Biodegradable Soybean Oil-Based 3D printed mesh in Guided Bone Regeneration.

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INTRODUCTION AND PURPOSE

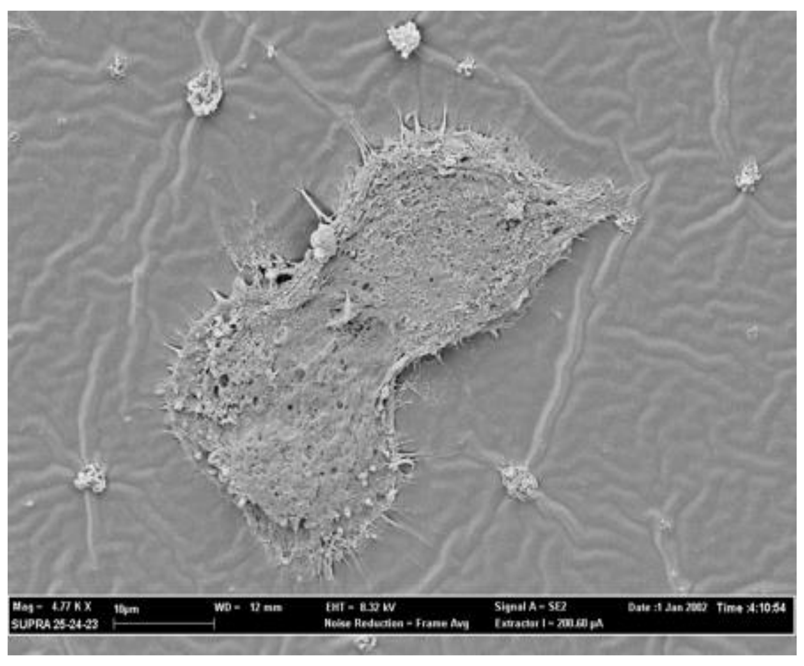
The application of a membrane to avoid non-osteogenic tissues from interfering with bone regeneration is the key factor of GBR. Both resorbable and non-resorbable membranes have been employed for vertical and/or horizontal critical-size defects. Among the non-resorbable membranes, customized Ti-meshes have been successfully used for GBR procedures regarding edentulous jaws.

Using Ti-meshes, many authors reported high complication rates: early or late exposures, infection of bone grafts and lacking bone volume due to pseudo-periosteum formation. Moreover, a second surgery is needed to remove the non-resorbable membranes, resulting in patient discomfort[1].

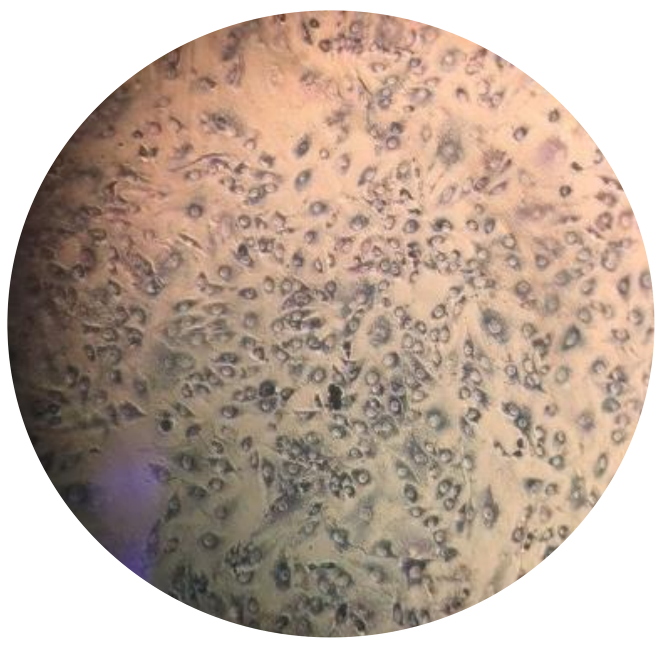
Thus emerges the need to develop a new biodegradable material, suitable for 3D printing[2], tailored on patients' bone defects. The aim of the study was the validation through biodegradability, citocompatibility and mechanical tests highlighting the qualities and the resistance of a 3D printed scaffold derived from Soybean Oil[3].

