

Study Aim

- *To determine the outcome of non-operative management using a SCBD in amputation-bound non-reconstructible CLI patients*
- *Primary endpoints were Limb Salvage and Mortality*
- *Secondary endpoints were increase in toe pressures, popliteal artery blood flow velocity, resolution of rest pain, healing of ulcers and cost effectiveness over primary amputation*

Patients and Methods

➤ Inclusion Criteria

- *Anatomical factors – (Absence of runoff vessel or autologous vein in the presence of poor runoff and previous failed ipsilateral bypass)*
 - -30 patients
- *Severe Co-morbidity precluding surgery*
 - - 05 patients

➤ Exclusion criteria

- *Severe infection in limb, Deep Vein Thrombosis, CCF, thrombophlebitis, bedridden patients and inability to tolerate compression*

Patient and Methods

- ❖ Male: female was 26:9 & Mean age was 74.3 years
- ❖ All patients were given best medical therapy (Aspirin, Statin, Clopidogrel and Ca+ Channel blocker)
- ❖ The patients underwent a 12-week treatment protocol with Art Assist (6 hours/day)
 - ❖ (Initial optimisation as in-patient and then further treatment in the community)
- ❖ Follow-up was by clinical assessment, ABI & Toe pressures and popliteal flow assessment, at inclusion and at 4 weekly intervals thereafter

Results- SCBD

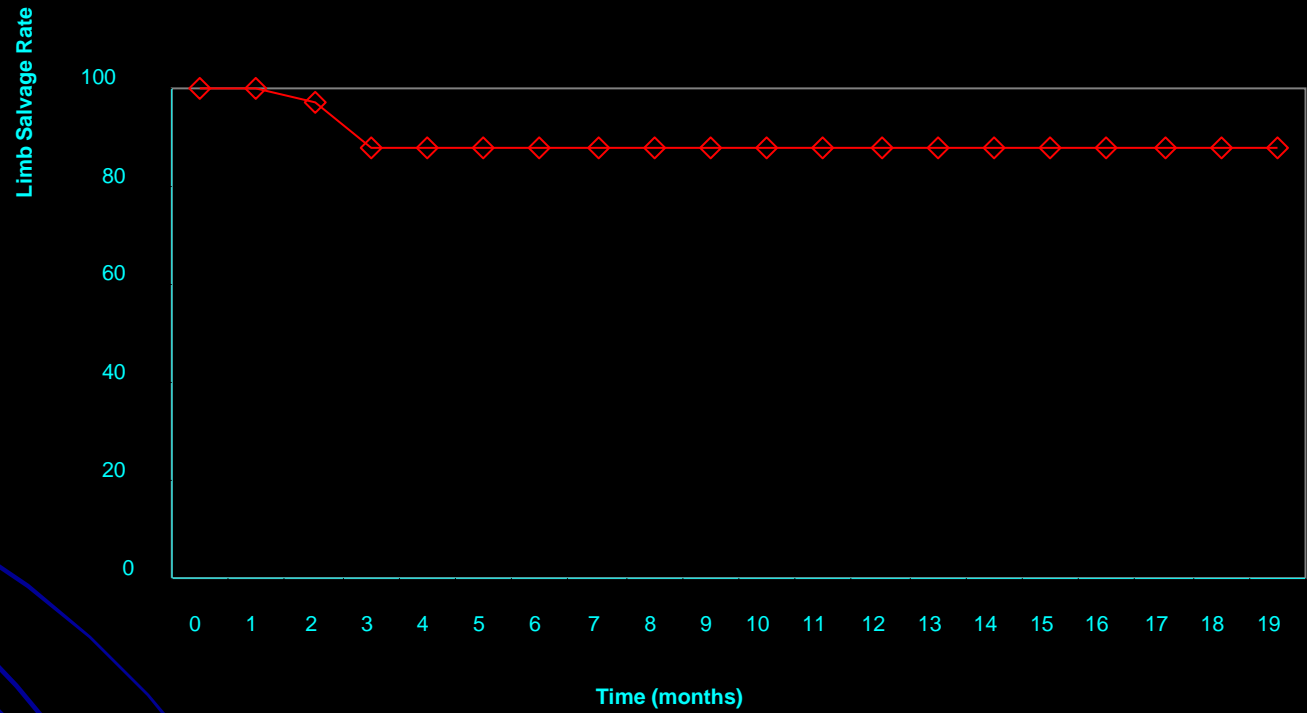
- ❖ Mean follow-up was 18 months (+/- SD 6 months)
- ❖ There were 4 amputations (AKA n=3, BKA n=1)
- ❖ Cumulative Limb salvage was 88% (+/- SE 7.62%).
- ❖ 90-day mortality was zero
- ❖ Cumulative survival at one year was 81.2%

