



■ KNEE

The STAK tool: evaluation of a new device to treat arthrofibrosis and poor range of movement following total knee arthroplasty and major knee surgery

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Aims

This study aims to evaluate a new home medical stretching device called the Self Treatment Assisted Knee (STAK) tool to treat knee arthrofibrosis.

Methods

35 patients post-major knee surgery with arthrofibrosis and mean range of movement (ROM) of 68° were recruited. Both the STAK intervention and control group received standard physiotherapy for eight weeks, with the intervention group additionally using the STAK at home. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Oxford Knee Scores (OKS) were collected at all timepoints. An acceptability and home exercise questionnaire capturing adherence was recorded after each of the interventions.

Results

Compared to the control group, the STAK intervention group made significant gains in mean ROM (30° versus 8°, $p < 0.0005$), WOMAC (19 points versus 3, $p < 0.0005$), and OKS (8 points versus 3, $p < 0.0005$). The improvements in the STAK group were maintained at long-term follow-up. No patients suffered any complications relating to the STAK, and 96% of patients found the STAK tool 'perfectly acceptable'.

Conclusion

The STAK tool is effective in increasing ROM and reducing pain and stiffness. Patients find it acceptable and adherence to treatment was high. This study indicates that the STAK tool would be of benefit in clinical practice and may offer a new, cost-effective treatment for arthrofibrosis.

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Introduction

Arthrofibrosis leading to poor outcome after total knee arthroplasty (TKA) is a growing problem worldwide.¹ Overall, 112,836 knee arthroplasty procedures are performed each year in the UK² and 700,000 in the USA³ at a total annual cost of around \$10.2 billion in the USA.⁴ Due to obesity and longevity, this is expected to increase six-fold to 672,000⁵ and 4,200,000 respectively by 2030;⁶ alongside this, the demand for better outcomes will continue to rise.

Stiffness following TKA is common, occurring in between 5% and 30% of patients.⁷ It accounts for 28% of hospital readmissions

due to surgical complications within 90 days of discharge and 10% of all revisions within five years of initial surgery.^{8,9} Stiffness is the primary cause of dissatisfaction with approximately 20% of patients being severely dissatisfied following TKA.¹⁰ This rate of dissatisfaction is consistently reported across countries.¹¹ Poor medium- to long-term patient outcomes following TKA are consistent between studies with only 50% of patients having a clinically important improvement in pain stiffness and function on the validated patient self-reported outcome measure (Western Ontario and

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McMaster Universities Osteoarthritis Index score; WOMAC) a year after surgery.¹²

The process of arthrofibrosis involves abnormal scarring of the joint caused by an exaggerated inflammatory response. It leads to loss of range of movement (ROM), oedema, pain, muscle weakness, and functional disability. Arthrofibrosis limits patients' ability to perform basic activities of daily living and contributes to chronic diffuse knee pain severely impairing a patient's quality of life.¹³ Biomechanical studies show patients require 67° ROM for walking on the flat, 90° to 100° to manage stairs, 95° to stand from a chair, 105° to tie shoelaces, up to 120° to ride a bike, 135° to get out of a bathtub, and kneeling, squatting, and sitting cross-legged require over 150° ROM.^{14,15} Research shows < 90° ROM leads to significant patient dissatisfaction and ongoing pain from the cause of stiffness.¹⁶

Conventional treatment is aggressive physiotherapy, progressing to manipulation under anaesthetic (MUA) or arthroscopic debridement if 90° flexion is not attained within six to 12 weeks post-surgery.¹⁷ MUA after primary TKA has been reported in up to 12% of patients and is a costly complication with some degree of risk attached to the procedure.¹⁶ MUA can lead to impressive increases in ROM¹⁸; however, initial gains may not be maintained¹⁹ and further surgery to restore ROM may be required with only 37% of these reporting satisfactory results.²⁰ Patients undergoing MUA also have twice the rate of revision surgery measured at seven to ten years post-primary TKA.²¹

