AND FRICTION FORCE LAWS VECTORS---
%(here commented is the interpretation with the middle plateau)

L1=0.225*gaitperc+0.3; F1=L1*mu;
L2=-0.075*gaitperc+3.9; F2=L2*mu; %L2=-0.115*gaitperc+4.38; F2=L2*mu;
                                %L3=(gaitperc*0+1)*1.5; F3=L3*mu;
L4=0.083*gaitperc-1.16; F4=L4*mu; %L4=0.136*gaitperc-3.804; F4=L4*mu;
L5=-0.225*gaitperc+14.25; F5=L5*mu;
L6=(gaitperc*0+1)*0.3; F6=L6*mu;

%Trimming last column of gaitperc to perform integration hereinafter
gaitperctrim=gaitperc; gaitperctrim(length(gaitperc))=[];
%Cut and paste load straight lines to generate ISO loading law
%(here commented is the interpretation with the middle plateau)
L=[L1(1:12), L2(13:32), L4(33:50), L5(51:62), L6(63:100)];
F=[F1(1:12), F2(13:32), F4(33:50), F5(51:62), F6(63:99)];
%L=[L1(1:12), L2(13:25), L3(26:39), L4(40:50), L5(51:62), L6(63:100)];
%F=[F1(1:12), F2(13:25), F3(26:39), F4(40:50), F5(51:62), F6(63:99)];

%----WAVEFORMS PLOTS-----

%ISO 14242-1 waveforms plot
figure(1);
subplot(1,2,1);
hold on
grid on
plot(gaitperc,feISO1, 'r', gaitperc,aaISO1, 'g', gaitperc,ierISO1, 'k')
legend('FE','AA','IER')
xlabel('Gaitperc [%]');ylabel('Angles [rad]'); title('ISO 14242-1 waveforms');
hold off;

%ISO 14242-3 waveforms plot
subplot(1,2,2);
hold on
grid on
plot(gaitperc, feISO3, 'r', gaitperc, aaISO3, 'g')
legend('FE','AA')
xlabel('Gaitperc [%]');ylabel('Angles [rad]'); title('ISO 14242-3 waveforms');
hold off;

%ISO 14242-1 polygonal curve plot
figure(2);
subplot(1,2,1);
hold on
grid on
plot(gaitperc,fepolyISO1, 'r', gaitperc,aapolyISO1, 'g', gaitperc,ierpolyISO1,
'k')
legend('FE','AA','IER')
xlabel('Gaitperc [%]');ylabel('Angles [rad]'); title('ISO 14242-1 polygonal
curve');
hold off;

%ISO 14242-3 polygonal curve plot
subplot(1,2,2);

```

```

hold on
grid on
plot(gaitperc, fepolyISO3, 'r', gaitperc, aapolyISO3, 'g')
legend('FE','AA')
xlabel('Gaitperc [%]');ylabel('Angles [rad]'); title('ISO 14242-3 polygonal
curve');
hold off;

%---MARKER PATH CALCULATION ON CUP BY CALLING Ematrix SUBROUTINE
%In this situation every marker (red, green and black) has to be thought as
%moving solidal with the femoral head, tracing its trajectory on the inside
%of the acetabular cup

%ISO 14242-1 vmark functions
[ vmark1ISO1 ] = Ematrix ( v1, gaitperc, feISO1, aaISO1, ierISO1 );
[ vmark2ISO1 ] = Ematrix ( v2, gaitperc, feISO1, aaISO1, ierISO1 );
[ vmark3ISO1 ] = Ematrix ( v3, gaitperc, feISO1, aaISO1, ierISO1 );

%ISO 14242-3 vmark functions
[ vmark1ISO3 ] = Ematrix ( v1, gaitperc, feISO3, aaISO3, ierISO3 );
[ vmark2ISO3 ] = Ematrix ( v2, gaitperc, feISO3, aaISO3, ierISO3 );
[ vmark3ISO3 ] = Ematrix ( v3, gaitperc, feISO3, aaISO3, ierISO3 );

%ISO 14242-1 polygonal curve vmark functions
[ vmark1polyISO1 ] = Ematrix ( v1, gaitperc, fepolyISO1, aapolyISO1, ierpolyISO1
);
[ vmark2polyISO1 ] = Ematrix ( v2, gaitperc, fepolyISO1, aapolyISO1, ierpolyISO1
);
[ vmark3polyISO1 ] = Ematrix ( v3, gaitperc, fepolyISO1, aapolyISO1, ierpolyISO1
);

%ISO 14242-3 polygonal curve vmark functions
[ vmark1polyISO3 ] = Ematrix ( v1, gaitperc, fepolyISO3, aapolyISO3, ierpolyISO3
);
[ vmark2polyISO3 ] = Ematrix ( v2, gaitperc, fepolyISO3, aapolyISO3, ierpolyISO3
);
[ vmark3polyISO3 ] = Ematrix ( v3, gaitperc, fepolyISO3, aapolyISO3, ierpolyISO3
);

%---MARKER PATH CALCULATION ON HEAD BY CALLING EmatrixInv SUBROUTINE
%In this situation every marker (red, green and black) has to be considered
%as fixed on the internal surface of the cup, tracing its trajectory on the
%surface of the femoral head

