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ONE OF THE FIRST PROSPECTIVE DOUBLE BLIND RANDOMISED CCT OF NON-HEALING WOUNDS WITH EXPOSED BONES AND TENDONS AMONG SPECIALISTS: TREATED WITH CHARGED POLYSTYRENE MICROSPHERES VS SOC

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Introduction: Recalcitrant chronic wounds (duration > 4 weeks) have long presented a challenge for the medical community, especially wounds with exposed bone, ligaments, and/or tendons.

Aim: To evaluate a new treatment modality using Charged Polystyrene Microspheres (CPM) for the treatment of recalcitrant wounds among specialists.

Material and methods: A prospective randomized double blind controlled clinical trial was undertaken using Charged Polystyrene Microspheres vs Saline (standard of care) in the treatment of recalcitrant chronic wounds. The primary endpoint was to achieve at least 75% granulation tissue. The secondary endpoints were time to complete wound closure (medically or surgically) and decrease in wound size. The patients were treated with Charged Polystyrene Microspheres or Saline for 4 weeks twice daily and then as per investigator's recommendation for an additional 8 weeks. Patients were treated on an outpatient basis and regularly evaluated.

Results: An interim analysis was performed after 4 weeks of treatment on 31 evaluable patients (17 CPM and 14 Saline). Both primary and secondary endpoints were achieved and were statistically significant. There were no adverse events in the Charged Polystyrene Microspheres group.

In patients treated with Charged Polystyrene Microspheres, 71% of the patients achieved granulation coverage of >75% of wound area, and 94% achieved >50% coverage. Among Saline patients, 21% achieved >75% granulation coverage, and 36% achieved >50% coverage. The difference between the Charged Polystyrene Microspheres and Saline groups was statistically significant $p<0.0001$. In the Charged Polystyrene Microspheres group, the average decrease in wound size was 26% from original wound area, $p=0.01$, and in the Saline group the average decrease in wound size was 5% from the original wound size, p-NS.

15 patients (8 CPM and 7 Saline) were also evaluated after the 2 month follow up period. A total of 6/15 wounds were fully closed: 5/8 from the Charged Polystyrene Microspheres group and 1/7 from the Saline group. Over the full three month trial period, the average decrease in wound size in the Charged Polystyrene Microspheres group was 95%,$p<0.07$, and in the Saline group was 47%, p-NS.

Conclusions: This is one of the first DB RCT in non-healing ulcers including exposed bones, tendons and ligaments among specialists. Treatment with Charged Polystyrene Microspheres was found to be safe and effective in treatment of these hard to heal chronic wounds and compares favorably vs standard of care.