SOCIO-ECONOMICAL IMPACT

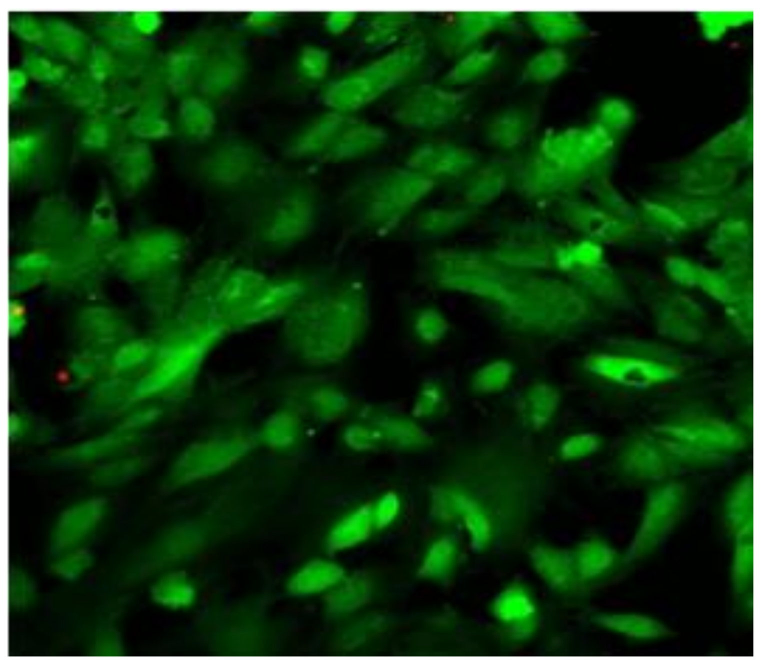
The reduction of production costs of the meshes and the in-office 3D printing possibility, compared to titanium, will allow the procedure to easily enter the market, providing a personalized medical approach.
This will result in an improved competitiveness and affordability of the product both for clinicians and patients.



3T3 Swiss fibroblast mitosis in contact with the scaffold.



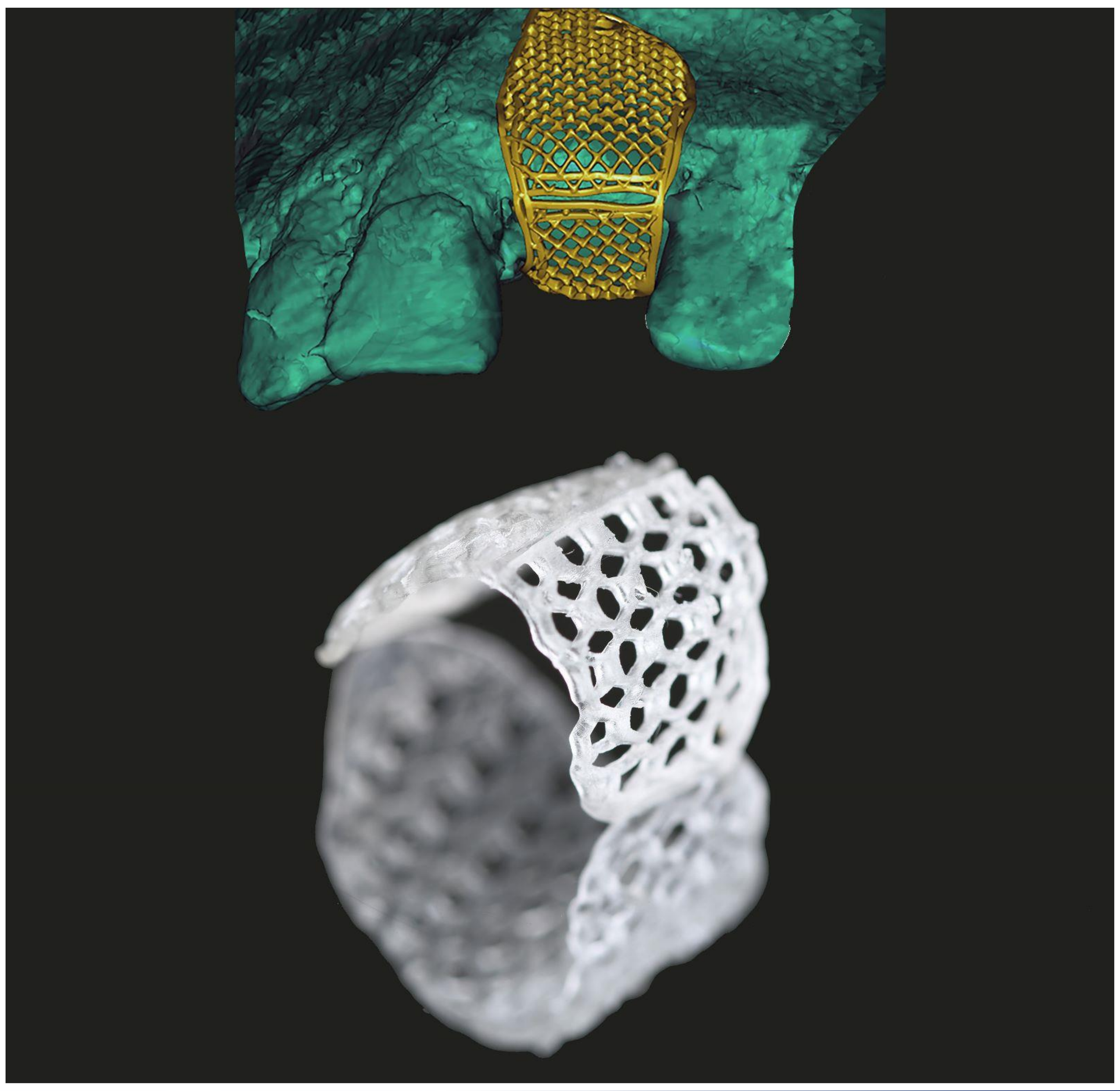
Sample surface after MTT assay: cell mortality is lower than 10%.



