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Research Article

Model in Orthesis in Elbow for Rehabilitation in Rigidity Articulate

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Dissertation presented to the University Federal of São Paulo, Brazil.

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Abstract:

Introduction: Joint stiffness is the most common complication in elbow injuries and may have several etiologies and pathophysiological mechanisms, affecting treatment and prognosis. The measures for prevention and treatment of joint contracture are based on the cause of stiffness, and early intervention should modify the course of this complication, bringing better results; Such methods may be conservative or surgical, isolated or combined, depending on each individual situation.

Objective: To develop a device for use by patients in rehabilitation of elbow injuries.

Method: The development of the device was approached through "Design Thinking", divided into four phases: "Discover", "Define", "Develop" and "Deliver". In the “Discover” phase, interviews were conducted with patients with elbow joint stiffness and professionals about the problem. Literature review and search for anteriority data collection was performed. In the “Define” stage, the anomaly to be included in the study was determined. In the stage “Develop”, search was held for ideas and prototypes and models. “Brainstorming” meetings on the topic were scheduled. In the “Deliver” stage, adjustments and refinements and prototype production were performed, as well as testing for improvements and corrections to the project. Results: In the "Discover" phase, collected questionnaire responses from patients. In the "Define" phase, it was established that joint stiffness was the complaint to be treated. In the “Develop” phase, answers were collected from the questionnaires of the professional groups and “brainstorming” was performed among these collaborators. In the "Deliver" phase, creation of the virtual orthotic model ready for three-dimensional printing.

Conclusion: A device was developed for individualized use and management, molded to each patient, to be used in the rehabilitation of elbow joint injuries.

Key words: robert uterus; septate uterus; endometrioma; dysmenorrhoea and infertility

Symbols

ABS Acrylonitrile butadiene styrene
ADM Range in moves
AM Additive manufacturing
AVD Atividade da vida diária
CAD Computer Aided Design
CAE Computer Aided Engineering
CAM Computer Aided Manufacturing
CINAHL Cumulative Index to Nursing and Allied Health Literature
CIP Classificação Internacional de Patente
COM Continuous Passive Motion
DT Design Thinking ESPACENET European Patent Office FDM Fused Deposition Modeling
GSC Geometry solid constructive
INPI Institute National from the Property Industrial
LILACS Literature Latin American It is of caribbean in Sciences from the Health
LOM Laminated object Manufacturing
MESH Medical Subject Headings
Minimum MVP viable Product
PETG Polyethylene terephthalate glycol
PLA Acid polylactic
RPT Rapid Prototyping Technology
SBOT Company Brazilian in Orthopedics It is Traumatology
SBCOC Title at Society Brazilian in Surgery of Shoulder It is Elbow
SIPO State Intellectual Property office
Selective SLS Laser sintering
SPS Static Progressive Stretch
SUS System Single in Health
TCLE Term in Consent Free It is Enlightened

UNIFESP University Federal in They are Paul
USPTO United States Patent and Trademark Office
WIPO World Intellectual Property Organization
3D Tridimensional

1. Introduction

A rigidity articulate It is the complication more frequent of illnesses joints at the elbow, being able to have miscellaneous etiologies It is mechanisms pathophysiology, affecting treatment and prognosis (LINDENHOVIUS & JUPITER, 2007; CHARALAMBOUS & MORREY, 2012; STANLEY, 2015).

Intrinsic or extrinsic injuries of the elbow It is factors as: age of patient, illnesses inflammatory, infectious or degenerative diseases, hemophilic diseases, trauma, burns, time in immobilization (associated or no the intervention surgical), ossification heterotopic, tumors, illnesses neurological It is congenital (LINDENHOVIUS & JUPITER, 2007).

Measures for the prevention and treatment of joint contracture are based on the cause of the stiffness, and early intervention should modify the course of that complication, bringing best results. Such methods used may be conservative or surgical, isolated or combined, the to depend decade individualized situation (SOCHOL et al., 2019).

O surgeon orthopedic he must be attentive not only the quality from the technique surgery to be used, providing precocious mobility to the post operated, as well as prioritizing rehabilitation of excellence, making use of in instruments what help the team at the treatment of miscellaneous infirmities. You can include the use of CPM (Continuous Passive Motion) and articulated orthoses as adjuvants in the process that, being well maids, It is in form early, will promote maintenance of gain from moves obtained in procedures surgical It is will minimize to the contracts articular (EVANS and al., 2009; Charalambous & MORREY, 2012).

The relevance of using an articulated orthosis in post-operative follow-up operation resides in the stretching and maintenance of the amplitude gain soft tissue joint (capsular, ligamentous, and tendinous structures) in all phases of treatment (SODHI et al., 2019).

O program in immobilization should to be continued, with average in three to four months after surgery, but its duration is variable in relation to the lesion complexity and response to treatment. the amount of time spent at the stretching of elbow in flexion It is extension, he must to be proportional the gravity from the stiffness in each direction: patients with flexion contracture should spend more time stretching in extension and vice versa (SANCHEZ-SOTELO et al., 2018).

In orthopedic practice, the common use of splints is observed. plastered or orthoses no articulated in postoperative in surgeries orthopedic, per period in time variable, aiming protection of surgical procedure performed. However, this method of immobilization hurts the principle that every joint must have early mobility, not being indicated absolute rest of the limb. The experts are in front of injuries complex capsuloligamentous, fractures serious It is unstable, deficiency of bone stock that generates fragility of osteosynthesis or arthroplasty. Therefore, there is a need for additional protection extrinsic after fixation surgical, or same after lesion what no need in approach invasive (SMITH & MORREY, 2009).

In between to the orthoses indicated for rehabilitation in injuries in elbow they are the articulated ones, in great superiority over the non-articulated ones, being difference basic what to the first allow O movement articulate. subdividing to the orthoses articulated, have each other to the static It is to the dynamics.

Static orthoses: allow the greatest tolerated stretching, sometimes in flexion maximum, now in extension maximum, in position constant (McCLURE et al., 1994). Dynamic orthoses: are securely adjustable and graduated to what no there is pain or instability, allowed charge constant in stretch (CHARALAMBOUS & MORREY, 2012). Progressive static orthoses: they are static with increment additional in strength, allowed adjustment at joint position (McCLURE et al., 1994).

There are several examples of orthoses produced worldwide, largely in developed countries. In Brazil, there is very little diffusion of the models used for rehabilitation, mainly us services public, whether due to high taxation, high cost, difficult access to low-income patients' income, precarious recommendation in doctors' experts or from the team in rehabilitation, poverty in knowledge technician about of subject, deficiency defined protocols or even the need to import products from others locations (MAGALHAES et al., 2001).

A leave from the need in obtaining in best results It is in form precocious, it is being stimulated O use in orthoses articulated at practice orthopedic, being important instrument in aid at rehabilitation in injuries simple or complex, aiming The protection articulate without lose The mobility, generating security to surgeon, The team in rehabilitation It is effects positives to the own patient, so much at the control painful, functionality precocious of member, as also acting in benefit psychic of operated, items no offered by orthoses traditional. O job from the three-dimensional technology combines its own customization qualities, low cost, production in scale It is reproducibility to the principle's rehabilitators of articulated orthoses.

2. Objective

"To create model in bracing articulated in elbow for the method in print 3D The to be used at injury rehabilitation.

3. Literature

TUCKER et al., (1978) referred to a causal relationship between the anatomy of soft tissues around the elbow joint and post-traumatic stiffness, existing several possibilities in emergence, as incongruity articulate, bone blockages, degenerative changes, ligament tissue damage or capsular. Arthrography examinations were performed in twelve patients, at the interval in four months The three years for clarify the etiology disabling. found contractures from the capsule previous in nine patients, in two the capsule he was normal It is in one occurred stiffness, probably from bone loss. They observed that capsular contracture is the cause more frequent us patients' carriers in elbow hard evidenced in radiological technique contrasted.

AKESON et al., (1980) reviewed knowledge of the effects of immobility of tissue connective fibrous It is outlined theories about the pathogenesis from the contracture articulate. One model experimental he was developed to assess the soft tissue response to immobility in laboratory. The hind limbs of dogs and rabbits had their knees blocked in flexion per fixation internal per until nine weeks, it is your fabrics periarticular connective tissues were examined immediately after death painless, using device called arthrograph, being measurements to the angular deformations with torque. There were changes in the composition of the connective tissue, such as reduced synthesis of hyaluronic acid, reduced of content of the glycosaminoglycans, increase in Connections crusades It is changes in the fibers of collagen. concluded what bones, muscles It is Cartilages are not only affected by disuse, but the fibrous structures of periarticular connective tissue are functionally disturbed.

ZANDER et al., (1992) reported success in reversing three cases contracture in elbow flexion, using the technique of serial splints made in fiber in glass until purchase amplitude in moves (ADM) satisfactory. From then on, a thermoplastic spigot was used in extension to maintenance. The mean flexion deformity was 44°, present for about in six months. O treatment consisted in methods traditional in stretching for to obtain the elasticity initial of tissue, followed in application of cylindrical fiberglass in the maximum extension position of the elbow. A

splint he was used per three the five days, after removed, it is all O process was repeated until the orthosis was placed in extension for two to three weeks during the day and subsequently six to eight weeks at night. He was reduction in the mean flexion contracture of thirty-seven degrees was achieved. You results indicate that O use of models in series It is technique worthy in consideration in the treatment of contractures in elbow flexion.

BONUTTI et al., (1994) studied O device SPS (Static Progressive Stretch) adding the principle of stress relaxation, through of stretching It is deformation plastic for restoration from the amplitude in movements. One loss in moves of elbow he can to occur due the contractures post-traumatic, postoperative, adhesions, immobilization, cerebral palsy and stroke. Functional restoration can be difficult. because of the proximity of musculature, joint congruence and soft tissue vulnerability. The orthosis was indicated for patients who decreased movement after post-traumatic contractures, as well as after surgery and immobilization. The aim of this study was to evaluate the efficiency from the therapy SPS driven to the patient at the treatment in rigidity articulate. Patients used the device in treatment protocols for thirty to sixty minutes a day, for a period of one to three months. Twenty patients with elbow contracted what had success limited with others modalities therapeutic, including fixed assets serials, splints dynamics, motor physiotherapy and surgery were submitted to the SPS. There was increase in movement average in 31st (69%). All you patients expressed satisfaction, without complications and none showed deficit of ADM during O follow-up on one year.

GELINAS et al., (2000) evaluated the effectiveness of the “turnbuckle” orthosis what uses O principle in immobilization static progressive us patients what presented failure of treatment conservative. They were evaluated twenty It is two patients (fifteen women and seven men), mean age of thirty-nine years, treaties in between 1992 It is 1995. They were excluded those ones with joint incongruence or heterotopic ossification. The average range of flexion before from the splint he was in 32 ± 10th to 108 ± 19th It is 26 ± 10th (P = 0.02) to 127

± 12th (P = 0.0001), with interval in follow-up in 4.5 ± 1.8 months. O mechanism described of device It is O relaxation in charge, what occurs when one tissue contracted It is stretched out, creating like this charge what if dispels to the faraway of time, causing response biological what allows modification permanent of the fabrics. You patients won "bow functional in movement", defined as, for the any less, 100° in admin, demonstrating to be treatment safe It is effective what he must to be considered in patients’ carriers in elbows contracted what no replied to the treatment physiotherapy.

CHARALAMBOUS & MORREY (2012) performed article in revision on the molecular pathogenesis of stiff elbow, its presentation and means assessment, and reported results in open surgery techniques and arthroscopic. reported what your gadgets used for to improve O movement can be dynamic, static or progressive static. splints dynamics have an adjustable spring that exerts a constant stretch load, adjusted to the extent that does not produce pain. In static, the maximum load tolerated comfortably It is applied. A splint dynamic It is based at fluency (increase in length with application of constant load for time prolonged) and in progressive static splints relaxation of the stress (reduction from the charge necessary for to maintain right length). Successful results have been reported in both. fixed assets static progressive they are favorites because they are better tolerated, he has shorter periods of use and may increase complacency. The use of orthoses dynamics immediately after the lesion initial or surgery, he can cause greater swelling and lead to the risk of definitive injury. The exact protocol for bracing is based on the degree of contracture, splint tolerance, circumstances personal, compliance and rate of correction deformity.

MULLER et al., (2013) performed meta-analysis It is revision systematic in thirteen studies about the efficiency from the bracing at the treatment from the restriction from the mobility no bony of elbow. O goal he was to analyze O use of the static, dynamic or progressive static appliances in the treatment of injuries in parts soft later the trauma or surgery what caused stiffness articulate. All clinical studies using dynamic bracing were included. or static in patients with elbow stiffness. The eligible results were changes in amplitude total of movement (flexion It is extension), sustainability of the results It is complications. They were included thirteen studies eligible, providing data about 14 groups treaties in 247 patients. The mean age was 34.5 ± 10.4 years, females represented 46% ± 12%. A duration average since O incident until O start of appliance treatment was 6.9 ± 5.1 months. The improvement in ROM was of 38.4 ± 8.9 (95% confidence interval, 39.5° to 41.8°). there was no difference at comparison in between bracing dynamics, static or static- progressive, however the authors recommended the use of the static- progressive three times in thirty minutes to the day in each direction as first-line treatment of stiff elbow without evidence of restriction or ossification periarticular.

