Review Article

Static progressive stretch orthosis—consensus modality to treat knee stiffness—rationale and literature review

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Abstract: The current literature supports static progressive stretch (SPS) orthoses as the consensus modality to treat joint stiffness as an adjunct to manual therapy. Over 50 published studies prove the efficacy and safety of this modality as an adjunct to therapy to improve range of motion (ROM) as well as decrease stiffness and pain. Data from a large prospective study on SPS effectiveness identified a 90% improvement in ROM, 84% reduction in stiffness and swelling, 70% reduction in pain, and no reports of complications or injury. Another 13 studies evaluating patients with knee stiffness have shown excellent results with SPS, and a reduced need for manipulation under anesthesia or additional surgeries. The bidirectional SPS device allows for ROM therapy in both flexion and extension, uses short, 5-minute incremental stretches for up to a 30-minute session applied 1 to 3 times per day for 8 weeks, though treatment might be needed for longer durations (8 to 12 weeks) in cases with chronic stiffness/contracture, to improve motion and significantly reduces need for manipulation or surgery for treatment of knee fibrosis. Earlier application of SPS therapy, even immediately postoperative following corrective surgery for motion loss, can greatly improve the results for patients who have limitations in knee motion.

Keywords: Bracing; static progressive stretching; physical therapy; knee fibrosis; knee arthroplasty

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Introduction

Following knee procedures, such as total knee arthroplasty, arthroscopy anterior cruciate ligament reconstruction, or traumatic events, a percentage of patients are "at risk" for developing post-operative fibrosis and stiffness (1-3). These patients typically require additional physical therapies, rehabilitation, and use of adjunctive mechanical stretch devices to improve their range of motion (ROM) and functional outcome. The literature has shown that the earlier these patients are identified, and the earlier the adjunctive mechanical stretch devices can be prescribed, the better the outcomes can be (4). However, if these patients are identified late, they risk chronic contracture, prolonged recovery, and potential lack of full functional improvement. Therefore, identifying these patients early and starting them on appropriate adjunctive therapies, such as mechanical stretch bracing, are critical elements for successful outcomes. Additionally, early initiation of adjunctive devices can potentially result in fewer physical therapy visits, and the visits that do occur, might be more effective for the patients. Furthermore, because the adjunctive ROM therapies can be delivered at home on a repeated and daily basis rather than through outpatient therapy visits,

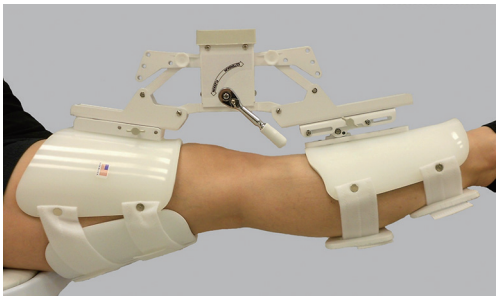

Figure 1 SPS brace with knee in extension. SPS, static progressive stretch.

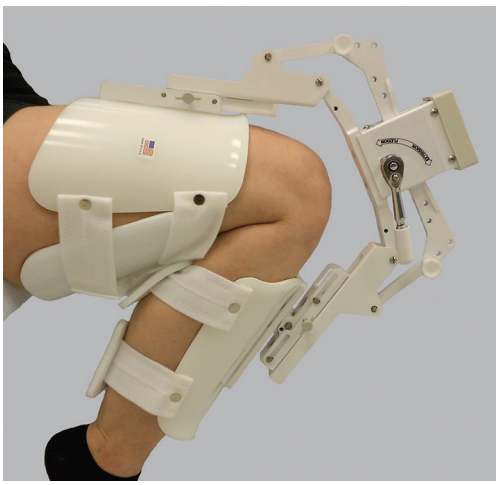

Figure 2 SPS brace with knee in flexion. SPS, static progressive stretch.

patients are more likely to be compliant and therefore have increased odds for improved ROM and recovery (5-7).