%ISO 14242-1 vmark functions
[ vmarkhead1ISO1 ] = EmatrixInv ( v1, gaitperc, feISO1, aaISO1, ierISO1 );
[ vmarkhead2ISO1 ] = EmatrixInv ( v2, gaitperc, feISO1, aaISO1, ierISO1 );
[ vmarkhead3ISO1 ] = EmatrixInv ( v3, gaitperc, feISO1, aaISO1, ierISO1 );

%ISO 14242-3 vmark functions
[ vmarkhead1ISO3 ] = EmatrixInv ( v1, gaitperc, feISO3, aaISO3, ierISO3 );
[ vmarkhead2ISO3 ] = EmatrixInv ( v2, gaitperc, feISO3, aaISO3, ierISO3 );
[ vmarkhead3ISO3 ] = EmatrixInv ( v3, gaitperc, feISO3, aaISO3, ierISO3 );

%ISO 14242-1 polygonal curve vmark functions
[ vmarkhead1polyISO1 ] = EmatrixInv ( v1, gaitperc, fepolyISO1, aapolyISO1,
ierpolyISO1 );
[ vmarkhead2polyISO1 ] = EmatrixInv ( v2, gaitperc, fepolyISO1, aapolyISO1,
ierpolyISO1 );

```

```
[ vmarkhead3polyISO1 ] = EmatrixInv ( v3, gaitperc, fepolyISO1, aapolyISO1,
ierpolyISO1 );
```

```
%ISO 14242-3 polygonal curve vmark functions
```

```
[ vmarkhead1polyISO3 ] = EmatrixInv ( v1, gaitperc, fepolyISO3, aapolyISO3,
ierpolyISO3 );
```

```
[ vmarkhead2polyISO3 ] = EmatrixInv ( v2, gaitperc, fepolyISO3, aapolyISO3,
ierpolyISO3 );
```

```
[ vmarkhead3polyISO3 ] = EmatrixInv ( v3, gaitperc, fepolyISO3, aapolyISO3,
ierpolyISO3 );
```

```
%----DISPLACEMENT DIRECTION ON HEAD BY CALLING EmatrixDirections SUBROUTINE
```

```
%ISO 14242-1 vmarkdir functions
```

```
[ vmarkdirISO1, truevmarkdir1ISO1 ] = EmatrixDirections ( vmarkhead1ISO1,
gaitperc, feISO1, aaISO1, ierISO1 );
```

```
[ vmarkdir1ISO3, truevmarkdir1ISO3 ] = EmatrixDirections ( vmarkhead1ISO3,
gaitperc, feISO3, aaISO3, ierISO3 );
```

```
[ vmarkdir1polyISO1, truevmarkdir1polyISO1 ] = EmatrixDirections (
vmarkhead1polyISO1, gaitperc, fepolyISO1, aapolyISO1, ierpolyISO1 );
```

```
[ vmarkdir1polyISO3, truevmarkdir1polyISO3 ] = EmatrixDirections (
vmarkhead1polyISO3, gaitperc, fepolyISO3, aapolyISO3, ierpolyISO3 );
```

```
%----"DIRECTION ROSE" WEIGHTED BY LOAD BY CALLING DirRose_final SUBROUTINE
```

```
%(The formula for the calculation of the wear factor (k) was taken from
%"A unified theory of wear for ultra-high molecular weight polyethylene in
%multi-directional sliding", [A. Wang] 2000. Since many factors that can be
%found in the formula are unknown or, in general, not applicable because of
%the simplicity of the model, the various k that are following are
%meaningful only when compared one another, and lose their meaning when
%considered as single numbers)
```

```
fprintf(2, '    ISO 14242-1 data:\n\n');
```

```
[ vmarkdir2d11, vmarkdir2d1load1, pythagoras1, nvec1, max_numn1, sectorn1,
mvec1, max_numm1, sectorm1, qvec1, max_numq1, sectorq1,...
```

```
directiondegn1, directiondegm1, directiondegq1, FMOvec1, ORTvec1, Wf1, Wo1,
w1, W1, Col, k1]...
```

```
= DirRose_final ( kprime, mu, d, a, Xc, gammac, L, truevmarkdir1ISO1,
gaitperc );
```

```
ISO1VEC= [ sectorn1, sectorm1, sectorq1, directiondegn1, directiondegm1,
directiondegq1, Wf1, Wo1, Col, k1, W1 ];
```

```
fprintf(2, '\n    ISO 14242-3 data:\n\n');
```

```
[ vmarkdir2d13, vmarkdir2d1load3, pythagoras3, nvec3, max_numn3, sectorn3,
mvec3, max_numm3, sectorm3, qvec3, max_numq3, sectorq3,...
```

```
directiondegn3, directiondegm3, directiondegq3, FMOvec3, ORTvec3, Wf3, Wo3,
w3, W3, Co3, k3]...
```

```
= DirRose_final ( kprime, mu, d, a, Xc, gammac, L, truevmarkdir1ISO3,
gaitperc );
```

```
ISO3VEC= [ sectorn3, sectorm3, sectorq3, directiondegn3, directiondegm3,
directiondegq3, Wf3, Wo3, Co3, k3, W3 ];
```

```
fprintf(2, '\n    ISO 14242-1 polygonal curve data:\n\n');
```

```
[ vmarkdir2d11p, vmarkdir2d1load1p, pythagoras1p, nvec1p, max_numn1p, sectorn1p,
mvec1p, max_numm1p, sectorm1p, qvec1p, max_numq1p, sectorq1p,...
```