Standard physiotherapy includes joint mobilizations and passive stretches where force is applied to the joint at its end of range by the physiotherapist to improve ROM.^{22,23} Although high-grade mobilizations may result in immediate improvements in ROM, these gains have been reported to be only temporary.²⁴

Regular high-intensity or prolonged stretching is required to achieve plastic deformation facilitating collagen fibres to be remodelled lineally in response to the lines of stress, resulting in permanent elongation of the tissue.²⁵

As part of standard physiotherapy, exercise sheets involving active assisted movement (self-applied over pressure using the patients contralateral unaffected limb) plus knee strengthening, stretching and functional exercise are also prescribed for patients to complete at home.^{22,26} However, home exercises have been found to produce less than 10% of the torque applied by a physiotherapist.²⁷

Home mechanical stretching devices can improve ROM and clinical outcomes by enabling patients to treat themselves daily.²⁸ There are two distinct kinds of stretching devices; high intensity stretch (HIS), displacement-control devices where tissues are placed under a large amount of stress near the end range of the joints movement.²⁹ Low-intensity stretching (LIS) devices use the technique

known as creep-loading or load-control. This involves a low load, constant, prolonged force over an extended period, such as between eight and 12 hours. Displacement control devices require much shorter treatment times and provide greater levels of patient acceptability and compliance to treatment.

Studies using displacement control devices have achieved significant ROM increases.³⁰⁻³³ The former two studies achieving the greatest gains in ROM used a patient-actuated serial stretch HIS (PASS) device which was found to apply the greatest force,^{27,34} require the shortest treatment time of 60 minutes a day and led to a reduced rate of additional surgery.²⁰ Although current devices on the market are a good start for a home solution, current devices on the market either require custom fitting, are cumbersome for home use and come with a significant price tag.

The purpose of this research is to assess the impact of eight weeks treatment at home using the Self Treatment Assisted Knee (STAK) tool, a PASS HIS medical stretching device, on patients' ROM, pain, stiffness and function (WOMAC and Oxford Knee Score (OKS) at eight weeks and at long-term follow-up. It also seeks information on the acceptability of the device to patients. This study will test the hypothesis that changes in ROM, WOMAC, and OKS will significantly differ from baseline to follow-up after using the STAK tool plus standard physiotherapy for eight weeks compared to the control group receiving standard physiotherapy alone for eight weeks and that the improvements in the STAK Intervention group will be maintained at long-term follow-up.

Methods

All study participants provided written informed consent. The study methodology utilized a block allocation strategy. 35 participants (15 males, 64 years ± 11 years, 177 cm ± 6 cm, 95 kg ± 14 kg; and 20 females, 64 years ± 7 years, 161 cm ± 6 cm, 80 kg ± 17 kg) with < 80° ROM or that had been prescribed intensive physiotherapy for stiffness by their surgeon were recruited consecutively into two groups. Sample size estimation was done in G*Power software (Heinrich-Heine-Universität Düsseldorf, Germany). Based on a previous study's³² power calculation to attain 80% power at a level of significance to 0.05 in a two tailed test with mean changes in ROM of 17° and 29.9° and pooled standard deviation (SD) 10° an effect size of 1.2 was produced and a suggested sample size of 24. To be cautious we reduced the anticipated effect size in our study to 0.99 calculating the estimated required sample size to be 34. 20 participants were allocated into the STAK device intervention group and a subsequent 15 allocated to the control group (see Figure 1). The groups were not quite fully balanced in their numbers as two dropouts in the intervention group were back filled (as per protocol), the overall target