GALLUTTI et al., (2014) evaluated, retrospectively, O treatment stiff elbow with the use of dynamic orthoses. 30 were included patients with ROM equal to or less than one hundred degrees and stable articulation and congruent without heterotopic ossification. The device was used in average, 78 days after the trauma, for an approximate period of 75 days, in the failure of rehabilitation programs. The mean ROM before treatment was 68°, between 109° to 41° with a gain of 37° after using the equipment, varying in between 126th The 21st, getting displacement constant It is strength variable, modifying and stretching the collagen fibers. The average follow-up was twenty-three months. Ten patients did not recover functional mobility. Twenty-three patients were satisfied with the treatment and seven were dissatisfied. The results suggest that dynamic orthoses are useful in the stiff elbow treatment. Average arch improvement of 37° was achieved in movement, what became the unnecessary arthrolysis in many cases.

Kim et al., (2018) developed one bracing personalized in fish, using scanner and 3D printer and evaluated its effect in the treatment of patients with localized pain in the wrist due to overuse syndrome articulation. They were evaluated in one rehearsal clinical prospective randomized, twenty-two patients, divided into eleven in the control group who used a ready-made orthosis, of the Spectra wrist bracket type, and eleven in the experimental group that used 3D printed orthosis for a week and evaluated after application. Significant pain relief was found in both your groups, without difference statistic (P = 0.109), It is scores in high levels of satisfaction, but with a statistically significant difference in the group experimental (P = 0.036 It is 0.004). concluded what the bracing printed in 3D was superior in satisfaction scores to the control orthosis and similar in improvement pain of fish.

BARRIOS-MURIEL et al., (2019) carried out a technological review about advances at manufacturing in orthoses It is prostheses. They were analyzed different additive manufacturing methodologies, along with key methods in collect in shapes 3D It is your application at manufacture in devices functional for rehabilitation purposes. Design tools aided by computer (CAD), engineering aided per computer (CAE) It is computer-aided manufacturing (CAM), prototyping technologies (RPT), techniques such as melt deposition modeling (FDM), selective laser sintering (SLS), laminated object manufacturing (LOM) It is print 3D they are some examples of methodologies available at industry in transformation. O use of RPT It is others modalities in print 3D represents an alternative for the orthoprosthetic industry. The aim is to accelerate the process in reconstruction in models anatomical in 3D for design orthoses. A application of these technologies he can cause improvement significant in the orthosis manufacturing process. They concluded that RPT contributes at optimization of process in manufacture, in addition in to improve design and functionality of the orthopedic devices.

WOJCIECHOWSKI et al., (2020) performed revision systematic for determine the feasibility of designing, manufacturing and delivering

ankle-to-foot orthoses foot, printed three-dimensionally. used bases in data electronics in January in 1985 The June in 2018, employing terms related the print 3D It is orthoses ankle-foot, under any technique in print 3D, related the capacity in locomotion, function biomechanics, properties mechanics, comfort of patient, pain It is inability. Found 11 studies who met the eligibility criteria. 3D printing was used for replicate orthoses ankle-foot traditional It is to develop new designs for optimize properties in stiffness or reduce Weight It is to improve the ease of its use. Customized, 3D-printed orthoses have been found to be comparable to traditional custom orthoses and prefabricated orthoses carbon fiber or other material, in terms of mechanical rigidity, kinematics and energy dissipation. They concluded that manufacture of orthoses ankle-foot he can to have benefits potentials in relationship The methods traditional, including projects what optimize rigidity It is dissipation in energy, improve the biomechanics to wander, comfort It is adjustment of device.

4 Methods

4.1 drawing of Study

It is a prospective, primary and developed in the Course of Master's degree Professional in Science, Technology It is Management Applied the Regeneration Tissue from the University Federal in They are Paul (UNIFESP).

it was treated in project belonging the UNIFESP, accomplished through of the concepts of Design Thinking, containing four phases of method double Diamond: discover, to define, to develop It is delivered, produced in form virtually entirely. Steps that needed collaborators: 1- Phase Discover of Design Thinking: contact with patients included at the project via email, Letter invitation It is quiz individual, through from the tool Google Forms.

3-Develop Phase of Design Thinking: contact with professionals included at the project, via email, Letter invitation It is quiz individual through from the tool Google Forms. Also, he was accomplished brainstorming, per conference call, live.

Second It is fourth phases, to define It is delivering no needed in collaborators.

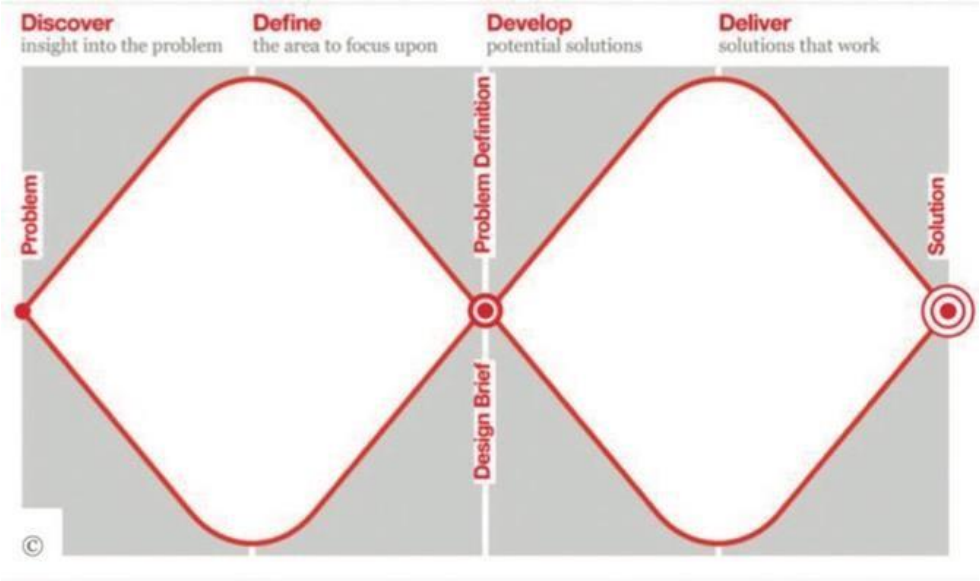


Figure 1: Diagram Double Diamond – description print shop of Design Thinking.

4.2 Aspects ethical

This study was approved by the Research Ethics Committee of the UNIFESP - EPM, under opinion No. 4,226,949, on August 20, 2020 (Appendix 1).

4.3 Application in concepts in Design thinking

4.3.1 Discover

- **Search In Priority**

Research was carried out on articulated elbow orthoses made under technique in print 3D in the platforms INPI (Institute National from the Property Industrial), SPACENET (Desk in Patent European), USPTO (Desk in Brands It is patents of the States United), WIPO (World Intellectual Property Organization) and SIPO (Office of Property Intellectual from the Republic of China).

- **Search Desk**

Desk research, a literature review was carried out to obtain information necessary for the development of the instrument. The purpose aimed to serve the target user/audience, that is, people with a disease in the elbow or rehabilitation clinic professionals who will benefit with O instrument.

Revised, without restrictions of time and language, articles in databases data and search engines, books with the intention of establishing and knowing studies already carried out that had as reference the theme of orthoses articulated in elbow.

They were used you next descriptors: "print three-dimensional", "gadgets orthopedics", "brackets", "elbow", "articulation of elbow", "contract" and "disorders of the joint".

Descritores traduzidos para língua inglesa: "printing", "three-dimensional", "elbow", "capsular contracture", "orthoses", "orthosis", "brace", "orthotic devices", "splints", "static splints", "dynamic splints", "elbow splint" (Tabel 1).

PUBMED	*(Printing, Three-Dimensional) OR Printing, Three- Dimensional[MeSH Terms) AND Elbow) OR Elbow[MeSH Terms]) AND Capsular Contracture) OR Capsular Contracture[MeSH Terms]) AND Orthoses) OR Orthoses[MeSH Terms]) AND Orthosis) OR Orthosis[MeSHTerms]) AND Brace) OR Brace[MeSH Terms]) AND OrthoticDevices) OR Orthotic Devices[MeSH Terms]) AND Splints) OR Splints[MeSH Terms]) AND Static Splints) OR Static Splints[MeSH Terms]) AND Dynamic Splints) OR Dynamic Splints[MeSH Terms]) AND Elbow Splint) OR Elbow Splint [MeSH Terms*])

LILACS	(*Orthoses OR Orthosis OR Brace OR Elbow Splint OR Orthotic Devices OR Static Splints OR Dynamic Splints ANDElbow OR Capsular Contracture OR Printing, Three-Dimensional*)

Table 1: Strategy in search of the articles

A search he was done at platform in search PUBMED It is base in data of MEDLINE and LILACS. Table 1 shows the strategy carried out. After selection of articles, introduced criteria in eligibility.

Criteria in inclusion:

- Rehearsal clinical;
- Rehearsal clinical randomized;
- Revision systematic;
- Meta-analysis;
- Article in revision;
- beings humans;
- Articles of the last 21 years.

Criteria in no inclusion:

- smaller population from 18 years;
- Opinion in specialist;
- Search in animals;
- Articles previous there is 21 years.

Criteria in exclusion:

- Studies in children;
- Orthoses dental;
- Orthoses own for epicondylitis side;
- Absence in complication in stiffness articulate or illnesses what no entail loss in ADM;
- Illnesses neurological central;
- Neuropathies peripheral;
- Illnesses of fish It is hand.

Due to the minimal number of publications related to orthoses digitally printed and with the intention of expanding knowledge about this technique in production 3D It is your applications at area doctor, there was need in search additional in articles specific about O theme in one new strategy search, including articles of the last ten years (Table 2).

PUBMED	*("orthotic devices"[MeSH Terms] OR ("orthotic"[All Fields] AND "devices"[All Fields]) OR "orthotic devices"[All Fields] OR "orthoses"[All Fields] OR ("orthotic devices"[MeSH Terms]OR ("orthotic"[All Fields] AND "devices"[All Fields]) OR "orthotic devices"[All Fields] OR "orthosis"[All Fields]) OR ("brace s"[All Fields] OR "braced"[All Fields] OR "braces"[MeSH Terms] OR "braces"[All Fields] OR "brace"[AllFields] OR "bracing"[All Fields])) AND ("printing, three dimensional"[MeSH Terms] OR ("printing"[All Fields] AND "three dimensional"[All Fields]) OR "three-dimensionalprinting"[All Fields] OR ("printing"[All Fields] AND "three"[All Fields] AND "dimensional"[All Fields]) OR "Printing three dimensional"[All Fields])*
LILACS	*Orthoses OR Orthosis OR Brace AND Printing, Three- Dimensional*

Table 2: Strategy in search of the articles about print 3D

- **Entrevistas Com Usuários**

Five users suffering from articular disease of elbow undergoing joint rehabilitation process to understand your doubts, complaints, behavior, understanding their needs and possible choices, come up with forms of assistance in the treatment, evaluate an instrument to gain mobility, their perspectives and aspirations.

The origin of the patients occurred via the physician's database orthopedist involved at thesis, Alisson Martins Farm Cavalcanti, analyzing patients operated on for elbow injuries that progressed to stiffness articulate, observing compatibility at the study. To the be potentials collaborators of project It is framed us criteria in eligibility, occurred recruitment per convenience, through in contact per email, invitation letter attached. Participants interested in joining the project, received via email: Term in Consent Free It is Enlightened (Appendix 3), for signature after their agreement.

Then, a questionnaire was sent to each participant, through the Google Forms filling tool. There was no need to face-to-face assessment or any displacement, it was free of any cost or need for intervention, there were no tests or procedures, nor risk to health of the same.

Criteria in eligibility of the patients:

- Illness articulates from the elbow;
- stiffness articulate gift;
- Age bigger or equal at twenty-one years;
- >= 6 months in injury or surgery;
- Absence in signals degenerative observed in x-rays;
- Absence in ossification heterotopic;
- Absence in illnesses neurological associated.

• To the first seven questions serve to understand the pains of user	**1.** Which your lesion?
	2. Realized surgery?
	3. How much time of the disease?
	4. How much wait in improvement from the mobility?
	5. it is in treatment rehabilitation? Which orwhich?
	6. How much time in rehabilitation?
	7. it is satisfied with O result therapeuticuntil now?
	8. O what you you're welcome what be likely to improve youramplitude of movements?
	9. Do you know some bracing articulated?
	10. Some method of otherization?
• From the octave the from above octave question O focus It is O increment from the articulated orthosis in the process of recovery, emphasizing possiblebenefit, cost, *design*, comfort,functionality of this modality therapy	**11.** O price average at the Marketplace (R$ 1,500.00)makes it difficult to acquisition?
	12. O what would you expect from this device?
	13. O that you understand printing 3D?
	14. bracing printed digitally it could himto benefit?
	15. Reduction of price It is *design* individualized of instrument would be taken in consideration?
	16. It could suggest some *design* specific?
	17. For better comfort of the orthosis, it could suggest some material at interface device/skin?

