Title of the Contribution:
Traumeel vs. diclofenac for reducing pain and improving ankle mobility after acute ankle sprain: a multicentre, randomised, blinded, controlled and non-inferiority trial.

Abstract:
Acute ankle sprains are common and activity limiting injuries, and topical diclofenac gel has proven efficacy in alleviating pain and restoring function. This trial aimed to compare a topical natural agent, Traumeel with topical diclofenac gel (1%) in the management of acute ankle sprain. This prospective, multicentre, randomised, blinded, active-control and non-inferiority study involved 449 physically active adults sustaining unilateral grade 1 or 2 ankle sprain within the past 24 h. Participants were randomised to receive 2 g of Traumeel ointment (T-O) (n = 152) or Traumeel gel (T-G) (n = 150) or diclofenac gel (D-G) (n = 147), administered topically to the ankle three times a day for 14 days, with 6-weeks follow up. Day 7 median percentage reductions in Visual Analogue Scale pain score were 60.6%, 71.1% and 68.9% for the T-O, T-G and D-G groups, respectively. Total pain relief was reported by 12 (8.5%), 7 (5.0%) and 8 (5.9%) participants in each group, respectively. Median improvements in Foot and Ankle Ability Measure Activities of Daily Living subscale score were 26.2, 26.2 and 25.0 points for T-O, T-G and D-G groups, respectively. Mann-Whitney effect sizes and lower bound confidence intervals demonstrated non-inferiority of Traumeel vs. diclofenac for reducing pain and functional improvement. At 6 weeks, participants reported total pain relief and normal
functioning. Adverse events (n = 43) were reported by 31/447 participants (6.9%). Treatments were equally well tolerated. T-O and T-G decreased pain and improved joint function to the same extent as D-G in acute ankle sprain, and were well tolerated.