



Patient satisfaction and outcomes of static progressive stretch bracing: a 10-year prospective analysis

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Background: Multiple surgical and non-surgical modalities are available for patients suffering from shoulder elbow, forearm, wrist, knee and ankle stiffness. For most patients, bracing can provide optimal therapy to restore functional range of motion (ROM). Three commonly used bracing mechanisms include static progressive stretch (SPS), turnbuckle, and dynamic bracing. However, although, in general, these three brace types have been shown to have successful outcomes, there are a number of different manufacturers, and company specific designs might affect outcomes. Therefore, the purpose of this study was to analyze 10 years of prospectively collected patient satisfaction and outcomes data from a single brace company. Specifically, we evaluated: (I) mobility, (II) pain, (III) stiffness, (IV) swelling, and (V) any adverse events of patients treated with an SPS brace.

Methods: From 2007 to 2017, data from a total of 167,751 patients treated with a JAS Brace (Joint Active Systems Inc., Effingham, IL, USA) were prospectively collected through a cross-sectional survey addressing various outcomes such as pain, stiffness, swelling and mobility. More specifically, patients were asked “Are you having pain?”, “Do you have any stiffness?”, “Do you have any swelling?”, and “Do you feel your mobility has improved?” Patients who answered “yes” were then asked to categorize their response as either worse, same, or better (or improvement) for pain, stiffness, and swelling. For mobility, patients answered either “yes”, “no”, or “undecided”. This data was then graphed and a yearly trends analysis was performed. We also assessed the number of complaints as well as any device related adverse events.

Results: In 2008, 59% of patients reported no pain, 45% no stiffness, and 79% no swelling after device use. Those numbers increased by 2013, to 70% of patients reporting no pain, 79% reporting no stiffness, and 84% reporting no swelling after brace use. A consistent positive trend was also seen for mobility, with at least 90% of patients reporting improved mobility after orthosis use. The number of complaints decreased from 38 in 2007 to 3 in 2017. No patients experienced any device related serious injuries.

Conclusions: Overall, to the best of the author’s knowledge, this study is the first to demonstrate a brace designed to improve ROM also has significant effect on pain, stiffness, and swelling. These results are of particular importance, since no other study reports prospective data on thousands of patients showing that a bracing system substantially reduces pain and stiffness. These data indicate that not only are these SPS braces effective in improving functional ROM with high rate of success and no significant complications, but this bracing system has a significant effect on improving pain and stiffness. Based on the results from this study, patients suffering from shoulder, elbow, forearm, wrist, knee and/or ankle pathology can expect excellent clinical outcomes by using one of the above braces.

Keywords: Static progressive stretch (SPS); bracing; non-operative management

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Introduction

Many non-surgical and surgical treatment modalities have been developed for patients suffering from shoulder, elbow, forearm, wrist, knee and ankle pathologies. Often surgical treatment plans are reserved for patients suffering from chronic stiffness that has not been relieved with other non-surgical treatment modalities. To help avoid potential joint stiffness, the pathological joint should be identified within 6 months or less after the initial trauma and treated with non-surgical treatment modalities, including turnbuckle, static progressive stretch (SPS), and/or dynamic braces (1,2). Although each type of brace seeks to achieve a similar ultimate goal, each bracing modality involves a different mechanism of action. Turnbuckle braces function by applying a low intensity, static force on the joint in order to aid in the release of a contracture, and are manually adjusted to generate the necessary tension level (3). SPS braces provide a low intensity, manually adjustable force that is incrementally increased as joint tissues relax in response to stress loads applied (4). SPS braces commonly work bi-directionally, allowing flexion and extension therapy with one device. Dynamic braces provide a constant level of low intensity force to the joint over a prolonged treatment time, commonly known as “creep” (5). Dynamic braces commonly work in one direction only, requiring one device to provide flexion and a second to provide extension stretch.