One of the first lines of treatment for these patients is to actively work on ROM to restore function. Active ROM is important for long term strength and functional results, and needs to be emphasized as opposed to passive ROM (8). It is well-documented that physical therapy helps restore ROM. Physical therapy and patient active exercise are considered first-line treatment for restoring joint ROM. However, when patients are not responding or plateau with motion improvement in physical therapy, then adjunctive bracing can be a low cost and benign treatment option. Adjunctive bracing can provide the appropriate amount of force over time, i.e., appropriate "clinical dosage" of stretch of the soft tissues to improve ROM. Bracing types for the knee typically include dynamic and static progressive stretch (SPS) devices. Dynamic braces apply a low intensity, constant load over extended periods of time (i.e., 8 to 12 hours) across the joint and usually requires 2 devices, one for each direction. However, given the low load, this bracing option can be very slow and inefficient, requiring months of continued therapy. SPS (*Figures 1,2*) bracing applies an incrementally adjusted static load, which can promote both relaxation and elongation of the joint tissues. SPS braces are applied for up to 30 minutes, 2 to 3 times per day, considerably less time compared to 8- to 12-hour Dynamic brace protocols, and SPS devices are typically bi-directional, requiring only one device for treatment of both directions of motion. These devices have been designed to simulate the work of a therapist, such that for the knee, a force is applied at the proximal femur and distal tibia in the plane of joint motion, but with the patient in control of how much force to apply. SPS braces can provide the appropriate amount of force over time, i.e., appropriate "clinical dosage" of stretch of the soft tissue to improve ROM.

Although these different bracing types exist, there is no generalized consensus on superiority. One bracing modality, SPS, however, has been shown to be potentially more promising and is considered the standard of care for knee fibrosis. In fact, the recent international consensus on the management of knee fibrosis identified static progressive splints as a cornerstone of management (*Figure 3*) (9). However, despite its widespread clinical acceptance, treatment protocols for SPS therapy are subjective, variable, and potentially sub-optimally utilized across the rehabilitation community. Therefore, the purpose of this paper was to review the evidence on SPS therapy in order to determine if there is rationale to support its acceptance as the optimal and standard of care treatment approach for knee fibrosis and joint motion loss. Specifically, we: (I) describe the biomechanics of SPS; (II) detail recent literature on this adjunctive therapy for the knee; and (III) recommend optimal evidence-based treatment protocols for SPS in order to standardize effective treatment for post-operative knee fibrosis in the rehabilitation community.

Methods

A systematic PubMed literature search was performed to identify studies on SPS braces for all joints, including the elbow, knee, and shoulder joints. Boolean operators, along with the following search terms were utilized to query the index: "brace", "static", "progressive", "knee", "joint", "consensus", "protocol", "fibrosis", "biomechanics", and "total end-range time".