```
directiondegn1p, directiondegm1p, directiondegq1p, FMOvec1p, ORTvec1p, Wf1p,
Wo1p, w1p, W1p, Colp, k1p]...
```

```

    = DirRose_final ( kprime, mu, d, a, Xc, gammac, L, truevmarkdir1polyISO1,
gaitperc );

ISO1pVEC= [ sectorn1p, sectorm1p, sectorq1p, directiondegn1p, directiondegm1p,
directiondegq1p, Wf1p, Wo1p, Co1p, k1p, W1p ];

fprintf(2, '\n    ISO 14242-3 polygonal curve data:\n\n');
[ vmarkdir2d13p, vmarkdir2d1load3p, pythagoras3p, nvec3p, max_numn3p, sectorn3p,
mvec3p, max_numm3p, sectorm3p, qvec3p, max_numq3p, sectorq3p,...
    directiondegn3p, directiondegm3p, directiondegq3p, FM0vec3p, ORTvec3p, Wf3p,
Wo3p, w3p, W3p, Co3p, k3p]...
    = DirRose_final ( kprime, mu, d, a, Xc, gammac, L, truevmarkdir1polyISO3,
gaitperc );

ISO3pVEC= [ sectorn3p, sectorm3p, sectorq3p, directiondegn3p, directiondegm3p,
directiondegq3p, Wf3p, Wo3p, Co3p, k3p, W3p ]

%----MARKER PATHS PLOTS-----

atan4quad1=atan2(vmarkdir2d11(2,:), vmarkdir2d11(1,:));
[ atan2quad1 ] = pi_rotation( atan4quad1 );

%----MARKER PATHS ON CUP PLOTS-----

figure(3);
hold on
grid on
set(gca, 'DataAspectRatio', [1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmark1ISO1(1,:),vmark1ISO1(2,:),vmark1ISO1(3,:), 'r');
scatter3(vmark2ISO1(1,:),vmark2ISO1(2,:),vmark2ISO1(3,:), 'g');
scatter3(vmark3ISO1(1,:),vmark3ISO1(2,:),vmark3ISO1(3,:), 'k');
scatter3(vmark1ISO3(1,:),vmark1ISO3(2,:),vmark1ISO3(3,:), 'r');
scatter3(vmark2ISO3(1,:),vmark2ISO3(2,:),vmark2ISO3(3,:), 'g');
scatter3(vmark3ISO3(1,:),vmark3ISO3(2,:),vmark3ISO3(3,:), 'k');
xlabel('feaxis [m]');ylabel('aaaxis [m]');zlabel('ieraxis [m]');
title('Markertrack on cup ISO 14242-1 - ISO 14242-3 harmo comparison');

figure(4);
hold on
grid on
set(gca, 'DataAspectRatio', [1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmark1polyISO1(1,:),vmark1polyISO1(2,:),vmark1polyISO1(3,:), 'r');
scatter3(vmark2polyISO1(1,:),vmark2polyISO1(2,:),vmark2polyISO1(3,:), 'g');
scatter3(vmark3polyISO1(1,:),vmark3polyISO1(2,:),vmark3polyISO1(3,:), 'k');
scatter3(vmark1polyISO3(1,:),vmark1polyISO3(2,:),vmark1polyISO3(3,:), 'r');
scatter3(vmark2polyISO3(1,:),vmark2polyISO3(2,:),vmark2polyISO3(3,:), 'g');
scatter3(vmark3polyISO3(1,:),vmark3polyISO3(2,:),vmark3polyISO3(3,:), 'k');
xlabel('feaxis [m]');ylabel('aaaxis [m]');zlabel('ieraxis [m]');
title('Markertrack on cup ISO 14242-1 - ISO 14242-3 poly comparison');

figure(5);
subplot(1,2,1);
hold on
grid on
set(gca, 'DataAspectRatio', [1 1 1])

```

```

[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmark1ISO1(1,:),vmark1ISO1(2,:),vmark1ISO1(3,:), 'r');
scatter3(vmark2ISO1(1,:),vmark2ISO1(2,:),vmark2ISO1(3,:), 'g');
scatter3(vmark3ISO1(1,:),vmark3ISO1(2,:),vmark3ISO1(3,:), 'k');
scatter3(vmark1polyISO1(1,:),vmark1polyISO1(2,:),vmark1polyISO1(3,:), '.r');
scatter3(vmark2polyISO1(1,:),vmark2polyISO1(2,:),vmark2polyISO1(3,:), '.g');
scatter3(vmark3polyISO1(1,:),vmark3polyISO1(2,:),vmark3polyISO1(3,:), '.k');
xlabel('feaxis [m]');ylabel('aaaxis [m]');zlabel('ieraxis [m]');
title('Markertrack on cup ISO 14242-1 harmo-poly comparison');

```