Table 3: Questionnaire sent to the users

4.3.2 To define

To the ideas they were refined, identifying standards for to arrive the conclusions based us data collected (FERREIRA et al., 2015).

Desk survey results and questionnaires were compiled and identified the main problem so that a practical solution could be sought and effective, directed to users.

Desk survey data related to the specific questions to be each group or other considerations were compiled in an Excel spreadsheet containing collected information.

4.3.3 To develop

Search for ideas and prototypes, models and models that was carried out aiming obtaining the best solutions from in group of people.

A selection of professionals was carried out, who were recruited by convenience, via e-mail, with an invitation letter attached. To those interested in collaborate with the project, was sent, by e-mail: Term of Commitment and confidentiality (Appendix two) It is Term in Consent Free It is Enlightened (Appendix 3) for signature after their agreement.

Initially, received questionnaires for analysis, you same containing the questions and answers collected in the Discover Phase, applied to the five users, aiming to understand the pain of patients, process of rehabilitation It is search per solutions.

received invitation The to participate in of project: five orthopedists' specialists in the shoulder and elbow area, five physiotherapists and five technical in print 3D

Criteria in eligibility of the surgeons	• Degree in the Brazilian Society of orthopedics and Traumatology (SBOT); • Degree in the Brazilian Society ofSurgery of Shoulder and Elbow (SBCOC); • Experience in for the any less three years at specialty; • Knowledge about appliancesorthopedic.
Criteria in eligibility of the physiotherapists	• Graduation in Physiotherapy; • Experience in for the any less three years in specialist; • Postgraduate in Physiotherapy trauma-orthopedic; • Postgraduate Degree in Rehabilitation Member Higher.
Eligibility criteria of the technical in print3D	• Criteria in eligibility of the technical inprint 3D: • Course technician in *design* digital; • Experience in for the any less three years atarea; • Training It is use in *software;* • Fitness in modeling and finishing.

Table 4: Criteria in eligibility of the surgeons, physiotherapists It is technical in print 3D

Then, a questionnaire was sent to each participating professional. through from the tool Google forms for fill. These they were answered and added to a spreadsheet, generating converging opinions and divergent analyzed in set.

QUESTIONNAIRE TO ORTHOPEDISTS	QUESTIONNAIRE TO PHYSIOTHERAPISTS	QUIZ TO THE TECHNICAL IN PRINT 3D

1. Do you have experience in treatment of patients with elbow hard? 2. What is your behavior in relation to patient with joint stiffness of elbow? 3. Realize benefits in use of orthoses articulated? 4. There is limitation for prescription of these gadgets? 5. usually indicate the use of this instrument during the rehabilitation in injuries? 6. Case opts for the use,which your indications? 7. Which principle in preference? Static, static progressive ordynamic? 8. what difficulties found you he hasgot that? 9. some specific *design*preferably? 10. taking in consideration the growing participation of 3D printing in practice in health, would you imagine viability in manufacturing from these instruments of this technique? 11. Name some benefits theorists possible.	1. Do you have experience in rehabilitation process of patients with elbow hard? 2. what difficulties found in these cases? 3. generally, the evolution usually to be satisfactory? 4. Which O period in recovery average? 5. What is the protocol rehabilitation that you usually use in users with rigidity articulate elbow? 6. You indicate use of bracing? 7. Observe benefit in this modality therapy? 8. Which principle in preference? Static, static progressive ordynamic? 9. what difficulties found you he hasgot that? 10. Some specific *design of* preference? 11. Leading in consideration the growing participation of 3D printing in practice of health, would you imagine viability in manufacturing from these instruments of this technique? 12. Name some benefits theorists possible.	1. You have experience in print 3D at area from the health? 2. What kind of printers do you use?or printing methods? 3. The method brings agility in theappliance production, equipment, inputs? 4. Regarding real estate orthopedics, there is justificationfor printing use 3D? 5. In front of articulated orthoses (immobilization devices that act at rehabilitation in injuries)and your production needs agile, *design* and finishes satisfactory. which printer 3D, method, feedstock It is *software* would you use? 6. The device printed it would have enough resistance to support charge about articulationof the elbow, goal of study? 7. observing changes anatomic in some patientsover of treatment, such as: swelling regression and decrease in circumferencemember, skin friable and sensitive.There is a possibility to adjust the device after regression of swelling, as well as what kindof material used as protective interface between skin and device? 8. Which hinge option forjoint mobilization you advise? 9. Mention advantages and disadvantagesthe use of this technology in orthopedics, especially in confection in orthosesarticulated.

Table 5: Quiz sent to the orthopedists, physiotherapists It is technical Printing 3D

To the questions, directed Each group in professionals, help at the process of understanding the problem, from different areas of performance, and search for viable solutions with the exercise of options arising from knowledge many different.

After each group to respond your related questionnaires, one session in "brainstorming" in between all you professionals involved he was carried out per through analysis of their responses, already grouped in a spreadsheet, occurring debate, criticism, obtaining in opinions in value, or until solution of the problems (FERREIRA et al., 2015).

A brainstorm was carried out in virtual and live mode, through conference call between all professionals. There was no need to intervention, tests or procedures to employees, without risk to their health.

There was one total in 15 professionals' participants It is all these Employees included had to sign the Confidentiality Agreement (Appendix 2) and the Informed Consent Form (Appendix 3 and 4).

4.3.4 Deliver

In order to optimize time and money, there was an evaluation of the prototype, identification of problems and suggestions for improvements. It was asked to collaborators of "brainstorming" from the phase "To develop" what evaluate your drawings, sketches and models for making the MVP (Minimum Viable product) It is production theoretical of device, being started process for deposit of patent.

Design proposed from clamps with button connection.

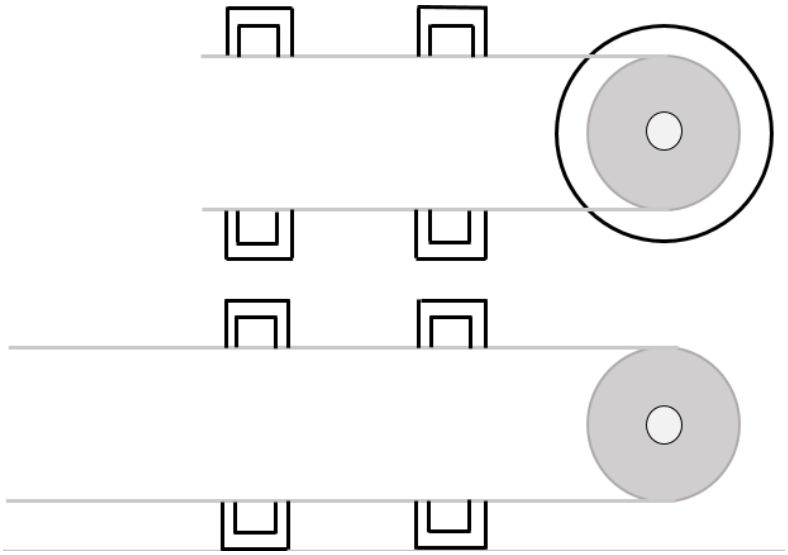


Figure 2: Outline drawn from bracing

5. Results

5.1. Discover

- **Search In Priority**

A similar invention object was found on the WIPO platform, registration CN112190380 and one on the ESPACENET platform, registration CN109147042, patents Chinese, at the which they were created devices orthopedics through the digital method of 3D printing, functioning as support for elbow injuries, rotational axis coincident with axis of rotation actual motion and articulated coupling between arm components and forearm.

To the patents they were identified in agreement with The Classification International in Patent (CIP) (Tables 1, 2 and 3).

CIP	Definition technological
A61F 5/058	Orthoses
A61F 5/37	Constraint devices for the body or parts of body; T-shirts restrictive

Frame 1: Patent CN112190380

CIP	Definition technological
G06T17/00	Model 3D computing print shop
G06T19/20	Edition in images 3D, per ex. to change shapesor colors, line up objects or position parts

Frame 2: Patent CN109147042

CIP	Definition technological
A61F 5/058	Orthoses
B29C64/10	Law Suit in manufacturing addictive in objectsthree-dimensional
G06T17/00	Model 3D computing print shop

Frame 3: Patent proposal

A bracing proposal diverge of the models CN112190380 It is CN109147042 for using a 3D scanner on the limb affected by the injury, increasing precision, to possess coupling in between clamps of type Chicago screw , there are lateral and medial hooks to support elastic garters for gain in strength in flexion of elbow It is hooks dorsals It is tunnel centralizer for coupling and directing springs, exerting extension load of elbow, aiming stretching of the fabrics soft It is gain progressive range of motion, not restricted to just immobilization or mobilization without exercise of cargo about articulation.

Differences techniques in between to the orthoses similar It is bracing proposal evidenced at the Frame 4.

	Model	patented	Model	patented	bracing proposal

	CN112190380	CN109147042	
Model custom	Construction computerized	tomography of member contralateral	3D *Scanner* member injured
Component articulated removable	Yes	No	No
Mobility	No		Yes
Use of elastic bandsIt is springs	No	No	Yes
connection ofclamps	connecting sphere with grooves and winch	cylinder offitting	Chicago *screw*
Principle ofrehabilitation	protection and mobility withoutcharge	protection and mobility withoutcharge	relaxation of stress/ fluency of movements Use in charge
clamp adjustmentto the member	Velcro	semi mold circumferential, semi-open	Velcro
support for leagues elastic and springs	No	No	Yes
centralizing tunnelsprings	No	No	Yes

Frame 4: Differences in between you model patented CN112190380, CN109147042 and bracing proposal

Figure 3: Model patented CN109147042

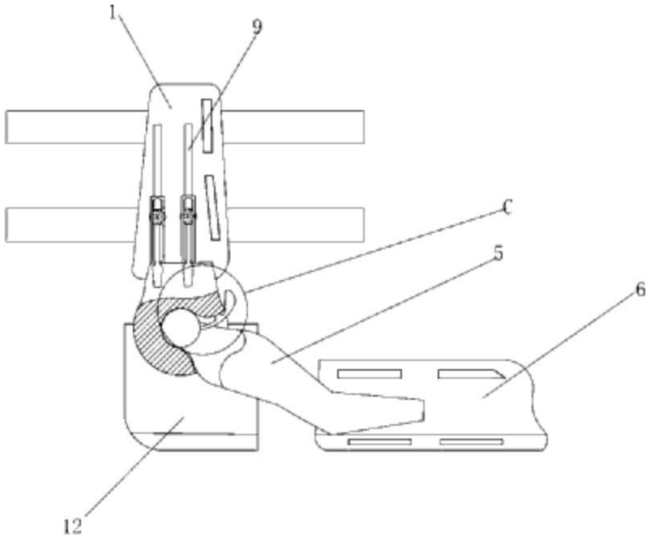


Figure 4: Model Patented CN112190380

O project in patent he was framed at the model in utility, device what will bring improvement functional at manufacturing of the gadgets previous, passable in application industrial, highlighting practicality It is speed of confection. It will have private investment, from companies that aim to innovation of methods immobilization and rehabilitation existing.

Claims:

1. Method of design digital It is 3D printing for clamp in rehabilitation of elbow customized;

2. Project digital in support with method three-dimensional designed in many different shapes in agreement with age and weight of patient;
3. Software in engineering reverse it will be the GEOMAGIC STUDIO.
4. modeling software doctor it will be AUTOCAD;
5. software from slicing of print 3D it will be No CURE;
6. O model of device can to be removed per big amount of alcohol;
7. Characterized for the model in clamp articulated printed using FDM method (Fused Deposition Modeling);
8. The structure in connection detachable;
9. A hinge he can to be connected per screws;
10. The model will have hooks for insertion in leagues elastic or springs;
11. decrease of edema he can justify other print;
12. Durability of device he can to be difficult in predict, depending on of the care and respect for the guidelines.

- **Search Desk**

They were selected 300 articles at the PUBMED It is six at the LILACS. After job of the criteria in inclusion It is no inclusion, they passed the 61 articles for the PUBMED and no article viewed in LILACS. After refinement of search, reading of the titles It is summaries, they were excluded articles no compatible with the theme, leaving 12 articles included in the study, all found at platform PUBMED.

