

LEMBI PRECARICATI IN DEVICE PER LA CONSERVAZIONE E L'UTILIZZO CHIRURGICO

Gianni Salvalaio, Alessandro Ruzza

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Simposio FBOV

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SCOPO

❑ Cornee PRE-tagliate

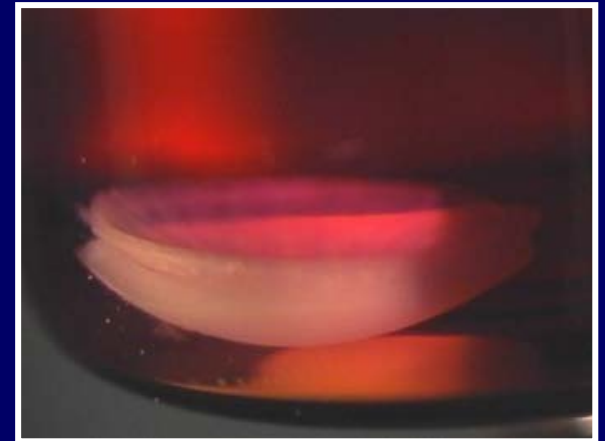
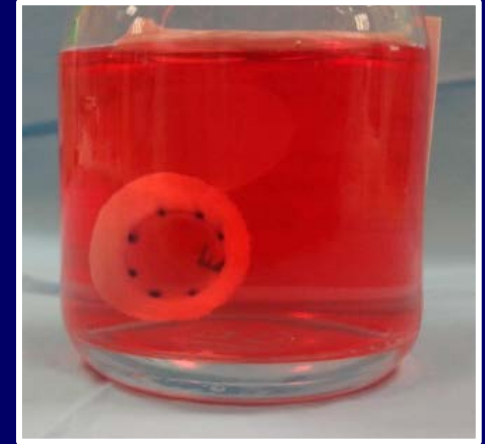
✓ 2014: 680

❑ Lenticoli POSTERIORI

■ Conservazione

- Ruzza et al. Banking of Donor Tissues for DSAEK.
Cornea Jrl. 2013 - 32(1):70-75

■ Trasporto (?)

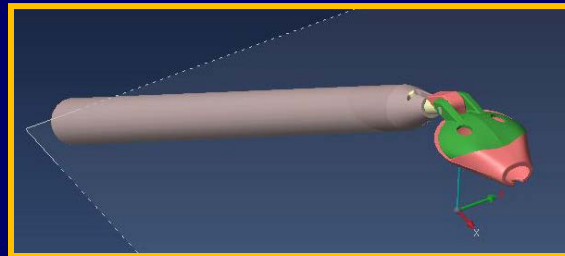
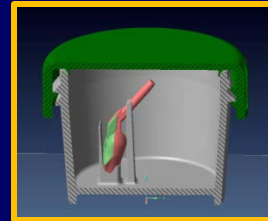
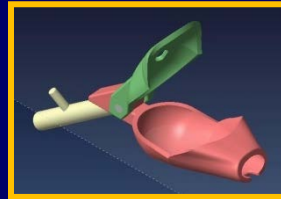
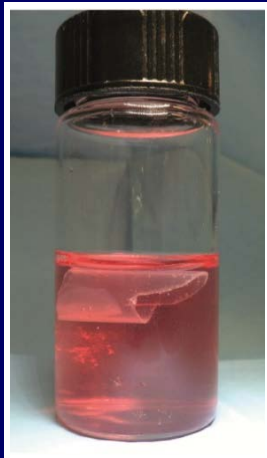
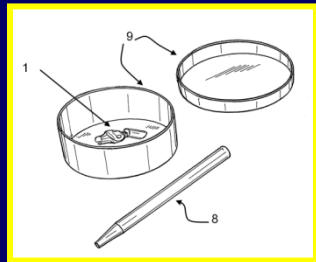
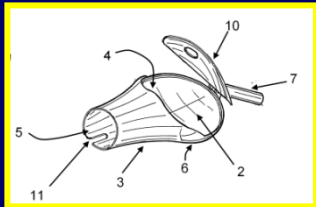


