Sodium Hyaluronate (Viscoseal®) Following Arthroscopic Knee Surgery; A Pilot, Single-Blind, Blinded Investigator, Controlled Study.

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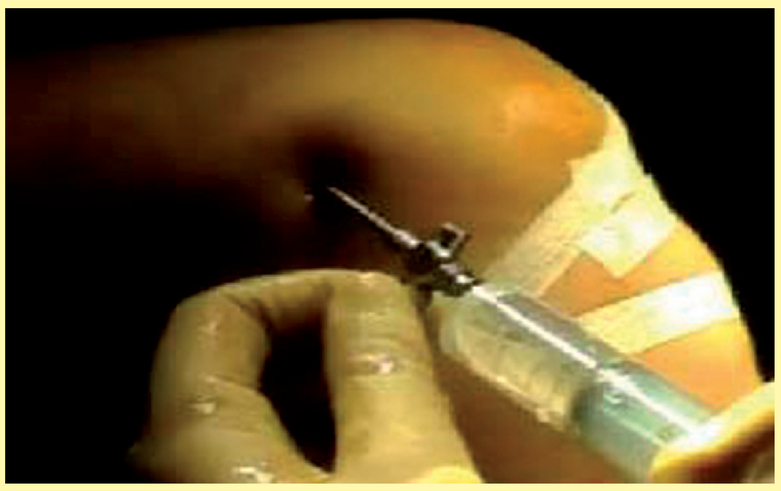
Introduction

Arthroscopic Knee Surgery is a universally accepted technique, causing less insult to external and surrounding structures, decreased incidence of complications, and a more rapid recovery and rehabilitation. In addition to surgically induced trauma, a contribution to side effects is made by irrigation solutions used during arthroscopies to flush debris from the locus of investigation. Because the irrigation solution washes out the synovial fluid (SF) that resides in all synovial joints, the protective and lubricating functions of the SF – conferred by the Hyaluronic Acid – based proteoglycan chains - are temporarily absent, and several days may elapse before the joint begins to replace the fluid that has been lost. Potentially detrimental effects on chondrosynthesis, caused by saline and the common practice of instilling local anaesthetic into the joint at the end of surgery, have been documented. (1-6). Viscoseal® (TRB Chemedica) is a 0.5% concentration, isotonic solution of Hyaluronan of fermentative origin licensed as a synovial fluid substitute for use following arthroscopic surgery or joint lavage. Instilled into the joint immediately after surgery, it displaces any irrigating solution left in the joint space, preventing impairment of cartilage metabolism. In addition, it re-establishes the protective coating of Hyaluronan over the surface of the articular cartilage and synovial membrane. By replacing the superficial layer of viscous Hyaluronan on the intima of the synovium, potential innervation of pain receptors is reduced. This reduction in pain helps to enhance joint mobility, which in turn promotes the production of endogenous Hyaluronan. Previous studies of Viscoseal® in knee, shoulder, and other joints report favourable outcomes with no adverse events (7-10).



Instilling Viscoseal via trochar bridge.

Aims

To determine whether a single 10ml instillation of a physiologic agent – Sodium Hyaluronate (Viscoseal®), at the end of knee arthroscopy, was comparable with standard therapy – intra articular Bupivacaine, on pain and function.

Methodology

Design. Pilot, single centre, single blind, blinded assessor, controlled study.

Inclusion Criteria

Patients over the age of 18 years listed for arthroscopic knee surgery as ppropriate to their clinical condition were invited to participate following written informed consent.

Exclusion Criteria

Known hypersensitivity to hyaluronic acid, other constituents of viscoseal, marcaine. Local infection. Pregnancy/Lactation.

Procedure

All procedures were carried out by the first author. Following removal of intra-capsular loose bodies/ trimming meniscus back to stable rim /debridement, saline was evacuated and either 50mg/10ml Sodium Hyaluronate (Viscoseal®) in the study group, or 10ml 0.5% Bupivacaine in the control group was injected into the capsule prior to closure. Randomisation was via pre-generated computer code number appended to patient notes at baseline visit and checked against master list, corresponding to study or control category, in theatre following surgery. Post operative regimes were standardised for both groups. Codydramol (10mg) was given as rescue medication for pain control.

End Points

Subjective post-operative pain levels at rest as evinced on a 10 point visual analogue scale with terminal descriptors. Blinded assessor Global Clinical Impression on a 5 point Likert type score with 0=Poor through 5=very good. VAS measures taken at baseline, 2 hours,24,hours, days 3, 7, and 28, and GCI scores taken at baseline and day 28 post-operatively.