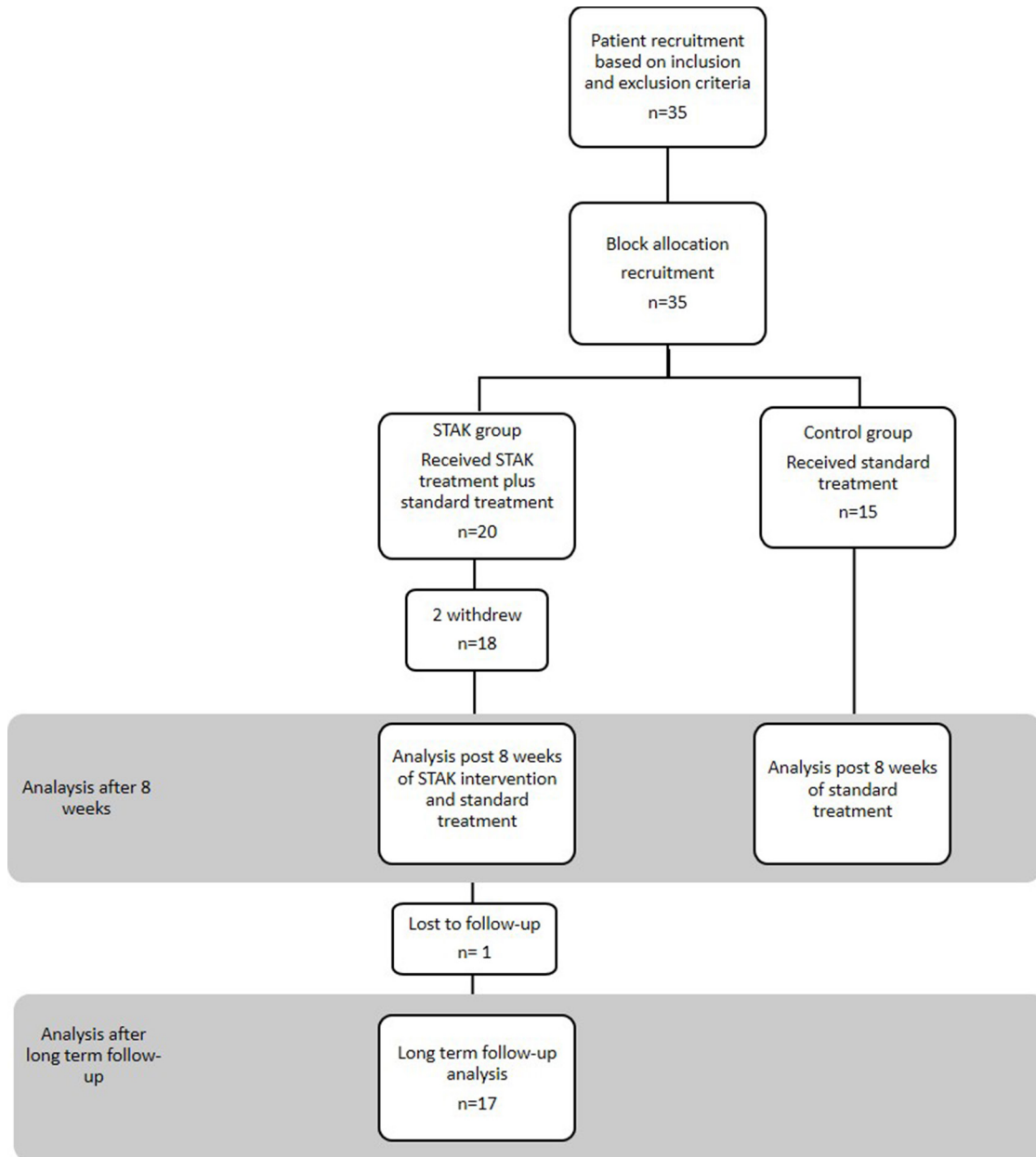


Fig. 1

Flowchart demonstrating patient recruitment, allocation and follow-up.

sample of 34 was attained on recruitment of the 14th participant into the control group.

The intervention group included 16 primary TKA, one unicompartmental knee, one patella fracture; the control group comprised 12 primary TKA, one revision TKA, one knee dislocation, and one patella fracture. All patients were recruited from a caseload of 15 knee surgeons' at UHL NHS trust. Patients were excluded if they had leaking wounds or infected joints, preoperative flexion < 90°, were post malignancy or the surgeon felt the patient was at risk of postoperative fracture, if they fell outside a weight of 44 kg and 159 kg or were unable to give consent themselves.

