PROCESS OF DESIGN A DEVICE TO MESURE THE MOVEMENTS OF THE SHOULDER ABDUCTION AND EXTENSION IN PEOPLE WITH INJURY IN THE ROTATOR CUFF

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Abstract. *The paper objective is to show the process of designing a device to measure internal rotation of the shoulder in people with limitation of this movement. Starts understanding the injuries, how they impact the movement and the shoulder anatomy and physiology, from this information and the need to make the measurement in people on foot were established three measurement procedures witch are: measurements on photographs, using an optical shield and use a mechanical device. All were evaluated and was chosen the mechanical device called bi-goniometer. Was made a mechanical design in CAD (computer aid design), simulating the movements of the components. With a prototype, measurements, with a procedure, were made to correct the device, this was an important step due to diversity of people to be measured. A repeatability study was made to validate the instrument that was used to measure a series of people in a shoulder injury study. Some suggestions were made to improve the device to make it more autonomous.*
Keywords*: shoulder measurement, design process, repeatability*

1. INTRODUCTION

Shoulder joint is composed of three bones: the clavicle, the scapula, and the humerus. Shoulders are the most movable joints in the body. They can also be unstable because the ball of the upper arm is larger than the shoulder socket that holds it. To remain in a stable or normal position, the shoulder must be anchored by muscles, tendons and ligaments. Because the shoulder can be unstable, it is the site of many common problems. They include sprains, strains, dislocations, separations, tendinitis, bursitis, torn rotator cuffs, frozen shoulder, fractures and arthritis, MedlinePlus (2011).

AAOS (2010), says that the orthopedic evaluation of your shoulder consists of three components:

- A medical history to gather information about current complaints; duration of symptoms, pain and limitations; injuries; and past treatment with medications or surgery.
- A physical examination to assess swelling, tenderness, range of motion, strength or weakness, instability, and/or deformity of the shoulder.
- Diagnostic tests, such as X-rays taken with the shoulder in various positions. Magnetic resonance imaging (MRI) may be helpful in assessing soft tissues in the shoulder. Computed tomography (CT) scan may be used to evaluate the bony parts of the shoulder.

Among these components, were chosen the range of motion within physical examinations component for the study because this is an important parameter to evaluate functional assessment of the shoulder. Again, it was necessary to choose among a series of possible positions that represents specific activities of daily living As the measurement of internal rotation is very subjective and there is not a well established method for that, it was chosen the medial rotation measurement by indirect method due the importance for the representation of the activities of daily living since its restriction disable greatly persons.

To examine the differences among the normal and the affected shoulder, it was developed an instrument to measure the angular position of the humerus shaft combined with medial rotation and extension, this combination of positions is also called medial rotation, by indirect method, and thus, compare the normal with the affected shoulder. This instrument was called bi-goniometer. A design sequence was followed in order to obtain the best final results, so the objective of this paper is to show the process of design, indicating the importance of a multi functional team, the use of modern CAD software, and the validation process.

2. ANATOMY OF THE SHOULDER

According to SCOI (2010) the two main bones of the shoulder are the humerus and the scapula “Fig. 1”. The joint cavity is cushioned by articular cartilage covering the head of the humerus and face of the glenoid. The scapula extends up and around the shoulder joint at the rear to form a roof called the acromion, and around the shoulder joint at the front to form the coracoid process.

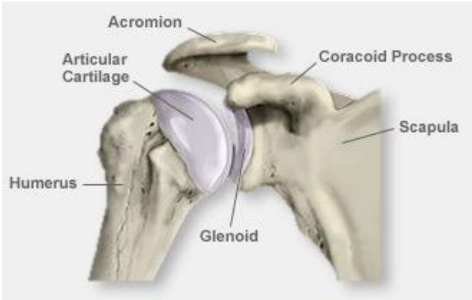


Figure 1. Shoulder bones. (SCOI, 2010)

Ligaments connect the bones of the shoulder, and tendons join the bones to surrounding muscles “Fig. 2”. Four short muscles originate on the scapula and pass around the shoulder where their tendons fuse together to form the rotator cuff.

