



A COST EFFECTIVE AND RELIABLE STATIC PROGRESSIVE ELBOW ORTHOSIS FOR JOINT STIFFNESS REHABILITATION

¹Jenifer T, ²Parthasarathi Swain, ³Pramita Swain, ⁴Dewendra Prasad, ⁵Sonali Mohanty

¹B.P.O. Intern, ²Assistant Professor (P&O), ⁴B.P.O. Programme Coordinator, ^{3,5} Demonstrator (P&O)

^{1,2,3,4,5} Department of Medical Science (Unit: Material Development - Aids & Appliances), National Institute for Empowerment of Persons with Multiple Disabilities (Divyangjan) (NIEPMD), Chennai, TN, India

Corresponding Author: Parthasarathi Swain

Department of Medical Science (Unit: Material Development - Aids & Appliances), National Institute for Empowerment of Persons with Multiple Disabilities (Divyangjan) (NIEPMD), Chennai, TN, India, 603112

ABSTRACT

Intensive rehabilitation of individuals with elbow flexion contracture poses a great challenge to the rehabilitation team and patients due to the unavailability of smooth adjustment to provide gradual elbow extension control. The people with elbow flexion contracture conditions that result in limited elbow joint movement strive to achieve functional goals. Orthotic braces are useful in elbow rehabilitation after acute injury or surgical fixation to decrease the risk of venous stasis and complex regional pain syndrome, which will allow movement within a safe ROM. The elbow brace with turnbuckle mechanism is a static progressive brace that may be useful in the treatment of an established elbow stiff joint Range of Motion. Previously there are various static progressive braces in existence, which is of high cost, and high maintenance demand. To overcome this problem, in the current study a new elbow joint with locking mechanism has been designed which offers adjustable ROM control and provides graded improvement in elbow range of motion in patients having elbow stiffness or elbow contractures.

KEYWORDS: Static progressive elbow orthosis, Joint stiffness, Range of Motion, Rehabilitation

I. INTRODUCTION

The etiologies resulting in a stiff elbow has been broadly categorized as traumatic and atraumatic injuries. Trauma, burns, and head injury are known causes of elbow contractures that directly proportional to the severity of the result. Elbow surgery involves controlled trauma to the tissues and may be complicated by postoperative stiffness. Atraumatic causes of the elbow stiffness include post-septic arthritis, osteoarthritis, inflammatory arthritis, multiple hemarthroses in

hemophiliacs and congenital contractures found in arthrogryposis and congenital radial head dislocation.²

Emily S Ho et al. (2019) reported, the median prevalence of elbow flexion contracture in Brachial Plexus Birth Injury (BPBI) was 48 percentage. The magnitude of the contractures was 5 degrees to 90 degrees. Contracture 30 degrees or more were found in 21 percent to 36 percent of children with BPBI. With recent clinical and lab studies shown that contractures are largely due to effects of the denervation causing failure in the growth of the affected elbow flexor muscles.¹

The stiffness of the elbow has been graded into 5 (five) types according to Kay's classification system. The kay's classification system is a common criterion for assessment of elbowstiffness, which classify the elbow contracture using grades.^{3,4.}

Currently, two types of intervention are followed for elbow contracture and stiffness: operative and non-operative. The operative treatment mainly involves open or arthroscopic release (removing the part of tissue), arthroplasty (It is a surgical procedure to restore the function of joint), and manipulation under anesthesia. Although these are efficient treatment methods, but surgery and manipulation under anesthesia are complex procedure and operativetreatments tend to cause neurovascular complications as well as recurrent elbow deformities if the surgical correction not maintained properly. The conservative treatment involves passive and assisted movement, continuous passive movement, serial bracing, and static and dynamic orthoses. However, the dynamic orthoses tend to cause soft tissue injury and inflammation under a constant load to the joint, which results in low compliance. Nowadays, static progressive orthoses have been used for the treatment of severe joint contracture after trauma and/or surgery. The underlying mechanism of static progressive orthoses on contracture is based on creep and stress relaxation.^{5, 3, 4, 6.}

Static Progressive Brace: This brace is used with turnbuckle or knob hinges, which provide gradual and comfortable flexion, extension distractive forces and specifically indicated for treatment of elbow stiffness and to prevent post-operative recurrent deformity.⁷

