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WEIGHT OF POLYPROPYLENE MESH IS NOT THE ONLY PROPERTY DEFINING IN VIVO MESH BIOMECHANICS.

Hypothesis / aims of study

An excessive inflammatory reaction to an implant may cause dysfunction and local complications. Reducing the amount of foreign material and/or changing the structure of the implant may temper the host response; hence result in a different stiffness of the scar [1]. Though intuitively logic, very few studies have substantiated this claim. We investigated whether reduction of the density and composition of synthetic mesh has an impact on tensiometric properties and is not at the expense of strength of the repair. Altering the structure or weight also affects surgical handling properties, so this was taken as an additional outcome.

Study design, materials and methods

Four experimental lightweight meshes were tested: (1) polypropylene (7.6 g/m²; **PP-8**); (2) PP-8 but sandwiched between polyglecaprone and polydioxanone sheets (**PP-s**); (3) polypropylene knitted with polyglecaprone fibers (32.0 g/m²; **PP-32**) and (4) polyvinylidinefluoride (24.9 g/m²; **PVDF**). From each material, six samples (2.0 cm by 4.0 cm) were first subjected to tensiometry ("dry tests"). All materials were tested in the most elastic direction (500N Zwicki; Zwick GmbH & Co. KG, Ulm, Germany) with a 200N loadcell. After the preconditioning phase (10 cycles at 20% elongation), the samples were tested until failure (60 mm/min). The *maximal stress* (N/cm²) and *the strain at maximal stress* (%) were recorded. An area of low and high stiffness can be discriminated, referred to as the *comfort zone* and *stress zone* [2]. The *stiffness* (N/mm²) in both zones was determined using TestXpert II software (Zwick) as the best-fit linear regression between two manually chosen references in each zone of the recorded stress/strain curves. The transition between both zones can be described by the strain corresponding with the *intersection* of both regression lines (%). This intersection is a measure of the length of the comfort zone. We used 40 New-Zealand white rabbits, each of them undergoing creation of 4 full thickness 2.0cm abdominal wall incisions, sutured primarily with Monocryl 4/0 (Fig 1). Rabbits were then randomly assigned to covering of all 4 defects with one of the tested materials (5.0 by 4.0cm), with its most elastic axis parallel to the incision (Fig 1). This provided 10 rabbits for each material, two of them sacrificed after 7, 14, 30, 60 and 120 d. At sacrifice, the implant was first measured, following which an area, including the material and underlying host tissue, was harvested. The explant was further reduced to two pieces of 4.0 cm (longitudinal) by 2.0 cm (transversal) and used for immediate biomechanical testing as above, again in the most elastic direction prior to implantation. Abdominal wall explants of 3 unoperated animals served as controls.

Results

Dry measurements showed different properties of the used materials. Dry PP-s samples had the highest strength and stiffness in both comfort and stress zones, as well as the lowest elongation at maximal stress or at the intersection. The mechanical properties of PP-32 samples were at the other end of the spectrum. None of the tested materials had in dry conditions properties comparable to that of native tissue. During implantation, the surgical handling properties of PP-8 were experienced as uncomfortable, because the material wrinkled. There was no shrinkage of PP-32 at any time point. After implantation PP-8 and PVDF samples shrank by +/- 20% from 7 d onwards. PP-s implants shrank significantly more than any of the other materials (49% @120 d). This coincided with folding of the mesh occurring in 70 % of the implant sites; therefore this material will not further be considered and discussed. There were no differences in maximal stress between PP-8, PP-32 and PVDF. At the end of the experiment, PP-32 but not PP-8 neither PVDF were significantly stronger than control native tissue. Elongation at maximal stress was lower for PP-8 than PP-32 (60 and 120 d) or PVDF (60 d). All explants ruptured at lower elongation (average 146.23±18.79%) when compared to controls (239.89±33.89%) at any of the time points studied. In the comfort zone, only minimal differences between implants were recorded (Fig 2). In brief, the explants were stiffer than native tissue in the comfort zone. In the stress zone, there were no differences in stiffness between materials, and they tended or were stiffer than native tissue. At 120 d, also the transition between comfort and stress zone was at lower strain for the explants as compared to native tissue.

Interpretation of results

PP-s implants wrinkled in 70% of cases, making further testing not only impossible, but rendering the product not appropriate for clinical use. PP-32 did not shrink whereas PP-8 and PVDF shrank by 20%. Explants of all types were at least as strong as the abdominal wall of controls. There were no measurable differences in stiffness in both the comfort and stress zone at any time. All materials were less compliant and had a shorter comfort zone than control values of native tissue.

Concluding message

Reduction of the weight of synthetic meshes does not compromise strength. Shrinkage was remarkably different between tested products. One very light product (PP-8; 7.6 gm/m²) was difficult to handle surgically. Its reinforcement with resorbable sheets (PP-s) overcomes this problem, but after implantation it folds, which is obviously unacceptable. PP-32 (commercially known as Prolift Plus M, Johnson & Johnson, Norderstedt, Germany) is heavier, and the addition of resorbable polyglecaprone fibers make it easier to handle. In this experiment, PP-32 induced the least shrinkage. Further, the reduction of the density of PP-meshes neither its composition had an impact on tensiometric properties of the explants. In other words weight reduction was not at the expense of strength of the repair. At this stage, when measured in the most elastic direction, not a single material

tested resulted in visco-elastic properties that were comparable to that of native tissue. Thus it seems that additional changes are possible to obtain ultimately properties that are closer to physiologic values, i.e. of native tissues.