Results-SCBD

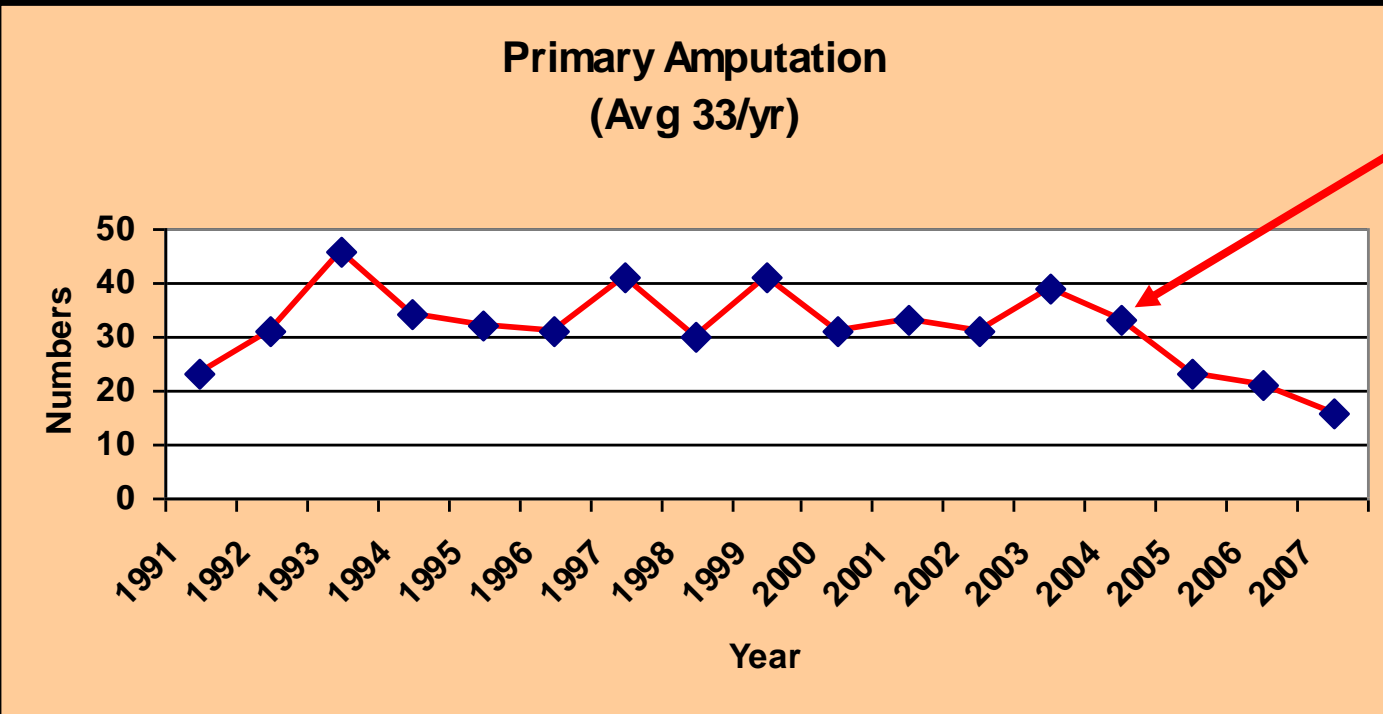
- *Rest pain resolved in all patients within one week*
- *Gangrene remained dry and non-progressive and ulceration healed in all except in 5 patients (4 major amputation, 1 toe amputation)*
- *No device-related complications*
- *Mean toe pressures increased from 38.2 to 61.9 mm Hg ($p < 0.0001$) (95 % CI 55 to 79)*
- *Popliteal artery blood flow velocity increased from 45 to 47.9 cm/s (95% CI (35.9-59.7)*