The ultimate goal of each of the above bracing modalities is to help patients regain a functional range of motion (ROM) to carry out activities of daily living (ADLs). For the elbow, normal ROM to successfully complete ADLs has been suggested to be 100 degrees of flexion (range, 30 to 130 degrees) along with 100 degrees of forearm rotation (50 degrees pronation and supination) (6). The mean shoulder ROM for ADLs has been described to be 121 degrees flexion, 46 degrees extension, 128 degrees of shoulder abduction, 116 degrees of shoulder cross-body abduction, 90 degrees of external rotation with abduction of 59 degrees, and 102 degrees of internal rotation with 0 degrees of abduction (7). Functional ROM for the wrist has been shown to be 38 degrees of wrist flexion, 40 degrees of wrist

extension, 38 degrees of ulnar deviation, and 28 degrees of radial deviation (8). For the knee, it has been reported that less than 90 degrees of knee flexion is required for gait, 90 to 120 degrees is required for stairs and chairs, and that 110 degrees of flexion is an appropriate goal for patient to achieve in order to carry out ADLs (9). The mean maximum ankle ROM to carry out ADLs has been suggested to be 28 degrees of dorsiflexion and 37 degrees of plantar flexion (10).

Recent studies have reported on the advantages of these braces for patient care (11,12). Using these studies in practice is critical, as current changes to the healthcare system are pushing for more evidence-based treatment plans in order to provide the most effective care for patients. An important part of this push for better patient treatment is based on patient reported outcomes. Although, in general, these above three brace types have been shown to have successful outcomes, there are a number of different manufacturers, and company specific designs might affect outcomes. Therefore, the purpose of this study was to analyze 10 years of prospectively collected patient satisfaction and outcomes data from a single brace company. Specifically, we evaluated: (I) mobility, (II) pain, (III) stiffness, (IV) swelling, and (V) any adverse events of patients treated with an SPS brace.

Methods

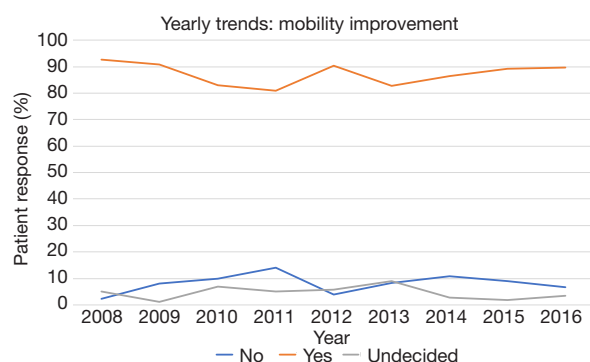
Patient selection

From 2007 to 2017, data from patients treated with a Static Progressive Stretch Brace (Joint Active Systems Inc., Effingham, IL, USA) were prospectively collected. The data was organized on a quarterly system, from which overall value means were calculated. A total of 167,751 patients were treated from January 1st, 2007 to December 31st, 2017, with the yearly breakdown of 11,846 patients in 2007, 12,294 patients in 2008, 14,140 patients in 2009, 15,185 patients in 2010, 15,880 patients in 2011, 15,500 patients in 2012, 15,938 patients in 2013, 16,674 patients in 2014, 16,780 patients in 2015, 16,394 patients in 2016, and 17,120 patients in 2017. Patient demographics of those who were

Table 1 Reasons for bracing treatment

Brace type	ICD-10 diagnosis
Elbow	Stiffness of R elbow, not elsewhere classified
Shoulder	Adhesive capsulitis of left shoulder
Knee	Unilateral primary osteoarthritis, R knee
Wrist	Unspecified fracture lower end of L radius, subsequent encounter for closed fracture with routine healing
Ankle	Contracture R ankle

ICD-10, International Statistical Classification of Disease-10.

**Figure 1** Yearly trends in mobility improvement.

treated were 41% male and 49% female; for 10% gender was not identified. The mean age was 48 years. The primary diagnosis or reason for treatment with each brace can be noted in *Table 1*. From all patients treated, 50 per month (600 per year) were randomly and prospectively selected to complete the survey.

Patient survey

Patients were given a cross-sectional survey addressing various outcomes such as pain, stiffness, swelling, and mobility. More specifically, each of those outcomes were assessed by asking “Are you having pain?”, “Do you have any stiffness?”, “Do you have any swelling?”, and “Do you feel your mobility has improved?” For questions concerning pain, stiffness, and swelling, patients who responded to the survey question answered either “yes” or “no”. Responses from 2007 to 2017 were collected and analyzed for pain, stiffness, and swelling. For mobility, patients answered either “yes”, “no”, or “undecided”. Any patient complaints, as well as device related serious injuries, were also tabulated.