SVILUPPO DEL DEVICE

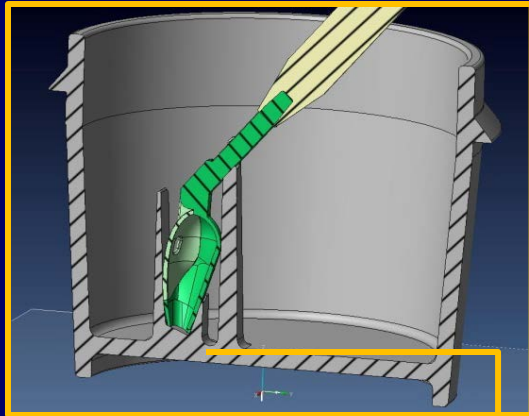
IDEA

MODEL

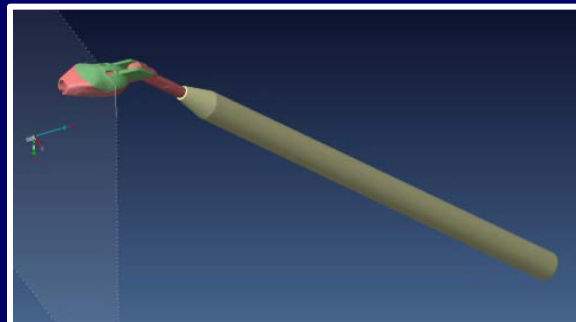
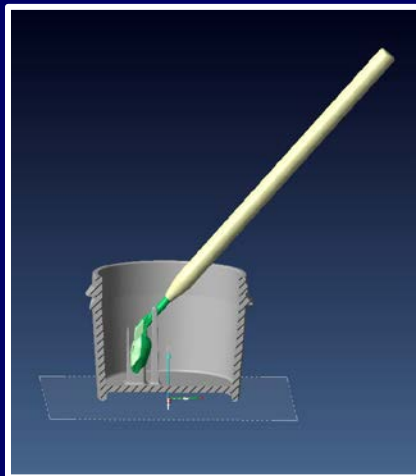
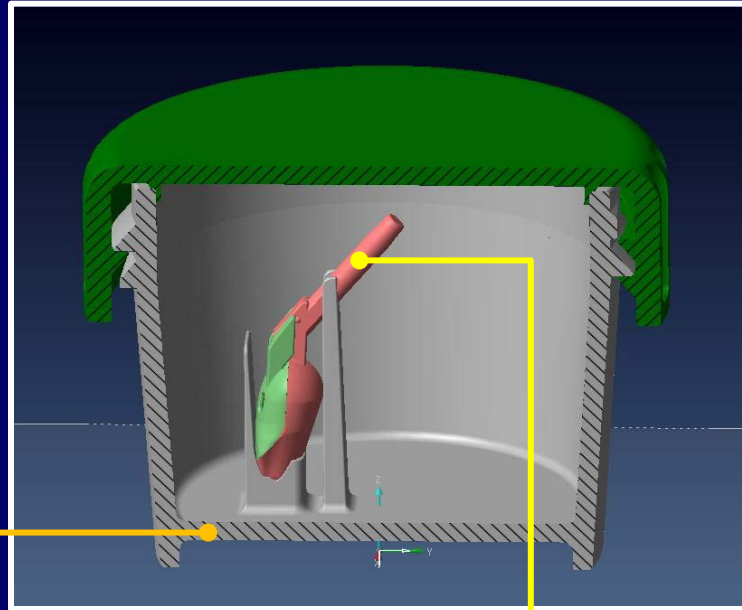
DESIGN



