A clinical trial considering the use of a new medical stretching device the STAK Tool (Self Treatment Assisted Knee) to treat patients with knee arthrofibrosis

ISAKOS Conference 2019
The Problem: Knee Arthrofibrosis
(extreme PAIN AND STIFFNESS)

Knee flexion is Crucial for QoL

- Up to 120° to manage chairs
- 90° walking up slopes
- 105° descending stairs
- 115° riding a bike

(Creighton 2012, Cosgara 1994)
Exponential Growth in Arthrofibrosis following Total Knee Arthroplasty (TKA)

- 112,836 TKA/year in UK (NJR 2018)
- 10% Arthrofibrosis (<90° flexion)

TKA $\uparrow 6 \times$ by 2030 = over 600,000 TKR /Year

Due to rising obesity & longevity (Fayaz 2011 and Culiford 2015)

- USA - 700,000 a year (AJRR 2018 Annual Report)
- Projection- increase to 3.48 million by 2030 (Kurtz 2007)
Treatments for arthrofibrosis - Stretching theory

- All connective tissue has the ability to stretch after it has been shortened due to its viscoelastic properties, including arthrofibrotic tissue.

- Elastic deformation - tissue reverts back to its original length once the force is removed

- **Plastic deformation** leads to permanent elongation and remodeling of the tissues (McElroy 2011) and is essential if ROM is to be restored.

- For treatment to be effective tissues must be stretched every 24 hours (Jacobs and Sciascia 2011; Davies and Ellenbecker 1999).
Standard Treatment

Physiotherapy to meet individual patient’s needs including:-

- Advice and education
- Home exercise programme
- Classes, hydrotherapy

Problem: NHS 1 session every 2 weeks is inadequate

- Manipulation under anaesthetic
Manipulation under anaesthetic (MUA)

- **Associated Risks** (Eg quadriceps tendon rupture, fracture, may require GA) (Gu 2018; Magit 2007)

- Good initial results (Esler 1999; Maloney 2001; Pariente 2006),
  - ~20% failure rate (Gu et al 2018)

- Cost implications MUA ≈£5000
- Requires an anaesthetist
- Requires inpatient stay in hospital
- CMP machine required whilst in hospital
- Extra Outpatient Physiotherapy/Hydrotherapy
Research into medical stretching devices for Home Use

Medical stretching devices have proved effective in treating arthrofibrosis post knee arthroplasty.

- Papotto and Mills (2012) The Flexionater (high intensity stretch): Mean flexion increase 29.9°
  - Low intensity stretching device: Mean flexion increase 17.0° (p < 0.001)
- Change in PROM significantly correlated with the WOMAC.
- Bonutti et al (2010) - JAS Device - Mean increase 25°
- McGrath (2009) - JAS Device - 20.6°
- Medical stretching devices enable patients to stretch daily at home essential to achieve plastic deformation resulting in significant increase in ROM.
High Intensity Stretch

Patient in control of pain threshold

STAK Tool - HOME USE SOLUTION

USE DAILY AT HOME

Safe

Inexpensive
Motivating
Easy to use
A clinical trial comparing 2 groups:

1) **Standard treatment plus STAK Tool** (Medical Stretching device)

2) **Standard treatment alone**

**Inclusion Criteria**

- Weight between 44kg and 159kg
- $<80^\circ$ flexion ROM at post-operative follow up apt OR prescribed intensive physiotherapy by their Dr.

**Exclusion Criteria**

- RA or Osteoporosis
- post malignancy
- leaking wounds or infected joints
- have undergone long term steroid treatment or the surgeon felt the patient was at risk of post-operative fracture.
- unable to give consent themselves (confusion, none English speaking patients)

**Participant pathologies:**

*Intervention: 16 primary TKR, 1 Uni Knee, 1 patella #*

*Control: 14 primary TKR, 1 revision TKR, 1 dislocation, 1 bedbound whilst awaiting hip surgery resulting in athrofibrosis.*

*Time post surgery/injury: Range 6 weeks - 20 months*
Clinical Trial Results:

1) Clinical Trial (36 patients) comparing 8 weeks STAK versus 8 weeks standard treatment completed.

Results:

<table>
<thead>
<tr>
<th></th>
<th>Mean Flexion increase</th>
<th>Mean WOMAC Score increase:</th>
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<tbody>
<tr>
<td>8 weeks STAK</td>
<td>29°</td>
<td>20.8</td>
</tr>
<tr>
<td>8 weeks standard</td>
<td>7°</td>
<td>4.9</td>
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(p<0.0001)

(Pain, Stiffness and Physical Function)

- Acceptability tested: Interview and questionnaire:
  - 100% would “definitely recommend STAK to a friend” & “Perfectly Acceptable”

- Completing 6 month follow ups currently to measure long term results.

Drop outs: 2 participants dropped out - Lack of time/family commitments/illness, 3 required MUA after STAK Treatment - Patients reported they felt they needed longer than 8 weeks on STAK.
STAK Group

18 participants completed 8 weeks STAK treatment

ROM
Mean Pre STAK: 66°
Mean Post STAK: 99°
Mean change 29.75 (range 12°–50°) (p<0.001)

WOMAC Scores:
Mean pre STAK : 51.7 Mean post STAK : 31.65
Mean change 20.8 points (p<0.001).

OKS
Pre: 20.6 Post: 27.85
Mean change 7.7 (p<0.001)

Control Group

16 participants completed 8 weeks standard treatment (ST):

ROM
Mean Pre: 64.3°
Mean post: 77.9°
Mean change 7.2° (-7°–36°) (p<0.01)

WOMAC Scores:
Mean pre Standard Treatment : 49.8 Mean post ST: 44.9
Mean change 4.9 points (p<0.21).

OKS
Mean Pre : 20 Post: 23.9
Mean change 3.9 (p<0.29)

STAK group Mean Change in ROM significantly greater than control group (p<0.001)
STAK Tool Advantages

- MOTIVATIONAL scale
- Promotes patient SELF-RESPONSIBILITY
- REMOTE MONITORING of patient’s progress
- Patient in CONTROL of stretch/pain threshold
- Usable at HOME and in hospital

Radical Improvements in Patient Treatment

££££ - create Revenue and Cost Saving for hospitals
References