The rotator cuff is a group of flat tendons ”Fig. 3” which fuse together and surround the front, back, and top of the shoulder joint. These tendons are connected individually to short, but very important, muscles that originate from the scapula. When the muscles contract, they pull on the rotator cuff tendon causing the shoulder to rotate upward, inward, or outward.

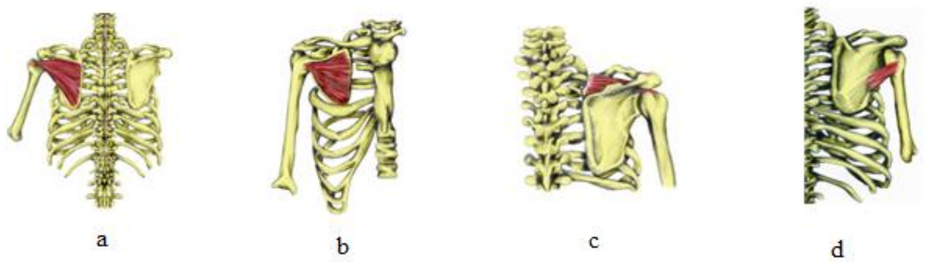


Figure 2. Rotator cuff muscles, (SIC, 2011). a. Infraspinatus b. Subscapularis c. Supraspinatus d. Teres Minor

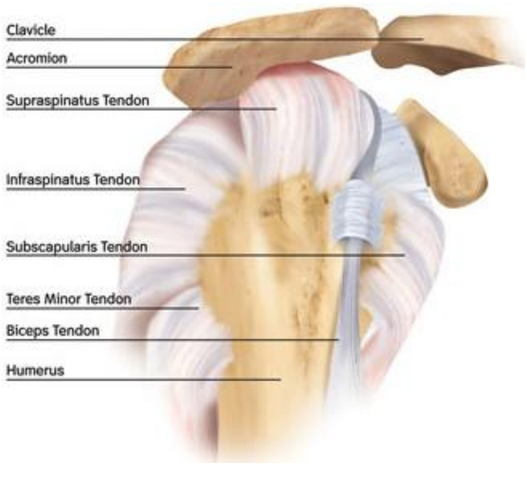


Figure 3. Rotator cuff tendons
(Smith & Nephew, 2011)

2.1. Anatomical planes of the body

Medical professionals often refer to sections of the body in terms of anatomical planes (flat surfaces) "Fig. 4". These planes are imaginary lines – vertical or horizontal – drawn through an upright body. The terms are used to describe a specific body part.

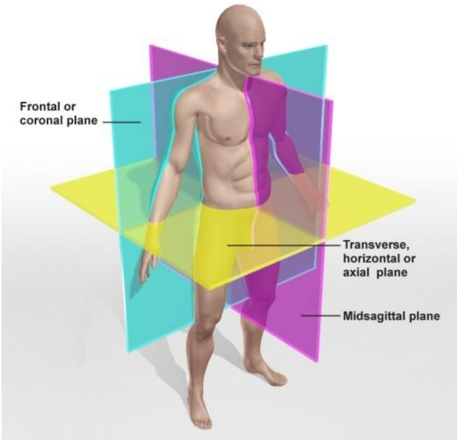


Figure 4. Anatomical planes (Anatomy.tv, 2006)

2.2. Shoulder physiology

According to Kapandji (2000), shoulder is one of the most mobile joint of the human body, it has three degrees of freedom and rotation "Fig. 5":

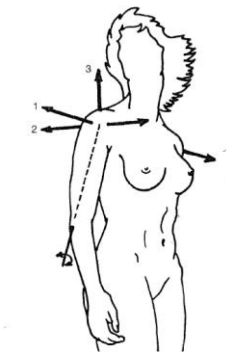


Figure 5. Shoulder degrees of freedom and rotation (Kapandji, 2000)

- Transverse axis, allow flexion – extension in the sagittal plane "Fig. 6";