LAYOUT

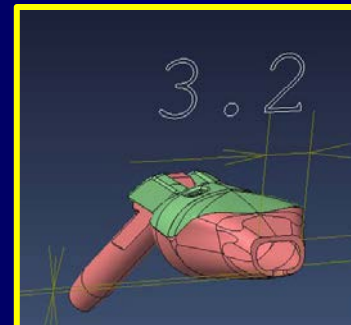
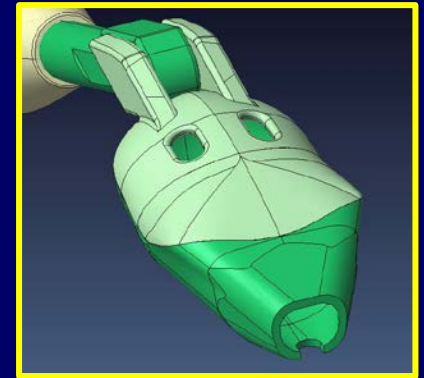
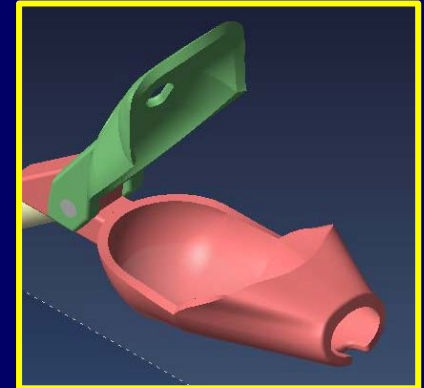


CONTENITORE

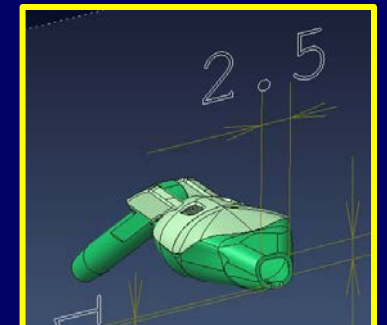


MANICO

GLIDES



PL Thickness > 120 μ m



PL Thickness $\leq$ 120 μ m

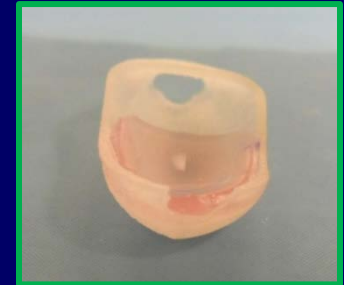
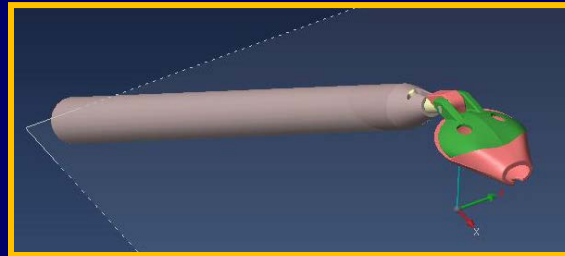
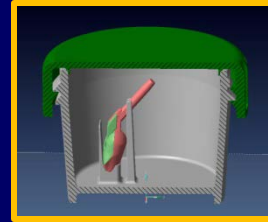
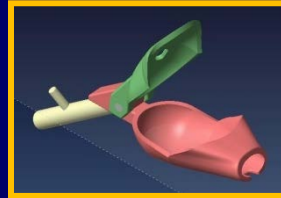
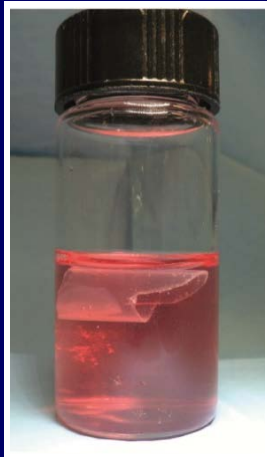
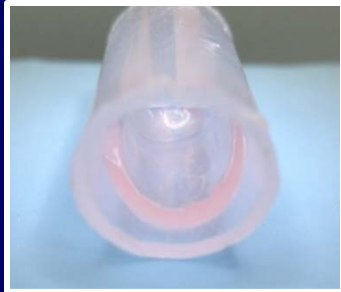
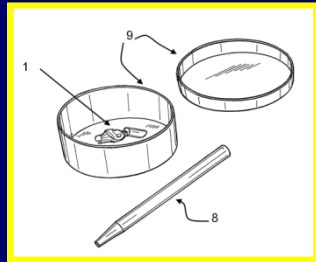
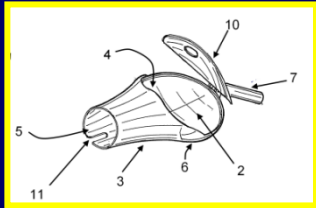
SVILUPPO DEL DEVICE