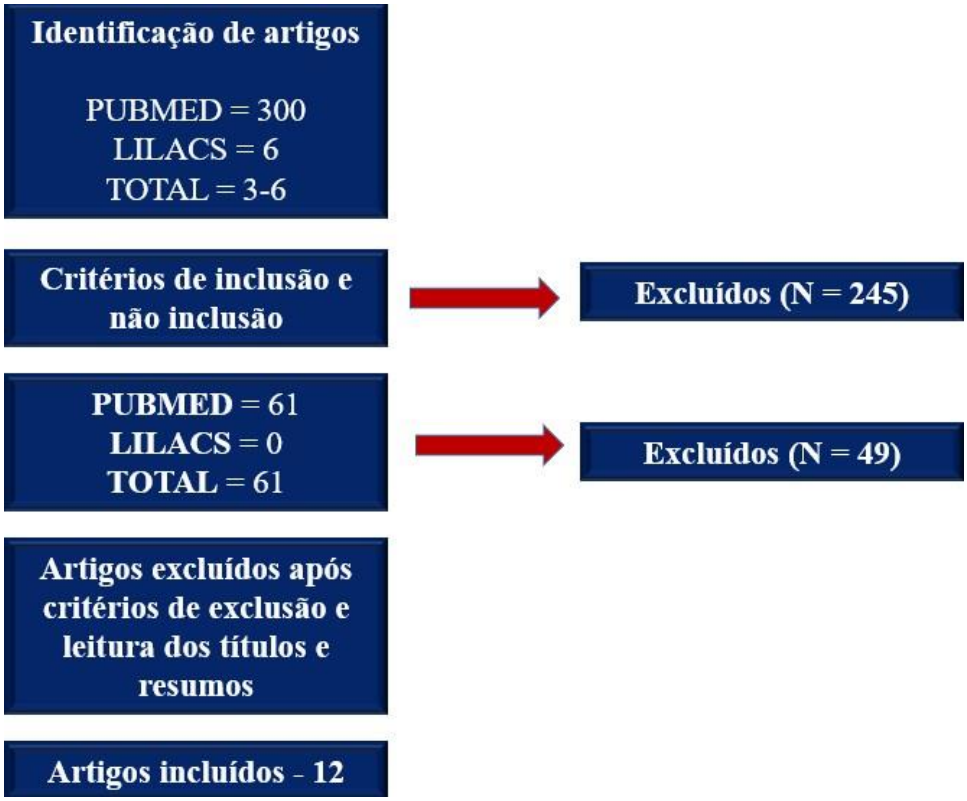


Figure 5: flowchart in identification from the literature

Complementary search results for specific articles on 3D printed orthoses, 95 articles were found in PUBMED and one in LILACS, being selected contents specific in print 3D It is correlation with orthoses. No publications were found containing orthoses of digitally printed elbows, but of other joints, such as ankle, fish, hand It is knee.

- **Interviews with Users**

At the purpose in to understand to the pains of the patients (public target), patients with lesions that require specific treatment, a questionnaire of 18 questions, subjective and objective, grouping from the understanding in your illness, treatment proposed, result functional objectified, satisfaction current It is knowledge about from the problematic It is technologies what may be introduced.

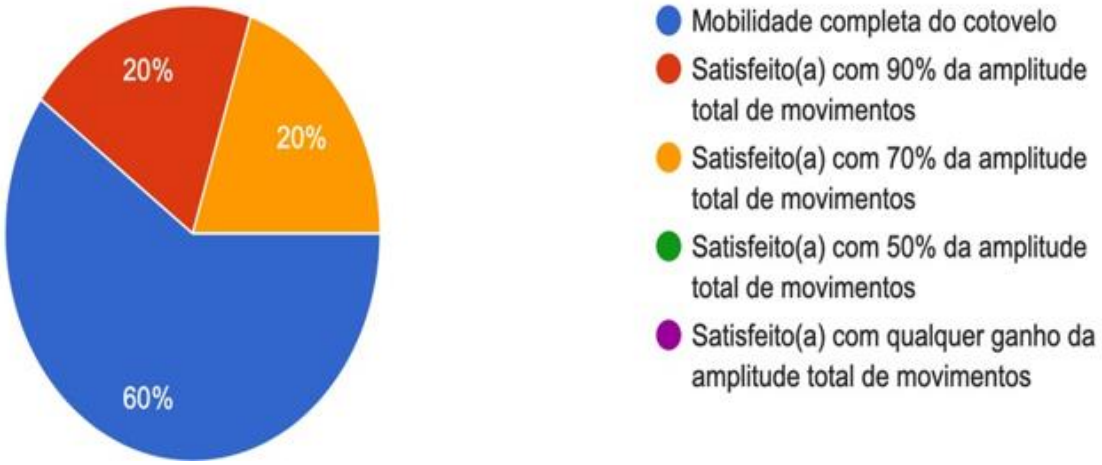
Application in quiz to the patients:

- **First question:** About which the lesion: occurred four results in fracture of elbow and one of injury elbow nonspecific.
- **Second question:** All replied what performed surgery.
- **Third question:** How long of the disease: One answered six months; one answered one year; one answered one year and two months; two replied four years.
- **Fourth question:** It was asked how much is expected from the improvement of mobility: Three (60%) responded that the full range of movements; one (20%) he responded what he was satisfied with 90% of the movements; one (20%) he responded as satisfied in 70% from the full mobility.

4. How much waiting for improvement of mobility?

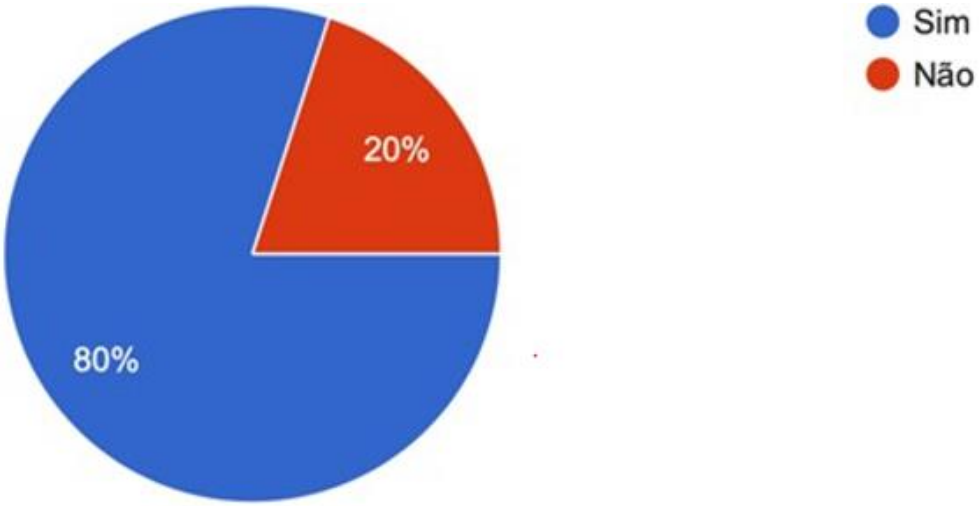
5 answers

- **Fifth question:** About if they were in treatment at the time: Two replied what Yes, It is others three performed treatment physiotherapy previously.
- **Sixth question:** Asked about the length of rehabilitation: One answered three and a half months; one indicated five months; one replied that a year; another that more on one year and last by three years.
- **seventh question:** questioned if they were satisfied with O therapeutic result so far: Four (80%) responded that yes, it is one (20%) replied what no.

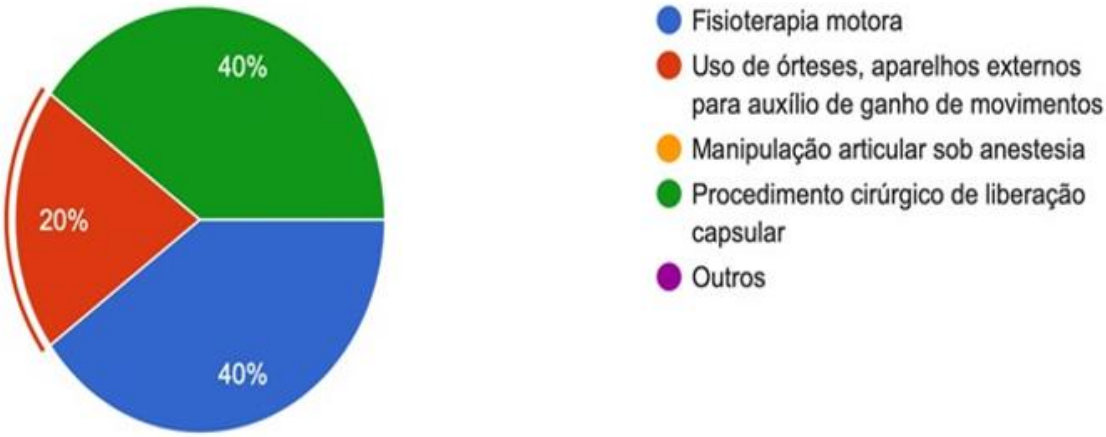


7. it is satisfied with O result therapeutic until O time?

5 answers



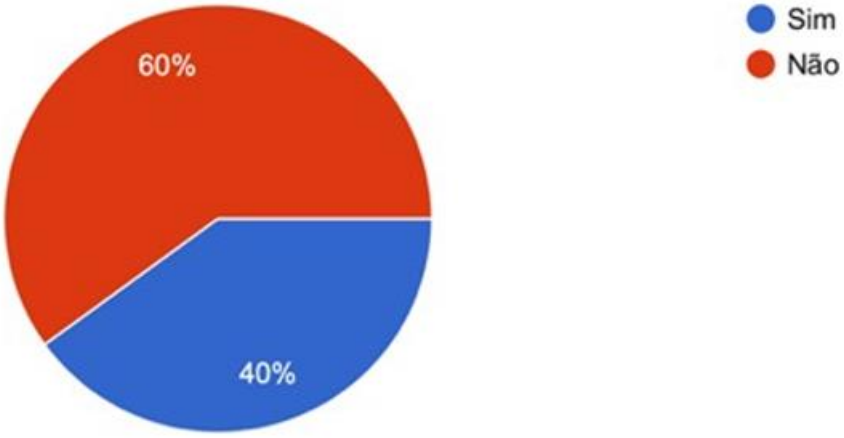
- **eighth question:** O who imagined what could to improve the range of motion? Two (40%) answered: procedure surgical capsular release; two (40%) answered: physiotherapy motor and one (20%) answered: use of orthoses, external devices for aid in gain in moves.



8. O what you you're welcome what be likely to improve your amplitude in movements?
5 answers

- **Ninth question:** Was asked if there was knowledge of any articulated orthosis: Three (60%) answered no and two (40%) replied what Yes.

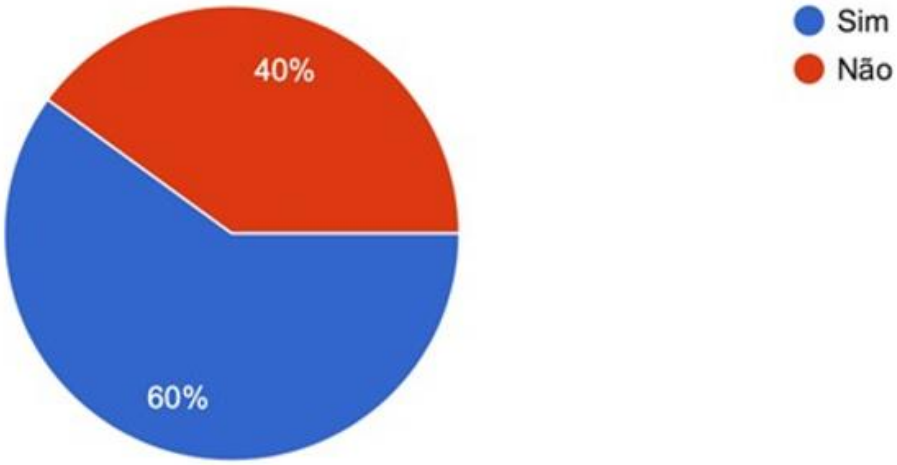
9. Do you know some bracing articulated?
5 answers



From above question: He was used some method in otherization? Three (60%) replied what Yes, it is two (40%) replied what no.

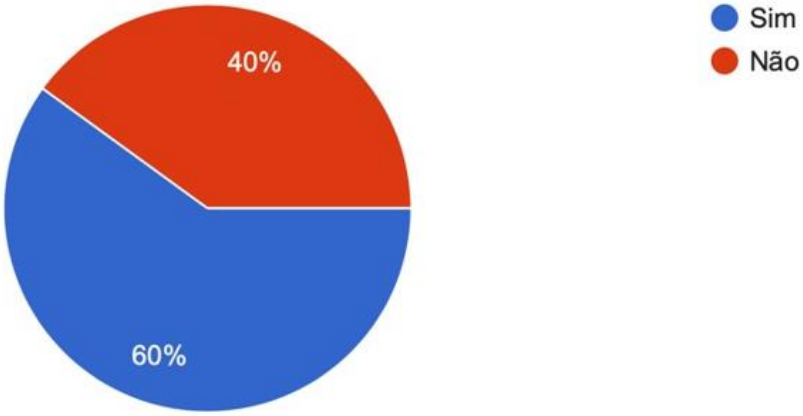
10. He was used some method in guidance?

5 answers



- **From above first question:** He was questioned if O price average employed in the R$ 1,500.00 market, would make it difficult to acquire bracing: Three (60%) answered yes and two (40%) answered what no.