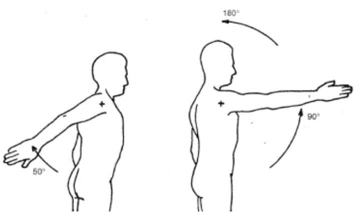


Figure 6. Flexion / extension movements (Kapandji, 2000)

- Anterior-posterior axis, allows the movements of abduction – adduction in the frontal plane "Fig. 7";

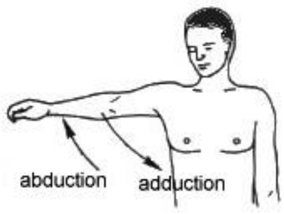


Figure 7. Abduction / Adduction movements (QMUL, 20??)

- Vertical axis, determined by the intersection the sagittal plane and the frontal plane with the arm in adduction of 90°, direct the movement of flexion-extension in the horizontal pane "Fig. 8".

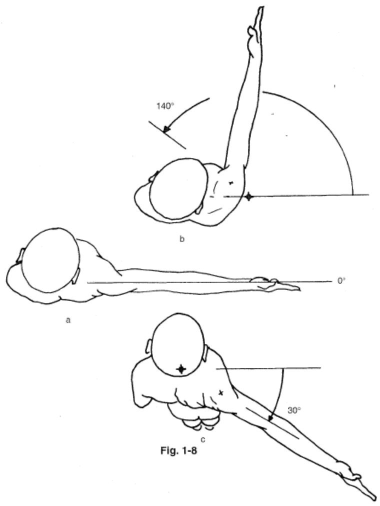


Figure 8. Horizontal Flexion / extension movements (Kapandji, 2000)

The arm rotation about its longitudinal axis can be held in any position of the shoulder. In general, this rotation is measured from the anatomical position of the arm that hangs vertically along the body. The anatomical position also called external/internal rotation 0° is basis to measure the amplitude movements it consist in flex the elbow 90° so that the forearm is in the sagittal plane

The external rotation amplitude "Fig.9 b" is 80°. The medial or internal rotation amplitude is 100 to 110°, "Fig. 9 c" shows at 95°, to accomplish this rotation, the forearm must necessarily be behind the trunk which requires a certain degree of shoulder extension Kapandji (2000).

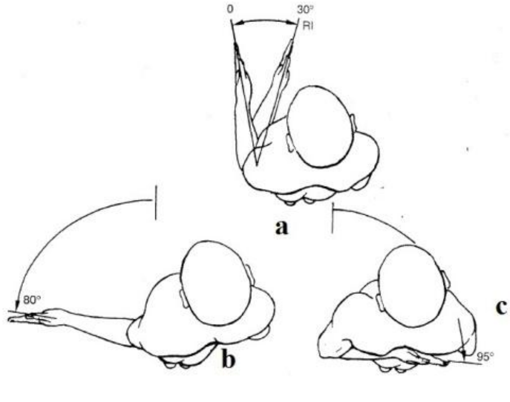
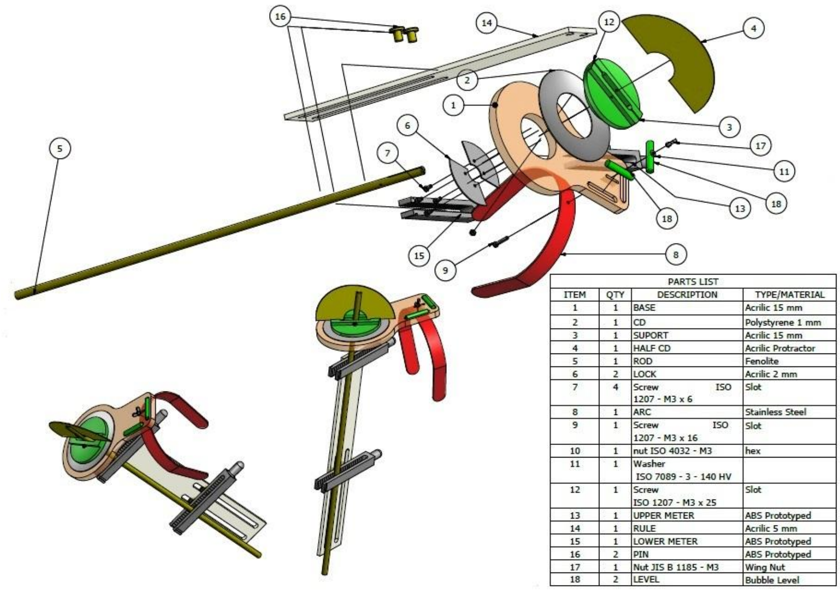


