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Anterior Cruciate Ligament Reconstruction Follow-up Instrumentation based on Centre of Rotation Videofluoroscopy Determination:

Development of an original equipment, CINARTRO, and first clinical use

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Abstract— The estimation of the Centre of Rotation (COR) of the knee is important for Anterior Cruciate Ligament reconstruction evaluation and therefore helps to put in place rehabilitation strategies, as well as to give feedback to the surgeon. The Tibial-Femoral Contact Point technique is implemented towards the design of an original clinical equipment (CINARTRO) which captures sequences of fluoroscopic Rx knee images during extension/flexion, allows interactive image processing and creates reports for the Electronic Clinical Record in CDA format. For the first time in our region, quantitative assessment of COR migration on the tibial plateau is possible.

Keywords—*Anterior Cruciate Ligament (ACL) Repair Follow-up, Knee Centre of Rotation (COR), Knee Biomechanics, CINARTRO, Original Equipment, Biomedical Engineering.*

I. INTRODUCTION

The knee articulation (KA) is responsible for two contradictory functions: static stability during full extension and adaptation to ground irregularities during gait and running [1]. Clinical appraisal of movement is subjective, which has suggested several methods of objective measurement, all circumscribed within research settings. One method is the Centre of Rotation (COR) and its migration during flexo/extension on the tibial plateau [2]. This determination of knee artrokynematics could be used as an objective method to evaluate Anterior Cruciate Ligament (ACL) reconstruction [3][4]. COR migration data also helps to put in place rehabilitation strategies and to monitor them, as well as to give feedback to the surgeon. We set ourselves the goal of developing a methodology and a clinical instrument for ACL follow-up, based on prior medical device development experience [5][6]. Clinical validation was performed.

II. RATIONALE AND SPECIFICATION OF THE INSTRUMENT

A. Relevance of the instrument designed

The incidence of ACL lesions is estimated as 1 every 3000 population, which accounts for over a billion dollars in surgical and rehabilitation costs only in the USA [7]. This overall cost is equivalent to US\$ 10.000 for every injured person including

6 months of rehabilitation [8]. Surgery and rehabilitation restore stability and the basic knee function. The main concern of the surgeon is to count on reliable and objective elements to evaluate the restoration and for the Physiotherapist the periodic COR estimation is a measure of the rehabilitation work done.

The instrument to be designed will add quantitative input to the traditional clinical approach of gait observation and tests such as the one described by Lachman using the artrometre, (e.g.: KT-1000 y KT- 2000) [9]. When the ACL is repaired, the rehabilitation process aims at strengthening muscular action and neuromuscular control, in order to preserve as much as possible all functions present prior to the lesion. In particular the initial training phases are critical in strengthening quadriceps involvement with ACL [10].

For ACL reconstruction evaluation, usual clinical practice includes imaging studies such as X rays, CT scans and NMR, all of which are purely static evaluations. Although anatomical structures may be shown in great detail, no dynamic aspects are addressed, which are part of the essence of knee joint functions. The instrument to be designed should record, evaluate and quantify kinematics characteristics of the KA.

B. Existing methods to determine the Centre of Rotation

The knee COR has been determined by several authors [11] [12] [13] [14] to quantify articular kinematics. It was shown that the COR is not fixed and follows a complex trajectory which allows the knee to be both stable and to perform rotations. In-vitro studies by Gill & O'Connor [11] (estimate the COR where ligaments cross. Others, such as Baltzopoulos 1999 [12], suggest in vivo COR determination as the contact point of two articular surfaces (femur and tibial plateau). Other researchers like Panjabi in 1982 [15] use the method of Reuleaux and there is still a more complex 3D method by Qi in 2013 which determines the COR migration in space during flexo-extension movements of the knee. [14]

C. Specification of the instrument to be designed

There are no instruments available today to spot quantitatively the COR during knee joint movement, to be used

during routine patient care. This instrument to be designed should compare the injured knee with the other knee and the injured knee prior and after surgery, as well as at set intervals during rehabilitation.