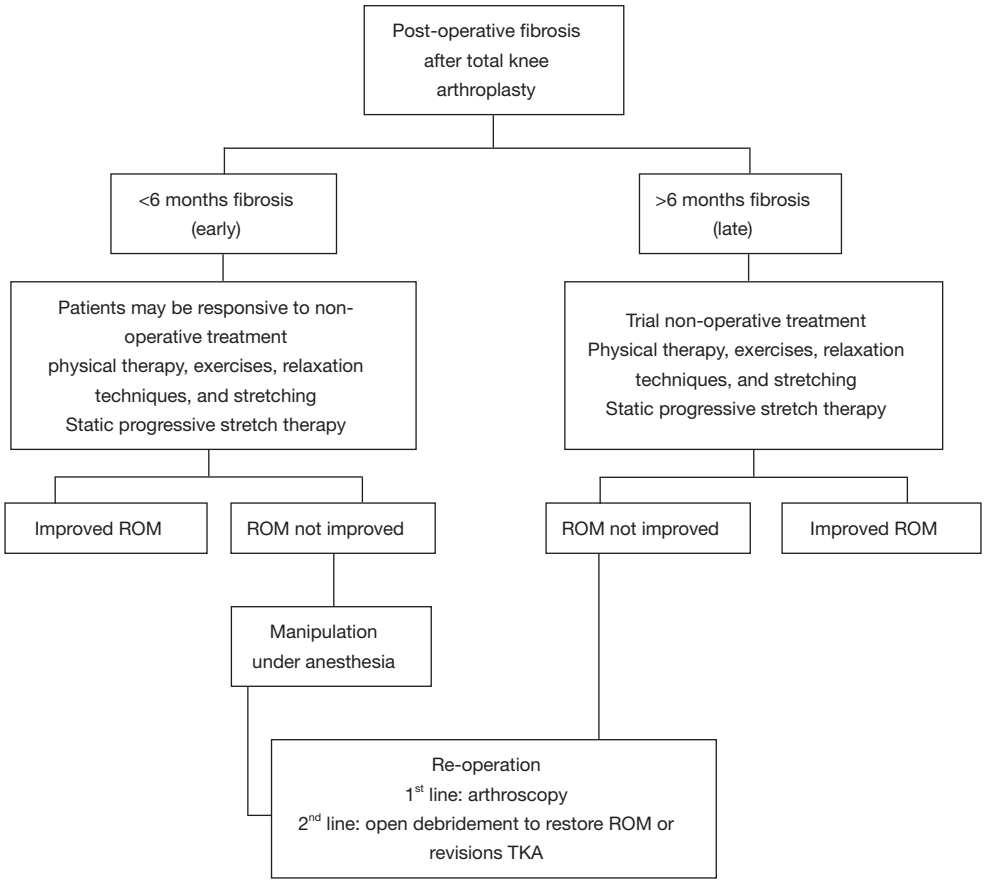

Figure 3 Treatment algorithm for management of post-operative fibrosis following TKA. TKA, total knee arthroplasty; ROM, range of motion.

The initial search resulted in 273 studies (*Figure 4*). Two authors (*, **) conducted the initial search and screened the titles and abstracts of identified articles in order to identify those that were most pertinent to the study aims. After this initial screening process, the full-text of selected articles were evaluated, in addition to references from all included studies. Studies were included if they addressed clinical outcomes, relied primarily on the brace for improvement of patient outcomes and not on surgery or physical therapies, described treatment protocols, and were written in English. Individually-fabricated braces were not included in our analysis, because these can be costly and are customized to a single patient. Therefore, the results from these braces are not as generalizable as compared to universal braces. After exclusionary criteria were considered, 61 studies were included for analysis.

Studies were evaluated to determine if there is rationale to support the acceptance of SPS as the optimal and standard of care treatment approach for knee fibrosis and joint motion loss. Specifically, definitions, descriptions, and, recommended optimal evidence-based treatment protocols for SPS are reported in order to help standardize effective treatment for post-operative knee fibrosis in the rehabilitation community. Additionally, correlative and comparative findings from each study are reported in addition to a summative discussion relating study findings to clinical practice recommendations.

Results

Biomechanics of SPS

The "total end-range time", or TERT, principle states that the increase in passive ROM in stiff joints is directly proportional to the time the joint is held at the end of range (10). Therefore, TERT is determined by multiplying the frequency and duration of time spent at end-range

