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Research Paper Review

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Adhesive capsulitis: Prospective observational multi-center study on the Niel-Asher Technique (NAT) International Journal of Osteopathic Medicine (article in press)

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Simeon Niel-Asher, BPhil, BSc, Suzanne Hibberd, BSc (Hons), Stuart Bentley, BSc (Hons) (Ost – Osteopath), Jonathan Reynolds, PhD

Reviewed by Professor Anthony Kay PhD Associate Professor of Biomechanics, University of Northampton

ABSTRACT:

Objective

To evaluate "The Niel-Asher Technique (NAT)" for adhesive capsulitis

Method

Prospective observational multi-center study

Subjects

154 patients (113 from Israel, 25 from the UK and 16 from the US) with pain, stiffness and globally restricted gleno-humeral mobility shoulder for more than three months.

Outcome measures

Change in active range of motion (AROM) Flexion and Abduction of the gleno-humeral joint measured by a goniometer; changes in pain as evaluated by the patients on a linear Visual Analogue Scale (VAS). Analysis was based on the intention-to-treat principle.

Results

Multivariate repeated measures analysis of covariance indicated that there was a significant improvement in AROM abduction and flexion across time, with no interaction between time and phase of illness (acute / stiff / resolving). The improvement in range of motion was significantly

more pronounced in patients from Israel compared to the UK and US. Similarly, among patients from Israel, large and statistically significant reduction in the VAS pain score between baseline and post-treatment assessments was observed.

Conclusions

All patients demonstrated a significant improvement in AROM for both flexion and abduction. The data supports the notion that NAT is autonomously reproducible. NAT demonstrated significant improvement in AROM for both flexion and abduction with a consistent average of twelve degrees improvement per treatment session. The mean number of treatments was 7. NAT expedites both pain reduction and increased mobility for adhesive capsulitis over and above the natural history.

ANALYSIS

Evidence of any bias from, say, funding source influence/author's affiliations No external funding was reported from any organisation; however several possibilities of bias exist: 1. The intervention was conducted in 3 institutes; however the institute with the best outcomes and most patients was where the therapist (Simeon Niel-Asher) is the likely creator of the therapy (Niel-Asher Technique) used in the study, which clearly introduces possible bias into the study. However, smaller yet similar gains were achieved in the other two centres; furthermore these studies were conducted prior to the researchers sharing data, which limits to some degree the possibility of bias. 2. Patients were self-funded, which may enhance the placebo effect (increased motivation to get better) and selection bias (increased motivation to attend, get better and complete the intervention), however these possibilities were reported by the authors and as such the authors acknowledge these limitations. **Summary of the research methods** A clinical trial was conducted in 3 centres, however no control group was included thus no randomisation or blinding was able to be performed, which limits the rigour of the methods although this is acknowledged by the authors. Inclusion/exclusion criteria are clearly stated, however only signs and symptoms of capsulitis were used for inclusion criteria rather than MRI evidence, thus possible causes are unknown and may limit understanding of responders and non-responders. Statistical analyses and methods are appropriate with the Niel-Asher Technique described in detail enabling reproduction of the study. **Strengths or weaknesses in the research methods** The lack of a control group limits the findings of the study as the authors report. This is especially the case in this study as capsulitis is normally a self-resolving condition, thus no comparison can be made with patients who undergo no therapy. Similarly as no control group was included, no randomisation of subjects nor blinding of subjects was able to be performed, again weakening the rigour of the methods as randomised control trials (RCT) are considered the gold standard methodology for clinical trials. **Appropriateness of the statistical analysis** Appropriate statistical analyses have been performed with one-way ANOVA for differences in subject populations between centres used to determine whether demographics could explain differences in outcomes between centres. A MANOVA, a very robust statistical test, was used for differences in outcome measures, which is appropriate given the complex interaction between centres, 3 outcome outcome measures, time, and stage of condition. Whether the quality of the research supports the authors' conclusions The authors' draw 2 appropriate conclusions: • All patients demonstrated a significant improvement in AROM for both flexion and abduction. The data supports the notion that NAT is autonomously reproducible. The conclusion is appropriate as similar findings were found across 3 centres • NAT expedites both pain reduction and increased mobility for adhesive capsulitis over and above the natural history. Pain reduction was only found in 1 or 3 centres where greater increases in ROM were also found, caution should be taken with this conclusion due to these differences. Furthermore, no control group was included so the

suggestion that this therapy increases ROM over and above the natural history does not take into account that this is a naturally resolving condition and while improvements were made, improvements in a control group should be expected. **Overall** The article is accepted but is still 'in press' in a relatively low-impact journal (0.58) and has not been subject to copyediting or full manuscript preparation, thus it is difficult to comment on the overall quality of the work as some changes may be made to the paper prior to publication in print. However, the article is well-written (mostly) and is useful for practitioners as it clearly describes the Niel-Asher Technique enabling therapists to copy the technique. Some caution should be taken with the findings and conclusions as including data from a centre where the therapist is the main author and the creator of the therapy itself, introduces concerns over possible bias. However similar findings occurred at other centres but more research from independent groups and therapists is needed to fully elucidate the effects of this therapy on adhesive capsulitis.

ACADEMY COMMENTS

Evidence of bias The comments on possible bias are very valid, but it is an unfortunate reality that this kind of research is seldom conducted independently due to paucity of funding. **Lack of a control group** The absence of a control group is relevant, but it is well documented elsewhere in medical literature that the natural course for Frozen Shoulder is about 30 months. **Overall** This study, conducted over 9 months, with an average 7 treatments over 11 weeks, produced similar outcomes to a previous RCT conducted at Addenbrookes Hospital. In evaluating the value of NAT, it is necessary to compare it with the best alternatives currently available and this paper provides good evidence of its effectiveness in that regard.