The instrument to be designed should determine the COR and its migration during flexo-extension and create a document for the Electronic Clinical Record of the patient, as well as a hard copy. The details of the determination should be decided by the specialist during an interactive software application, minimizing errors and uncertainties. The instrument will show both the contra-lateral knee joint images and COR determination as well as those of the injured knee, allowing easy reference and comparisons [16]. Similarly the instrument should include presentation modes to show the follow-up of a knee joint being reeducated.

The instrument was called CINARTRO to suggest kinematics (“CIN”) and joint (“ARTROS”), meaning an instrument to study joint movement, in this case of knee joints.

D. Experimental set up to design the instrument

In order to obtain a proof of concept and to validate the method, an experimental set up was initially build to analyze results on practical, real data. To this end the following elements were secured and connected

- C-arm Xray equipment with video data acquisition
- Data acquisition hardware to digitize the images
- Software to determine the fiducial points of every knee joint image, to define the tibial plateau and the femur and therefore determination of the COR in every image
- Software to calculate the percentage of migration of COR over the tibial plateau

The method used consists of obtaining for every KA a series of 30 X ray images during extension and 30 images during flexion, instructing the seated patient to perform each extension/flexion in 2 + 2 seconds. The overall dosis delivered by the C-arm was 250 microGy (J/Kg) absorbed every 2 seconds movement.

In order to record exact dimensions, prior to every patient study, a phantom consisting of a matrix of lead spheres (3 mm diameter, 1 cm apart from each other) is placed between the X ray emitter and the fluoroscope, thus allowing calibration.

III. PROJECT AND BUILDING BLOCKS

To tackle the clinical need for the instrument specified, we suggest a configuration such as the one represented in Fig. 1. A C-arm apparatus used for coronariography was temporarily used for the proof of concept, giving us standard sequences of images to be processed later. A calibration phantom was developed with x-ray transparent support in which small lead spheres were glued.

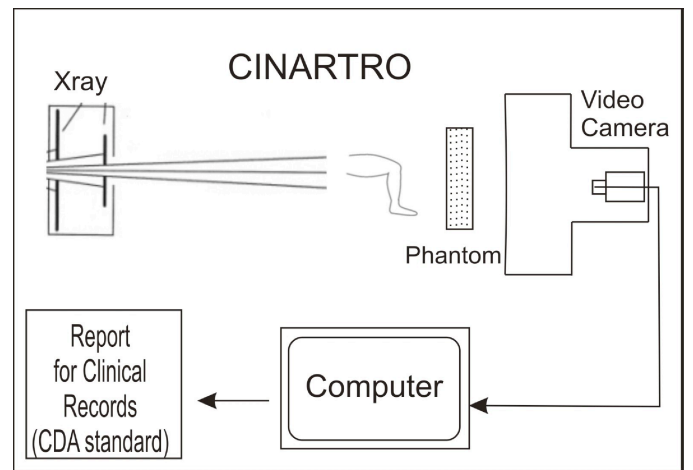


Fig. 1. Block diagram of CINARTRO. Serial X ray images are obtained during flexo-extension. Fiducial points are marked for every image, allowing Center of Rotation (COR) to be determined. The clinical report shows the migration of the COR projection along the tibial plateau.

The X-ray apparatus used for the preliminary proof of concept of CINARTRO is available but cumbersome to use and expensive (C arm for cardiac procedures). We are working towards the design of a dedicated compact X-ray device, probably derived from veterinary equipment which will allow us to design a simple, portable CINARTRO.

IV. CLINICAL RESULTS USING CINARTRO

The system was used to evaluate ACL reconstruction of four subjects, after securing Ethics Committee approval. In Fig. 2 one of the 30 images is shown with the points marked by the user using a preliminary version of CINARTRO software. The information of both segments (straight line for tibial plateau and three points curve for femur) is used to determine the COR according to the Baltzopoulos method [17].