Results

Limb Salvage Rate

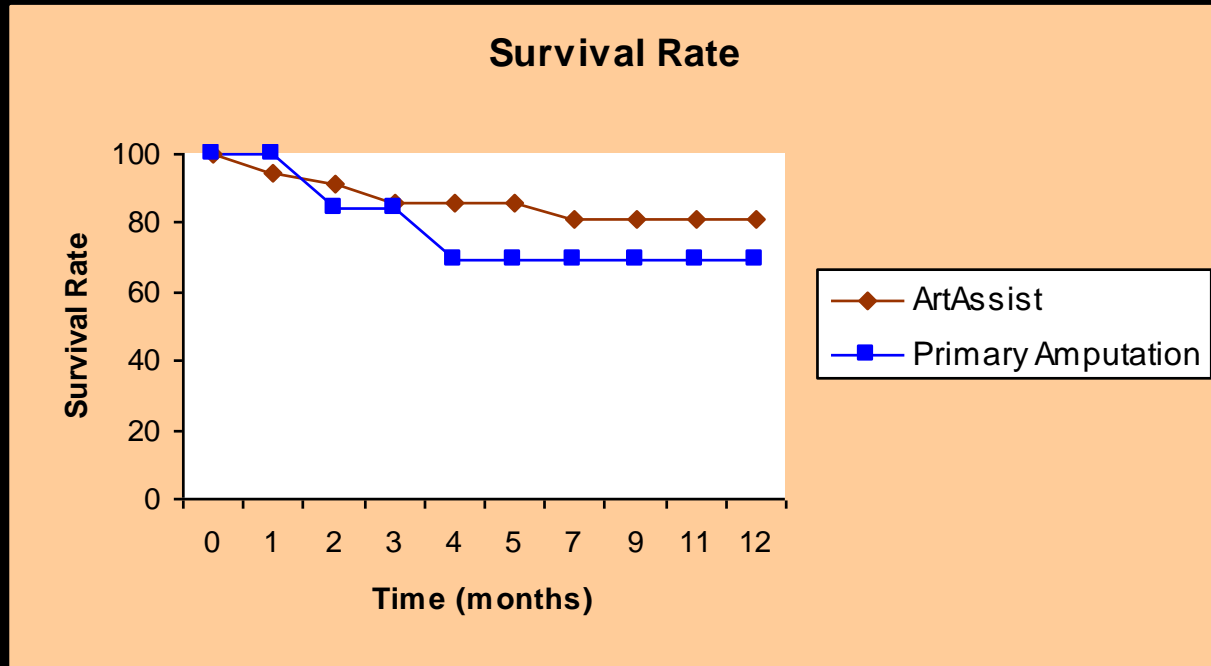


SCBD Vs Primary Amputations



Introduction of Artassist

SCBD Vs Primary Amputations



- In all cause mortality, on an intention to treat basis, the cumulative survival at 12 months was 81.2% (SE +/- 11.1) for SCBD & for primary amputees was 69.2% (SE +/- 12.8)

Conclusion

- *Sequential compression treatment for a period of 90-days enhanced limb salvage in amputation-bound non-reconstructible CLI patients*
- *It is suitable for home therapy and carries low morbidity and mortality compared with surgical procedures*