Low toxicity at the Confocal analysis: live cells in green and dead cells in red.

MATERIALS & METHODS

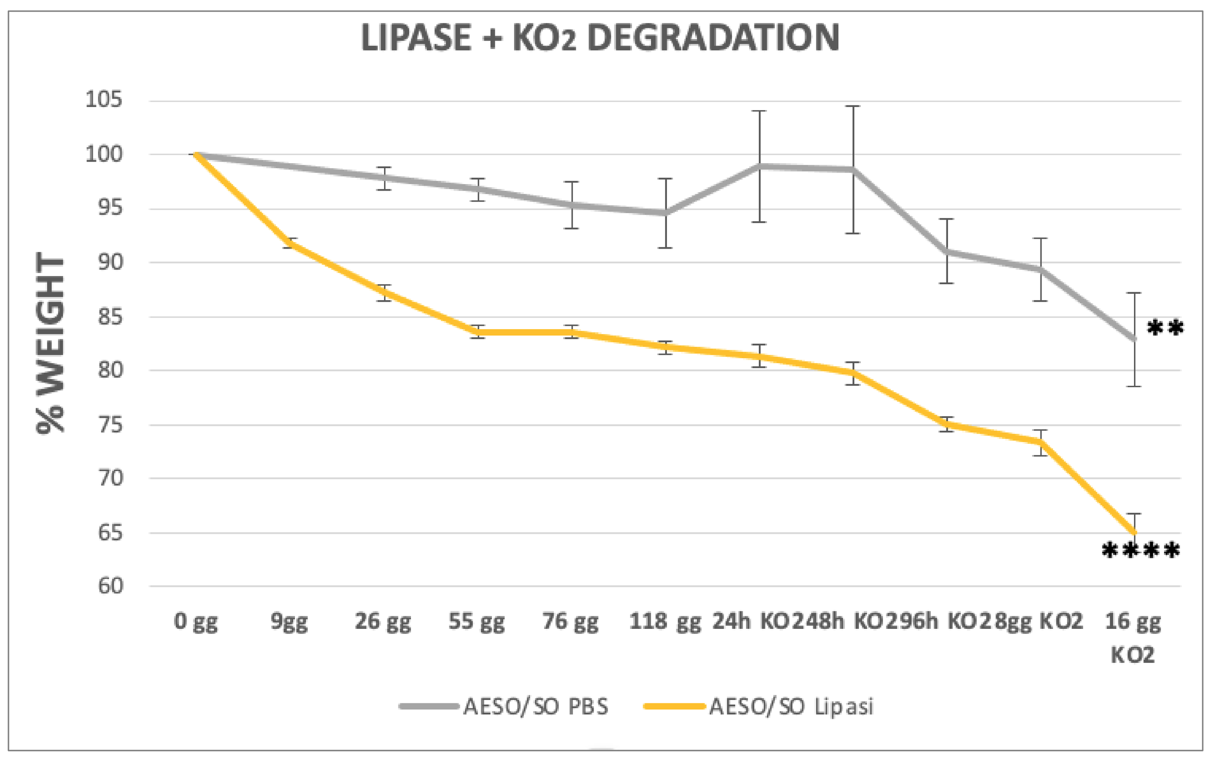
Soybean oil-based crosslinked polymer scaffold was prepared by DLP printing. Acrylated Epoxidized Soybean Oil (AESO) was mixed with Soybean Oil (SO) to obtain an ideal viscosity suitable for printing. AESO/SO was then employed as photocurable resin to form crosslinked polymer networks. In order to promote UV curing, BAPO 1% was added as a photoinitiator.
Degradation tests were carried out to evaluate the susceptibility of the material to hydrolytic (PBS 0.1M, pH 7.4), enzymatic (lipase from *Candida rugosa* 175 u/mL) and oxidative (KO^2 0.2M) degradation pathways.
Samples were subjected to MTT (direct contact test 24h), confocal microscopy (direct contact 48h) and SEM (indirect contact 24h), to assess cell viability, proliferation, and eventually cytotoxicity of the material.