Figure 9. External / Internal rotations (Kapandji, 2000)

3. BI-GONIOMETER DESCRIPTION



PARTS LIST			
ITEM	QTY	DESCRIPTION	TYPE/MATERIAL
1	1	BASE	Acrilic 15 mm
2	1	CD	Polystyrene 1 mm
3	1	SUPORT	Acrilic 15 mm
4	1	HALF CD	Acrilic Protractor
5	1	ROD	Fenolite
6	2	LOCK	Acrilic 2 mm
7	4	Screw ISO 1207 - M3 x 6	Slot
8	1	ARC	Stainless Steel
9	1	Screw ISO 1207 - M3 x 16	Slot
10	1	nut ISO 4032 - M3	hex
11	1	Washer ISO 7089 - 3 - 140 HV	
12	1	Screw ISO 1207 - M3 x 25	Slot
13	1	UPPER METER	ABS Prototyped
14	1	RULE	Acrilic 5 mm
15	1	LOWER METER	ABS Prototyped
16	2	PIN	ABS Prototyped
17	1	Nut JIS B 1185 - M3	Wing Nut
18	2	LEVEL	Bubble Level

Figure 10. Three perspective with one exploded of the bi-goniometer

The drawing "Fig 10 "shows three pictures of the equipment used in the measurements. It is composed of 18 parts described below:

- Part 1, base, it was cut from an acrylic plate of 10 mm in thickness and serves to support the rest of the parts of the mechanism;
- Part 2, CD, it was cut from a plate of polystyrene of 1 mm, serves as a friction reducing ring allowing smoother rotation of the support;
- Part 3, support, it was cut from an acrylic plate of 15 mm and then turned and milled to acquire format designed, serve to support the half CD and the rod, is also responsible for determining an angle;
- Part 4, half CD, it was made from an acrylic protractor cut;
- Part 5, rod, it was cut from a tube of 8 mm phenolite should be positioned parallel to the humerus allows you to read angles;
- Part 6, locks, cut into 2 mm acrylic, serves to hold support at the base;
- Part 7, M3 slotted screw, fixing the lock on the support;
- Part 8, arc, cut from a stainless steel plate, serves to facilitate the placement of equipment on the person's body;
- Part 9, M3 slotted screw, fixed to the arch base;
- Part 10, M3 hex nut;
- Part 11, A3 flat washer, assist in setting the support base;
- Part 12, M3 screw slot, fixes the rod to the support allowing rotation of the rod;
- Part 13, upper meter, was prototyped in ABS plastic (acrylonitrile butadiene styrene or acrylonitrile butadiene styrene) responsible for the spacing between the rod and the epicondyle in person;
- Part 14, ruler, cut into 5 mm acrylic, was subsequently milled to obtain the parallelism of the tears keeps meter upper and lower parallel;
- Part 15, meter lower, was prototyped in ABS plastic, must be supported at the lateral edge of the acromion and later at the tip of the olecranon;
- Part 16, pin, was prototyped in ABS plastic, fixes the meter below the rule allowing the same up and down parallel to the upper meter;
- Part 17, wing nut M3, facilitates the adjustment of the base;
- Part 18, bubble level, keeps the base positioned horizontally.