Interventions. In addition to standard physiotherapy, patients in the intervention group also used the STAK tool daily at home for eight weeks. STAK is a non-motorized medical stretching device similar to a patient actuated serial stretch (PASS) that incorporates the principles of stress relaxation, with a series of high-intensity stretches at end range applied for a short duration. The patient has full control over the intensity and duration of the stretch. While seated in a chair, the patient places their foot into the STAK tool which is set to the limit of their current knee flexion ability. The patient then applies force using their body weight and leverage to stretch their knee to the limit of their pain threshold at their end range of movement



Fig. 2

Photograph of the STAK showing the scale and adjustable footplate.

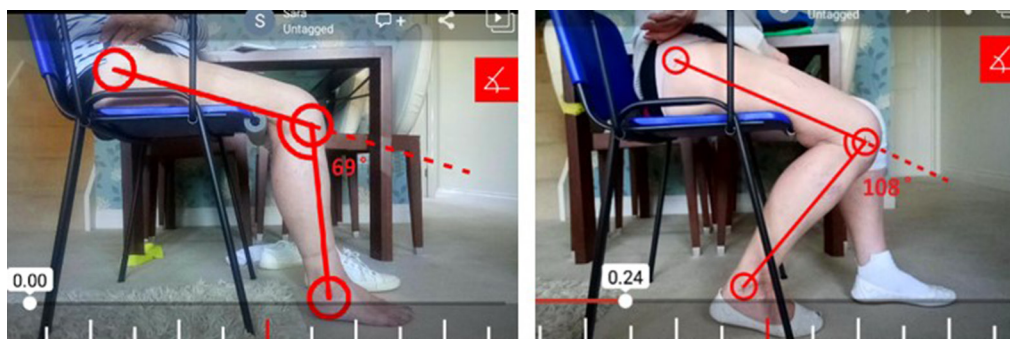


Fig. 3

Patient ROM measured by Hudl Ubersense smartphone app.

holding the stretch for as long as they feel able (approximately five minutes). The intense long stretch allows the collagen fibres to achieve plastic deformation, realign and lengthen. Participants were required to stretch for a total of 60 minutes each day.

This stretching protocol is similar to those used effectively by Noyes and Barber-Westin (2010)³⁵ and Davies and Ellenbecker (1999).²³ The STAK tool has a motivational scale which provides feedback for patients on their progress in gaining ROM (see Figure 2). Following the intervention periods, both the groups were asked to complete a home exercise questionnaire. This captured adherence to treatment, duration/intensity of stretch (dose). Patients were telephoned once a week to check there were no problems using the device. Patients in both the intervention and control group received standard physiotherapy treatment for the eight week treatment period. Standard physiotherapy treatment included stretching, range of movement and strengthening exercises, gait training and education, a home exercise programme and if required hydrotherapy and land-based classes. The physiotherapist altered the treatment of arthrofibrosis depending on

individual patient's needs. The mean frequency of treatment was one treatment every two weeks.

Outcomes. Both groups had knee ROM, WOMAC, and OKS recorded before and after the eight-week treatment period and the STAK group was re-measured at long-term follow-up (minimum seven months). The OKS and WOMAC are well validated patient reported outcome measures demonstrating strong validity, reliability and sensitivity to change in TKA populations and patients undergoing lower limb rehabilitation.^{36,37} A high WOMAC score indicates extreme pain/dysfunction, conversely a low OKS score indicates extreme pain/difficulty. A home exercise questionnaire was completed by patients at the end of the eight-week intervention period to capture their compliance to the treatments and an acceptability questionnaire was administered to quantify their views on the STAK tool's acceptability.

The primary outcome measure was active ROM which was measured using a 12" universal goniometer in a standardized procedure with the participant seated in a chair. A photographic record and measure were also taken using the Hudl Ubersense smartphone

Table I. Comparison of patient age, BMI, and length of time from surgery to entering the study (mean ± SD) between knee stretching device and control group.