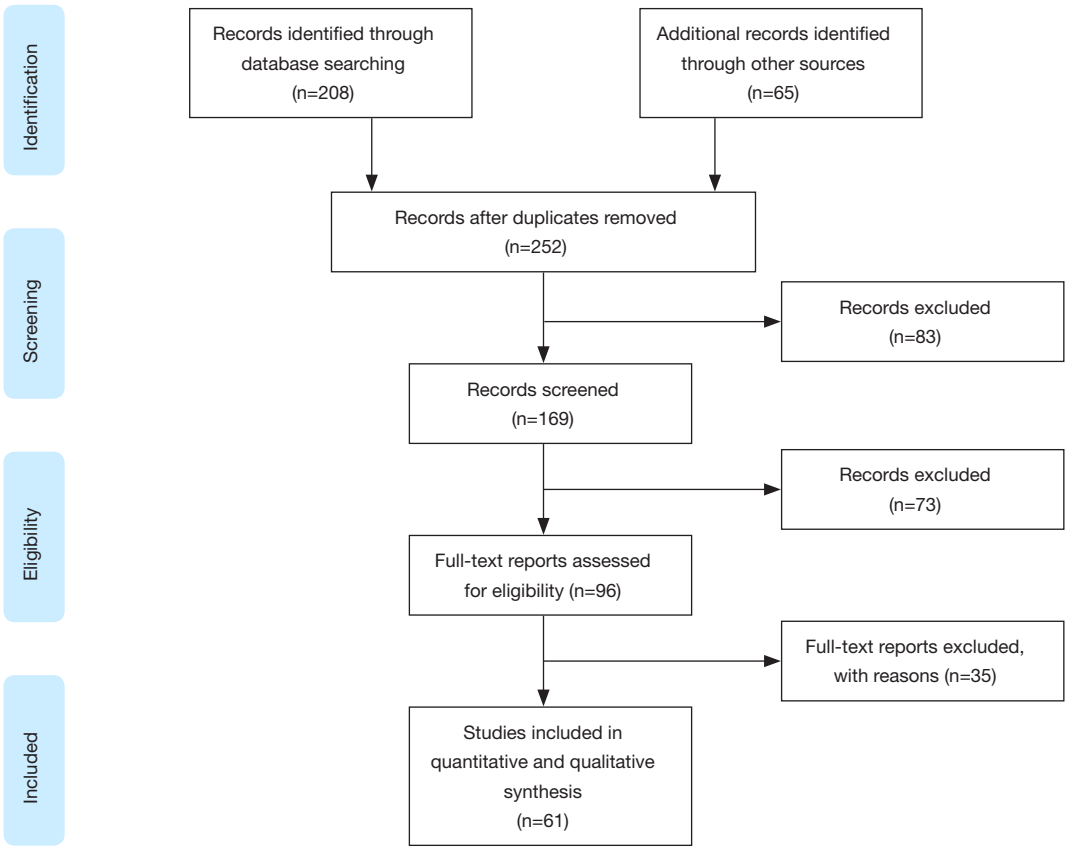

Figure 4 PRISMA diagram for study selection.

daily (11). The TERT dose necessary to increase range-of-motion varies by the condition of each joint. This is comprised of, the duration, frequency, and intensity of the force, which also play critical roles (12).

The duration of force is the amount of time tissues are held in a stretched position. Duration is calculated based on the amount of time applied per day, e.g., 4 sessions of 30 minutes each session is a TERT of 120 minutes. The duration of low stress force must be applied long enough to produce biologic remodeling of joint tissues, which results in tissue elongation. High stress, short duration loading has a greater risk of exceeding pain limits and/or producing tissue tearing and injury.

Frequency has two components: daily and weekly. Intensity is the amount of force applied by the splint or device. Inadequate intensity may result in a temporary or elastic tissue response with little or no gain in range-of-motion. Excessive intensity can result in ischemia or microscopic tears which stimulate inflammation and pain. Because patients experience stretch before they feel pain, intensity is usually limited by the patient's pain tolerance.