As shown in "Fig.11" the bi-goniometer is capable of measuring two angles at the same time, the first being the angle of adduction and abduction of the shoulder performed in the frontal plane what is called the angle Y and the second angle rotation also in relation to the frontal plane is called the angle X. The angles are measured with the person in two different positions, resting with the palm facing the body and medial rotation position shown in item c of "Fig 9.

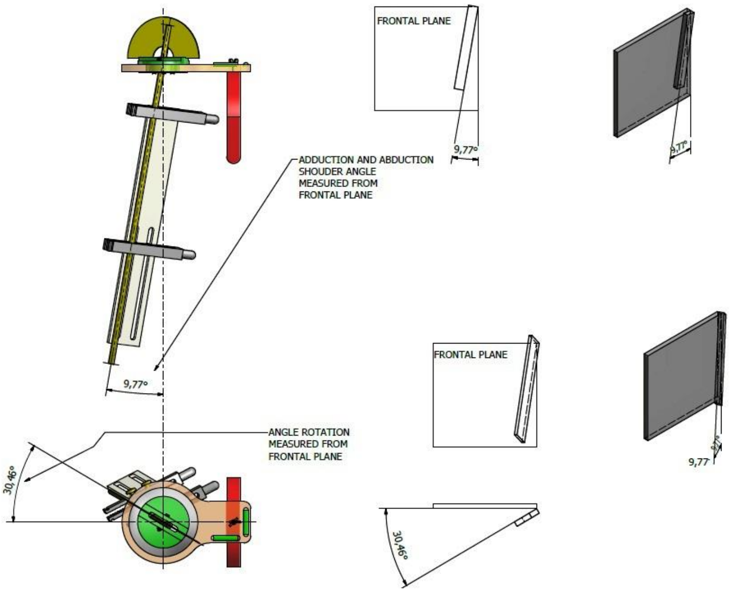


Figure 11. Angles measured by bi-goniometer

4. PRODUCT DEVELOPMENT PROCESS

As Kaminski (2000), all projects have a basic feature: do not grow linearly with each step being fully detailed before moving to the next. The project development is interactive, each item depends on another for the system as a whole to function harmoniously. Thus, an image that clearly defines the design process is a spiral "Figure 12 "where each turn has a refinement to converge to the final configuration.

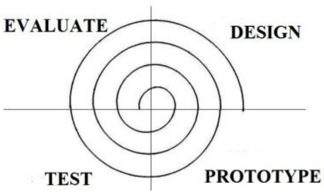


Figure 12. Design Spiral

Kamisnki (2000) cites that, regardless of individual characteristics of each product, the various steps required for their development are in a common general method. A project is developed in sequential stages. It must be considered the whole cycle of production and consumption, but with different priorities depending on the product. It can be defined seven stages for the development of a project:

1st phase – Feasibility study, initial phase where it reaches a set of feasible solutions to the problem;
2nd phase – Basic project, choose between the solutions of the first phase the best and set it;
3rd phase – Project Executive, it is the complete product specifications;
4th phase – Production planning **-** verifying the need to produce the product;
5th phase – Planning for the provision to the customer, such as getting the product to the end customer without damaging it;
6th phase – Planning the use of the product, it is the procedures for use of the product;
7th phase **-** Planning of the abandonment of the product, determine how the product is discarded after its useful life.

For the developed device, the spiral design can be verified with the various modifications made to each test increasingly improving the measurement process. At this point, It should emphasize the importance of multi disciplinary team consisting of doctors, engineers and statistician working together in order to obtain a complete picture of the system. It has began with the planning of the experiment, including the specification of needs and variables in the design and ending with the technology to be employed for the solution. There were several meetings where without the contribution of each one it would not have reached the final result.

Then, follows a description of the development of each of the seven phases of the bi-goniometer:

1st phase, feasibility study - the need was brought by a team of doctors who wanted to measure more precisely the position of the shoulder of the injured people, and the desired measurement done after the shoulder medial rotation.

One limitation is that the measure should be made with the person standing. Three proposals were raised, these are: photographing the person affected and taking measurements in the picture with the help of software or scale, the second proposal was to use an acrylic shield that would be placed beside the patient and with the help of rules angles were plotted in this screen and then be made the measurements with the aid of scales and protractors.

