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Advancements and Innovations in Elbow Orthoses: An Extensive Review of Design, Development, and Clinical Applications

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ABSTRACT

There are different types of elbow orthoses, medical devices engineered to support and stabilize the elbow joint, assisting in recovery from injuries or surgeries, and managing chronic conditions through movement restriction and essential immobilization. The development of elbow orthoses has evolved significantly from rudimentary splints in early medical practices to advanced, custom-fitted devices utilizing modern materials and biomechanical principles. This review provided researchers with a comprehensive overview of the history and development of elbow orthoses. It offered insights into the effectiveness, utilization, and clinical applications of different types of elbow orthotic designs. Additionally, this review contributed to the body of knowledge by comparing traditional and modern elbow orthotic technologies, offering valuable guidance for future research directions in this area of study. Furthermore, this review underscored the challenges and prospects within the field, paving the way for concerted endeavors among academics, healthcare practitioners, and industrial experts to propel the development of elbow orthotic technologies and improve patient results. Thus, researchers potentially could have developed more effective treatment strategies in clinical practice and improved the quality of life for patients.

Keywords: Elbow orthoses, rehabilitation, biomechanics, personalized medicine

1 Introduction

The elbow joint, or articulatio cubiti, is a complex synovial hinge joint comprising the distal humerus, proximal ulna, and head of the Radius [1]. It includes three primary articulations known as the humeroulnar, humeroradial, and proximal radioulnar joints, which facilitate flexion, extension, pronation, and supination [2]. Stability is provided by the medial and lateral collateral ligaments as well as the annular ligament [3]. The surrounding musculature, including the biceps brachii, brachialis, and triceps brachii, supports joint function and stability [4]. The proximity of critical neurovascular structures, including the ulnar, radial, and median nerves, along with the brachial artery, necessitates a thorough understanding of elbow anatomy for accurate clinical assessment and intervention [5]. There are numerous elbow injuries and disorders, including lateral epicondylitis, medial epicondylitis, olecranon bursitis, cubital tunnel syndrome, and ligamentous injuries, that frequently occur and require precise and effective rehabilitation protocols [6]. The primary goals of elbow rehabilitation encompass pain management, reduction of inflammation, and restoration of functional mobility and strength [7-9]. Conventional therapeutic protocols encompass manual therapy, specific therapeutic exercises, cryotherapy, and neuromuscular electrical stimulation [10]. The implementation of elbow orthoses stands

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out as a crucial intervention in the management of these conditions [11]. Orthoses provide crucial joint stabilization, mitigate pain, and facilitate controlled mobilization, thereby enhancing the healing process [12]. By restricting deleterious movements and reducing mechanical stress on the affected structures, orthoses not only promote tissue recovery but also prevent recurrence of injury, making them an indispensable component of a comprehensive rehabilitation strategy for elbow disorders [13].

Elbow orthoses, encompassing passive, active, and semi-active modalities, are extensively utilized in the treatment and management of a spectrum of conditions including epicondylitis, elbow instability, fractures, and traumatic injuries [14-15]. Passive orthoses typically offer stable support, allowing the elbow to rest comfortably [16]. Active orthoses promote elbow motion alongside restricting excessive movement [17]. Semi-active orthoses facilitate a specific range of motion, enabling users to engage muscle strength and movement [18]. The working principles of these orthoses are to stabilize the elbow in accordance with biomechanical principles, restrict undesirable movements, and apply pressure to the affected site [19]. These designs are typically made from lightweight and durable materials such as titanium [20], aluminum [21], or carbon fiber [22] and can be adjusted according to individual needs.

Elbow orthoses, initially introduced in the medical field in the early twentieth century, found their earliest applications in the management of conditions such as epicondylitis and elbow fractures [23]. The historical evolution of elbow orthoses has been marked by advancements in mechanical design, structural composition, and manufacturing processes [24]. Early orthoses were often rudimentary, consisting of simple splints or braces constructed from materials such as metal or leather [25]. Over time, innovations in materials science led to the development of lighter, more durable orthotic materials, including plastics, carbon fiber [27], and thermoplastics [28]. Concurrently, improvements in biomechanical understanding and orthotic design principles have enhanced the effectiveness and comfort of elbow orthoses [28]. Today, elbow orthoses remain a crucial component of conservative treatment strategies for a range of elbow pathologies, offering targeted support [30-31], stability [32], and pain relief [33] to patients.