11. O price at the Marketplace (R$ 1,500.00) hinders the acquisition from the bracing?



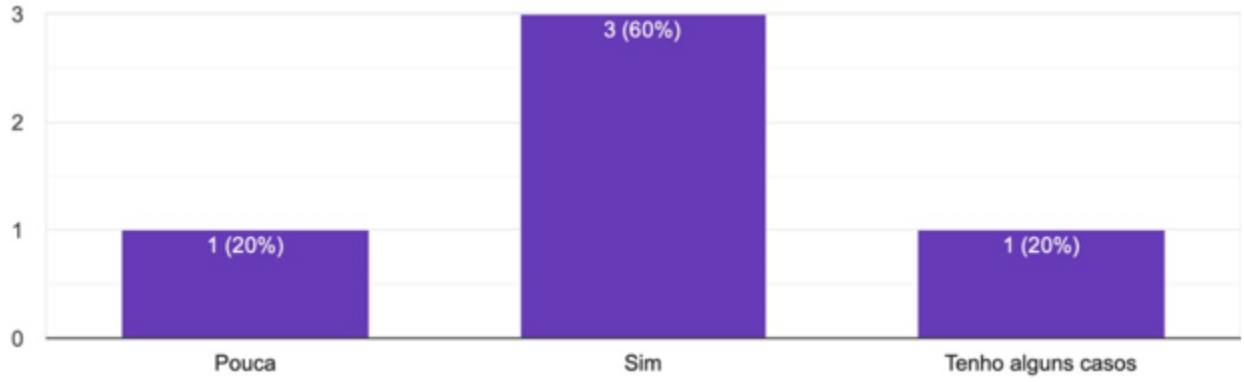
5 answers

- From above second question: questioned about O what would wait of that device: Three (60%) replied what would wait to have mobility complete in movements; one (20%) he responded wait improvement considerable in amplitude in movements; one (20%) he responded to improve The mobility articulate.
- Thirteenth question: Was asked what if understands of 3D printing: One answered that it would be three-dimensional bracing; other did you understand what It is one print in three dimensions, length, height It is width; other referred print in

something palpable and with movement; other he responded what It is one tool indispensable for the elaboration of a treatment plan and the latter replied that does not know instrument.

- From above fourth question: questioned if the bracing digital it could him to benefit: All replied Yes.
- From above fifth question: asked if the reduction of price It is design individualized of instrument would be taken in consideration: All replied what Yes.
- Sixteenth question: The possibility of suggesting some specific design for the orthosis: One (20%) answered no; one (20%) answered that it was suitable for each type of injury; one (20%) responded that it was as close as possible to the anatomy of the elbow, including skin color; one (20%) answered that maybe was something good discreet.
- Seventeenth question: For better comfort of the orthosis, could suggest some material on the device/skin interface? Three (60%) did not could opine or did not know O subject; one (20%) indicated some material comfortable, soft, no specifying which; one (20%) indicated foams It is orthoses with holes for better ventilation, remembering the weather experienced by same.
- Eighteenth question: In order to reach the maximum limit of flexion or extension of the elbow, would there be any idea or suggestion of what mechanical mechanism to use? Example: springs, elastic alloys, hydrostatic pressure: Two (40%) answered elastic garters; one (20%) he responded what no; one (20%) he responded pressure hydrostatic.

5.2 To define



- **Second question:** Was asked what the conduct in relation to a patient with rigidity articulate in elbow: Two replied motor physiotherapy and then surgical treatment; the third mentioned physiotherapy initially; other indicated treatment individualized It is O the latter responded by restoring the functional range of motion of the elbow.
- **Third question:** Realize benefits at use in orthoses articulated? Four (80%) replied what Yes, it is one (20%) he responded that no he has experience at the treatment.

Against of answers provided by the patients, it was observed what all suffered injuries elbow It is were subjected to procedure surgery with disease duration ranging from six months to four years, evolving with the presence of joint stiffness. Everyone expects improvement range of motion and also performed motor physiotherapy with time varying in three months It is quite the three years. Sixty Percent are unaware of any type of articulated orthosis and only 60% of them were submitted to some orthoticization, which can be articulated or not articulated. Sixty Percent of the patients report difficulty in purchase O device at the price currently employed, agreeing that a reduction in price It is design individualized of instrument would be taken in consideration. All expected what O device could to improve the range of motion and believed that production technology technique in print 3D it could benefit them, considering O design It is cost smaller.

5.3 To develop

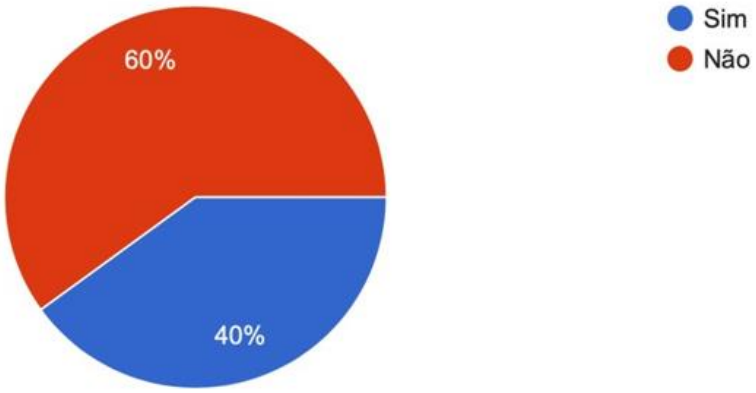
A leave of answers collected of the patients, understanding your pains, they were applied questionnaires to the professionals selected, aiming construction of device with opinions divergent, areas miscellaneous in knowledge to build a consensual idea rich in information and details that could achieve the creation objective and meet the demands of the users.

5.3.1 Application in quiz to the orthopedists

- **First question:** He was questioned if O collaborator he had experience in the treatment of stiff elbow: Three answered that yes; other that he had some cases It is another, reported few experiences.
- **Fourth question:** He was asked if there was limitation for prescription of device: All replied what Yes.
- **Fifth question:** He was questioned if usually indicate that instrument in the rehabilitation of injuries: Three (60%) answered that it is not two (40%) replied what Yes.

5. usually indicate the use of that instrument during the rehabilitation of injuries?

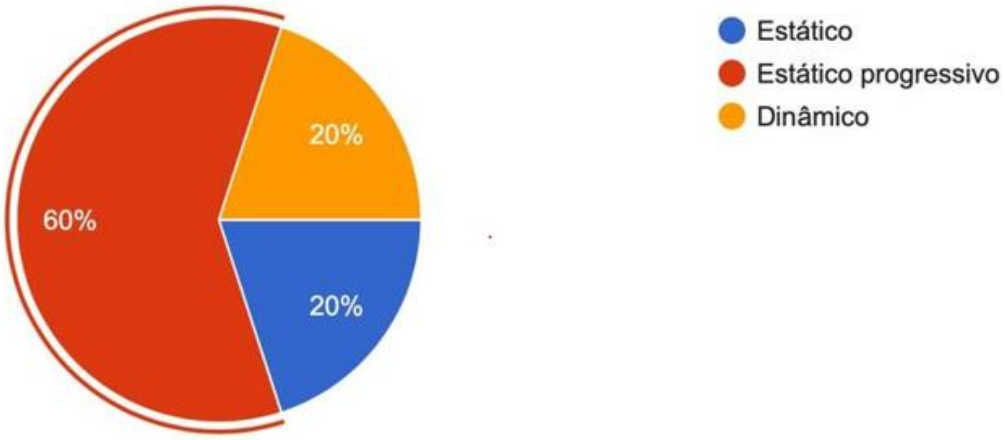
5 answers



- **Friday question:** he wondered, case choose for the use from the orthosis, what are its indications: One answered that postoperative reconstruction ligament; other what gain in amplitude in movement stable; third indicated that if there is no improvement in physiotherapy motor It is before in consider approach surgical, or same before in consider greater amplitude loss during rehabilitation; the fourth responded in the postoperative period of fractures or ligament injuries of elbow It is O last no he responded.
- **Seventh question:** The preference principle was asked: Three (60%) answered: dynamic; one (20%) answered: static and one (20%) replied progressive static.

7. Which O principle in preference? Static, static progressive or dynamic?

5 answers



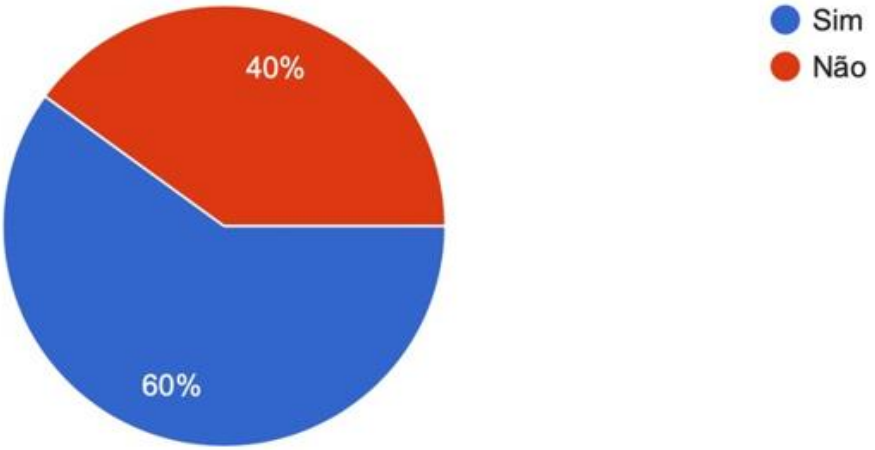
- **eighth question:** Which difficulties you he has got that? O first answered the cost; the second answered hard orthoses access, high cost It is lack in good physiotherapists; O third answered material; room replied availability in the market and cost It is O fifth no he responded.
- **Ninth question:** Was asked about any design preference: Three (60%) replied what no; one (20%) he responded bracing dynamics with use of springs it is a (20%) replied polyethylene.
- **From above question:** To the if to take in consideration The growing participation of 3D printing in healthcare practices, would you imagine feasibility of making these instruments using this technique? All replied what Yes.
- **Eleventh question:** It was requested that some benefits theorists possible: O first he responded molding more anatomical It is results more predictable; O second, he responded individualization; the third answered greater accessibility and less cost, good as the realization in components patient-specific; O fourth answered orthosis with anatomical model and the fifth answered better range of motion to Final of the treatment.

5.3.2 Application in quiz to the physiotherapists

- **First question:** You he has experience at the process in rehabilitation of patients with stiff elbow? All replied Yes.
- **Second question:** They were questioned which difficulties found in these cases: Two (40%) replied O gain in range of motion; one (20%) answered joint contracture and difficulty in performing activities of daily living by the patient; one (20%) he responded what adhesions It is limitations in amplitude in movement and the last reported difficulty in defining the indication of the better model for each case of joint stiffness.
- **Third question:** Is the evolution usually satisfactory? Three (60%) replied what Yes, it is two (40%) replied what no.

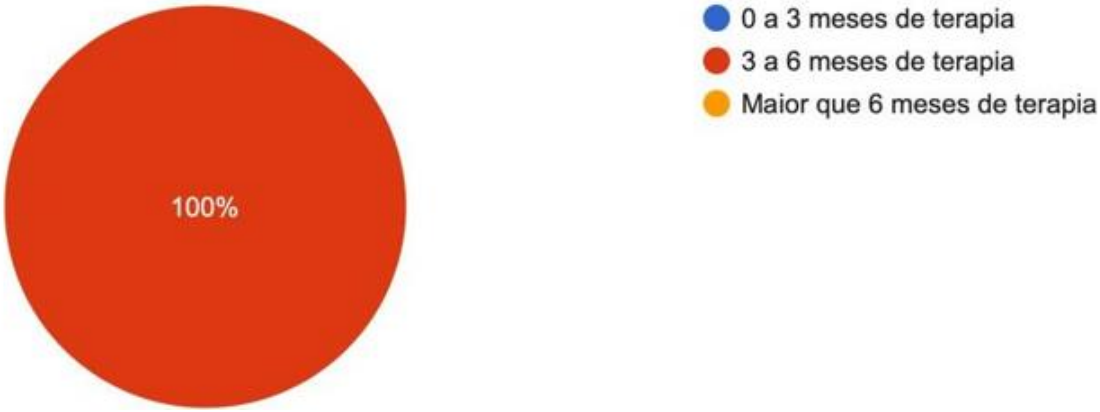
3. Generally The evolution usually to be satisfactory?

5 answers

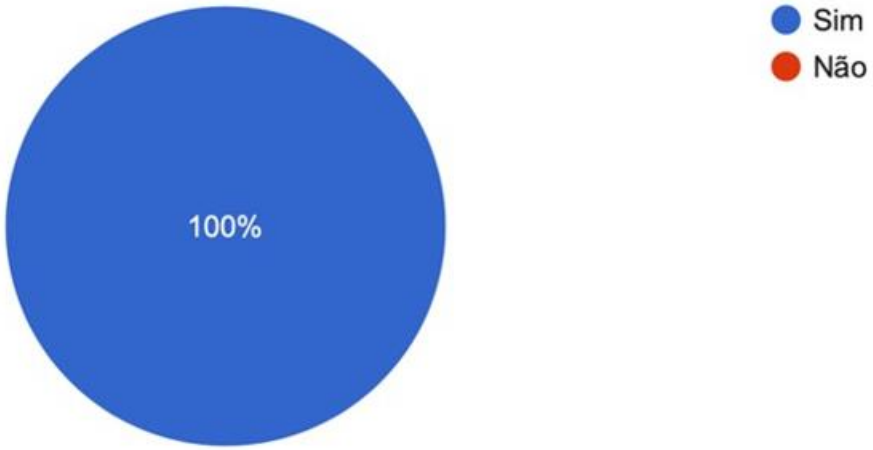


- **Fourth question:** What is the average recovery period? All replied in three the six months.