Figure 13. Measurement with the acrylic shield

"Fig. 13"; the third method was the construction of a device supported on the shoulder of the person with a rod parallel to the humerus, made the reading of two angles determining the position of extension and rotation.

2nd phase, Basic design - the three proposals were presented and demonstrated in a multi disciplinary meeting and selection criteria have been established with the main measure the person standing time for the measurement, portability, cost and ease of manufacture and use. After manipulation, discussions, brainstorms and weights, it was agreed that the proposal closer to the criteria established was the angle-measuring device called a bi-goniometer. Despite the brief description, it was a step that required comprehensive team's creativity and time consumed in preparing prototypes for each of the proposals in order to have full understanding of each situation.

3rd phase, Executive project - the proposal is chosen, it has moved to the detailing phase, shaping the product in three-dimensional CAD software "Fig 14 "to facilitate the communication of the specifications with the multidisciplinary team and the implementation of technical drawings.

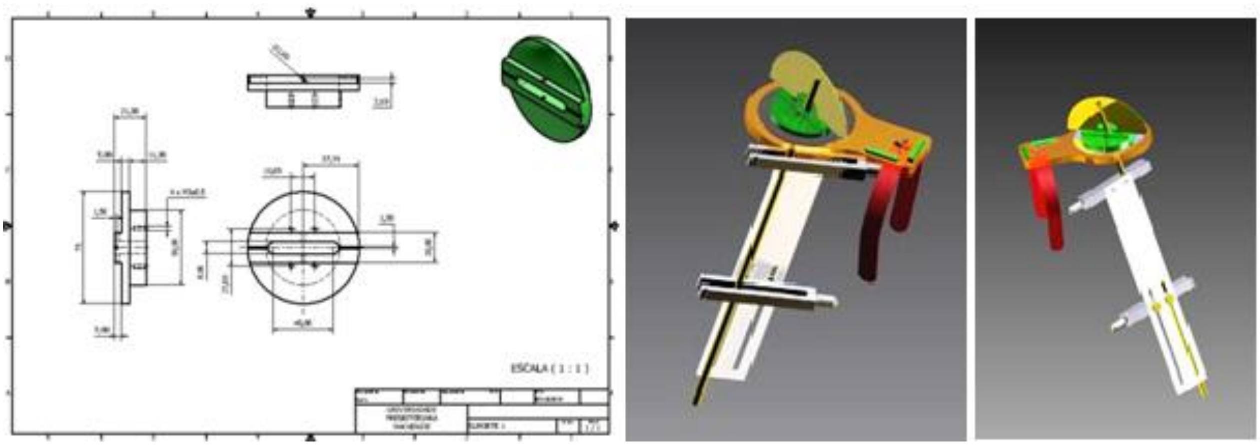


Figure 14. CAD drawings used to show the detail of the device

4th phase, Production planning - with the approved design and material selection, built-in device "Fig 15 ", it is important to mention that complex parts were made by the rapid prototyping process in a machine of type FDM (fused deposition modeling) greatly reducing the manufacturing cycle.

Figure 15. Final product and detail of the number prototyped.

5th phase, Planning available to the client - this phase did not apply in this case.

6th phase, Planning the use of the product - a written procedure of how it should be operated bi-goniometer was made jointly by the team and sometimes reviewed after testing and modifications. This point was crucial to the success of the readings and spent some time in discussions on positioning repeatability and angles involved "Fig 16 "was important to know the anatomy of the shoulder by the team in making decisions.

7th phase, Planning of the abandonment of the product - this phase did not apply in this case.

Figure 16. Tests for making use of the procedures.

5. STUDY OF REPEATABILITY AND REPRODUCIBILITY

The measurement instrument was validated by analyzing separately the repeatability and reproducibility. Repeatability is the degree of agreement between the results of successive measurements of the same size made with the same method, same operator, in the same patient and with the same conditions of use. The reproducibility is the degree of concordance between results of measurements of the same magnitude, in which individual measurements are made, varying the operators with the same method in the same patients, using the same instrument and the same conditions of use.