Fig. 2. X ray of a knee joint taken by CINARTRO experimental set up. Note the tibial plateau highlighted by 2 points selected by the user with the software and 3 points of the femur contour. The COR is determined as the midpoint of the shortest segment between femur and tibial plateau.

After the points have been marked, the software calculates, for every angle of the KA, the position of the COR relative to the tibial plateau segment. This information is key for the evaluation of the KA kinematics, and therefore is graphed in the format shown in Fig. 3. Once the COR migration is determined in the three situations, all curves are shown simultaneously, as in Fig. 4. The three instances shown are: prior and after surgery and the other knee.

In Fig. 4 the Flexo/extension angle is shown on the x-axis (from 20° to 90°) while COR migration distance along the tibial plateau is shown on the y-axis (range of 10% to 62% of total tibial plateau length). Fig. 4 shows the data of a patient whose knee fluoroscopy was obtained prior to surgery on both legs and after ACL reconstruction. The healthy knee has a migration of 52% of plateau, reduced to 23% when injured and back to 34% after reconstruction. The uncertainty of these measurements on several patients [4] was found to be smaller than 7 % of total tibial plateau length.

V. DISCUSSION

Clinical practice of ACL reconstruction follow-up has demanded for many years a practical instrument to benefit from research in KA kinematics. On one side research explained the dynamics of the consequences of ACL rupture and the partial reconstruction obtained with different surgical techniques. This explanation remained within the realm of academic work, while clinicians had no other way to record the evolution of a repaired ACL but static images and their observations of the patient with limited displacement tests.

By developing CINARTRO we are suggesting an objective procedure to record the result of ACL reconstructive surgery immediately after inflammation lowers, and later at intervals during physiotherapy and rehabilitation.

As a conclusion we may state that fundamental research on the behaviour of KA kinematics with estimations of the COR migration has led to fill a clinical need by giving rise to a new instrument, specially designed to capture and process fluoroscopic images, during rehabilitation.

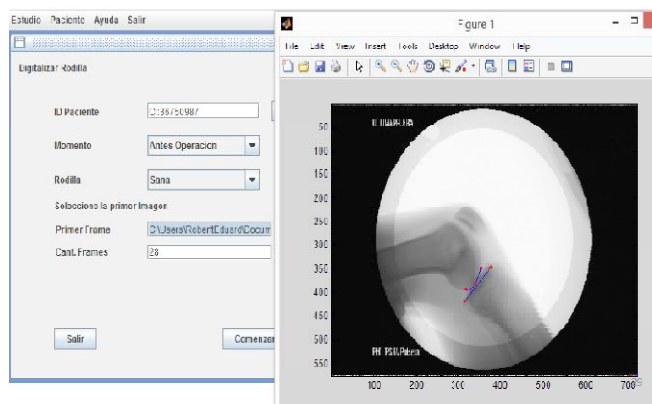


Fig. 3. Software prototype of CINARTRO, to ease the task to select points, to calibrate images and to create a clinical report.

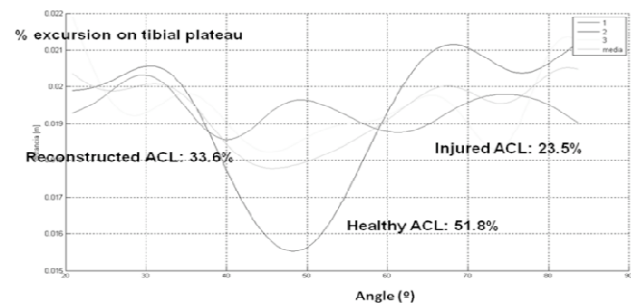


Fig. 4. Migration of centre of rotation (COR) along the tibial plateau determined by CINARTRO. Flexo/extension angle is shown on the x-axis, (20° to 90°) while COR migration on the tibial plateau is shown on the y-axis (10% to 62%). This patient has a contralateral knee migration of 52%, reduced to 23% by ACL rupture and back to 34% after surgery.

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