Data analysis

All patient data was initially collected from the patient’s medical records. All corresponding demographic data was also collected based on the patient’s medical record. All personal patient information was de-identified and all pertinent information concerning pain, stiffness, swelling, mobility, and complaints were transferred to an Excel sheet for analysis. Patient responses were analyzed by taking the mean percentage of the quarterly responses to obtain a yearly mean percentage for each respective outcome. A yearly trend analysis was also performed.

Results

Mobility

From 2008 to 2016, the percentage of patients who reported improved mobility after brace use remained fairly constant, with an overall mean of roughly 90%. On average, from 2008 to 2016, less than 10% of patients reported no improvement in mobility. The exact yearly trends for improvements in mobility can be seen in *Figure 1*.

Pain

The yearly trends in pain revealed an increase in the percent of patients reporting no pain after brace use from 2008 to 2013. Specifically, in 2013, 70% of patients reported no pain after using their brace, while in 2008, 59% of patients reported no pain after using their brace. The exact yearly trends for pain can be seen in *Figure 2*.

Stiffness

The yearly trends in stiffness indicate a decrease in stiffness

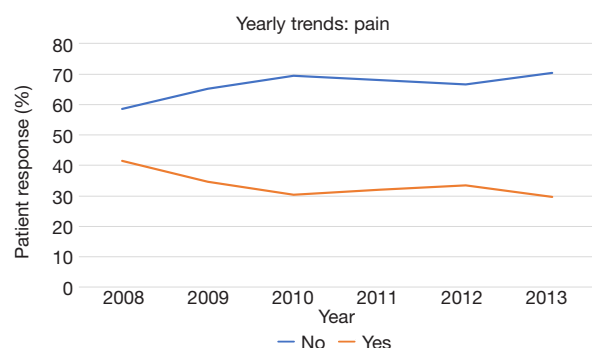


Figure 2 Years trends in pain response.

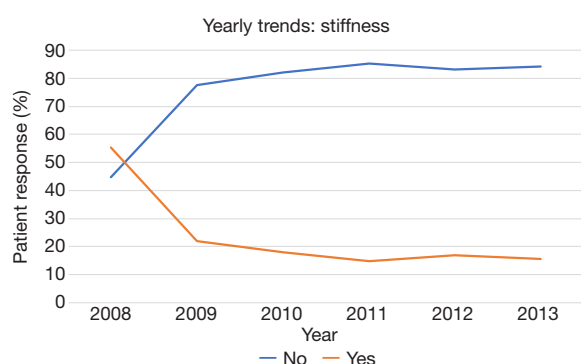


Figure 3 Yearly trends in stiffness response.

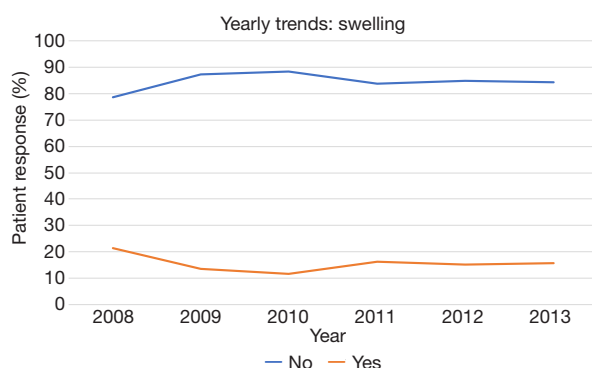


Figure 4 Yearly trends in swelling response.

after brace use from 2008 to 2013. Specifically, in 2013, 84% of patients reported no stiffness after using their brace, while in 2008, 45% of patients reported no stiffness after using their brace. The exact yearly trends for stiffness can be seen in *Figure 3*.