For all quantities studied were considered consistent measures that do not differ in modulus by more than 15º. This decision was due to the characteristics of the studied and prevents the analysis of the measurement system as usual. We decided then to check on reproducibility, repeated measurements in the amplitude of the same patient by the same operator and the reproducibility of the difference between the modulus measurements made by the two operators in the same patient.

To validate the instrument were first made five measurements of each of the variables used by each operator in six patients. The amplitudes obtained by measurements taken by each operator in the 6 patients are presented in Table 1:

Table 1 - Magnitude of the five measurements made by the same operator

Variable \ Amplitude	0	5	10	15	>15	Total
Neutral X º OD	3	6	3	0	0	12
Neutral Y º OD	1	5	6	0	0	12
RM X º OD	4	4	4	0	0	12
RM Y º OD	4	3	5	0	0	12
COT OD	12	0	0	0	0	12
Neutral X º OE	0	9	3	0	0	12
Neutral Y º OE	0	4	8	0	0	12
RM X º OE	1	11	0	0	0	12
RM Y º OE	2	3	5	2	0	12
COT OE	12	0	0	0	0	12

Neutral X OD – angle measurement in X of the right shoulder in the rest position
Neutral Y OD – angle measurement in Y of the right shoulder in the rest position
RM X OD – angle measurement X of right shoulder in medial rotation
RM Y OD - angle measurement Y of right shoulder in medial rotation
COT OD – angle of the elbow when the right shoulder in medial rotation
Neutral X OE – angle measurement in X of the left shoulder in the rest position
Neutral Y OE – angle measurement in Y of the left shoulder in the rest position
RM X OE – angle measurement X of the left shoulder in medial rotation
RM Y OE - angle measurement Y of the left shoulder in medial rotation
COT OE – angle of the elbow when the left shoulder in medial rotation

It appears that in only one variable, Y RM of OE, such amplitude exceeded 10 degrees, still getting these at 15 degrees, a value considered negligible. This result testified to the measurement repeatability.

Then, it was made for each variable measured by each of the two operators in 16 different patients. Table 2 shows the differences in modulus values between the two measures in the same patient, performed by two operators.

Table 2 - Difference of measurements taken by the two

Variable \ Diference	0	5	10	15	>15	Total
Neutral X º OD	9	6	1	0	0	16
Neutral Y º OD	12	4	0	0	0	16
RM X º OD	11	3	2	0	0	16
RM Y º OD	12	2	2	0	0	16
COT OD	16	0	0	0	0	16
Neutral X º OE	11	5	0	0	0	16
Neutral Y º OE	8	4	3	1	0	16
RM X º OE	10	6	0	0	0	16
RM Y º OE	7	5	4	0	0	16
COT OE	16	0	0	0	0	16

It is noted that only one variable, Y ° Neutral OE, this difference exceeded 10 degrees, still getting it at 15 degrees, a value considered negligible. This result confirms the reproducibility of measurements

6. CONCLUSION

Projects that involve the medical field, especially movements of the human body already inherently possess certain difficulties arising from the variability in size and shape of people and this was no exception, be compounded by the shoulder joint with more degrees of freedom of the human body. The multidisciplinary team, with a methodology have become critical factors for successful development of the measuring device. One of the most critical was the understanding of the measures needed to assess the injured shoulder and should be treated as such. It was repeatedly passed up the spiral design seeking improvements in the quality of measurements. Again multidisciplinary should be cited as a major contributing factor for obtaining results. Even with the repeatability and reproducibility attested, the measurement device still has some difficulties in patient positioning for the implementation of measures; the bubble levels are sensitive requiring greater dexterity of the operators keep the device aligned. Thus, even allowing injured patients to make assessments must again turn the spiral project in order to design a bracket that can support more rigidly in patients easier to read angles and therefore improving the precision of the device.

7. REFERENCES

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