```

subplot(1,2,2);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmark1ISO3(1,:),vmark1ISO3(2,:),vmark1ISO3(3,:), 'r');
scatter3(vmark2ISO3(1,:),vmark2ISO3(2,:),vmark2ISO3(3,:), 'g');
scatter3(vmark3ISO3(1,:),vmark3ISO3(2,:),vmark3ISO3(3,:), 'k');
scatter3(vmark1polyISO3(1,:),vmark1polyISO3(2,:),vmark1polyISO3(3,:), '.r');
scatter3(vmark2polyISO3(1,:),vmark2polyISO3(2,:),vmark2polyISO3(3,:), '.g');
scatter3(vmark3polyISO3(1,:),vmark3polyISO3(2,:),vmark3polyISO3(3,:), '.k');
xlabel('feaxis [m]');ylabel('aaaxis [m]');zlabel('ieraxis [m]');
title('Markertrack on cup ISO 14242-3 harmo-poly comparison');

```

%----MARKER PATHS ON HEAD PLOTS-----

```

figure(6);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmarkhead1ISO1(1,:),vmarkhead1ISO1(2,:),vmarkhead1ISO1(3,:), 'r');
scatter3(vmarkhead2ISO1(1,:),vmarkhead2ISO1(2,:),vmarkhead2ISO1(3,:), 'g');
scatter3(vmarkhead3ISO1(1,:),vmarkhead3ISO1(2,:),vmarkhead3ISO1(3,:), 'k');
scatter3(vmarkhead1ISO3(1,:),vmarkhead1ISO3(2,:),vmarkhead1ISO3(3,:), '.r');
scatter3(vmarkhead2ISO3(1,:),vmarkhead2ISO3(2,:),vmarkhead2ISO3(3,:), '.g');
scatter3(vmarkhead3ISO3(1,:),vmarkhead3ISO3(2,:),vmarkhead3ISO3(3,:), '.k');
xlabel('feaxis [m]');ylabel('aaaxis [m]');zlabel('ieraxis [m]');
title('Markertrack on head ISO 14242-1 - ISO 14242-3 poly comparison');

```

```

figure(7);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmarkhead1polyISO1(1,:),vmarkhead1polyISO1(2,:),vmarkhead1polyISO1(3,:),
, 'r');
scatter3(vmarkhead2polyISO1(1,:),vmarkhead2polyISO1(2,:),vmarkhead2polyISO1(3,:),
, 'g');
scatter3(vmarkhead3polyISO1(1,:),vmarkhead3polyISO1(2,:),vmarkhead3polyISO1(3,:),
, 'k');
scatter3(vmarkhead1polyISO3(1,:),vmarkhead1polyISO3(2,:),vmarkhead1polyISO3(3,:),
, '.r');
scatter3(vmarkhead2polyISO3(1,:),vmarkhead2polyISO3(2,:),vmarkhead2polyISO3(3,:),
, '.g');
scatter3(vmarkhead3polyISO3(1,:),vmarkhead3polyISO3(2,:),vmarkhead3polyISO3(3,:),
, '.k');

```

```

xlabel('feaxis [m]');ylabel('aaaxis [m]');zlabel('ieraxis [m]');
title('Markertrack on head ISO 14242-1 - ISO 14242-3 poly comparison');

figure(8);
subplot(1,2,1);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmarkhead1ISO1(1,:),vmarkhead1ISO1(2,:),vmarkhead1ISO1(3,:), 'r');
scatter3(vmarkhead2ISO1(1,:),vmarkhead2ISO1(2,:),vmarkhead2ISO1(3,:), 'g');
scatter3(vmarkhead3ISO1(1,:),vmarkhead3ISO1(2,:),vmarkhead3ISO1(3,:), 'k');
scatter3(vmarkhead1polyISO1(1,:),vmarkhead1polyISO1(2,:),vmarkhead1polyISO1(3,:),
, 'r');
scatter3(vmarkhead2polyISO1(1,:),vmarkhead2polyISO1(2,:),vmarkhead2polyISO1(3,:),
, 'g');
scatter3(vmarkhead3polyISO1(1,:),vmarkhead3polyISO1(2,:),vmarkhead3polyISO1(3,:),
, 'k');
xlabel('feaxis [m]');ylabel('aaaxis [m]');zlabel('ieraxis [m]');
title('Markertrack on head ISO 14242-1 harmo-poly comparison');

subplot(1,2,2);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmarkhead1ISO3(1,:),vmarkhead1ISO3(2,:),vmarkhead1ISO3(3,:), 'r');
scatter3(vmarkhead2ISO3(1,:),vmarkhead2ISO3(2,:),vmarkhead2ISO3(3,:), 'g');
scatter3(vmarkhead3ISO3(1,:),vmarkhead3ISO3(2,:),vmarkhead3ISO3(3,:), 'k');
scatter3(vmarkhead1polyISO3(1,:),vmarkhead1polyISO3(2,:),vmarkhead1polyISO3(3,:),
, 'r');
scatter3(vmarkhead2polyISO3(1,:),vmarkhead2polyISO3(2,:),vmarkhead2polyISO3(3,:),
, 'g');
scatter3(vmarkhead3polyISO3(1,:),vmarkhead3polyISO3(2,:),vmarkhead3polyISO3(3,:),
, 'k');
xlabel('feaxis [m]');ylabel('aaaxis [m]');zlabel('ieraxis [m]');
title('Markertrack on head ISO 14242-3 harmo-poly comparison');

