Retrospective analysis on the use of sterilised tendon allografts in orthopaedic surgery

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Aims

Allografts are used in 78% of revisions and in 42 % of primary ACL surgeries in the USA. Interestingly, this number is much lower in Europe and the type of graft to use still remains a controversial topic. The "ideal" graft should fit into the site of interest, provide biomechanical stability, biological tunnel incorporation and facilitate the return of neuromuscular control. Here, we tested whether allografts sterilised using peracetic acid perform similar to or better than autografts in regards to revision rates.

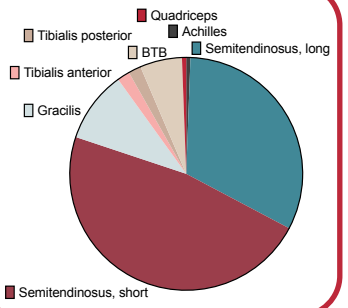
Methods

Surgeons across Germany were contacted for their use of sterilised tendon allografts. A total of 171 questionnaires were received. Allografts were used in knee (117) and shoulder (47) reconstruction. Tendon allograft use was also reported in ankle reconstruction (2), hip (1) and elbow (3) surgery

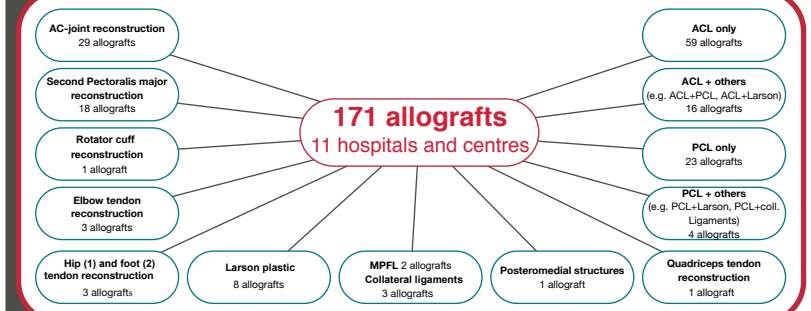
Graft preparation

All tissues are acquired from non-profit tissue recovery partners after informed consent. Tendons and ligaments are thawed at 2 - 8°C and remnants of blood, fat and connective tissue are removed. For sterilisation, tissues are fully submerged in validated tissue-preserving sterilisation solution (2% peracetic acid, 96% ethanol, aqua ad iniectabilia; ratio v/v/v | 2/1/1) and incubated with constant agitation, at low pressure and at room temperature for 4 hours. Subsequently, tissues are rinsed in a washing process using aqua ad iniectabilia. Under aseptic conditions (class A clean rooms) the sterile grafts are then transferred into primary and secondary packaging. The allografts are stored at - 40°C and can be used for up to two years.

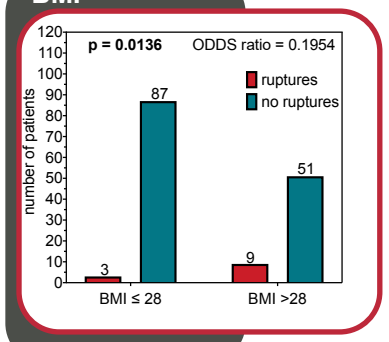
Tendons



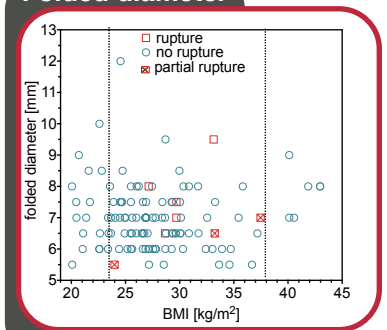
Procedures



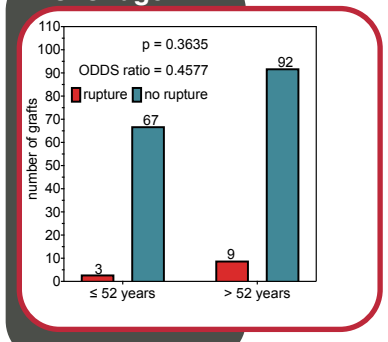
BMI



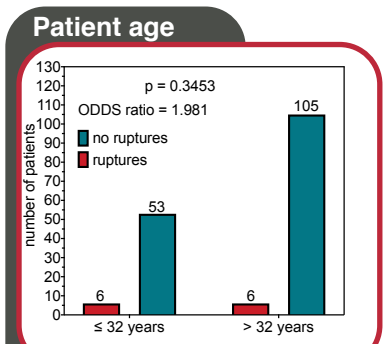
Folded diameter



Donor age



Patient age



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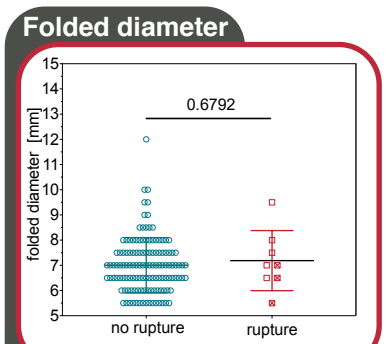
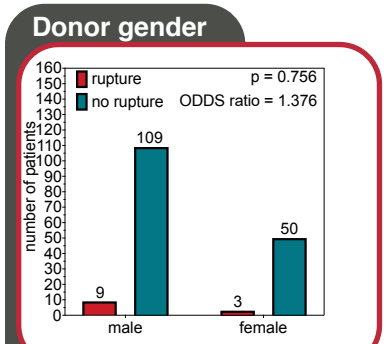


Donor gender



Results

- A 7,0 % rerupture rate (including partial reruptures) similar to that of autografts (1.4-15.3%) and allografts (1,6-11%).

- 9 grafts reruptured with 7 reported as adequate re-trauma's and 2 grafts (1 patient) ruptured due to non-compliance with therapeutic instructions.

- Three grafts, used for secondary reconstruction of the pectoralis major displayed partial reruptures.

- No correlation between donor age and increased reruptures (p = 0.3635).

- Patients with a BMI <24 and >38 did not experience reruptures, whereas a higher BMI was considered a risk factor with an increased revision rate (ODDS ratio for patients with BMI<28: 0.1954 and p=0.0136).

- No difference in the re-rupture rate of semitendinosus, gracilis and tibialis. Mean graft size for the rerupture group was 7.188 ± 1.193 mm (n = 8, range 5.5-9.5 mm) and for the non-rupture group: 7.008 ± 1.093 mm (n = 127, range 5.5-12 mm, p = 0.6792).

Conclusion

Peracetic acid sterilised allografts do not lead to higher rerupture rates.

BMI is a predictor of higher rerupture rates

Rerupture rate was not affected by donor age, donor gender or graft size.