IDEA

MODEL

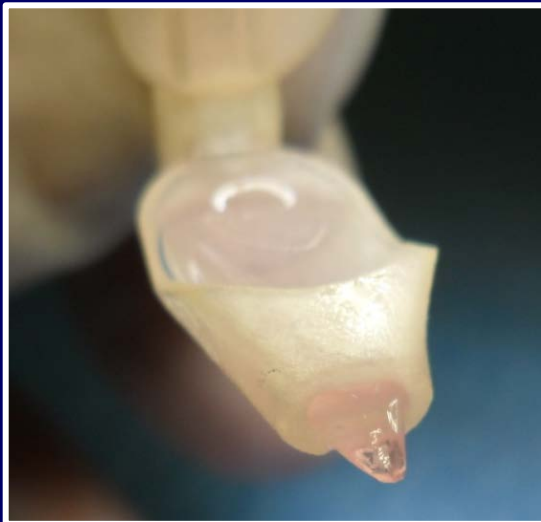
DESIGN

PROTOTYPE



PROTOTIPIZZAZIONE

- Stampa in 3D
- Funzionalità
- Materiale
 - *Class: USP-VI*
 - Testato *in vivo*
 - *Medical device*
- Test di validazione
 - Laboratorio
 - Chirurgica

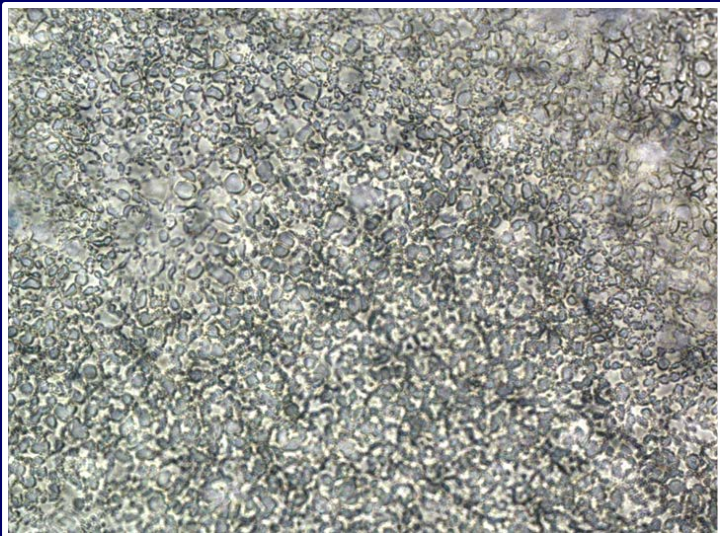


VALIDAZIONE IN LABORATORIO

PRE-CUT (n=17)			PRE-LOADED for 7 days in MEM+Dextran		
Density (cell/mm ²)	Mortality (%)	Thickness (μm)	Density (cell/mm ²)	Mortality (%)	Cell loss (cell/mm ²)
2153±407	0,01±0.05	130±45	2064±379	0,03±0,12	88±99