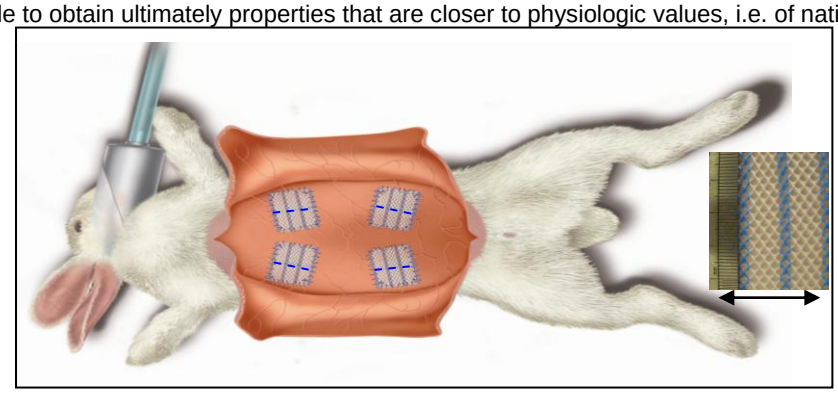

Figure 1: New Zealand White Rabbit abdominal wall incisional model. Full thickness incisions along the axis of the body (lines - - - -) were primarily closed and the repair was augmented with mesh. Insert: schematic representation of an implant; the arrows indicate the most elastic direction of the implant.

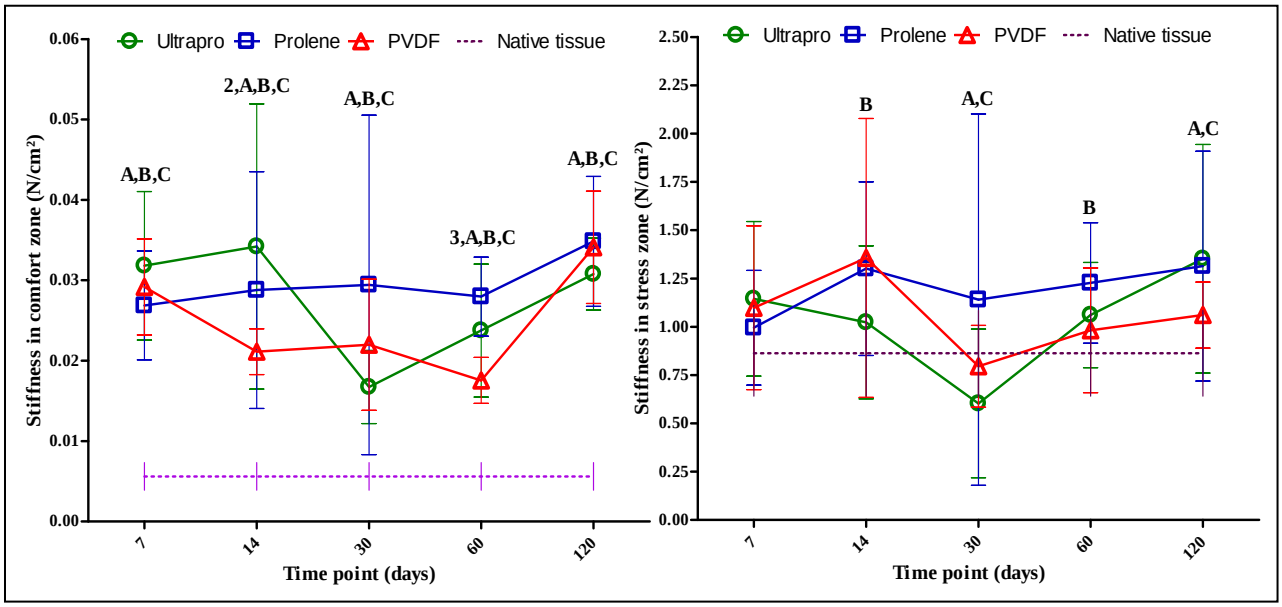

Figure 2: Biomechanical evaluation of implanted explants, compared to native abdominal wall tissue from control animals. Data are displayed as mean ± S.E.M. [1]P<0.05 for PP-8 compared to PP-32; [2]p<0.05 for PVDF compared to PP-32; [3]p<0.05 for PVDF compared to PP-8; [A]p<0.05 for PP-32 compared to control group; [B]p<0.05 for PP-8 compared to control group and [C]p<0.05 for PVDF compared to control group (Mann-Whitney U test).

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Is this a clinical trial?	**No**
What were the subjects in the study?	**ANIMAL**
Were guidelines for care and use of laboratory animals followed or ethical committee approval obtained?	**Yes**
Name of ethics committee	**Ethics Committee for Animal Experimentation of the Faculty of Medicine of the K.U.Leuven**