

Summary of Clinical Program to Support Use of 3M™ Coban™ 2 Compression Systems for Lymphoedema Bandaging

To expand the evidence to support use of 3M™ Coban™ 2 Compression Systems for lymphoedema treatment, 3M has completed a number of clinical and economic studies in partnership with leading clinicians. The body of work includes:

- Randomised controlled trial on 82 patients with arm and leg lymphoedema from which application frequency, clinical outcomes and cost of total treatment were captured
- Proof of concept study of effective volume reduction over 24 hours on 30 leg lymphoedema patients
- Observational case series on use of the new materials on 24 patients, and report of clinician and patient experiences and a qualitative study using focus groups

Randomised Controlled Trial ¹

A randomised controlled trial was conducted to investigate the efficacy and safety of the Coban™ 2 Compression System compared to traditional short stretch multi-layer bandaging. This multi-centre, prospective study was performed with 82 patients suffering from lymphoedema stage II or late stage II, either as secondary arm lymphoedema or as primary or secondary leg lymphoedema. All patients were randomly allocated to treatment regimen and the study duration was 19 days. Limb volume as well as adverse events, were recorded at each study visit. Mobility was assessed at the end of each week. The % volume reduction of the study limb was the primary endpoint.

Proof of Concept Study ²

A prospective randomised study to demonstrate proof of concept for the Coban™ 2 Compression System was conducted. This study included 30 patients hospitalized for conventional treatment of moderate to severe lymphoedema (Stage II-III) of the leg. Patients were treated with Coban™ 2 Compression System or traditional bandages used in this facility. In both groups initial bandages were removed after 2 hours, and replaced by new bandages for the following 22 hours. No other therapeutic intervention was performed. Leg volume and interface pressures were measured.

Observational Case Series ^{3,4,5}

- A qualitative study has been conducted to explore the experience of patients who have undergone a period of Complete Decongestive Therapy using the Coban 2 Compression System. Qualitative data were collected from 12 patients from the UK and 8 from Canada with a range of presentations of lymphoedema. Single semi-structured interviews were used and participants were asked questions relating to their experience of diagnosis, the impact of lymphoedema on their lives, previous treatment using multilayer lymphoedema bandaging and their experiences of the 3M System.³
- Quantitative data were collected from the clinicians and patients involved in the qualitative study above. In total 24 patients were entered into this prospective study (12 from UK, 12 from Canada) with a variety of clinical indications. Bandages were replaced according to clinical need and the protocol of the centre undertaking this study. Efficacy parameters and patient reported symptom relief was measured.⁴
- A qualitative study using focus groups in Canada and the UK exploring the professional challenges of treating patients with complex/severe forms of chronic oedema/lymphoedema with compression therapy.⁵

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