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MINI-SLINGS: WHAT IS KNOWN ABOUT ANCHORAGE SYSTEMS?

Hypothesis / aims of study
In the last years incontinence surgery has changed a lot - with new and often smaller devices on the market for incontinence as well as for prolapse surgery. One important issue of these Mini-Slings are anchorage systems, which keep devices in place during the procedure as well as in the early postoperative time. Efficient comparing of different anchorage systems cannot be done in patients for clear ethical reasons. Clinical data are often insufficient in answering single aspects since success rates of surgical procedures rely on several factors.
Our study is the first to develop an animal model in combination with a technical method using photoelastic studies in ballistic gelatine to directly compare different materials and different shapes and sizes of anchorage systems in regard to possible dislocation at different pull-out forces.

Study design, materials and methods
Seven different anchorage systems were measured with pull-out tests in an animal model using rectus fascia of a pig and four anchorage symptoms were additionally tested using a ballistic gelatine model. Our animal model was a minipig. Certain structures which can be found in the female human pelvis such as the arcus tendineus and the sacrouterine ligaments are missing in the animal model. Furthermore, the strength of the local structures was considerably lower than that known for humans. After comparison with human tissue, we used rectus fascia with underlying muscles to test the different anchorage systems. We compared pull-out forces of seven different anchor systems
For visualisation of local strain we further used a method developed by Staat et al. 2012 (1). A tensile test was performed with a preload of 1 N at a cross-head speed of 10 mm/min and a test speed of 40 mm/min until failure. The stress profile around the anchor was assessed with a polariscope consisting of a light source and at least two polarising filters. For comparison we performed ANOVA with post-hoc Bonferroni. Results were presented as means whereby a significance level of $p < 0.05$ was considered to be significant.

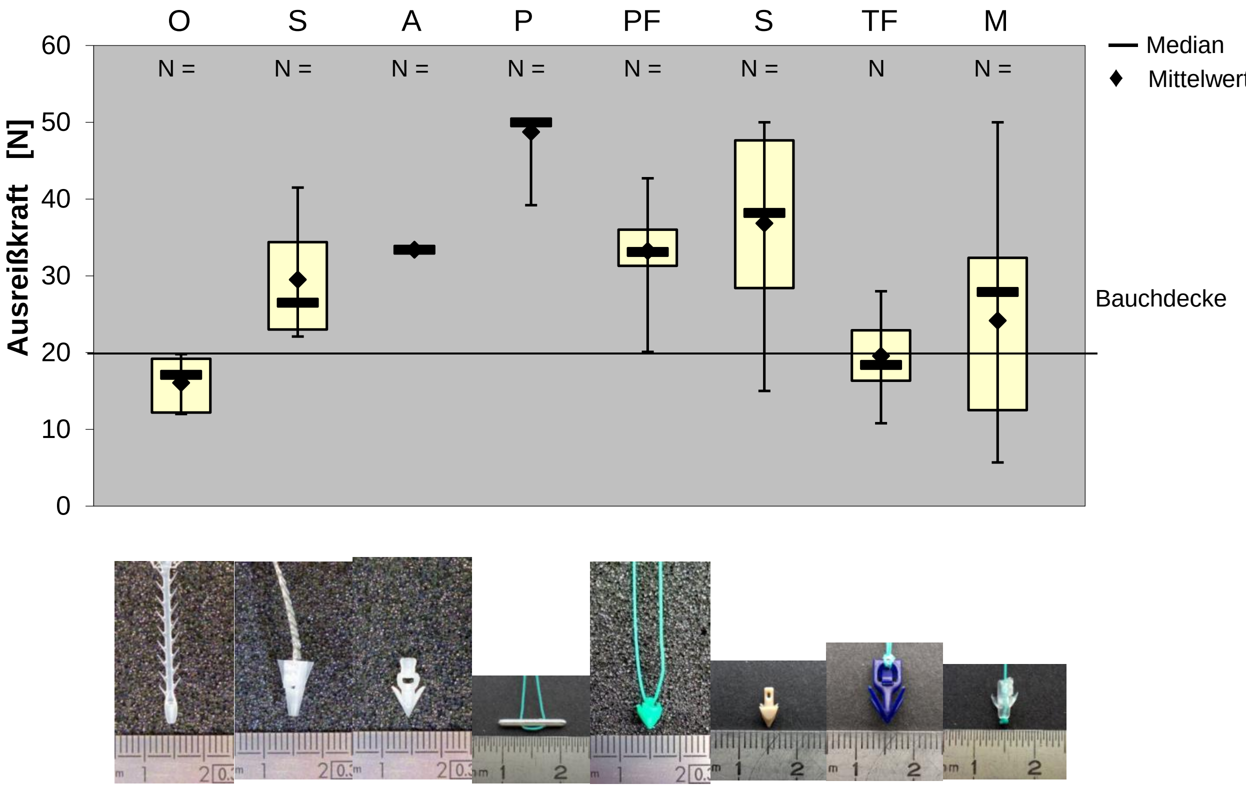
Results
The different systems showed significantly different pull-out forces. Findings of testing in the animal model could be confirmed in the technical model. Depending on the textile structure, size and form of the anchorage systems mechanical strain resulted in considerable lacing deformation with local peak pressures. The uniaxial tension to achieve extraction of the anchors was then measured after placing the anchorage systems in the freed anterior rectus sheath of adult pigs. Considering 20 N/cm as the maximum resistance for rupture of pelvic tissue ((2) Cosson et al. 2004) some anchor systems could guarantee this in all cases, whereas the retaining force with three of the anchors sometimes was much lower. The main reason for slippage in the biological tissue as well as in the ballistic gelatine was that the wings of two of the anchors were turned over and thus the anchors basically lost their capability to withstand extraction forces. (table 1)

Concluding message
Our testing clearly revealed significant differences between different anchorage systems in their ability to keep implants in place. In combination with testing in especially designed ballistic gelatine, we present a good model for testing different anchorage systems in vitro and in vivo. However we still have to define the biomechanical requirements for keeping devices in place during the surgical procedures as well as in the early postoperative period.

References
1. Cosson M, Lambaudie E, Boukerrou M, Lobry P, Crépin G, Ego A. A biomechanical study of the strength of vaginal tissues. Results on 16 post-menopausal patients presenting with genital prolapse. Eur J Obstet Gynecol Reprod Biol. 2004 Feb 10;112(2):201-5.
2. M. Staat, E. Trenz, P. Lohmann, U. Klinge, R. Tabaza, R. Kirschner-Hermanns, New measurement to compare soft tissue anchoring systems in pelvic floor surgery J Biomed Mater Res B Appl Biomater. 2012 Jan 28. doi: 10.1002/jbm.b.32654. Epub ahead of print

Disclosures
Funding: German governement grant, ZIM (Zentrales Inovationsprogramm Mittelstand) KF 2553401AJ9 **Clinical Trial:** No **Subjects:** ANIMAL **Species:** Young domestic pigs, which underwent euthanasia. Their weight lay between 30 and 40 kg. **Ethics Committee:** Ethic committee of the University hospital RWTH Aachen

Table 1



Legend:
O= Promedon – Ophira
S= Bosten Scientific - Solyx SIS System
A= Bard - Avaulta plus
P= FEG – PelFix
PF= FEG - PelFix 5.4
S= Neomedic-surelift
TF= TFS
M= AMS – MiniArc