Variables	STAK group, mean ± SD (range)	Control group, mean ± SD (range)	p-value
Age (years)	62 ± 8 (49 to 79)	67 ± 8 (54 to 81)	0.067*
BMI (kg/m ²)	31 ± 7 (23 to 53)	30 ± 5 (23 to 39)	0.331*
Sex (female:male)	11:9	9:6	0.771†
Time from surgery to entering study (weeks)	26 ± 20 (8 to 67)	20 ± 22 (6 to 87)	0.358*
Baseline			
ROM (°)	66 ± 9	71 ± 11	0.132*
OKS	20 ± 9 (6 to 40)	20 ± 7 (9 to 30)	0.985*
WOMAC	54 ± 14 (26 to 70)	51 ± 13 (29 to 73)	0.488*

STAK, Self Treatment Assisted Knee; SD, standard deviation; BMI, body mass index; ROM, range of movement; OKS, Oxford Knee Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

*Independent samples *t*-test.

†Chi-squared.

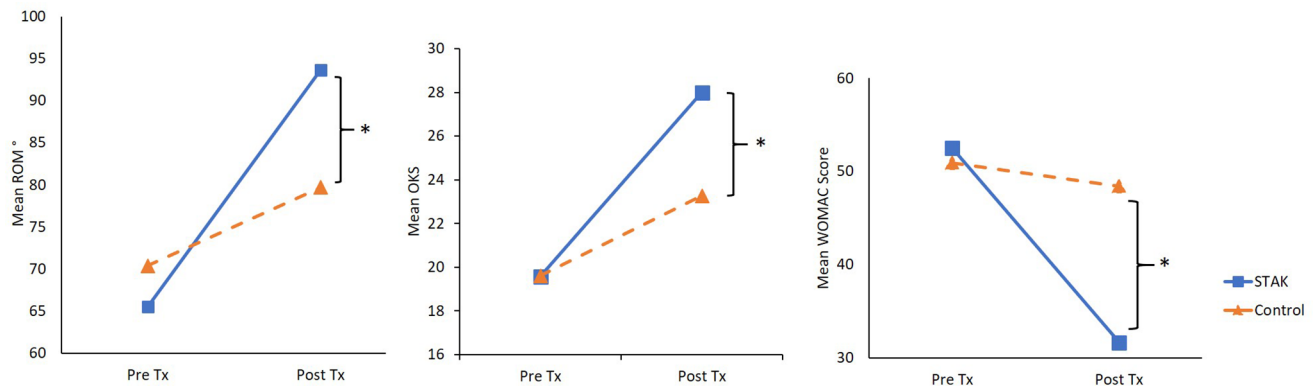


Fig. 4

Mean ROM, OKS, and WOMAC before and after eight-week treatment period (Tx) - STAK versus standard treatment. A high WOMAC score indicates extreme pain/dysfunction, a low OKS score indicates extreme pain/difficulty *The STAK group demonstrated a significantly larger mean improvement in ROM, WOMAC, and OKS (p < 0.0005).

Table II. Range of movement, OKS, and WOMAC before and after treatment with STAK compared to standard treatment control group.

Variable	STAK group			Control group		
	Preoperative, mean ± SD	Postoperative, mean ± SD	Change, mean ± SD	Preoperative, mean ± SD	Postoperative, mean ± SD	Change, mean ± SD
ROM° Goniometer	65° ± 9° (44 to 75)	95° ± 9° (78 to 110)	30** (12 to 50) p < 0.0005	71° ± 11° (49 to 93)	79° ± 14° (42 to 93)	8* (-7 to 36) p = 0.004
ROM° app	65° ± 9° (44 to 75)	96° ± 9° (81 to 111)	31** (12 to 50) p < 0.0005	71° ± 11° (49 to 93)	79° ± 14° (43 to 96)	8** (-7 to 37) p = 0.004
WOMAC	52 ± 16° (26 to 70)	33 ± 18 (29 to 68)	19* (4 to 49) p < 0.0005	51 ± 13 (29 to 73)	48 ± 15 (21 to 72)	3* (-23 to 19) p = 0.390
OKS	20 ± 9° (6 to 40)	28 ± 10 (6 to 44)	8* (0 to 20) p < 0.01	20 ± 7 (9 to 30)	23 ± 9 (11 to 37)	3* (-6 to 17) p = 0.051

*p < 0.0005; STAK group mean change significantly greater than control group change.