SPS technology was pioneered by Joint Active Systems (JAS) (Effingham, Illinois), with principles of open architecture, triangulation, patient directed force, and short treatment protocols (up to 30 minutes) to stretch tissue and increase range-of-motion. SPS devices use inelastic components to apply stress-relaxation (SR) loading to stiff tissues (13). SR is the force load that also forms the basis for manual therapy stretching techniques. Stress relaxation loading utilizes a low-intensity force to position a joint at its end ROM and hold joint tissues at their maximal therapeutic length (14). It is a constant displacement variable force, so that the tissue is stretched to a maximal position, then the force drops over time, resulting in relaxation. This action allows maximum time at the end ROM to optimize tissue lengthening. One device (JAS SPS) avoids direct contact with the knee allows immediate post-operative use as needed. The device is a single plane that triangulated the force, so that it is always applied in the angle of the joint through ROM, as opposed to hinges at

the joint, which force the joint to follow a mechanical hinge that is non-anatomic.

As tissues lengthen in response to the applied stress, the SPS device is adjusted to position the joint tissues at their new maximal therapeutic length, which can increase ROM (15,16). This process of stretching and holding is repeated several times during a treatment session, and sessions are performed daily to improve tissue elasticity and achieve plastic deformation to lengthen soft tissue. Stretching with an orthosis does not cause the tissue to lengthen by growing. The only time tissue can grow by lengthening is when the tissue has been cut and then stressed. Stretching the tissue in its plastic ROM can help restore ROM. Therefore, the dose in therapy or the force over time is critical. SPS braces can apply an adequate force to get tissue through its plastic ROM to optimize stretching.

Recent literature

Our search yielded over 50 publications on SPS use, with 13 references to use in patients with knee pathologies (9,13,17-39) (*Table 1*). The studies consisted of prospectively and retrospectively collected data, reporting on patient outcomes following SPS use (40-63).

McGinn *et al.* compared 47 patients who received a combined innovative multi-modal physical therapy (IMMPT) regimen that included standard of care plus SPS bracing and neuromuscular electrical stimulation to 80 patients who underwent standard of care therapy alone (41). All patients were post primary total knee arthroplasty. The group found the IMMPT and control cohorts achieved a similar desired ROM (≥110 degrees flexion and ≤5 degrees extension). However, the IMMPT cohort had substantially fewer patients require manipulation under anesthesia (2% *vs.* 13%). A similar study compared 57 total patients who underwent manipulation under anesthesia following total knee arthroplasty (42). A total of 22 of these patients underwent multi-modal physical therapy, which included SPS bracing and standard physical therapy, while the remaining 35 underwent standard physical therapy alone. After 6 months, 100% of patients in the multi-modal cohort achieved desired ROM, while only 50% of patients (P=0.005) in the standard physical therapy cohort achieved the same outcome. Furthermore, patients in the multi-modal cohort achieved a statistically significant higher mean flexion ROM as compared to those who were in the standard of care group (116 *vs.* 106; P=0.005).

Another study evaluated 25 patients who underwent TKA and had persistent knee stiffness without improvement after standard therapy were then treated with SPS bracing (43). After a median of 7 weeks (range, 3–16 weeks), the median increase in ROM was 25 degrees (range, 8–82 degrees), the median gain in knee active flexion was 19 degrees (range, 5–80 degrees), and 92% of patients reported that they were satisfied with their results.

Suksathien *et al.* evaluated 11 patients who underwent SPS treatment for knee flexion contractures, and found after 9 weeks, the mean increase in knee extension was 38.6 degrees, and the average arc of motion increased by 44.9 degrees (44). Another study by Bonutti *et al.* evaluated 41 patients treated with SPS therapy and found after 9 weeks of use, total arc of motion increased by a mean of 33 degrees (range, 0–85 degrees) (45). An increase in motion was also seen in 98% of patients, and 93% of patients with satisfied with their outcomes. Importantly, compared to the literature, the positive outcomes occurred at a shorter mean treatment time than for historic controls.