The purpose of this review paper was to provide a comprehensive synthesis of the existing literature concerning elbow orthoses. It delved into various aspects including their typologies, indications, applications, and efficacy in managing a spectrum of elbow pathologies such as epicondylitis, instability, fractures, and traumatic injuries. Furthermore, it scrutinized the biomechanical underpinnings of orthotic design, the materials utilized in orthosis fabrication, and technological advancements in the field. Through an exhaustive analysis and synthesis of prior research, this review paper contributed to the academic discourse by elucidating evidence-based practices in elbow orthotic management and identifying avenues for future research and innovation. The necessity for a review paper on elbow orthoses arises from the increasing prevalence of elbow-related injuries and conditions and the need for a comprehensive understanding of the efficacy and applications of orthotic interventions in their management. The structure of the paper was delineated as follows. In Section 2, the focus was on the development and advancements in dynamic elbow orthoses, showcasing innovative designs and technological features intended to improve functional results and rehabilitation processes. Finally, a thorough review of the concluding remarks was conducted in Section 3.

2 Orthotic Innovations in Elbow Rehabilitation

In recent years, significant advancements have been achieved in the design and application of elbow orthoses for various clinical conditions. These devices have evolved to provide enhanced support, stability, and therapeutic benefits, utilizing innovative technologies and materials. This section provides a concise overview of notable studies and developments in the field of elbow orthoses, highlighting their clinical implications and technological advancements. There is an extensive collection of studies available in the open literature. Figure 1 illustrates the number of academic publications indexed by Web of Science (WoS) between 1980 and 2023. This review paper highlights several studies noted for their innovative contributions (see Figure 2). For example; Deharde and Patchel (1997) developed a dynamic splint incorporating a bi-directional torsional power unit for extension or flexion support, featuring adjustable force, compactness, and lightweight design. This invention utilized a hinge-mounted power unit to selectively oppose joint movement, with self-aligning contour plates ensuring anatomical conformity and stability. Innovative features encompassed a universal soft cuff/strap design, infinitely adjustable telescoping struts, and a cam locking mechanism for secure positioning [34]. Johnson et al. (2001) developed the Motorized Upper-Limb Orthotic System as an advanced powered orthosis designed for individuals with disabilities or limb weakness. It featured five degrees of freedom focusing on shoulder, elbow, and pronation/supination movements. The system operated in assistive, continuous passive motion therapy, and potential exercise modes, demonstrating capability in providing controlled movements and effective therapy programming, with attention to safety considerations for future enhancements in operation and control interfaces [35]. Bahadir et al. (2005) conducted a study to investigate the effect of using the Bobath sling on glenohumeral subluxation and functional improvement in hemiplegic patients. A total of 32 hemiplegic patients with an average age of 58.7 were included in the study. The comparison between patients using the Bobath sling and those not using it revealed that after one month of treatment, patients using the Bobath sling experienced a decrease in glenohumeral subluxation or stability without progression. These findings indicated that the use of the Bobath sling could be beneficial in preventing the development and progression of glenohumeral subluxation in hemiplegic patients [36]. Vanderniepen et al. (2008) discussed the design challenges and unique characteristics of orthopaedic rehabilitation for the elbow joint using a powered orthosis with MACCEPA actuators. The paper highlighted the differences in approaches between neuro-rehabilitation and orthopaedic rehabilitation, emphasizing the specific considerations needed for effective elbow joint rehabilitation. Additionally, the paper detailed the mechanical design and requirements of the orthosis, particularly focusing on the innovative features of MACCEPA actuators with online adaptable compliance [37]. Schulz et al. (2009) developed a non-invasive, modular FES-hybrid orthosis for upper extremity rehabilitation in cervical spinal cord injured patients. This orthosis integrated orthotic stability with FES muscle activation to restore function and enable training. By using miniaturized flexible fluidic actuators and innovative user interfaces based on muscle activity and movement intention detection, the system aimed to address grasping function loss, enhancing independence and autonomy for patients [38]. Kesmezacar et al. (2010) conducted a study to investigate the clinical and radiographic outcomes of conservatively managed simple elbow dislocations. Patients treated with closed reduction and short-term immobilization exhibited notable restrictions in joint range of motion, and most patients did not report feeling fully healed. These findings suggested a correlation between significant joint mobility limitations and the treatment approach for simple elbow dislocations, despite the effectiveness of these methods in terms of functional scores [39].