The people with elbow flexion contracture condition that result in dysfunction of movement strive to achieve functional goals, braces are useful in elbow rehabilitation after acute injury or surgical fixation to decrease the risk of venous stasis and complex regional pain syndrome, which will allow movement within a safe ROM. The disadvantages of applying mobilization braces are their cost.⁸

The elbow brace with turnbuckle mechanism is a static progressive brace which may be useful in the treatment of an established elbow stiffness. It is applied and adjusted incrementally by the Orthotist/Rehab professionals to perform progressive stretch at the elbow in either flexion or extension. The efficacy of turnbuckle splinting for the treatment of elbow contractures has received little attention. But the drawback of this splinting method is many patients found difficulty in sleeping and carrying out of daily living activities while wearing the splint.²

As in current scenario, all existed static progressive braces are high cost and needs high maintenance to use. To overcome this problem, in this study a new elbow joint with locking mechanism has been designed which offers adjustable ROM control and it will provide graded improvement in elbow range of motion in patients having elbow stiffness/post-operative elbow contractures. This design was provided at low cost, good cosmetic appearance and with added therapeutic benefits to overcome the disadvantages encountered in the existing design.

II. METHODOLOGY

Methodology is a system of broad principles or rules from which specific methods or procedures may be derived to interpret or solve. The goal of the study was to restore the physiologic integrity of the contracted muscle gradually and prevent recurrent deformity at elbow joint which usually happens after contracture release. To meet this goal, the design

concept of the orthosis based on “a static progressive elbow orthosis” which provides graded extension movement at elbow joint, thus increase the range of motion gradually.

Components of the new prototype design:

1. Forearm shell
2. Arm shell
3. Newly developed 3D printed ROM elbow joint with adjustable locking mechanism.
4. Overlapping elbow joint

FABRICATION PROCEDURE:

The fabrication procedure for this prototype design was started from making the layout followed by the common clinical procedure and used the available materials and machineries of Prosthetics and Orthotics department. Patient having history of elbow stiffness was accessed by examination, radiological and other lab reports.

STEP 1: Measurements

linear, circumferential and diameter of affected upper limb were taken. The followings linear measurement: Axilla to lateral epicondyle, Acromion process to lateral epicondyle, Lateral epicondyle to styloid process, Axilla to styloid process; Circumferential measurement: Maximum forearm, Minimum forearm, Elbow joint, Maximum arm, Minimum arm & Diameter measurement: Maximum forearm, Minimum forearm, Maximum arm, Minimum arm are taken.

STEP 2: Casting & Rectification Procedure

A standard clinical Palster of Paris (POP) bandage cast taking procedure was followed according to P&O guidelines (Fig.1), appropriate POP slurry, after setting of the pop, the cast over it was removed by plaster cutter and the overhanging materials were removed and with the use of POP powder the positive mold was prepared and after removal of plaster bandage the obtained positive mold smoothened with the help of wire mess and sand paper.



Fig.1 (Casting Procedure)

STEP 3: Alignment of the newly designed orthotic elbow joint

Before the joint alignment the anatomical elbow axis was marked medially and laterally in the positive mold which is 1 inch proximal to the anatomical elbow axis. The orthotic ROM joint was aligned laterally, 1 inch proximal to the anatomical elbow axis (lateral epicondyle of humerus) and it was shaped to give a flare to the orthotic ROM elbow joint. (Fig.2) Medially bony clearance has been created at the same mechanical elbow axis horizontal line. 3mm Polypropylene sheet was cut and shaped having radius of 1.5cm and placed at the medial elbow axis of the mold. (Fig. 3)



Fig. 2 (Elbow joint placement over modified mold)



Fig. 3 (Overlapping elbow joint)

STEP 4: 3D Design Procedure

The elbow joint was designed and printed using ABS-CF10 material in the 3D printing lab at NIEPMD. The 2D design of the elbow joint was prepared according to the specified measurement given in AutoCAD software. (Fig. 4)



Fig.4 (3D designing of the newly designed ROM elbow joint)

Then, the 2D model was converted into 3D model (Fig. 5 & Fig.6). This design was imported to 3D printing machine for printing the physical component of the elbow joint using Fused Deposition Modelling (FDM Stratasys F370) machine.