4. Which O period in recovery average?
5 answers



- **Fifth question:** Which O protocol in rehabilitation what you do you usually use in users with elbow joint stiffness? O first answered analgesia, kinesiotherapy, use of static orthosis series or dynamic orthosis and ADL training; the second replied gain in amplitude in movement after release of surgeon, use in bracing dynamics for gain in flexion It is static progressive for gain elbow extension; the third answered how I attend through SUS (Hospital University) O protocol kinesiotherapy It is splint plastered nocturnal progressive; O room he responded bracing, moves active It is passive, contract-relax; fifth: bracing associate The kinesiotherapy.
- • **Sixth question:** Do you recommend the use of bracing? One hundred percent replied what Yes

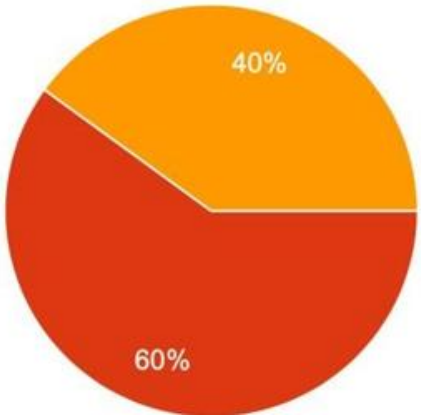


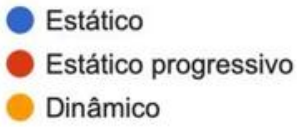
- **seventh question:** observe benefit in this modality therapy? All replied what Yes.

- **Eighth questioning:** Which O principle in preference? Three (60%) responded static progressive, and 2 (40%) responded dynamic.

8. Which principle in preference? Static, static progressive or dynamic?

5 answers





- **Ninth question:** Which difficulties found you he has got that? The first replied that patients usually adapt well to the use from the bracing; O second he responded what O access /forwarding patient's physician until physiotherapy with orthosis prescription; O third answered that the preference is for the dynamic orthosis, however the cost It is high It is no exist at table of SUS that type in bracing, making it difficult to purchase material and pay for SUS; the fourth he responded far away period in rehabilitation, value of material of orthoses; O fifth replied adjustment of dynamic orthosis.

- **From above second question:** quote some benefits theorists possible: O first he responded decrease of cost, sanitation, portability, lightness It is comfort; O second, he responded cost from the bracing; the third answered low cost and carrying out measurements without the direct contact, through 3D scanners; the room responded with lightness and better cost for O patient; O fifth he responded decrease of cost Final It is individualization of model.

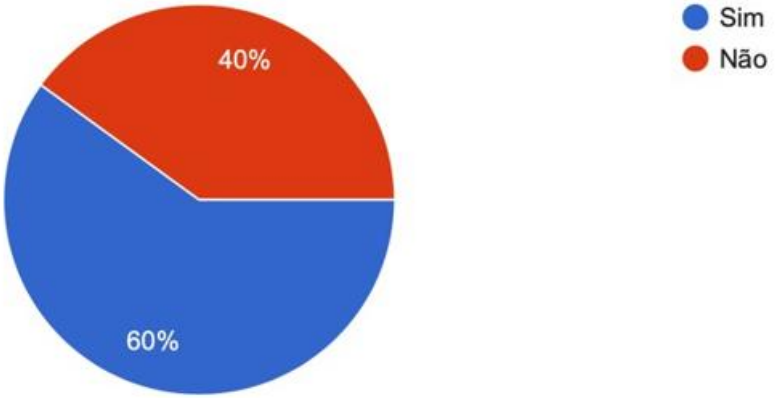
- **From above question:** some design in preference? O first he responded what I make under measure for each patient; O second replied that he has no design preference; the third replied dynamic thermoplastic orthosis with elastic traction; O room he responded what no he has preference in design, being ventral or dorsal depending on the objective; the fifth replied that he prefers bracing progressive static.
- **Eleventh question:** Taking into account the growing participation of 3D printing in healthcare practices, would you imagine feasibility of making these instruments using this technique? Hundred Percent replied what Yes.

5.3.3 Application in quiz to the professionals in print 3D

- **First question:** Do you have 3D printing experience in the field from the health? Three (60%) replied what Yes, it's two (40%) that no.

1.You he has experience in print 3D at area from the health?

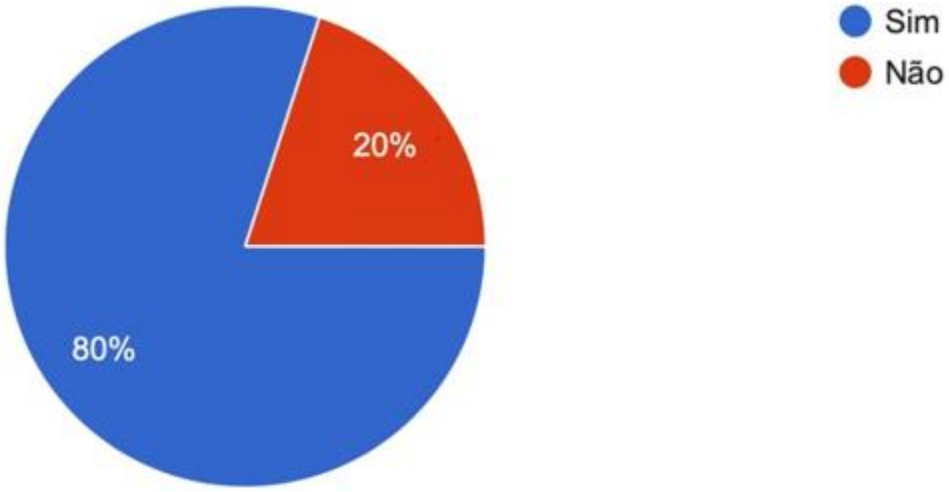
5 answers



- **At second question:** Uses what type in printers or method in impression: First answer: yes; second answer 3D printer; third answer FDM type printer; fourth printer answer winbo, print per extrusion; fifth response printer type FDM.
- **In the third question:** Asked if the method brings agility in the production in gadgets, equipment, inputs: Four (80%) replied what Yes It is one (20%) replied that no.

3.O method bring agility at production in gadgets, equipment, inputs?

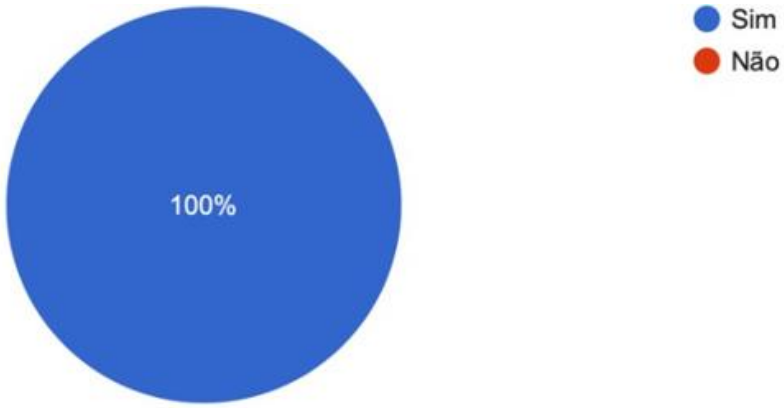
5 answers



- **Fourth question:** In relationship The fixed assets, there is reasoning for use from the print 3D? Hundred Percent replied Yes.

4. In relationship The fixed assets, there is reasoning for use from the print 3D?

5 answers



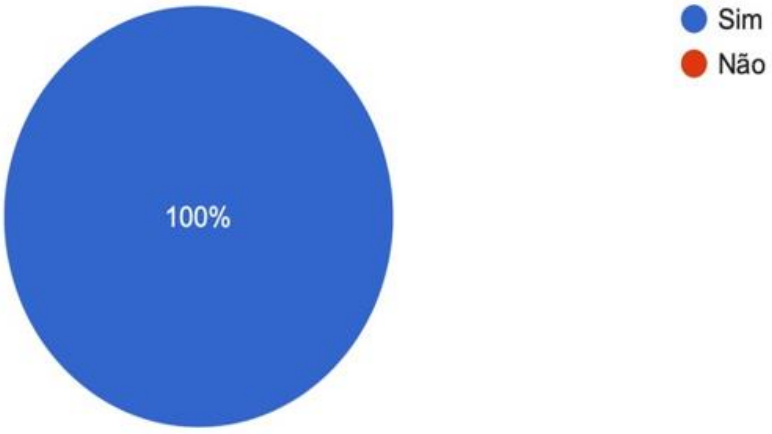
- **Fifth question :** Against in orthoses articulated (gadgets in immobilization that act in the rehabilitation of injuries) and their need in production agile, design It is finishes satisfactory. Which printer 3D, method, feedstock It is software you would you use? First response printer ZMorph, PLA, CURE; second response Zymorph vx, PLA and ABS, voxelizer software ; third answer Sethi 3D S3, FDM, PLA, Simplify 3D Slicing software ; fourth answer Winbo printers with their own software for adaptation 3D model, modeling program like 3dmax; fifth FDM

printer response, PLA or PETG plastic, CURA software , OpenShape or similar.

- **Friday question :** O device printed it would have resistance enough for to support charge about articulation of elbow, goal of study? Hundred percent responded what Yes.

6. O device printed it would have resistance enough for to support charge about articulation of the elbow, objective of the study?

5 answers



- **seventh question:** observing changes anatomical in some patients throughout the treatment, such as: swelling regression and decreased limb circumference, friable and sensitive skin. There is possibility of adjusting the device after the swelling subsides, such as also what kind of material is used as a protective interface between skin It is device? O first _ he responded what there is as accomplish settings, protection can be made with fabrics made with cotton; the second answered yes, use of PLA allows some level of adjustment later with the heating of the item, making it moldable certain point; the third answered yes, PLA is a thermo plastic moldable; the fourth replied that regression imposes a new impression, regarding material for protective interface, perhaps the neoprene; the fifth replied that I wouldn't know the answer, could it be reprinted with due adjustments.
- **eighth question:** Which option in hinge for mobilization articulate you advise? Three replied what the hinge he would be produced for the own printer, drawn at own part; O second and third added that it could use some metal; O room It is O fifth no knew to respond.
- **Ninth question :** He was requested what were cited benefits It is disadvantages of using this technology in orthopedics, especially in confection in orthoses articulated: O first he responded as advantage, ease at the access in materials, equipment It is production of orthoses It is disadvantage, O high cost of printers 3D, execution time of an orthosis, materials with effort restriction, difficulties at modeling 3D; O second he responded as advantage, freedom in planning It is production, O limit It is The creativity. As disadvantage, high level in knowledge in 3D modeling, in addition to being expensive compared to other possibilities; the third indicated as advantages, capacity in customization, to work with matter cousin coming from in sources renewable It is gain in comfort at the use. Disadvantages: smaller resistance when compared with models traditional, few trained professionals in the segment, resistance of the medical class; the fourth responded as an advantage, agility in the production of parts individually, considering patients' needs. Disadvantage: level of knowledge needed to make the model 3D It is to handle the printer; O fifth no knew to respond.

5.3.4 Results of brainstorming

He was carried out meeting in group of the professionals elected as collaborators, per via digital, platform zoom, occurring Preview assessment of answers of the questionnaires of the patients It is of the professionals' collaborators. Everyone was able to express their opinions for the solution of problems and equalize product doubts, given the varied responses of their individual questionnaires, until there is uniformity of thought and stand out product consistent with basement multidisciplinary. Considered all to the answers performed It is against from the doubt or tiebreaker, in case of no consensus, The majority would prevail.

Chosen preference principle: static progressive, printed by 3D printer type Zmorph vx, method FDM (Fused Deposition Modeling), raw material used: PLA (polylactyl acid). opted for use of 3D scanner to generate reliable limb reconstruction stricken. Software _ in engineering reverse chosen he was GEOMAGIC STUDIO. 3D modeling software chosen was AUTOCAD. Software of slicing chosen he was CURE.

Coupling of parts printed of arm It is forearm, as fitting and hinge would be printed by the printer itself, lock on button with aid in metal (Chicago screw).

Faced with the protective interface between the skin and the device, it was decided too none specific. In cases in hypersensitivity to the PLA, one can use foams or fabrics in cotton, preventing O counted directly with O plastic.