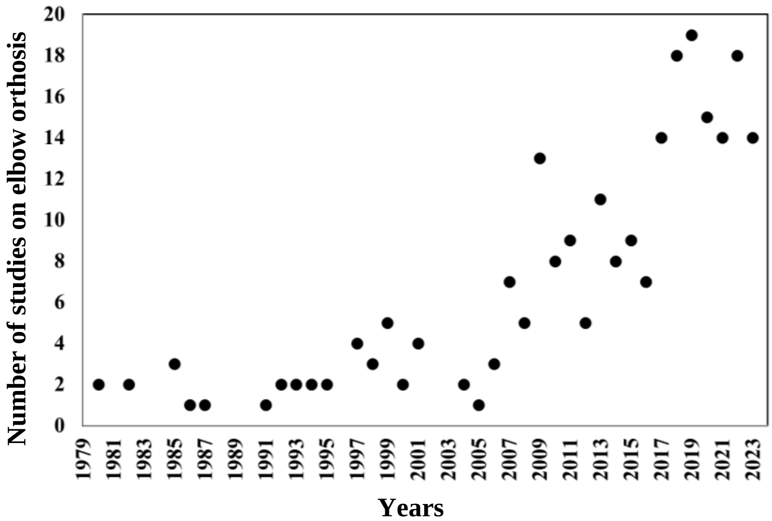

Figure 1: Academic publication trends on elbow orthosis in web of science

Figure 2: Compilation of elbow orthosis designs from reviewed studies

Pau et al. (2012) developed a neuromuscular interface (NI) for the elbow joint that predicts motion using electromyographic (EMG) signals from the biceps and triceps. The study demonstrated that the NI, which did not rely on additional weights or other sensors, achieved an average root-mean-square error of 6.53° for single cycles and 22.4° for random cycles, validating its potential for both able-bodied and less-abled users [40]. Bonutti et al. (2012) conducted a patent study and devised an orthosis that enabled hand and arm bone movement. The orthosis included a main gear assembly with a lower cuff for wrist and hand grip, allowing adjustments for pronation and supination. A lower cuff arm stabilized the forearm, and an upper cuff arm supported the upper arm, accommodating angular adjustments for personalized therapy sessions [41]. Cempini et al. (2013) introduced enhancements to the NEUROExos, a wearable exoskeleton designed for mobilizing paretic/spastic elbows. The study focused on the exoskeleton's actuation, transmission, and control systems, incorporating a safety clutch and a series elastic actuation architecture with a novel torsional spring element to improve joint compliance and enable both position and torque control methods. The revised NEUROExos was designed to be portable and accessible for clinical application [42]. Ripel et al. (2014) designed a motorized active elbow orthosis (AEO) for rehabilitation, utilizing robotic exoskeleton principles. The device measures patient motion using a strain gauge and controls the actuator to aid elbow movement, offering exercises similar to those of a physiotherapist. Initial tests demonstrated successful improvement in elbow joint motion, suggesting potential for home-based rehabilitation with further validation needed for widespread clinical adoption [43]. Vitiello et al. (2016) developed an advanced version of the NEUROExos robotic elbow exoskeleton, targeting rehabilitation for stroke patients in both acute and subacute phases. This version introduced a novel series elastic actuation system, an anatomical alignment mechanism with four passive degrees of freedom, and one active degree of freedom with remote cable-driven actuation. Initial trials with chronic post-stroke patients indicated the system's effectiveness in assessing joint rigidity and its potential for rehabilitation application [44]. Herrnstadt et al. (2016) designed a one DOF elbow orthosis for tremor suppression, utilizing a speed-controlled, voluntary-driven approach. In contrast to traditional methods that canceled tremor signals, this orthosis estimated and actuated based on voluntary movement, achieving over 99% reduction in tremor power with minimal impact on voluntary motion. The feasibility of this approach was demonstrated through testing with a robotic system that simulated the human arm [45]. Ataoğlu et al. (2017) evaluated the efficacy of closed reduction followed by early mobilization in patients with simple elbow dislocations. The study included 18 adults treated with closed reduction under sedation, followed by a week of immobilization in a long arm cast and early active movement initiation. After one year, evaluations using the Quick Disabilities of the Arm, Shoulder, and Hand (Quick-DASH) and Oxford Elbow Score showed no significant differences compared to the contralateral elbow. Early mobilization resulted in quicker return to work and no recurrent dislocations, demonstrating its safety and