Swelling

Similarly, the yearly trends in patients reporting no joint swelling after brace use increased from 2008 to 2013. Specifically, in 2013, 84% of patients reported no swelling after using their brace, while in 2008, 79% of patients reported no swelling after using their brace. The exact yearly trends for swelling can be seen in *Figure 4*.

Total complaints

Overall, the total number of complaints during the 10-year period were trended downwards from 2007 (n=38) to 2017 (n=3) (*Table 2*). In 2008 a peak of 46 complaints were made, while 2017 had the fewest complaints. From 2007 to 2017, no patients experienced any device related serious injuries. Majority of complaints were non-severe, such as slight discomfort due to device size. The number of complaints for each year can be seen in *Table 2*.

Discussion

Patients suffering from upper and/or lower extremity joint stiffness due to atraumatic or traumatic injury have multiple non-surgical to surgical treatment modalities to choose from. However, physicians and patients alike tend to prefer non-surgical treatment options. This preference has led to a number of different bracing modalities such as SPS, turnbuckle, and dynamic braces. SPS braces in particular have shown to provide better patient outcomes when compared to turnbuckle and dynamic braces (13). This study found that the yearly mean percentage for pain, stiffness, and swelling has steadily decreased in patients treated with an SPS brace. In 2008, 59% of patient reported no pain after treatment, while in 2013, that number increased to 70% of patients who reported no pain. Similar trends were seen in stiffness and swelling; in 2008, 45% of patients reported no stiffness and 79% of patients reported no swelling compared to 84% of patients who reported no stiffness and 84% of patients reported no swelling in 2013. Patients also consistently reported improvements in mobility. Based on these patient-reported clinical and satisfaction data, the braces analyzed in this study are highly effective and patient friendly, and should therefore be recommended to patients suffering from elbow, shoulder, or knee pathology.

In addition to the articulating joints covered in this analysis, several studies have also reported braces to be an

Table 2 Total complaints 2007 to 2017

Year	Total number of devices	Total complaints	Number of medical device reports to the FDA
2007	11,846	38	0
2008	12,294	46	0
2009	14,140	23	0
2010	15,185	20	0
2011	15,880	13	0
2012	15,500	22	0
2013	15,938	19	0
2014	16,674	13	0
2015	16,780	5	0
2016	16,394	10	0
2017	17,120	3	0
Total	167,751	212	0

effective non-surgical treatment modality for wrist, forearm, and ankle pathologies (4,14,15).

There are some limitations to this study. The patient data collected for this study was based on patients specifically treated with brace modalities from a single company. For this reason, the data could not be compared to other bracing companies. Additionally, this study analyzed patient reported satisfaction and outcomes data collected from surveys. However, as is part of any long-term study, some patients were lost to follow-up or simply did not complete the survey. However, given the large patient population and longevity of the patient responses over the years, this study still provides a comprehensive evaluation.

Conclusions

Overall, this study found that patients managed with an SPS brace over the past 10 years have experienced decreased pain, stiffness, and swelling after orthosis treatment. Furthermore, these patients have also experienced a steady increase in mobility over the 10 years with this orthosis treatment. Additionally, over the past 10 years, there have been no reports of serious injury, and a trend towards a reduced number of complaints can also be noted. These results are of particular importance, since no other study reports prospective data on thousands of patients showing that a bracing system substantially reduces pain and stiffness. These data indicate that not only are these braces effective in improving functional ROM with high rate of success

and no significant complications, but this bracing system has a significant effect on improving pain and stiffness. Therefore, based on the results from this prospective study of nearly 170,000 patients, patients suffering from upper or lower extremity joint pathology can expect excellent clinical outcomes using any of the analyzed ROM therapy braces.

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None.

Footnote

Conflicts of Interest: MA Mont—AAOS, Cymedica, DJ Orthopaedics, Johnson & Johnson, *Journal of Arthroplasty*, *Journal of Knee Surgery*, Microport, National Institutes of Health (NIAMS & NICHD), Ongoing Care Solutions, Orthopedics, Orthosensor, Pacira, Peerwell, Performance Dynamics Inc., Sage, Stryker—IP royalties, Surgical Technologies International, Kolon TissueGene. The other authors have no conflicts of interest to declare.

Ethical Statement: Study approval and patient consent was obtained.

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