The use of SPS therapy has also been found to be effective for other joints, such as the elbow, shoulder, wrist/forearm and ankle. In one of the largest studies to date, 167,751 who were treated with SPS bracing were evaluated over a 10-year period (17). Outcomes measured were: (I) mobility; (II) pain; (III) stiffness; (IV) swelling; and (V) any adverse events of patients treated with an SPS brace. The group found that patients who utilized the brace consistently reported excellent (roughly 90%) improvements in mobility, with only a small portion (<10%) of patients reporting no improvements. Comparing pain, patients continuously reported decreasing pain, with over 70% of patients reporting no pain at final follow up. Similarly, for stiffness, at final follow up, 84% of patients reported no stiffness. For swelling as well, 84% of patients reported no joint swelling after SPS therapy use. Importantly, during the most recent year, only three patients (0.02%) reported any device complaints. Throughout the 10-year study period, none of the 167,751 patients experienced any device related serious injuries.

Based on the above data, it is clear that SPS therapy has a critical role in the management of knee pathologies. Particularly patients suffering from knee fibrosis have been found to achieve substantial improvements in function and ROM. This treatment type is also simple and easy to use, so

Table 1 Recent Literature on SPS bracing

Study	Population	Factors evaluated	Outcomes	Conclusions
Sodhi *et al.* (17)	167,751 patients who received SPS therapy	Mobility	90% improved mobility	Patients suffering from shoulder, elbow, forearm, wrist, knee and/or ankle pathology can expect excellent clinical outcomes with SPS braces
		Pain	70% no pain	
		Stiffness	79% no stiffness	
		Swelling	84% no swelling	
		Any complaints	0.02% complaints	
		Adverse events	No adverse events	
Foran *et al.* (40)	10 patients who underwent multimodal physical therapy (SPS bracing, daily home exercise program, and physical therapy for 4 weeks) following TKA *vs.* 31 who underwent MUA following TKA	Patient satisfaction with program	Median satisfaction: very satisfied (6/7 points)	Multimodal physical therapy can have similar outcomes as manipulation under anesthesia
		ROM outcomes	Similar ROM outcomes (110°±14° *vs.* 109°±11°)	
		Need for MUA in MPT patients	3/10 MPT patients required MUA (2 had previous contralateral MUA)	
Kalson *et al.* (9)	Consensus to develop a definition of post-operative fibrosis of the knee	–	–	Panel identified SPS splinting as an effective and recommended non-operative treatment measure for knee fibrosis, prior to surgical intervention
McGinn *et al.* (41)	47 patients who underwent multi-modal physical therapy *vs.* 80 patients who underwent standard therapy	Range of motion (≥110° flexion and ≤5° extension)	Achieve ROM: 81% *vs.* 82%	Multi-modal PT was able to help similar achieve optimal range, but substantially fewer MUAs compared to standard therapy
		MUA rates	MUA rates: 2% *vs.* 13%	
Chughtai *et al.* (42)	57 total patients with prior MUA	6-month ROM improvements	Substantially improved ROM (100% *vs.* 50%)	Multi-modal PT can help patients improved ROM and reduce the need for MUAs
	22 patients with multi-modal PT	Rate of repeat MUA	Substantially fewer MUAs in multi-modal PT cohort (0 *vs.* 20%)	
	35 patients with standard PT			
Bonutti *et al.* (43)	25 patients with knee stiffness following TKA prescribed SPS bracing	Duration of device use	Median duration of device use: 7 weeks	SPS therapy can help increase ROM for patients who developed arthrofibrosis following TKA
		ROM increase	ROM increase: 25°	
		Flexion increase	Increase knee flexion: 19°	
		Extension increase	Increase knee extension: 7°	
		Patient satisfaction	92% patient satisfaction	
Suksathien *et al.* (44)	11 patients with fixed flexion contractures of the knee	Duration of splint use	Mean duration: 9.2 weeks	SPS can be an effective, and low-cost method for managing knee contractures
		Increase in extension	Mean extension increase: 38.6°	
		Increase arc of motion	Mean arc of motion increase: 44.9°	

Table 1 (*continued*)