effectiveness [46]. Cilaci et al. (2018) documented the rehabilitation process of a 33-year-old woman with localized scleroderma, focusing on severe joint contractures in her left upper extremity. The therapy had included heated modalities, active stretching and strengthening exercises, and the use of a dynamic orthosis. Over one month, improvements were noted in range of motion, particularly elbow extension and shoulder abduction, with a significant increase in grip strength and improved DASH scores. These findings highlighted the effectiveness of conventional rehabilitation methods augmented by dynamic orthoses in treating rigid contractures in localized scleroderma [47]. Murugan et al. (2018) developed an ergonomic elbow orthosis to address elbow hyperextension, utilizing a 3D scanned model of the human hand for a personalized design. The orthosis, constructed from ABS material through additive manufacturing, was optimized for weight and stiffness, ensuring comfort and faster recovery compared to conventional methods [48]. Wee et al. (2019) developed an elbow-flexion assist orthosis for individuals with arthrogryposis multiplex congenita (AMC), aiming to aid elbow flexion using a spring mechanism combined with a sliding joint to increase elbow torque. The prototype demonstrated increased elbow flexion from 87 degrees without the device to 120 degrees with it, allowing the user to bring her hand to her mouth more easily. This lightweight, easily concealable orthosis offered a practical solution for enhancing elbow movement in AMC patients [49]. Bancud et al. (2019) designed a powered wearable orthosis for managing spasticity and contractures resulting from neurological and orthopedic pathologies. This portable device enabled patients to perform repeated-passive-dynamic exercises in non-clinical environments. Equipped with electrogoniometers and torque sensors, the orthosis recorded kinematic and dynamic data, providing valuable insights for clinicians and supporting further research. The modular design allowed adaptability to various anatomies and conditions, addressing limitations of existing robotic rehabilitation devices [50]. Minh et al. (2019) developed a low-cost, mechatronic orthosis for home-based rehabilitation of elbow injuries, which used EMG sensors to detect and translate muscle signals into motor movements. The device, regulated for various users, utilized adaptive control algorithms including linear quadratic Gaussian and Kalman filter to achieve a 94% accuracy, with a maximum error of 6.9° over a 122° movement range [51]. Dindorf and Wos (2019) developed a wearable elbow joint orthosis featuring a bimuscular pneumatic servo-drive controlled by bioelectric signals. The study presented the use of brain activity and muscle tension to manage the orthosis, utilizing a distributed control system with a master and direct layer. The orthosis facilitated natural elbow movements and provided effective support for rehabilitation and muscle force recovery [52]. Bonutti et al. (2019) introduced a novel invention, a patented orthosis aimed at facilitating supination and/or pronation of the wearer's forearm. The orthosis consisted of a base, an upper arm support securing the wearer's upper arm, a rotation assembly enabling rotation within a defined plane, and a forearm support engaging the wearer's wrist and forearm. This innovation aimed to provide effective support for forearm rotation, enhancing rehabilitation and mobility for individuals [53]. Nikolaev et al. (2020) aimed to develop an adaptive elbow orthosis allowing for customizable motor activity engagement and remote control. The proposed design included