%----FORCE, DISPLACEMENT AND WORK PLOTS-----
%Trimming vectors to let them fit in the plot (100 columns-->99 columns)
pythagoras1trim=pythagoras1; pythagoras1trim(:,1)=[];
vmatrixhead1=pythagoras1trim/deltat;
pythagoras3trim=pythagoras3; pythagoras3trim(:,1)=[];
vmatrixhead3=pythagoras3trim/deltat;
pythagoras1ptrim=pythagoras1p; pythagoras1ptrim(:,1)=[];
vmatrixhead1p=pythagoras1ptrim/deltat;
pythagoras3ptrim=pythagoras3p; pythagoras3ptrim(:,1)=[];
vmatrixhead3p=pythagoras3ptrim/deltat;
wltrim=w1; wltrim(:,1)=[]; w3trim=w3; w3trim(:,1)=[];
wlptrim=w1p; wlptrim(:,1)=[]; w3ptrim=w3p; w3ptrim(:,1)=[];

%Note that in plot 9 the speed plot lies perfectly over the displacement
%plot since:
%1)the displacement values were intentionally multiplied by 100 in the plot
%to fit better the "y-axis scale"; and so every value, which in the
%original vector is in meters [m], in the plot is in centimeters [cm].
%i.e. in the plot 0.03 means three tens of millimeters
%2)the velocity is calculated by dividing the "elementary distance run"

```

```

%(a hundredth of the complete gait) by the "elementary lapse of time"
%(T/100, with T=1 s in this case)
figure(9);
subplot(1,2,1);
hold on
grid on
plot(gaitperctrim, F, 'm');
%plot(gaitperctrim, L, 'O-m');
plot(gaitperctrim, pythagoras1trim*100, 'r'); plot(gaitperctrim,
pythagoras3trim*100, 'g');
plot(gaitperctrim, pythagoras1ptrim*100, 'b'); plot(gaitperctrim,
pythagoras3ptrim*100, 'k');
plot(gaitperctrim, vmatrixhead1, '.-r'); plot(gaitperctrim, vmatrixhead3, '.-
g');
plot(gaitperctrim, vmatrixhead1p, '.-b'); plot(gaitperctrim, vmatrixhead3p, '.-
k');
legend('Frictional force','ISO-1 harmonic \Deltax','ISO-3 harmonic
\Deltax','ISO-1 poly \Deltax',...
'ISO-3 poly \Deltax','ISO-1 harmonic v','ISO-3 harmonic v','ISO-1 poly v','ISO-2
poly v')
xlabel('Gaitperc [%]');ylabel('Frictional force law [kN] - \Deltax*100 [m*100] -
v'); title('Loading law');

subplot(1,2,2);
hold on
grid on
plot(gaitperctrim, wltrim, 'r'); plot(gaitperctrim, w3trim, 'g');
plot(gaitperctrim, wlptrim, 'b'); plot(gaitperctrim, w3ptrim, 'k');
legend('ISO-1 harmonic','ISO-3 harmonic','ISO-1 poly','ISO-3 poly')
xlabel('Gaitperc [%]');ylabel('Work [kJ]'); title('Work per cycle');
hold off;

%In figures 10, 11, 12, 13, appear: in red, the old
%vmarkdir plot, and in green, the new vmarkdir, called truevmarkdir, in
%which all the directions were corrected by using the ier angle

figure(10);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmarkdirISO1(1,:),vmarkdirISO1(2,:),vmarkdirISO1(3,:), 'r');
scatter3(truevmarkdir1ISO1(1,:),truevmarkdir1ISO1(2,:),truevmarkdir1ISO1(3,:),
'g'); %newplot
xlabel('[m]');ylabel('[m]');zlabel('[m]');
title('Markertrack direction on head ISO 14242-1');

figure(11);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmarkdir1ISO3(1,:),vmarkdir1ISO3(2,:),vmarkdir1ISO3(3,:), 'r');
scatter3(truevmarkdir1ISO3(1,:),truevmarkdir1ISO3(2,:),truevmarkdir1ISO3(3,:),
'g'); %newplot
xlabel('[m]');ylabel('[m]');zlabel('[m]');
title('Markertrack direction on head ISO 14242-3');

figure(12);

```

```

hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmarkdir1polyISO1(1,:),vmarkdir1polyISO1(2,:),vmarkdir1polyISO1(3,:),
'r');
scatter3(truevmarkdir1polyISO1(1,:),truevmarkdir1polyISO1(2,:),truevmarkdir1poly
ISO1(3,:), 'g'); %newplot
xlabel('[m]');ylabel('[m]');zlabel('[m]');
title('Markertrack direction on head ISO 14242-1 poly curve');

figure(13);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
[x,y,z]=sphere(20);
surf(x*r,y*r,z*r); colormap([1 1 1]);
scatter3(vmarkdir1polyISO3(1,:),vmarkdir1polyISO3(2,:),vmarkdir1polyISO3(3,:),
'r');
scatter3(truevmarkdir1polyISO3(1,:),truevmarkdir1polyISO3(2,:),truevmarkdir1poly
ISO3(3,:), 'g'); %newplot
xlabel('[m]');ylabel('[m]');zlabel('[m]');
title('Markertrack direction on head ISO 14242-3 poly curve');