STAK, Self Treatment Assisted Knee; SD, standard deviation; ROM, range of movement; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; OKS, Oxford Knee Score.

app (Agile Sports Technologies, Lincoln, Nebraska, USA) (see Figure 3). A recent study has found the app to have high levels of concurrent validity and intra-rater reliability demonstrating a mean 0.80° difference in a study comparing 40 knee measurements to the gold standard measuring instrument the electrogoniometer.³⁸ Naylor et al's (2011)³⁹ evidence based standardized method for

identifying bony landmarks was employed, including marking the distal flare of the lateral malleolus, the centre of rotation of the knee and the proximal flare of the greater trochanter. The assessor visually checked the knee joint was in the sagittal plane ensuring a 2D image was photographed. The same physiotherapist (SKA) recorded all ROM measurements for each patient, angles



Fig. 5

Patient who achieved increase of 50° ROM using the STAK after failed manipulation under anaesthetic.

were randomly double checked by a blinded third-party clinician.

After the eight weeks treatment period, patients in the intervention group were asked to rate the acceptability of the STAK. This involved marking responses to three questions (one on a seven-point and two on five-point Likert scales), where one denotes a negative response (completely unacceptable) and seven denotes a positive response (perfectly acceptable).

Statistical analysis. Variables with the potential to effect results were limited as both groups comprised similar participants in terms of age, sex, body mass index, pre-treatment ROM, OKS, and WOMAC scores. The STAK intervention group and standard physiotherapy control groups' ROM, OKS and WOMAC score data were normally distributed. The pre- to post-treatment and post

STAK treatment to long-term follow-up ROM, OKS, and WOMAC were analyzed using a paired *t*-test. The difference in the change in the intervention and control group was analyzed using an independent *t*-test. Pearson's product-moment correlation coefficients were calculated to determine the relationship between knee ROM and the OKS and WOMAC scores. Variables were also assessed by age, sex and length of time from onset of stiffness to treatment to determine whether any of these factors were associated with change in range of movement. All statistical analyses were performed with the SPSS 25.0 (IBM, Armonk, New York, USA). Patient scores of acceptability and likelihood of recommendation are described using appropriate summary statistics. The home exercise questionnaires provide information regarding adherence including frequency and intensity of STAK and home stretching exercises completed.

Results

Participant demographics, baseline measures of ROM, OKS, WOMAC score and time from surgery to entering the study were compared at baseline and no statistically significant differences between the groups were identified (see Table I). All TKAs had been performed to manage osteoarthritis. Patients were recruited at a mean of 26 weeks post-surgery in the intervention and following a mean of 20 weeks in the control group. In all, 20 patients received the STAK intervention at home in addition to standard physiotherapy and 15 patients received the control intervention receiving physiotherapy alone.

There were two withdrawals from the STAK intervention group during the eight-week treatment period due to family commitments and illness (unrelated to the intervention). One patient was not contactable at long-term follow-up (see Figure 1).

The STAK intervention group made significant gains in ROM (mean 30°) compared to control group (8°) ($p < 0.0005$). The STAK made significant improvements in WOMAC (19 points) versus controls (3 points) ($p < 0.0005$) (see Figure 4). This was also supported by significant improvements in OKS (8 points) versus controls (3 points) ($p < 0.0005$). (See Table II for details including SD, range, *p*-values).

Reliability of the results is strengthened by very strong positive correlation between the measurements taken with the Hudl App and universal goniometer with a correlation co-efficient of $r = 0.991$; $p = 0.0005$. (Correlation is significant at $p < 0.01$ level). Two patients in the STAK intervention group had previously failed to improve ROM after both extensive physiotherapy and MUA with ROM of only 44° and 73°, but following use of the STAK for eight weeks they achieved 94° and 103° with changes of 50° and 29° respectively (see Figure 5).