individual sockets for the shoulder and forearm, elastic elements for torque balance, adaptation drives, and a control system operated via an Android mobile app with feedback [54]. Golovin et al. (2021) investigated a new orthosis design for patients with upper limb paresis, addressing the limitations of existing devices. Their prototype, combining elastic elements and external energy sources, enabled precise control of auxiliary force via a smartphone application, potentially enhancing rehabilitation effectiveness [55]. Demirsoy et al. (2022) developed a Raspberry Pi-controlled remote monitoring system. This system utilized EMG signals, storing the data in the cloud for access by physiotherapists. The study introduced a low-cost, portable, and lightweight elbow rehabilitation device prototype. This device could be used for the treatment of nerve and tendon injuries, supporting active exercises, and enabling physiotherapists to monitor the rehabilitation progress [56]. Rodriguez et al. (2022) designed and simulated a 3 DOF mechatronic orthosis to support physical rehabilitation for individuals with musculoskeletal disabilities. The orthosis, tested on a 22-year-old subject, utilized 6061 aluminum rods, servomotors, and an Arduino Nano for control, along with a Matlab GUI for customization. Simulation results indicated that the orthosis achieved the desired angular movements for shoulder, arm, and elbow, showing potential for effective home-based rehabilitation [57]. Lavrenko et al. (2022) developed a prototype orthosis for elbow joint rehabilitation, focusing on stress-strain analysis and material selection for structural elements. The orthosis design incorporated a bevel gear mechanism, ensuring proper torque transmission, and was tested using FEMAP with NASTRAN to optimize its mechanical performance. The prototype demonstrated potential for post-traumatic rehabilitation and could be adapted for other joints [58]. Rosero et al. (2022) designed a mechatronic orthosis to aid elbow rehabilitation by facilitating flexion-extension and pronation-supination movements. Evaluated in practical applications, the device demonstrated potential as a low-cost, functional prototype for treating elbow pathologies, despite some identified design limitations and areas for improvement [59]. Said et al. (2022) purposed a smart elbow brace (SEB) designed for home-based rehabilitation of poststroke or traumatic elbow injuries. The SEB aimed to reduce elbow stiffness by facilitating extension, flexion, pronation, and supination motions. It incorporated a sliding joint to distribute forces and featured rehabilitation exercises for interactive engagement. However, clinical efficacy and signal delays remained as limitations, suggesting areas for future improvement [60]. Petrov et al. (2023) developed an autonomous controller for an active elbow orthosis, enabling parameterization by physiotherapists and independent use by patients at home. The controller operated in two modes, either without electromyographic feedback or using feedback from the biceps brachii muscle to initiate movement. The prototype was designed for both left and right elbows and included adjustable length options for different patient sizes [61]. In examining studies presented in the open literature, evidence suggested that elbow orthoses experienced significant advancements by incorporating modern technologies to provide superior support and therapeutic benefits. The ongoing development in this field had the potential to further refine and innovate, thus shaping the future of orthopedic rehabilitation. Section 3 summarized the main results of the studies on elbow orthoses.