%In plots 14, 15, 16, 17, the direction rose is normalised (all unit
%vectors, round rose), and the red marks represnt the same vecors but
%weighted by the frictional work
figure(14);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
scatter(vmarkdir2d11(1,:),vmarkdir2d11(2,:), 'b');
scatter(0.08*10*vmarkdir2d11load1(1,:),0.08*10*vmarkdir2d11load1(2,:), 'r');
xlabel('dimensionless - [kJ*10]');ylabel('dimensionless - [kJ*10]');
title('Direction rose ISO 14242-1 (unit vectors and frictional work vectors)');

figure(15);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
scatter(vmarkdir2d13(1,:),vmarkdir2d13(2,:), 'b');
scatter(0.08*10*vmarkdir2d11load3(1,:),0.08*10*vmarkdir2d11load3(2,:), 'r');
xlabel('dimensionless - [kJ*10]');ylabel('dimensionless - [kJ*10]');
title('Direction rose ISO 14242-3 (unit vectors and frictional work vectors)');

figure(16);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
scatter(vmarkdir2d11p(1,:),vmarkdir2d11p(2,:), 'b');
scatter(0.08*10*vmarkdir2d11load1p(1,:),0.08*10*vmarkdir2d11load1p(2,:), 'r');
xlabel('dimensionless - [kJ*10]');ylabel('dimensionless - [kJ*10]');
title('Direction rose ISO 14242-1 poly (unit vectors and frictional work
vectors)');

figure(17);
hold on
grid on
set(gca,'DataAspectRatio',[1 1 1])
scatter(vmarkdir2d13p(1,:),vmarkdir2d13p(2,:), 'b');

```

```

scatter(0.08*10*vmarkdir2d1load3p(1,:),0.08*10*vmarkdir2d1load3p(2,:), 'r');
xlabel('dimensionless - [kJ*10]');ylabel('dimensionless - [kJ*10]');
title('Direction rose ISO 14242-3 poly (unit vectors and frictional work
vectors)');

%creating the data matrix for table output

%I Table
data=zeros(4,11);

data(1,:)=ISO1VEC(1,:);
data(2,:)=ISO3VEC(1,:);
data(3,:)=ISO1pVEC(1,:);
data(4,:)=ISO3pVEC(1,:);

table1=figure('Name', 'Summarising table', 'Position', [100 100 1040 200]);

colNames1 = {'sectorn', 'sectorm', 'sectorq', 'directiondegn', 'directiondegm',
'directiondegq', 'Wf [J]', 'Wo [J]', 'Co', 'k','Wcycle [J]'};
rowNames1 = {'ISO1', 'ISO3', 'ISO1poly', 'ISO3poly'};

t1 = uitable('parent', table1, 'Data', data,
'ColumnName',colNames1,'RowName',rowNames1,...
'ColumnWidth', 'auto','Position', [10 10 928 94]);

%Bars for nvec
figure(19);
subplot(2,2,1);
hold on
grid on
bar(nvec1)
xlabel('Sectors');ylabel('Occurrence');
title('nvec for ISO 14242-1');
hold off;

subplot(2,2,2);
hold on
grid on
bar(nvec3)
xlabel('Sectors');ylabel('Occurrence');title('nvec for ISO 14242-3');
hold off;

subplot(2,2,3);
hold on
grid on
bar(nvec1p)
xlabel('Sectors');ylabel('Occurrence');title('nvec for ISO 14242-1 poly');
hold off;

subplot(2,2,4);
hold on
grid on
bar(nvec3p)
xlabel('Sectors');ylabel('Occurrence');title('nvec for ISO 14242-3 poly');
hold off;

%Bars for mvec

```

```

figure(20);
subplot(2,2,1);
hold on
grid on
bar(mvec1)
xlabel('Sectors');ylabel('Occurrence');title('mvec for ISO 14242-1');
hold off;

subplot(2,2,2);
hold on
grid on
bar(mvec3)
xlabel('Sectors');ylabel('Occurrence');title('mvec for ISO 14242-3');
hold off;

subplot(2,2,3);
hold on
grid on
bar(mvec1p)
xlabel('Sectors');ylabel('Occurrence');title('mvec for ISO 14242-1 poly');
hold off;

subplot(2,2,4);
hold on
grid on
bar(mvec3p)
xlabel('Sectors');ylabel('Occurrence');title('mvec for ISO 14242-3 poly');
hold off;

%Bars for qvec
figure(21);
subplot(2,2,1);
hold on
grid on
bar(qvec1)
xlabel('Sectors');ylabel('Occurrence');title('qvec for ISO 14242-1');
hold off;

subplot(2,2,2);
hold on
grid on
bar(qvec3)
xlabel('Sectors');ylabel('Occurrence');title('qvec for ISO 14242-3');
hold off;

subplot(2,2,3);
hold on
grid on
bar(qvec1p)
xlabel('Sectors');ylabel('Occurrence');title('qvec for ISO 14242-1 poly');
hold off;

subplot(2,2,4);
hold on
grid on
bar(qvec3p)
xlabel('Sectors');ylabel('Occurrence');title('qvec for ISO 14242-3 poly');
hold off;

```

```

nvec1
%polar and compass diagrams
[ polarnvec1, compassnvec1, rnvec1 ] = polararrange( nvec1 );
[ polarnvec3, compassnvec3, rnvec3 ] = polararrange( nvec3 );
[ polarnvec1p, compassnvec1p, rnvec1p ] = polararrange( nvec1p );
[ polarnvec3p, compassnvec3p, rnvec3p ] = polararrange( nvec3p );