Discussion

Long-term follow-up. Patients in the STAK intervention group maintained their ROM, WOMAC, and OKS at long-term follow-up (mean 10.5 months, (7 to 15); mean 16 months post-surgery (10 to 24)). ROM fell by mean 2° to 93° ($p = 0.644$), WOMAC improved by mean 2 points to 31 points ($p = 0.410$). OKS also improved by 2 points to a mean score of 30 ($p = 0.291$). One patient who achieved 94° following the STAK treatment may have later regressed her ROM as her surgeon felt MUA was still necessary. At long-term follow-up (ten months post starting the STAK treatment (one-year post-TKA) she had 98°.

Adherence and dose. Analysis of home exercise questionnaires showed participants from both groups adhered to their intervention, although adherence was higher in the STAK intervention group with patients using the STAK for an average three times a day at a 'very intense' level of stretch for average 13 minutes per session for seven days a week. While the control completed the home exercises on average twice a day at a 'moderate intensity' level of stretch for 14 minutes per session for 4.8 days a week. This adds up to a much lower total end range time (TERT) dose in the control standard physiotherapy group.

Acceptability. Acceptability of the STAK tool intervention was high with a mean score of 6.8 out of a possible 7 and 96% acceptability for the question, 'how acceptable did you find the STAK tool?', 98% of patients were 'extremely likely' to 'recommend the STAK to a friend', and 93% of patients felt the STAK was wholly responsible for their change in knee ROM. No adverse events relating to either of the interventions were reported.

Discussion

The purpose of this initial trial was to compare the effectiveness of home use of the STAK (PASS HIS device) and standard physiotherapy compared to standard physiotherapy treatment alone in a sample of patients with severe arthrofibrosis, and to assess the long-term outcomes following the STAK intervention. The hypothesis was accepted as the HIS STAK intervention achieved significantly greater improvements in ROM ($p < 0.0005$) and patient reported outcome measures (WOMAC ($p < 0.0005$), OKS ($p < 0.0005$) and maintained these at long-term follow-up (mean 10.5 months from starting the STAK intervention).

The ROM scores correlate closely with the WOMAC ($r = -4.17$; $p = 0.008$) and OKS ($r = -3.333$; $p = 0.016$) and it is likely that the mean increase in ROM of 30° in the intervention group resulted in reduced pain and stiffness and improved function measured in WOMAC and OKS scores (mean improvement 19 and 8 points respectively). Poor flexion ROM is the primary reason for poor satisfaction following TKA²⁶ and symptoms of stiffness are associated with lower function.⁴⁰ In clinical practice if 90° ROM is not attained an MUA is often performed.⁴¹

66% of patients in the STAK intervention group achieved ROM over 90° (mean increase 30°). Patients in our study had very poor ROM (mean 65°) with 69% of the sample starting with 70° ROM or less. Seven patients had undergone MUA without significant improvement with ROM below 78°. Further MUA or revision knee arthroplasty surgery may have been required, however the two patients who used the STAK increased their ROM by 50° and 29° in eight weeks. This eliminated the need for a further MUA and the associated risks and complications (fracture wound dehiscence, patella ligament avulsions, hemarthrosis, and pulmonary embolism)^{28,32} as well as making considerable cost savings to the NHS. MUAs are expensive requiring an overnight stay in hospital costing £4,300⁴², revision surgery costs approximately £30,011⁴³ and 20% to 25% do not result in lasting gains in ROM.⁴⁴

The intervention group using the STAK tool improved their OKS score by 8 points, and the control group by only 3 points. An improvement of over 4.3 is regarded as a clinically relevant improvement after TKA.⁴⁵ The control group is below this threshold whereas the STAK group exceeds this which in this group of patients with extreme arthrofibrosis is exceptional. All patients stated that they would have liked use of the STAK on discharge from hospital and considered it would have prevented development of their arthrofibrosis.