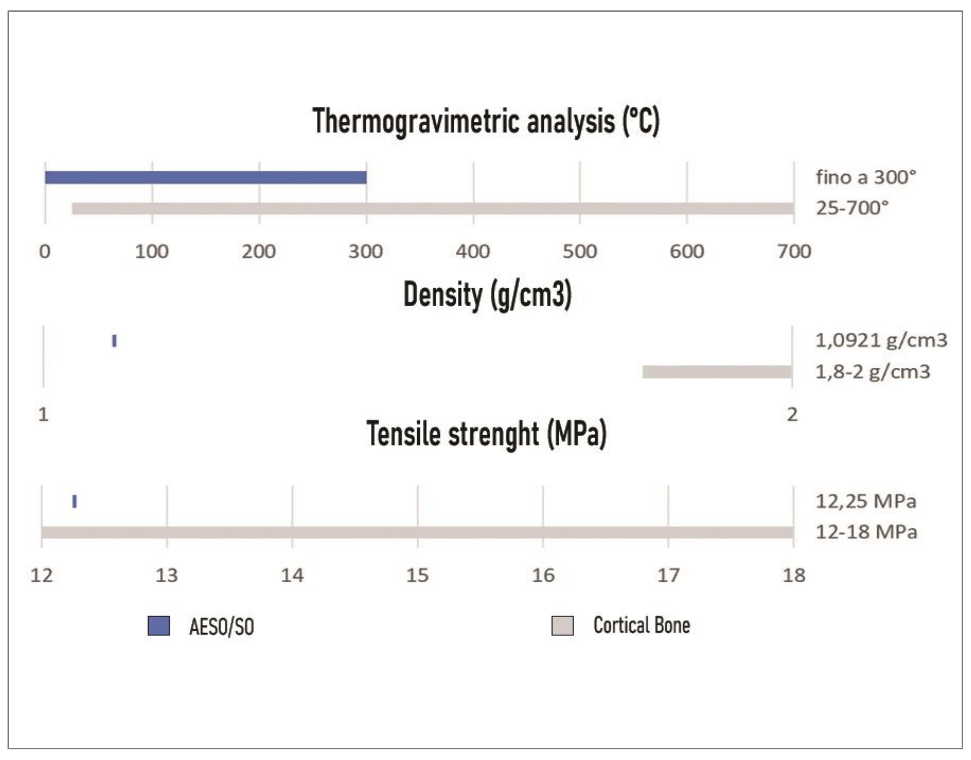


Regarding the biomaterial's validation, the following mechanical tests were done: viscosity of the liquid polymer was analyzed by a viscometer spindle at rotational speeds between 1.5 and 30 rpm; Ft-IR was used to study the crosslink of the material; optical microscopy was used to asses the morphology and thickness of the single layers; thermal analyses were conducted both with thermogravimetric analysis (TGA) to evaluate the thermal stability, and with differential scanning calorimetry (DSC) to assess glass transition temperature; density measurement according to Archimedes' principle; hardness was examined by Durometer test *Shore A;* uniaxial tensile tests were performed to observe the mechanical properties of the 3D printed material: i.e. tensile modulus (E), tensile strength (σmax), Strain at break (εmax).

RESULTS & CONCLUSION

AESO/SO polymer degraded about 18% of its initial weight after 118 days in phosphate buffer solution (pH 7.2) through the addition of lipase enzyme from *Candida rugosa*. Subsequently, the polymer was placed into a KO_2 solution for 16 days, losing an additional 17% of weight.
Degradation test in PBS demonstrated that AESO/SO was modified in vitro by both hydrolitic and oxidative degradation.
MTT assay showed that cells mortality was less then 10% after 24h. Therefore, AESO/SO is not to be considered a cytotoxic material.
The previous outcome is supported by confocal microscopy analyses, according to which cell mortality was about 6.5% after 48h.
SEM imaging confirmed that fibroblasts preserved their own morphology and their ability to adhere and proliferate once in contact with the samples.
The viscosity of the liquid polymer was found to be suitable for 3D printing and optical microscopy revealed a structure of the scaffold without porosity or any other anomalies.
Likewise Ft-IR analyses confirmed an appropriate polymerization due to the loss of the acrylate bond; both thermal tests proved that this material is highly stable without changes even when exposed to high temperatures.
The density of the 3D-printed biodegradable scaffolds made in this study were found to be compatible with human bone density.
At the same time, scaffolds made of AESO/SO are able to withstand a similar mechanical stress as that of the cortical bone. Thus, this material turns out to be an innovation in regenerative surgery, a low-cost product, and an easy-to-learn procedure. Further *in vivo* clinical studies will be necessary to fully complete this scientific study.





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