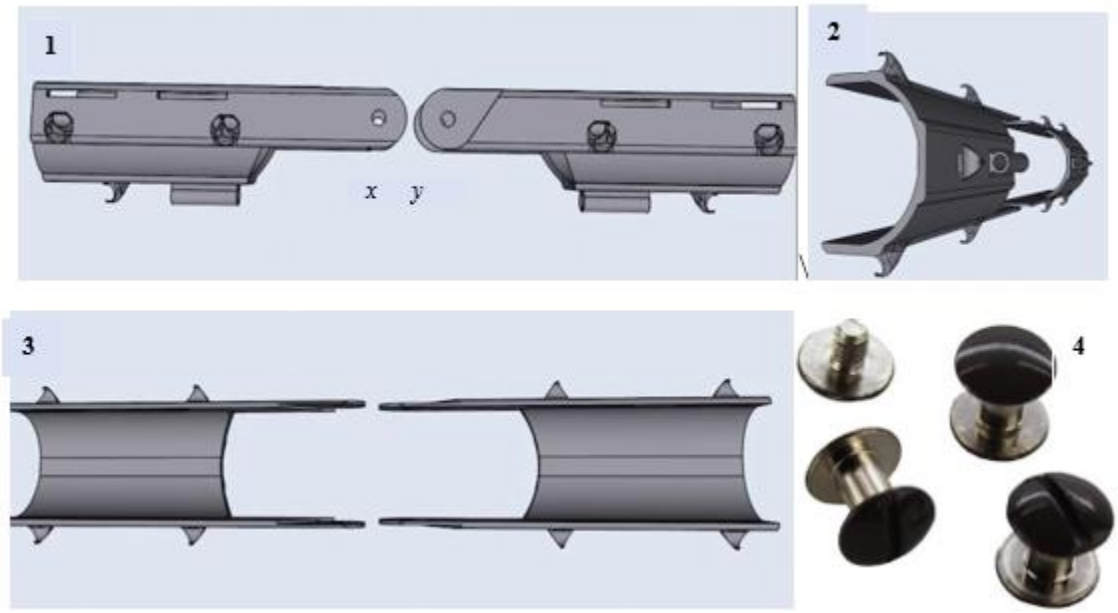


Figure 6: Model produced at the brainstorming, in the visions 1- side, two- dorsal, 3- ventral, 4- Screw Chicago coupled us holes x, y (vision 1).

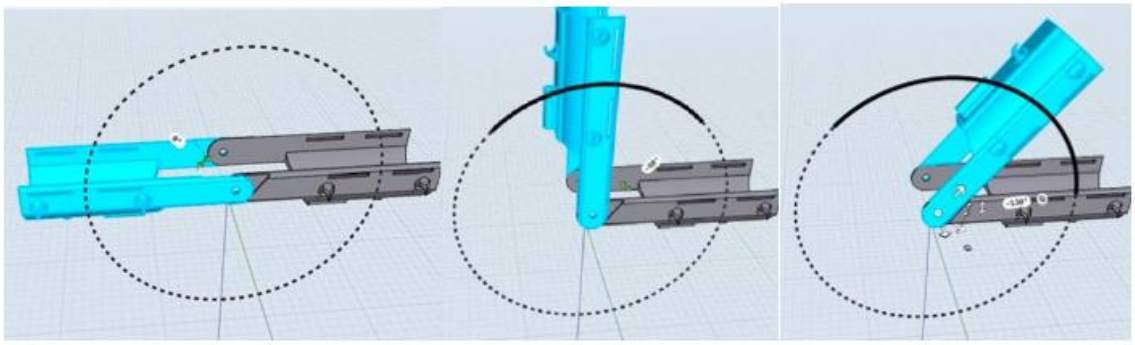


Figure 7: Vision three-dimensional with It is made in movement

5.4 Deliver

In this phase was sought from assessment of the prototype, identification in problems and suggestions. The collaborators of the "brainstorming" evaluated designs, sketches for production of MVP (Minimum viable Product). Posteriorly, O model it will be delivered for deposit in patent, through of next phases:

- **Field Technician**

The invention relates to the field of orthopedic medical devices for rehabilitation treatment of elbow joint injuries. Accomplished in design digital It is method in print 3D, custom It is individualized in agreement with to the many different anatomies existing at population.

- **Technology In Bottom and Summary Invention**

O goal from the invention It is to supply design digital at the method in print 3D, as support custom The anatomy of member higher, Format articulated at the elbow, allowed moves It is providing support extrinsic able in stabilize the articulation, benefiting O patient in the more diverse injuries.

AND Reached O goal by the next means technical:

- To supply design digital, it is method in print 3D for to the arm and forearm clamps, in addition to the hinge located on the axis of rotation of elbow;
- Applied the three-dimensional laser scanner on the upper limb of the affected side, from shoulder to wrist, data being collected in the cloud and imported into reverse engineering software for digital design in the next phases:
  - **Step 1:** Modify the point cloud data in the engineering reverse for delimit O contour from the skin digitized (model in slice);
  - **Stage 2:** performs smoothing of contour from the skin, remove O data processing, such as features and tips, and perform external addition at the triangle from the surface of contour from the skin from the portion in scan extracted, generating model three-dimensional similar the shell It is O model after the operation of design digital It is saved as file in STL format;
  - **Step 3:** Import the STL file into the modeling software. In agreement with your requirements in project, one combination in operation Boolean and CAD design is adopted, and the model is excavated, the hinge structure lockable It is added It is the disassembly in opening It is closure It is selected. O flat cut the key It is he adds structure in connection detachable to save the processed file as a template file in the STL format;

- **Stage 4:** It matters O file STL for O software in pre-processing in print 3D for to generate file in support for the support structure and adjust you printing parameters;
- **Step 5:** Combines the template file obtained in step 3 with the support file obtained in step 4 and saves the file as file in STL format;
- **Step 6:** Copy the file processed in step 5 on a 3D printer for print for to obtain model of orthosis elbow

The reverse engineering software is GEOMAGIC STUDIO. O software modeling and the AUTOCAD.

O software in preprocessing in print 3D is No CURE.

Preferably, the detachable connection structure in the third step is button connection structure and the hinge with lock is structure that can to be adjusted It is locked dynamically.

• Description of the Designs

Figure 8 demonstrates the MVP (outline of the final product), containing clamp adjustable for O arm It is other for O forearm, produced separately the leave of design digital, it is each unit contains two slits for placing in one Velcro adjustable in each, in addition in two hooks side It is medial in each clamp for placing in ribbons elastic with goal of elbow flexion strength. It also contains, a hook and a tunnel centralizer located posteriorly Each clamp for ticket in elastic with purpose of extension force of the joint.

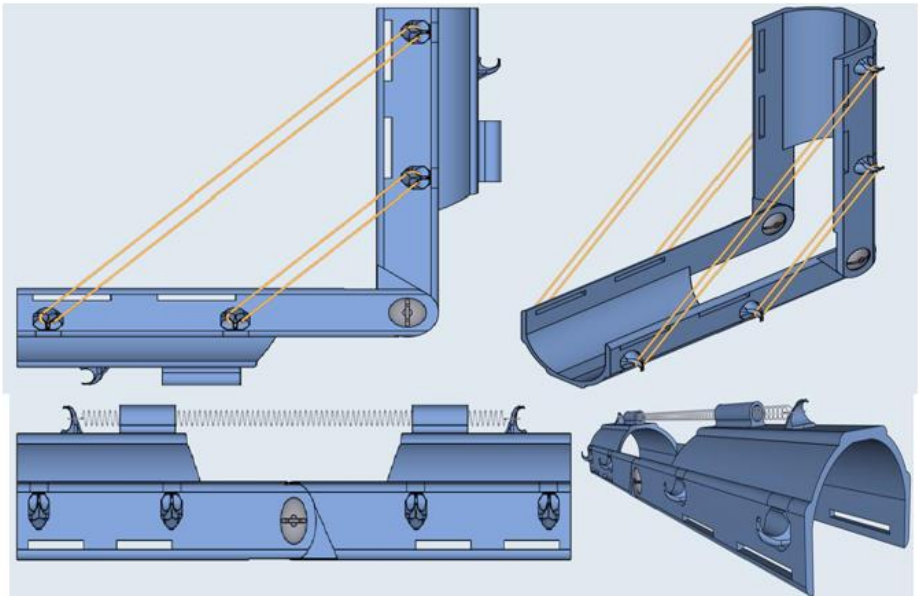


Figure 8: bracing Final with leagues elastic fixed in hooks side, exerting bending force and spring attached to posterior hooks, exerting load in extension

O scanner three-dimensional will get data sent for cloud of member higher, separated per segments proximal It is distal, arm It is forearm, respectively. the scanner 3D The laser no it has radiation, It is your process in collect It is fast It is convenient. You data from the cloud in points they are imported from the reverse engineering software , the profile being digitized triangular contour of the skin, smoothing and modeling properly. A Triangular part of surface is externally thickened to generate model three-dimensional in form in bark in thickness specific It is O model saved at the Format STL. distally, at clamp of arm It is proximally, at the forearm, are visualized bows what will be coupled one to the other as O center in rotation of elbow, providing O spin for The mobility articulate. O file STL It is imported for O software in modeling It is The combination boolean It is design CAD, It is adopted as requirement in design It is O model produced with The structure in hinge added. O file saved O Format STL It is imported for O software in preprocessing in print for to generate file in support It is adjust you parameters in print. Combined you files in model with O in support, It is generated other at the Format STL, being sent The print 3D for originate model in bracing articulated in elbow.

6. Discussion

To the to analyze O concept in stiffness articulate, possible causes, gravity of the disorder and response to treatment, one can observe the complexity and diversity in your management. At the moment, news technologies they are being maids for minimize sequels It is to improve function in members compromised, contributing to a better quality of life for patients from the illness.

Assessing you questionnaires of the patients It is your pains, it was possible understand that there were surgical injuries to one elbow of each patient, occurring posterior procedure surgical liquid Paper It is evolution for joint stiffness.

The disease duration was varied, however, all of them were over six months, determining one maturation at healing of collagen It is smaller possibility of functional improvement without a new therapeutic modality (GELINS et al ., 2000).

All demonstrated interest at improvement from the amplitude in movements, some content with full mobility, and others even with mobility partial. A majority of activities from the life daily he can to be carried out with 100° of elbow flexion and 100° of forearm rotation (GELINAS et al ., 2000). A bigger part from them already there was closed O process in rehabilitation physiotherapy. In general, declared be satisfied with O treatment proposed, although as visa previously, all seek clinical improvement. When asked which method could determine gain of movements, 40% defined it as motor physiotherapy, another 40% by surgery in capsulotomy It is The smaller portion (20%), per methods in orthotization, demonstrating choose for the treatment already employee, or per methods known to them, with a predominant lack of knowledge of the that it would be orthotic treatment, a fact confirmed in the sequence, where the majority replied not having knowledge about those gadgets.

It was found that 60% of the patients reported using an orthosis and 40% did not use it, however, it should be remembered that the plaster cast is a procedure orthotic no articulated, commonly used at protection in surgeries elbow complexes, aiming at the protection and safety of the procedure, employed in these patients, no being those objectified orthoses at the study. Per more what it is tempted to offer protection in serious injuries with splint non-articulated plaster cast, it is one of the main risk factors for stiffness articulate. With that no if he can refer what those patients used rehabilitation device for mobility gain. Additionally, 60% of patients reported that the price of R$ 1,500.00 for the device would make it difficult to acquisition and 40% of the patients denied this difficulty. consistent with literature, disadvantages in such gadgets include expenses, efforts It is delays involved in building custom device (BANO & KAHLON, 2006).

Most patients expect the hinged brace to improve their mobility articulate It is in your majority unaware The technology 3D, although everyone understands that this technology can benefit them and consequently would be taken in consideration per all.

In relationship to the design suggested, 40% no suggested some in preference, 20% what were adequate The each type in lesion, 20% replied that approximated as much as possible the anatomy of the elbow, including skin color and 20% answered that the model was discreet; fact that demonstrates the divergence in this aspect and, perhaps, the concern about the functionality prevail in relation to design .

Regarding the comfort of the orthosis, would it be possible to suggest some material at the interface between device and skin; most patients no opined, demonstrating unfamiliarity about O subject, It is two suggested material soft and comfortable or foams.

Already aiming to reach the maximum limit of flexion or extension of the elbow, would there be any idea or suggestion of what mechanical mechanism the be used? Forty percent opted for elastic alloys, 20% for pressure hydrostatic, 40% no opined; demonstrating misinformation The respect of device and your mechanism of acting.

In view of the evaluation of the orthopedists' questionnaires, most have experience at the treatment in patients with elbow hard. Eighty percent perceive benefits in the use of articulated orthoses, however, all have limitations in their prescription, and 60% do not usually indicate per difficulties as O cost high, unavailability at the Marketplace, difficult access of the patients or material unavailable. Eighty percent would choose to use it in the postoperative period of fractures or injuries ligaments, or aiming to gain mobility and, at the same time, keeping the stabilization articulate.

Sixty percent of orthopedists opted for the static principle progressive, having agreement with The literature when, same having similar results between them, the chosen method becomes more acceptable for the smaller need in time in use of device, therefore, more tolerable, introducing smaller discomfort It is smaller index in withdrawal from use (SHAHAR et al ., 2019). Most have no design preference It is all believe at viability from the print 3D at construction of orthopedic orthoses, citing the benefits of anatomical modeling, individualization, lower cost and rehabilitation.