[ polarmvec1, compassmvec1, rmvec1 ] = polararrange( mvec1 );
[ polarmvec3, compassmvec3, rmvec3 ] = polararrange( mvec3 );
[ polarmvec1p, compassmvec1p, rmvec1p ] = polararrange( mvec1p );
[ polarmvec3p, compassmvec3p, rmvec3p ] = polararrange( mvec3p );

[ polarqvec1, compassqvec1, rqvec1 ] = polararrange( qvec1 );
[ polarqvec3, compassqvec3, rqvec3 ] = polararrange( qvec3 );
[ polarqvec1p, compassqvec1p, rqvec1p ] = polararrange( qvec1p );
[ polarqvec3p, compassqvec3p, rqvec3p ] = polararrange( qvec3p );

figure(22);
subplot(2,2,1);
polar(polarnvec1(1,:), polarnvec1(2,:), '-or')
subplot(2,2,2);
polar(polarnvec3(1,:), polarnvec3(2,:), '-or')
subplot(2,2,3);
polar(polarnvec1p(1,:), polarnvec1p(2,:), '-or')
subplot(2,2,4);
polar(polarnvec3p(1,:), polarnvec3p(2,:), '-or')

figure(23);
subplot(2,2,1);
polar(polarmvec1(1,:), polarmvec1(2,:), '-or')
subplot(2,2,2);
polar(polarmvec3(1,:), polarmvec3(2,:), '-or')
subplot(2,2,3);
polar(polarmvec1p(1,:), polarmvec1p(2,:), '-or')
subplot(2,2,4);
polar(polarmvec3p(1,:), polarmvec3p(2,:), '-or')

figure(24);
subplot(2,2,1);
polar(polarqvec1(1,:), polarqvec1(2,:), '-or')
subplot(2,2,2);
polar(polarqvec3(1,:), polarqvec3(2,:), '-or')
subplot(2,2,3);
polar(polarqvec1p(1,:), polarqvec1p(2,:), '-or')
subplot(2,2,4);
polar(polarqvec3p(1,:), polarqvec3p(2,:), '-or')

figure(25);
subplot(2,2,1);
compass(compassnvec1(1,:), compassnvec1(2,:))
subplot(2,2,2);
compass(compassnvec3(1,:), compassnvec3(2,:))
subplot(2,2,3);
compass(compassnvec1p(1,:), compassnvec1p(2,:))
subplot(2,2,4);
compass(compassnvec3p(1,:), compassnvec3p(2,:))

figure(26);
subplot(2,2,1);

```

```

compass(compassmvec1(1,:), compassmvec1(2,:))
subplot(2,2,2);
compass(compassmvec3(1,:), compassmvec3(2,:))
subplot(2,2,3);
compass(compassmvec1p(1,:), compassmvec1p(2,:))
subplot(2,2,4);
compass(compassmvec3p(1,:), compassmvec3p(2,:))

```

```

figure(27);
subplot(2,2,1);
compass(compassqvec1(1,:), compassqvec1(2,:))
subplot(2,2,2);
compass(compassqvec3(1,:), compassqvec3(2,:))
subplot(2,2,3);
compass(compassqvec1p(1,:), compassqvec1p(2,:))
subplot(2,2,4);
compass(compassqvec3p(1,:), compassqvec3p(2,:))

```

```

figure(28);
subplot(2,2,1);
rose(rnvec1, 16)
subplot(2,2,2);
rose(rnvec3, 16)
subplot(2,2,3);
rose(rnvec1p, 16)
subplot(2,2,4);
rose(rnvec3p, 16)

```

```

figure(29);
subplot(2,2,1);
rose(rmvec1, 16)
subplot(2,2,2);
rose(rmvec3, 16)
subplot(2,2,3);
rose(rmvec1p, 16)
subplot(2,2,4);
rose(rmvec3p, 16)

```

```

figure(30);
subplot(2,2,1);
rose(rqvec1, 16)
subplot(2,2,2);
rose(rqvec3, 16)
subplot(2,2,3);
rose(rqvec1p, 16)
subplot(2,2,4);
rose(rqvec3p, 16)

```

```

figure(31);
hold on
grid on
plot(gaitperc, L, 'r');
plot(gaitperctrim, F, 'm');
legend('Loading law','Frictional force')
xlabel('Gaitperc [%]');ylabel('Load [kN] - Frictional force [kN]');
title('Loading law and frictional force law');

```

```

figure(35);
hold on
grid on
plot(gaitperc, L, 'r');
legend('Loading law')
xlabel('Gaitperc [%]');ylabel('Load [kN]'); title('Loading law');

%----WAVEFORMS OVERLAPPING PLOTS-----

%ISO 14242-1 waveforms plot
figure(36);
subplot(1,2,1);
hold on
grid on
plot(gaitperc,feISO1, 'r', gaitperc,aaISO1, 'g', gaitperc,ierISO1, 'k')
plot(gaitperc,fepolyISO1, 'r', gaitperc,aapolyISO1, 'g', gaitperc,ierpolyISO1,
'k')
legend('FE','AA','IER')
xlabel('Gaitperc [%]');ylabel('Angles [rad]'); title('ISO 14242-1 waveforms-poly
comparison');
hold off;