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Study	Population	Factors evaluated	Outcomes	Conclusions
Bonutti *et al.* (45)	41 patients with knee stiffness not improved with standard PT who were then prescribed SPS bracing	Duration of use	Duration: 9 weeks of use (range, 3 to 27 weeks)	SPS therapy can be a successful treatment option for patients with refractory knee stiffness after standard PT
		Increase in arc of motion	Mean arc of motion increase: 33° (range, 0° to 85°)	
		Increase ROM	Increased ROM: 98%	
		Patient satisfaction	Patient satisfaction: 93%	
Seyler *et al.* (46)	Diagnosis of dysfunction following TKA and success with various rehabilitation and treatment modalities, botulinum toxin injections, use of a custom knee device, a JAS SPS device, and peroneal nerve release	–	–	These techniques can improve ROM and enhance clinical outcomes, even when standard rehabilitation protocols were ineffective
Jansen *et al.* (47)	Case report on patient who developed stiffness despite following a 7-week course of physical therapy. Patient then prescribed SPS therapy, 3 months following standard PT	Increase active extension	Increase active extension: 17 degrees after 29 days of SPS therapy	Standard PT provided minimal benefits
		Time to increase		Despite being initiated 3 months after standard PT, SPS therapy was able to substantially improve active extension in 29 days
McElroy *et al.* (48)	Review article on devices used to prevent and treat decreased range of motion	–	–	The authors recommended the use of bracing therapies to manage pain and dysfunction following TKA
Millett *et al.* (49)	Review article on devices for the prevention and treatment of decreased range of motion of the knee after total knee arthroplasty	–	–	The authors concluded that static progressive stretch and dynamic splint devices are effective therapies for range of motion deficits
Sodhi *et al.* (18)	Comprehensive literature review on static progressive stretch, dynamic, and turnbuckle braces for the management of elbow, knee, and shoulder pathology	–	–	SPS bracing has shown potential for patients to achieve optimal outcomes. There currently is a paucity of data on dynamic and turnbuckle braces
Sodhi *et al.* (19)	Review article on brace modalities for elbow stiffness	–	–	SPS required wear time 13× less than that for the turnbuckle and 5 times less than that for the dynamic devices
				63% of SPS patients achieved functional ROM
Veltman *et al.* (20)	Systematic review on SPS *vs.* dynamic splinting for posttraumatic elbow stiffness: 8 studies; 232 patients: 160 SPS patients; 72 dynamic patients	Increase arc ROM	SPS arc ROM improved by 36°, to mean of 108°	SPS and dynamic splinting can have good results elbow stiffness treatment
			Dynamic arc ROM improved by 37° to mean of 100°	

Table 1 (*continued*)

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Study	Population	Factors evaluated	Outcomes	Conclusions
Muller *et al.* (21)	Systematic review and meta-analysis: 247 patients	Changes in ROM	Mean ROM improvement: 38.4°	Static progressive and dynamic bracing are effective and safe
Lindenhovius *et al.* (22)	66 patients with posttraumatic elbow stiffness: 35 SPS patients; 31 dynamic bracing	Improvement arc of flexion	Dynamic *vs.* SPS improvement arc of flexion: 47° *vs.* 49°	SPS and dynamic bracing can help improve posttraumatic elbow stiffness over 6 to 12 months
		Disabilities of the Arm, Shoulder and Hand scores	DASH score: 28 *vs.* 26 points	
Schwartz (23)	Literature review	Level of evidence of literature	16 out of 65 studies were LOE 4 or better	Although data is limited, incorporating SPS therapies can have positive patient outcomes
Bhat *et al.* (24)	28 patients who received SPS bracing for elbow stiffness following surgery or trauma	Duration of use	Mean duration: 5 months (range, 3 to 8 months)	SPS can help patients suffering from elbow stiffness
		Reduction in flexion contracture	Mean flexion contracture reduction: 32 degrees	
		Functional ROM	Increase functional ROM: 45 degrees	
Ulrich *et al.* (25)	37 elbows	Improvements in ROM	Mean improvement ROM: 26 degrees (range, 2 to 60 degrees)	SPS can provide consistent ROM improvements over a short period of time
		Analgesic use	Improvements occurred in 35/37 patients	
	Protocol: 30-minute stretching protocol, 1 to 3× daily	Patient satisfaction	Lower analgesic use	
	Mean of 10 weeks (range, 2–22 weeks)		Patients highly satisfied (8.5/10 points)	
Ibrahim *et al.* (50)	60 patients with adhesive capsulitis of the shoulder	Shoulder ROM	SPS brace patients had significant improvements for all outcomes	Adding SPS therapy to standard of care PT can substantially provide positive outcomes for patients with adhesive capsulitis of the shoulder
		Disabilities of the Arm, Shoulder and Hand score		
	Randomly assigned standard PT *vs.* standard PT with SPS bracing	Visual Analogue Scale pain score		