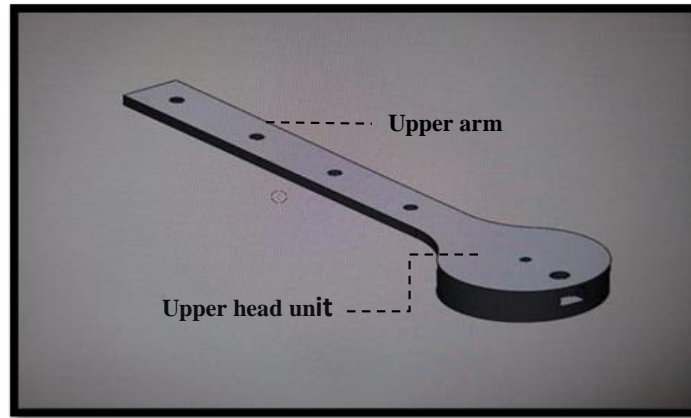


Fig.5 (Upper arm of the elbow joint)

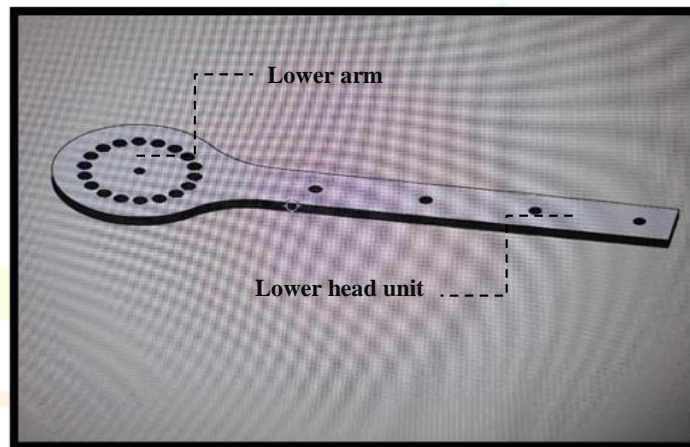


Fig.6 (Lower arm of the elbow joint)

The orthotic ROM elbow joint consist of 2 arms; Upper arm (The upper arm is an immovable arm which will be fixed at arm shell), Lower arm (The lower arm is movable arm which will be fixed at the forearm shell):

PARTS	HEIGHT	WIDTH	THICKNESS
UPPER ARM (Fig. 5)	18cm from the axis	It contains 2cm width excluding the upper head unit	6mm
LOWER ARM (Fig. 6)	18cm from the axis	It contains 2cm width excluding the lower head unit	6mm

TABLE.1 (Specification of both arms of newly designed ROM elbow joint)

PARTS	FUNCTION	THICKNESS	RADIUS
UPPERARM HEAD UNIT (Fig. 5)	This head unit is provided with a lever for locking and unlocking of the elbow joint.	1 cm	5 cm

UPPERARM HEAD UNIT (Fig. 6)	<p>The head unit contains 18 number of holes arranged in 20^0 intervals.</p> <p>It allows the joint to lock in 20^0 of interval throughout the full range of motion.</p>	6 cm	5 cm
-----------------------------------	--	------	------

TABLE.2 (Specification of both head unit of newly designed ROM elbow joint)

STEP 5: Molding, Trimlines & Finishing Procedure

The 4(four) mm polypropylene sheet was used for molding of arm shell and forearm shell. Initially the arm shell was molded, after the ROM elbow joint has been positioned in the mold. The obtained arm shell was trimmed which has an anterior opening and the distal trimline of the medial side covered the medial epicondyle including the clearance given to provide articulation at the elbow joint. The forearm shell was molded over the trimmed arm shell. The obtained forearm shell was trimmed, which has an anterior opening for donning and doffing and the proximal trimline covered the medial epicondyle of elbow.

Thus, medially the distal aspect of the upper arm shell and proximal aspect of the forearm shell will create an overlapping type of orthotic joint, which will allow free motion at the elbow.

The trimlines of the prototype static progressive elbow brace:

- The Postero-superior trim line of arm shell covers proximal $1/3^{\text{rd}}$ of arm, and it extended distally just above to the olecranon process.
- The Postero-superior trim line of the forearm shell extended 1"- 2" below to the olecranon process, and distally it covers the distal $1/3^{\text{rd}}$ of the forearm.