%ISO 14242-3 waveforms plot
subplot(1,2,2);
hold on
grid on
plot(gaitperc, feISO3, 'r', gaitperc, aaISO3, 'g')
plot(gaitperc, fepolyISO3, 'r', gaitperc, aapolyISO3, 'g')
legend('FE','AA')
xlabel('Gaitperc [%]');ylabel('Angles [rad]'); title('ISO 14242-3 waveforms-poly
comparison');
hold off;

%II Table
[h,p]=jbtest(atan2quad1)
meandist=mean(atan2quad1)
stddist=std(atan2quad1)
skewnessdist=skewness(atan2quad1)
kurtosisdist=kurtosis(atan2quad1)
dfittool(atan2quad1)

datadist=zeros(1,6);

datadist=[h, p, meandist, stddist, skewnessdist, kurtosisdist];

table2=figure('Name', 'Statistical analysis', 'Position', [100 100 600 150]);

colNames2 = {'I-O jbtest', 'probability jbtest', 'mean [rad]', 'standad
deviation', 'skewness', 'kurtosis'};
rowNames2 = {'values'};

t2 = uitable('parent', table2, 'Data', datadist,
'ColumnName',colNames2,'RowName',rowNames2,...
'ColumnWidth', 'auto','Position', [20 20 570 40]);

```

pi_rotation.m

```

function [ atan2 ] = pi_rotation( atan4 )
%PI_ROTATION: This function takes the anglar values in of vector atan4 and
%rotates the negative vlues by an angle of +pi
% Detailed explanation goes here

atan21=sign(atan4);

atan22=(atan21).*(atan21);

atan23=atan21-atan22;

atan24=sign(atan23);

atan25=-pi*atan24;

atan2=atan4+atan25;

end

```

polararrange.m

```

function [ polarnvec, compassnvec, rnvec1 ] = polararrange( nvec )
%POLARARRANGE: this functin, given the nvec input, returns the vector
%accompanied by a new line indicating the angle corrsponding to the value
%that is in the column

polarnvec=zeros(2,length(nvec));
angles=pi/(2*length(nvec)):pi/(length(nvec)):pi
polarnvec(1,:)=angles; polarnvec(2,:)=nvec;
%polarnvec

compassnvec=zeros(2,length(nvec));
compassnvec(1,:)=nvec(:).*cos(angles(:));
compassnvec(2,:)=nvec(:).*sin(angles(:));
%compassnvec

%if the vector in question in not composed of all integers, the code
%generates a new vector the numbers of which are 1.000.000 times the previous
%one. This because the columns of the vector, when are not integers, are
%very little, and so this is performed to find a new vector that is
%proportional to the old one and the numbers are rounded to the closest
%unit

%nvec-round(nvec);
%sum(nvec-floor(nvec));
if sum(nvec-floor(nvec))~=0
    nvec=1000000.*nvec;
end

rnvec=round(nvec);
i=1;
rnveci=((pi/(2*length(nvec)))+pi/(length(nvec))*(i-1)).*ones(1,rnvec(i));
rnvec1=rnveci;
i=i+1;
for n=2:length(nvec)
    rnveci=((pi/(2*length(nvec)))+pi/(length(nvec))*(i-1)).*ones(1,rnvec(i));
    rnvec1=[rnvec1, rnveci];
    i=i+1;
end

```

end

Bibliography

- [1] I. A. Kapandji, *The Physiology of the Joints, Volume Two Lower Limb*, Churchill Livingstone, 1987.
- [2] N. Petrone, «Richiami di anatomia descrittiva del sistema muscolo scheletrico,» Padua.
- [3] G. D. Baura, *Medical Devices, Total Hip Prostheses (Ch. 18)*, Elsevier Inc., 2012.
- [4] M. A. Mont, P. S. Ragland, G. Etienne, T. M. Seyler e T. P. Schmalzried, «Hip resurfacing arthroplasty,» *Journal of the American Academy of Orthopaedic Surgeons*, 2006.
- [5] «"Metal-on-metal Hip Implants",» U.S. Food and Drug Administration, 2011.
- [6] V. Saikko e O. Calonijs, «Slide track analysis of the relative motion between femoral head and acetabular cup in walking and in hip simulators,» *Journal of Biomechanics*, 2001.
- [7] N. Petrone, «Biomeccanica dell'anca e Protesi d'anca,» Padua.
- [8] G. Bergmann, G. Deuretzbacher, M. Heller, F. Graichen, A. Rohlmann, J. Strauss e G. N. Duda, «Hip contact forces and gait patterns from routine activities,» *Journal of Biomechanics*, 2001.
- [9] «ISO 14242-1 Implants for surgery - Wear of total hip-joint prostheses - Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test,» 2002.
- [10] «ISO 14242-2 Implants for surgery - Wear of total hip-joint prostheses - Part 2: Methods of measurement,» 2000.
- [11] «ISO 14242-3 Implants for surgery - Wear of total hip-joint prostheses - Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test,» 2009.
- [12] A. Wang, A. Essner e J. Cooper, «The clinical relevance of hip simulator testing of high performance implants,» in *Seminars in Arthroplasty*, 2006.
- [13] A. Wang, "A unified theory of wear for ultra-high molecular weight polyethylene in multi-directional sliding," *Wear*, 2001.
- [14] «ISO 14242-3 Implants for surgery - Wear of total hip-joint prostheses - Part 3: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test,» 2002.