3 Conclusions

The development of elbow orthoses was profoundly influenced by advancements in materials, design methodologies, and technological breakthroughs. These innovations drove a transformative shift in orthopedic rehabilitation, underscoring the remarkable progress and potential within the realm of elbow orthoses. The primary focus of elbow orthoses was to provide support, stability, and pain relief, with recent developments expanding their therapeutic potential to include dynamic rehabilitation, personalized intervention, and remote monitoring capabilities. One notable trend in recent research was the integration of advanced technologies into orthotic design, such as EMG sensors, mechatronic actuators, and adaptive control systems. These innovations enabled orthoses to respond dynamically to the patient's physiological signals, providing tailored support and facilitating more natural movement patterns during rehabilitation. Additionally, the incorporation of remote monitoring features allowed for real-time assessment of patient progress and adjustment of treatment protocols, enhancing the efficiency and effectiveness of rehabilitation interventions. Moreover, the emphasis on personalized medicine spurred the development of custom orthotic solutions tailored to individual patient anatomy and pathology. The application of 3D scanning and additive manufacturing technologies enabled the precise fabrication of orthoses tailored to the unique biomechanical requirements of patients, thereby optimizing comfort, fit, and therapeutic results. This personalized method not only enhanced patient adherence and satisfaction but also maximized the therapeutic efficacy of orthotic interventions. Furthermore, the expansion of orthotic applications beyond traditional rehabilitation centers was evident in recent research endeavors. The integration of elbow orthoses into patients' daily activities extended beyond clinical settings, ranging from home-based rehabilitation systems to assistive devices. This trend exemplified a broader paradigm shift towards patient-centered care and empowerment, wherein individuals were actively involved in the management of their health and well-being.

However, several challenges and limitations persist in the field of elbow orthoses. First, the high cost of advanced orthotic devices poses a significant barrier, limiting accessibility, particularly in low- and middle-income countries. Second, the effective utilization of these sophisticated technologies requires specialized training for both clinicians and patients, potentially hindering optimal use and reducing therapeutic benefits. Third, there is an insufficiency of comprehensive long-term studies evaluating the efficacy and reliability of these devices, making it difficult to draw definitive conclusions about their long-term benefits and potential complications. Fourth, the customization process for personalized orthoses faces biomechanical design challenges, as the unique anatomical and biomechanical characteristics of each patient require highly individualized solutions. Finally, the integration of smart technologies raises concerns about data security and patient privacy, necessitating robust measures to protect sensitive health information. Addressing these challenges through continued research and interdisciplinary collaboration will be essential for further advancement in the field. In light of the significant global health ramifications, it becomes imperative to prioritize the resolution of these challenges to facilitate equitable access to orthotic solutions on a global scale.

In conclusion, the field of elbow orthoses witnessed significant advancements towards personalized, technology-driven rehabilitation solutions that extended beyond conventional limits. Despite significant advancements in the design and application of elbow orthoses, several knowledge gaps remain. Future research should focus on the long-term efficacy of orthoses, enhancing personalization through advanced materials and AI-driven customization, and integrating smart technologies for real-time data collection and feedback. Additionally, optimizing biomechanical design and conducting comprehensive clinical trials will be crucial. Furthermore, the development of standardized protocols for training and data management can enhance the integration and efficacy of these devices. As research continued to push the boundaries of innovation, the future held promise for even more sophisticated orthotic interventions that improved patient benefits, promoted independence, and enhanced the quality of life for individuals with elbow-related conditions. In closing, the trajectory of elbow orthoses exemplifies a remarkable fusion of innovation and patient-centered ethos, offering a glimpse into a future wherein rehabilitation is not only effective but also seamlessly tailored to individual needs, ushering in a new era of orthopedic care.

4 Declarations

4.1 Study Limitations

None.

4.2 Acknowledgements

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4.4 Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

4.5 Authors' Contributions

Hamid ASADI DERESHGI provided supervision and guidance throughout the review process, ensuring the methodological rigor and integrity of the study. He participated in the conceptualization and design of the review, critically reviewed and revised the manuscript, and provided valuable intellectual contributions. He offered expertise in the field of elbow orthoses and contributed to the final approval of the manuscript.

Sezer BICER assisted in the conception and design of the review study, contributed to the selection and screening of relevant literature, and provided critical revisions to the manuscript for important intellectual content. He played a key role in synthesizing the information from the reviewed papers and ensuring the coherence of the narrative.

Ozge Naz GURBUZ contributed to the critical evaluation and synthesis of the reviewed literature, ensuring the accuracy and integrity of the information presented.

Dilan DEMIR contributed to the data collection process by identifying and retrieving relevant papers, and contributed to the development of figures included in the manuscript.

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