Statistical Analysis

Between groups comparative analysis of VAS was performed at all time points, and GCI analysis at baseline and day 28 using a Mann-Whitney U test.

Results

A total of 12 patients were randomised into 2 groups, 7 in the study group and 5 controls. Study group (Viscoseal®) and ontrol group (Bupivacaine) were evenly matched at baseline with no significant differences in pain scores (VAS), Blinded Assessor Global Clinical Impression (GCI), age, or degree of pathology on X Ray. (Table 1). Significant differences in VAS scores favouring the study group were found at 24 hours, day 3, day 7, and day 28 post-operatively (Table 2 & Figure 1.). There were no significant differences at any point in GCI scores, both groups showed improvement

Discussion

The primary aim of our study was to determine whether adequate analgesia, following simple knee arthroscopy, could be achieved without the use of intra-articular Bupivacaine. Our results are concordant with previous studies, showing a gradual reduction in VAS scores over time, as would be expected, with Bupivacaine providing a slightly greater degree of relief in the immediate post-operative period, then a gradual divergence in VAS scores favouring the Viscoseal® group, with statistically significant differences at 24 hours, days 3, 7 and 28. Mean Global Clinical Impression scores, carried out by a blinded physiotherapist, showed no significant differences at any point. Our study was limited by small numbers of participants, and caution must necessarily be exercised when inferring from these results. However, within the context of what we set out to discover, the results were sufficiently encouraging to prompt our department to carry out a larger trial – currently in progress - sufficiently powered to determine any differences with greater accuracy.

Baseline.	Study Group (Viscoseal®)	Control Group (Bupivacaine)	Difference (*p*)
Mean Age (SD, Range)	53.9 (10.2, 42.6 - 71)	51.1 (9.7, 38 - 62)	*ns*
Gender (M/F)	5/2	4/1	*ns*
Mean *Kellgren-Lawrence* Score	III	III	*ns*
Mean GCI	3	3	*ns*
Mean VAS	6.1	5.8	*ns*

Table 1. Baseline demographics. ns = not significant.

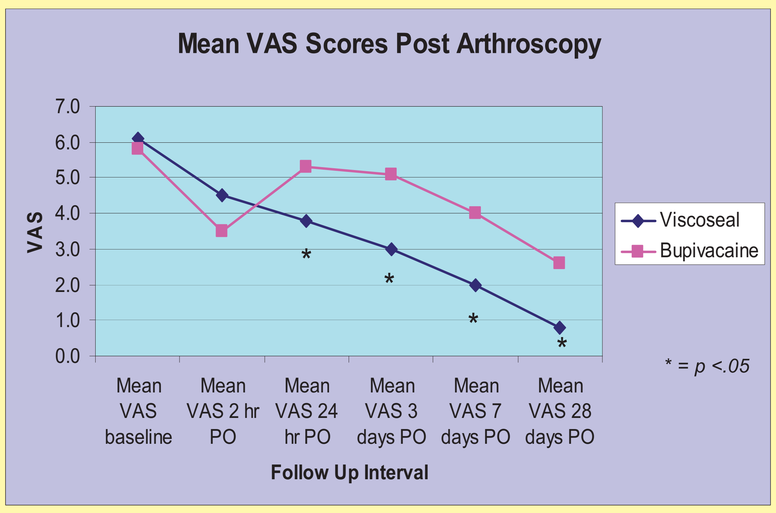


Figure 1. Mean VAS scores at post-operative follow up intervals.

Variable	Time Post Operatively	Mann-Whitney U	*p*
Mean VAS	24 hours	3.5	.016
Mean VAS	Day 3	1.0	.006
Mean VAS	Day 7	2.0	.009
Mean VAS	Day 28	1.5	.007

Table 2. Significant differences in VAS scores favouring study (Viscoseal®) group post – operatively.

Conclusion

10 ml of intra-articular 0.5% Sodium Hyaluronate (Viscoseal®) proved effective in providing good post-operative analgesia for patients who had undergone simple knee arthroscopy. There were no adverse events, and Sodium Hyaluronate has been shown to be physiologic, with no deleterious effects on joint metabolism. Further studies on larger cohorts are needed.

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Disclosure: The authors did not receive any outside funding or grants in support of their research for or preparation of this work. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, division, center, clinical practice, or other charitable or nonprofit organization with which the authors, or a member of their immediate families, are affiliated or associated.