Finally, the shells were trimmed, edges were grinded & smoothened. The elbow joint was fixed in the shells with the help of aluminium rivets. The required hook & loop straps are attached in the shells. 2mm Etha flex was used for soft lining. (Fig.7)



Fig.7 (Final Prototype Model)

DESIGN CONCEPT & LOCKING MECHANISM

The ROM elbow joint is specifically designed to hold the anatomical stiff elbow in the static position and apply maximum load that can be tolerated comfortably. When the tissue stretches the load becomes more tolerated and the load is further increased for further stretching. As the tissue stretch, the load needed to maintain this stretched state reduces gradually. So, this newly designed brace can be readjusted by the next increment of 20 degrees, so that the load application will be simultaneous with respect to the tissue stretching. This helps to regain joint motion by giving force on the contracted tissue and induce progressive change. The new ROM orthotic joint attached to the proximal arm and distal forearm shell laterally which provide adjustable range of motion and non-overlapping type of orthotic joint which is placed medially allows free motion at the elbow joint.

The locking mechanism of the prototype design works by the inner spring mechanism and outer lever mechanism for locking and unlocking the elbow joint (Fig. 8 & Fig. 9) which is fixed inside of upper head unit. The lower head unit contains 18 number of holes arranged in 20 degrees interval; and it allow the joint to lock in 20 degrees of interval throughout the full range of motion. By applying slight downward pressure at the lever, the joint unlocked, and allow free motion. For locking elbow unit in any desired position the lever pushed slightly towards right and upward direction.



Fig.8 (Parts of the joint locking mechanism)



Fig.9 (Elbow joint with locking mechanism)

III. RESULT

The elbow stiffness refers to those individuals who experiences pain or problems when extending/ flexing their elbow greater than 30 degrees. The treatment goal is achieved by operative and non-operative treatment. The operative treatment mainly involves open or arthroscopic release (removing the part of tissue), arthroplasty (It is a surgical procedure to restore the function of joint), and manipulation under anesthesia and surgery. Manipulation under anesthesia are complex

procedure and operative treatments tend to cause neurovascular complications as well as recurrent elbow deformities. Nowadays, static progressive orthoses and dynamic bracing management have been used for the treatment of severe joint contracture after trauma and/or surgery. The conservative treatment like dynamic elbow bracing cause constant loading of the joint, results in low compliance. Whereas static progressive orthosis provides passive assisted movement, which apply gradual loading in the joint, results in high compliance.

The principle of static progressive brace helps to improve the ROM gradually by using visco-elastic property of soft tissues to produce tissue elongation. so, the shortened muscle fibers can achieve their physiological integrity gradually and maintained within rest length by using the ROM elbow brace. The relaxation occurs due to the realignment of fibers because of tissue elongation when tissues are held in a fixed position over time, thus will helps to regain the elbow joint ROM.

In this study a static progressive type of elbow brace was designed which provide adjustable ROM in 20 degrees increments with locking mechanism. This brace provides a constant traction to the stiff elbow, by maintain the passive range of motion of the elbow in parasagittal plane. This will help to prevent the elbow from developing stiffness and recurrent elbow flexion deformity after post-surgery by creep and stress relaxation principle.

IV. DISCUSSION

The management of the elbow injuries, loss of motion and recurrent elbow contracture are one of the more frequent & raising complications now-a-days. The available treatment criteria for elbow stiffness includes physical therapy, forced manipulation, surgery & bracing. But the efficacy of bracing is often underestimated, to exert appropriate distractive forces on the soft tissue exploiting their visco-elastic properties.

According to Gelinas J.J et al (2000)², the static progressive braces are effective in treating elbow stiffness and contracture, although the results were not satisfactory. Unsatisfactory results are due to its cost and poor patient compliance in wearing the orthosis during sleep and Activities of Daily Living. The study results also shown that the efficacy of turnbuckle splinting has received little attention due to difficulty in sleeping and carrying out of daily living while wearing the splint.

Anneluuk L. et al. (2012)⁹, investigated the efficacy of dynamic and static progressive splints for post traumatic elbow stiffness. Unsatisfactory result noted, even though there is a minor ROM increased after using both the splint, but there is no significant difference found in flexion arc.