ROM, range of motion; SPS, static progressive stretch; TKA, total knee arthroplasty; MUA, manipulation under anesthesia; JAS, Joint Active Systems; PT, physical therapy; MPT, multimodal physical therapy; LOE, level of evidence.

can be utilized widely for all types of patients.

Recommended protocol

Given the proven and optimal biomechanics behind the design of the SPS brace and the clinical evidence suggesting efficacy, there is a clear need for a standardized protocol for this therapy. Some studies report protocols for patients to participate in daily treatment sessions for the first 5 days of treatment (43). These treatment sessions then increase to a maximum of 3 treatment sessions per day. Patients then continued this protocol for up to 7 weeks (range, 3–16 weeks). Another study followed a similar protocol, except patients continued therapy until no further improvements were seen for at least 1 week. In this study, patients underwent treatment for a mean of 9 weeks (range,

3–27 weeks) (45).

Based on the reported literature, patients should utilize SPS therapy for 5-minute incremental stretches for up to a 30-minute session applied up to 3 times per day. The force applied is best determined by the patient as each joint or stiffness varies and patient has full control to adjust the force to tolerance. The goal is to avoid pain, while achieving the maximum stretch tolerable. The therapy should be continued for as long as the patient experiences improvements, which is likely around 8 weeks, though in cases of chronic stiffness/contracture, might be longer (8 to 12 weeks).

Critical to success is early identification and initiation of brace use, prior to the onset of fibrotic tissue buildup. Importantly, as is recommended by the recent consensus on the definition and classification of fibrosis, it is critical to identify these patients early, and begin intervention promptly. Managing patients with SPS bracing within the first 12 weeks (i.e., those with stiffness), when connective tissues are most responsive to remodeling, instead of those with chronic contractures (>6 months) can yield more optimal results. The longer a patient waits, the more connective tissue remolding and fibrotic development, the less progress can potentially be made. In any case, SPS braces should be utilized in cases of acute or chronic fibrosis prior to any surgical procedures.

Conclusions

Improving ROM is critical to optimize function in patients following knee surgery, injury, arthroplasty, or any other traumatic events. SPS therapies have clearly shown to have meaning benefits in the number of clinical trials that report on their effects on patient outcomes. The recent consensus on knee fibrosis also recommends that patients with acute or chronic knee fibrosis utilize SPS therapy as a standard of care prior to any surgical intervention. However, to date, there a standardized protocol of use for SPS knee braces has not been reported. We recommend sessions lasting 5 to 30 minutes, up to 3 times per day. Additionally, it is important to realize that the earlier the device is utilized, the better results patients can expect. Providers should note if patients are not making appropriate gains in ROM through other therapeutic measures, SPS can be used earlier for potentially better and faster results. Although these braces can be effective at any time point, identifying patient need within the first 12 weeks (i.e., those with stiffness) instead of those with chronic contractures (>6 months) can yield enhanced outcomes. Adjunctive utilization of SPS therapy can help patients achieve optimal ROM and function, and should be part of routine care when managing patients with knee fibrosis.

Acknowledgments

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: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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