A View from the assessment of the questionnaires of the physiotherapists, all expressed experience in the rehabilitation of joint stiffness, and the majority indicated, as difficulty, the gain of amplitude of movements, although 60% referred evolution satisfying at the treatment, at the term average in three The six months in therapy. All indicate orthoses at rehabilitation in stiffness articulate, together with others modalities therapeutic, in addition in all you physiotherapists observe benefits in the orthotization of patients.

Against from the analysis of the questionnaires of the professionals in print 3D, The majority he has experience in acting at area doctor using, mainly, FDM type printer (Fused Deposition Modeling), most used and known modality, simple to manipulate and that requires smaller experience technique. Eighty Percent agreed what O method bring agility at production in equipment It is inputs, having total agreement at reasoning in your use at print 3D. Printer more indicated he was Zmorph vx , method FDM, matter cousin used was PLA (polylactyl acid), biodegradable, lower cost, software in slicing chosen he was CURE, in code open, free, prepare The part for printing.

All agreed what O equipment printed he would be enough resistant to the to support charge of member affected It is O material it could to be moldable, adjustable, mainly using PLA, polymer in resistance compatible to the your purpose, easy in to work, little allergenic, can be polished, and if you need skin protection, it is possible to use cotton or neoprene (WOJCIECHOWSKI et al. , 2020). About hinge articulate, it could to be printed for the own printer in fitting mechanism, coupling, threadable, among other formats or using hinge metallic, offering satisfying support, resistance, smaller deterioration, for example: Chicago screw.

When analyzing advantages and disadvantages mentioned by professionals of 3D printing, there are differences of opinion, mainly at the level cost, and there may be variability when using raw materials or printer model costly or not, material strength as well variable, in agreement with each choice It is method in manufacture, although wide freedom in planning, production, design, creativity It is agility, weighing against the need for modeling knowledge 3D.

To the benefits from the bracing printed 3D in comparison to the conventional include its lower cost, due to energy and raw material savings, customization and manufacturing speed. The orthosis needs simplicity, affordable cost, flexibility and sustainability to achieve its effectiveness. He must to be comfortable, light, functional, in easy use It is aesthetically pleasant for the patient, during the performance of the function for which it was designed (LUNSFORD et al ., 2016).

There is few literature relevant about O management therapeutic specific of stiff elbow. Most of the studies on the subject contain shortcomings methodological aspects in the comparison between modalities of articulated orthoses of elbow, sometimes control groups are lacking, others lack evaluators independent, others times O size of samples It is inappropriate, occurring small relevance clinic. To the information usually to be concepts global in rehabilitation, in turn in assessment It is treatment specific. So elbow stiffness after injury is challenging dilemma for surgeon, therapist and patient (ABREU IN SOUZA et al ., 2017).

Joint contracture is one of the most common complications after trauma, which may lead to surgical treatment in up to 12% of cases. the pain and O swelling after O trauma or surgery play paper essential at promotion from the rigidity. A retraction capsular It is contracture in parts soft they were identified as bigger contributors in stiffness in elbow after bone and ligament restoration and alignment (ABREU DE SOUZA et al ., 2017). Non-surgical management involves the use of CPM (Continuous Passive Motion) and use of static and dynamic orthoses, which are becoming more popular at the treatment (ZHENG et al . al ., 2020).

A stiffness articulate he can to occur in injuries in treatment conservative or post-surgery, proportionally depending on the severity of the injury, the time of immobilization by non-articulated methods, of the psychic picture involved, from the reduction anatomical in eventual surgery, from the stability capsuloligamentous, absence or presence of heterotopic ossification, osteonecrosis, in illnesses degenerative or inflammatory, in frame dystrophic or neurovascular injury, active infection, among others (ABREU IN SOUZA et al ., 2017).

Orthoses they were categorized in two purposes: protection It is movement recovery. Protective immobilization is generally not articulated, without movements, maintained in position in comfort The 90 the It is started after O trauma; to the step what immobilization with goal in to recover movement is usually articulated, initiated after certain healing of the fabrics It is application subsequent The one charge low in stretching prolonged, used to increase The ADM (ZHENG et al ., 2020).

To the to analyze prospectively, The satisfaction in patients It is your results clinical after use in bracing static progressive, in between you years in 2007 The 2017, they were evaluated: mobility, pain, stiffness, edema It is any Adverse events, it was observed It is made significant at pain, stiffness It is swelling, in addition to the already known improvement in ROM (ABREU DE SOUZA et al ., 2017). To the orthoses dynamics tend The cause bigger lesion in parts soft It is inflammation under one charge constant at articulation, O what results in low complacency. To the orthoses static progressive can to achieve bigger stretching for the principle in relaxation in stress.

In a systematic review study, containing 232 patients, 160 used bracing static progressive with gain average in 36th _ after O treatment and 72 used dynamic orthosis, mean gain of 37 o after treatment It is concluded what both presented Good results at the treatment in stiffness in elbow, being The choice of treatment based at surgeon and patient preference et al,. 2015).

To the orthoses static progressive he has lots of benefits:

1. Adjustment in strength It is amplitude in moves for intensity tolerable maximum;
2. Tolerable load controlled by the patient according to sensation subjective;
3. Bigger tolerance It is conformity;
4. Mobility, O patient it could to do exercises active after to remove easily the orthoses;
5. Effective, efficient, economical, requires less time and money with use of orthoses static progressive (OPENING IN SOUZA et al ., 2017).

ADM gain occurs mostly in the first six months of the use of orthoses, however, in their randomized controlled clinical trial, patients carriers in stiffness articulate, submitted The bracing static progressive or dynamic, a gain was noted in a group evaluated between six and twelve months, demonstrating that persistence and patience in the treatment surgical they are important It is needed (LINDENHOUVIUS et al ., 2012).

It is known that early joint mobility should be prioritized for result clinical Final satisfactory. It is observed what stabilization extrinsic The leave in orthoses Assists effectively at security in procedure carried out, from the immobilization and environment favorable to the healing of capsuloligamentous and bony structures. This method, such as a cast or splint plastered provides stability It is reduce The streaming in strength at the local from the soft tissue fracture or injury to allow the structures to heal bony It is ligaments to the around from the articulation, although when used in form excessive, can cause secondary stiffness and contracture (ZHENG et al ., 2020). In addition no to allow O gain precocious in moves yet it presents The disadvantage from the inconvenience during O cleanliness body, hygiene difficult, need in exchanges, interfere at quality of the exams radiological, possibility in effects allergic, requires time at the procedure, constant gaps in the plaster cast can cause harmful circulatory disorders, joint stiffness, loss of muscle mass, necrosis cutaneous or up syndrome compartmental.

Therefore, the articulated orthosis option allows early mobility It is protection in procedure accomplished, already what blocks moves malefics in varus It is valgus, making possible healing in injuries ligaments acute or reconstructions of chronic injuries, preservation of fractures, procedures chondrals, arthroplasties, etc. Provides protection with joint mobility, recovering briefly The functionality, decreasing O frame painful, providing comfort at use, leading The benefit at circulation limb blood, avoiding joint stiffening.

In according to the Academy American in Orthoses It is prostheses, O The number of people using orthoses is expected to increase by at least 31%. A print three-dimensional (3D) It is method in manufacturing aided per computer what he can to create objects 3D using several materials, as plastic, metal, liquids or same cells cheers. One turn what it is technology is beneficial in terms of cost effectiveness, customization and increased productivity, has attracted much interest in the biomedical field. A application of 3D printing technology for the development of new orthoses It is considered path promising for reduction in costs with manufacturing fast in comparison with others orthoses. At the moment, The majority of the studies refers to devices for lower limbs, including ankle and foot orthoses, few sources refer to upper limbs (OPENING IN SOUZA et al ., 2017).

The procedure essentially includes 3D scanning and scanning of the upper limb; then the polygon data (STL file) is Processed in software to create proper splint in 3D Computer Aided Design (CAD), which is finally manufactured using printing technique 3D (GUIDE et al. , 2019).

Advantages of 3D printing include personalized results, fast design , low cost, availability of a variety of materials, properties mechanics optimized It is casualties barriers facilitating O performance in underdeveloped countries. The potential applications for 3D printing include simulation education and training, prosthetics or orthoses, planning preoperative, design It is prototyping fast, manufacturing in instruments personalized for patients, implants Individualized routine manufacturing of medical devices and applications of engineering in fabrics (SHAHAR et al ., 2019).

When comparing the effects of 3D printed bracing and plate bracing low-temperature thermoplastic, in patients with wrist stiffness and accident vascular cerebral hemiparetic chronic, in rehearsal clinical randomized and controlled trial, it was concluded that 3D printed orthoses led to a reduction in wrist spasticity and swelling, improving function motor and the amplitude passive of extension (ZHENG et al ., 2020).

Given the benefits of the type of orthosis to be manufactured, it is possible to quote the individuality of the device, personalized measures and diameters, lightness of material, speed at manufacture, possibility in big scale in production, investment relatively low at confection, reproducibility, accessible material, diffusion and improvement of techniques, possibility of production of all the items members of equipment.

To the to discuss choices performed at the brainstorming , developed product from different lines of knowledge, defining that this articulated orthosis would be used in the postoperative period of elbow surgeries, from the first days, using a bandage over the surgical wound and cover removal only after complete healing of the skin.

A progressive static model was chosen due to its greater tolerability and shorter time of use for effects similar to other methods; it's in it the principle of stress relaxation, where constant load is carried out enabling elongation of parts soft (SODHI et al ., 2019).

Zmorph vx type 3D printer and FDM method (Fused Deposition Modeling), bring lower cost in the acquisition of this printer model, in addition to the deposit and fusion modeling technique being the most used and known, with lower technical requirements, it presents lower cost of matter cousin: PLA (acid polylactyl) what comparatively The other plastic, ABS (acrylonitrile butadiene styrene) he has smaller price, It is biodegradable, allows bigger precision It is ease at modeling It is print, it has any less requirements to the use, It is compatible with wide diversity of printers, but has less resistance to heat and abrasion (YOO et al ., 2019).

opted for the use in scanner 3D for to generate reconstruction reliable image of the affected limb for better anatomical fit of the orthosis. It uses laser on skin points and collects data, favoring its individualization, comfort, functionality It is facilitating O process in later modeling (KIM et al ., 2018). Reverse engineering software chosen was GEOMAGIC STUDIO . Chosen 3D modeling software he was AUTOCAD, quite widespread for the world at creation in projects in computer, such as 3D modeling. Chosen slicing software was CURE, in code open, free, slice O model created 3D It is prepare The part for printing. Pay attention to the anatomical molding of the product, since the member affected generally would be with bigger circumference what your contralateral limb. Consider the need for individualization of cases, observing silhouettes, hinge, edema post operative, regression of swelling, blister, friable areas, possibility of temporary discontinuation due to complications, seeking to use it indefinitely, until reaching the apex of movements and stabilization of this passive gain is active.

To the surfaces in coupling of parts printed of arm It is forearm, as fitting It is hinge, would be printed for the own printer, with metal-assisted button locking (Chicago screw), option defined because it is a place of greater degradation of the device and crash metallic enables bigger durability It is resistance. Presence in two slits in the arm and forearm for the passage of two velcros each, to adjustment of device It is straps in connection in leagues elastic, so much previous, as hindquarters, to gain flexion and extension, respectively, promoting O principle in relaxation in stress, own of orthoses static progressive. These alloys can be adjusted, increasing or decreasing the charge, The to depend from the amount in leagues It is your positioning. To the leagues for flexors would only get stuck on the hooks and the extension garter needs pass through centralizing tunnels, avoiding change of vector of strength.

In view of the protective interface between the skin and the device, it was decided to none specific, already what O PLA allows your own polishing, being good tolerated, beyond in behave settings It is satisfying accommodation anatomical.

A bracing articulated produced in 3D he can to be more it needs It is efficient what immobilization plastered It is more functional what gadgets orthotics no joints, combining the protection benefits of a surgical intervention and early rehabilitation, reducing the risk of joint stiffening. Device can to be used at the Format built, It is reproducible, individualized It is accessible. Expected validation clinic of product per quite in studies later for employment populational in Large scale.

6.1. Impact Social

The device designed can help in the postoperative period of surgeries elbow traumato-orthopedics, prevention of the complication of stiffness articulate, frame what occurs with frequency at the SUS, due to the smaller access doctor and physiotherapeutic.

Many patients return from surgeries with prolonged immobilization plastered, purpose in protection of procedure surgical, demanding bigger time in recovery in movements, or loss sequel of ADM, justifying this device that stabilizes and also rehabilitates affected member.

6.2. Economic Impact

The product can be advertised in public or private hospitals, orthopedic or rehabilitation clinics in need of a 3D printer basic or outsourcing from the production.

The device collaborates with the early return to physical activities and labor, reducing the possibility of joint release surgeries for movement gain, but also directly influences smaller costs of hospital treatment or out-of-hospital rehabilitation, in addition to avoid greater burdens labor and social security.

Conclusion

"He was produced one model virtual in bracing articulated in elbow by the 3D printing method with technical modifications to the gadgets traditional, making possible new tool for O treatment or prevention of stiff elbow".

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