[EP029] Safety and efficacy of hyaluronan based bio-inductive dermal substitute in coverage of cancellous bone after surgical debridement for severe diabetic foot infection in reconstructive surgical approach: prospective, observational study

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Aim: Prospective observational study to evaluate efficacy and safety of bio-inductive dermal substitute constituted by 100% hyaluronic acid benzyl ester (HYAFF) in coverage of cancellous bone exposition after deep debridement in diabetic foot infection in order to perform a less severe definitive partial foot amputation.

Method:

During a period of four months, we enrolled consecutively 129 patients with following characteristics:

- DM type 1: 11 patients // DM type 2: 118 patients
- Mean age 65±12 years
- DM: 17±10 years)
- Neuropathy: 83 patients
- PVD: 115 patients with TcPo2 < 30 mmHg ➔ PTA successful in 97 patients
- Neuro-Ischemia: 55 patients
- Nefropathy: 35 patients
- Diabetic Retinopathy: 65 patients
- CHD: 93 patients 128mmHg

Ulcer characteristics:

- Forefoot (ray amputation) 41 patients
- Midfoot 61 patients
  (Chopart amp.: 25 patients, TMA amp.: 20 patients, Transcuneiform amp.: 16 patients)
- Heel: 24 patients
- Region of achilleas tendon: 3 patients
- Bone exposure: 111 patients

Treatment protocol consisted of:

- Emergent surgery
  - aggressive debridement
  - open minor amputation
- Revascularization procedures when needed (PTA or Bypass)
- Daily dressing obtaining a vital and bleeding wound bed
- Second surgical step
  - meticulous debridement with bleeding cancellous bone exposure
  - application of Hyalomatrix (HYAFF) with or without silicon layer
- Compressive dressing by grease gauze

First surgical look aggressive surgical debridement to remove infected and non-vital tissue performing minor amputation reaching vital and bleeding tissue and cancellous bone. Empiric antibiotic therapy (Piperacillin-Tazobactam + Daptomycin) followed antibiotic therapy cultural swab guided. Second surgical look (reconstructive surgery): meticulous debridement of soft tissue and bone, bio-inductive, hyaluronan dermal substitute (with and without silicon) fixed on wound edges with clips and covered by grease gauze and secondary dressing. We considered as ulcer healing both second intention healing and skin graft. At hospital discharge a visit was booked at out-patient diabetic foot clinic for weekly dressing change. Patients were not allowed to load the foot.

Results / Discussion: Bone coverage was observed in 94/111 patients (84%) in 38±25 days. Ulcers healed completely on 81/129 patients (62%) and nearly 30/129 as follows

- Skin graft: 24 patients in 19±16 days
- Second closure: 57 patients (44%) in 227±122 days
- Nearly healed: 30 patients
- Residual bon exposure: 3 patients
- 10 reinfections were observed treated successfully with debridement and antibiotic therapy
- 5 patients submitted to BTK amputation due to intractable soft tissue and bone infection

Conclusion:

Our prospective observational study demonstrated that dermal substitute based on hyaluronic acid benzyl ester (HYAFF) can be considered as a safe and effective option in treatment of severe diabetic foot infected ulcer with wide loss of soft tissue and bone exposure in reconstructive surgery avoiding proximal foot amputation.

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