This study demonstrates that the STAK HIS device significantly improves patients' ROM, pain stiffness, and function even in the most severe arthrofibrosis patients when intensive standard physiotherapy and possibly even MUA has failed. Improvements in ROM compare favourably over research using the JAS knee device (Joint Active Systems, Effingham, Illinois, USA) (median 19° flexion³³ and mean 24° flexion³⁰ and also in comparison with published increases in ROM following MUA (mean 26.5°, 0° to 80°).⁴⁶ The current study supports other research finding HIS home mechanical therapy devices work more effectively than physiotherapy alone.^{20,31,32,47} Stretching theory supports this as HIS devices apply forces to the joint that are similar to those applied by physiotherapists, whereas force generated by home exercises is much lower.²⁷ Applying too low a force (home exercises), or applying force for too short of a period of time (biweekly physiotherapy session) produces elastic deformation that does not correspond with a lasting change in ROM.^{23,29,48} Research involving 60,000 patients with knee arthrofibrosis found HIS PASS devices had a lower risk of hospital readmissions compared to low intensity stretch (LIS) devices²⁰ and groups receiving standard physiotherapy were 71% more likely to require revision surgery compared with the HIS device users.²⁰

The STAK enables the patient to use their own body weight and leverage to generate the HIS and have finely adjustable control over their stretch. The short duration stretch is better tolerated and limits damage to the tissue

as the patient actuates the device to the limit of their pain threshold.³¹ This together with the motivational scale providing feedback on progress enables and empowers patients to take control of their rehabilitation increasing self-efficacy. This is supported by the high adherence rates captured by the home exercise and acceptability questionnaires. Research in the joint arthroplasty field has found higher levels of postoperative self-efficacy lead to better longer term outcomes⁴⁹ and enhance adherence to home exercises.⁵⁰ This current study indicates the STAK programme achieves this and maintains these improvements at long term follow-up (mean 10.5 months (7 to 15), which made patients a mean 16 months post-surgery (10 to 24).

Limitations. The study did not formerly randomize the sample. The first 20 patients were allocated to the intervention group and the next available 15 to the control. Although a traditional randomization procedure was not conducted analysis reveals no significant difference in patient demographics or baseline characteristics including ROM, OKS, and WOMAC scores between the groups (see Table II). Physiotherapists carrying out standard treatment were blinded to the research, but it is possible patients may have communicated to their physiotherapist that they were using the STAK at home while receiving standard treatment. Patients received an average of four physiotherapy appointments during the eight weeks. Improvements in all the STAK group outcome measures were maintained at long term follow-up; however, no long-term follow-up measures were taken from the control group. A future study comparing long-term follow-up data including a control group would enable long-term comparisons to be made.

Conclusion

Patients undertaking the STAK home treatment programme and standard physiotherapy demonstrated significantly greater gains in ROM, WOMAC, and OKS than the control group receiving standard physiotherapy alone. The improvements were also maintained at long term follow-up. Adherence to the STAK programme and acceptability of the device were high and no complications occurred as a result of its use.

The results suggest that the STAK programme enables knee arthrofibrosis patients to perform high intensity self-stretching effectively at home with exceptional patient adherence levels. Incorporation of the STAK into clinical practice would significantly improve patient's outcomes, satisfaction and result in considerable cost savings on physiotherapy and further surgery.

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Animation

Patient: ID: 05 Demonstrating her progress after using the STAK: <https://youtu.be/swUNRIZ3nHM>

Patient: ID: 13 Discussing her experience of using the STAK tool: <https://youtu.be/DVuPLf84qME>

Mr Aujla (Orthopaedic Knee Surgeon) outlining the potential of the STAK Tool to treat the stiff knee: <https://youtu.be/krwsS6ZrCXE>

Professor Ashford (Orthopaedic Knee Surgeon) describes how the STAK is effective in enabling patients to quickly regain function following knee replacement <https://youtu.be/aCuRI2hfRZg>

Mr Elsorafy (Orthopaedic Knee Surgeon) describes his patient's progress using the STAK Tool <https://youtu.be/Oa4XjBfPZnw>

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- S. K. Aspinall: Principal investigator, Carried out statistical analysis, Wrote the paper.
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Ethical review statement

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