In contrast, according to Deborah A. et al. (2012)¹⁰ the evidence demonstrated a clear trend towards positive outcome following the use of static progressive orthosis.

Marinelli A. et al. (2010)⁷, assessed the efficacy of the mobilization brace in post-traumatic elbow stiffness patients. In post-traumatic contracture, mobilization braces are effectively employable in two main critical situations: to treat recent onset contractures which do not respond to physical therapy alone and to help in preserving ROM gained after surgical release. The study shown satisfactory result with the use of static progressive orthosis.

V. CONCLUSION

The novel elbow rehabilitative orthosis is effective in specific conditions like elbow injuries, post-operative management of elbow contracture, to obtain stretching of retracting on retracted soft tissues. The available elbow braces are expensive, requires a satisfactory patient compliance, need frequent follow up visits and more time consuming for professional regarding explanation and whereas the orthosis used in the study is a removable device, which can be managed for a longer time at home instead of frequent visit to service provider for readjustment. With correct indication, this newly designed static progressive rehabilitative elbow orthosis can exhibit good result and can improve the physiological range of motion. The limitation of the current study is Lack of clinical trial & Reduction of ROM angle needed for improve therapeutic advantages.

Conflict of interest: The authors does not have any conflict of interest regarding research, authorship, and publication of this article.

Funding: The authors received no financial support for the research, authorship, and/or publication of this article.

Acknowledgement: I wish to express my heartfelt appreciation to Shri. Dewendra prasad, B.P.O. Programme Co-Ordinator, Shri. Parthasarathi Swain, Assistant Professor (P&O) & Mrs. Pramita Swain, Demonstrator (P&O) NIEPMD, Chennai, for their sincere and valuable guidance. Special thanks to Shri. Anish Arumugam, Senior Application Engineer at ALTEM Technologies Pvt. Ltd., Bangalore, for his assistance in 3D designing and printing. I would also like to extend my gratitude to all the faculty and technical staff at the Prosthetic & Orthotic Unit, NIEPMD, for their unwavering support. Lastly, I am thankful to my family, teachers, and friends for their encouragement and support.

REFERENCES

1. Emily S H, Kim D, Klar K, Anthony A, Davidge K, Borschel G.H, Seven H, Clarke H.H, Wright F.V. Prevalence, and etiology of elbow flexion contractures in brachial plexus birth injury: A scooping review. Journal of pediatric rehabilitation medicine. 2019; 12(1): 75-86.
2. Gelinas J.J, Faber K.J, Patterson S. D, King G.J.W. The effectiveness of turnbuckle splinting for elbow contractures. J Bone Joint Surg [Br]. 2000; 82-B: 74-78.
3. Masci G, Cazzato G, Milano G, Ciolli G, Malerba G, Perisano C, Greco T, Osvaldo P, Maccauro G, Liuzza F. The stiff elbow: Current concepts. Orthopedic reviews. 2020; 12(s1): 8661.
4. Blonna D, Bellato E, Marini E, Scelsi M, Castoldi F. Arthroscopic Treatment of Stiff Elbow. International scholarly research network ISRN surgery. 2011; 6: 1-7.
5. Chen B, Lin J, Liu L, Niu W. Static Progressive Orthoses for Elbow Contracture: A Systematic Review. Hindawi journal of health care engineering. 2017; 1-8.
6. Olsen s BO. Treatment of the stiff elbow joint. Orthopaedics and trauma. 2012; 26(6): 397- 401.
7. Marinelli A, bettelli G, Guerra E, nigrisoli M, Rotini R. Mobilization brace in post-traumatic elbow stiffness.

Musculoskelet surg. 2010; 94 (suppl 1): S37-S45.

8. Fusaro et al. The use of braces in the rehabilitation treatment of the post-traumatic elbow, Joints. 2014; 2 (2): 81-86.
9. Anneluuk L. C. Lindenhovius, job N, Doornberg, Kim M, Brouwer, Jesse B, Chaitanya S, Mudgal, David R. A Prospective Randomized Controlled Trail of Dynamic versus Static Progressive Elbow splinting for Posttraumatic elbow stiffness. J Bone Joint Surg Arm. 2012; 94: 694-700.
10. Deborah A, Schwartz. Static progressive orthoses for upper extremity: a comprehensive literature review. 2012; 7(1): 10-17.