P=0,52

4%



100x – Sucrose and Trypan blue

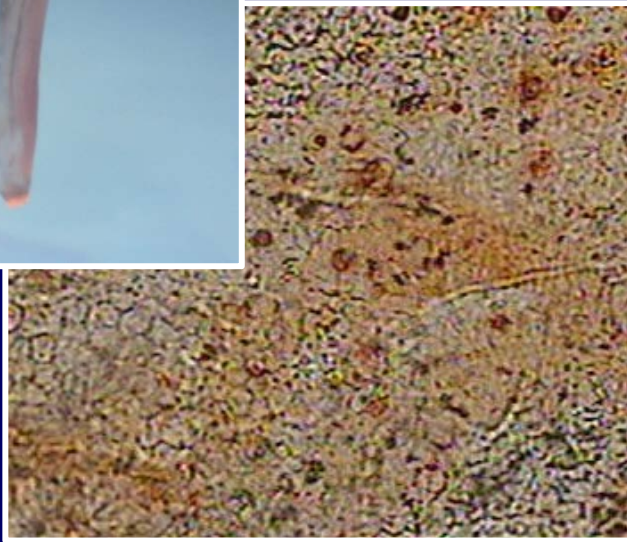
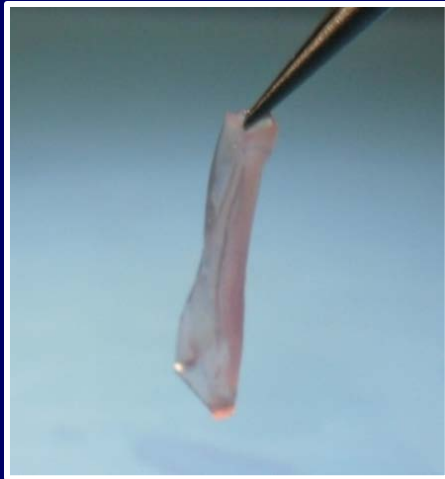
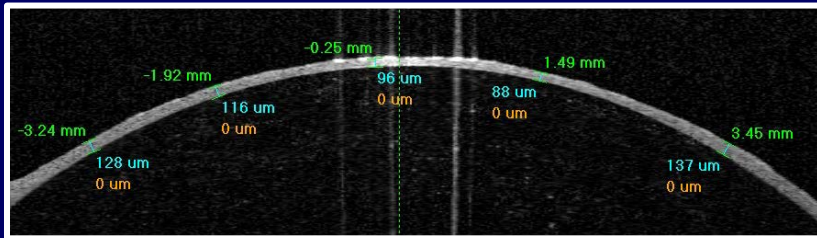


100x – Sucrose and Trypan blue

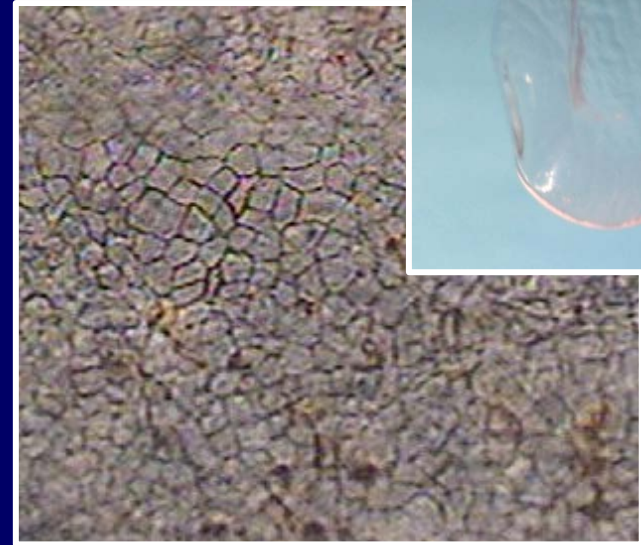
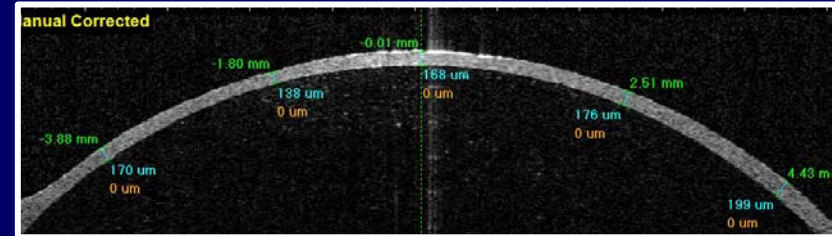
SUPPORTO STROMALE

SPESSORE

100 μm

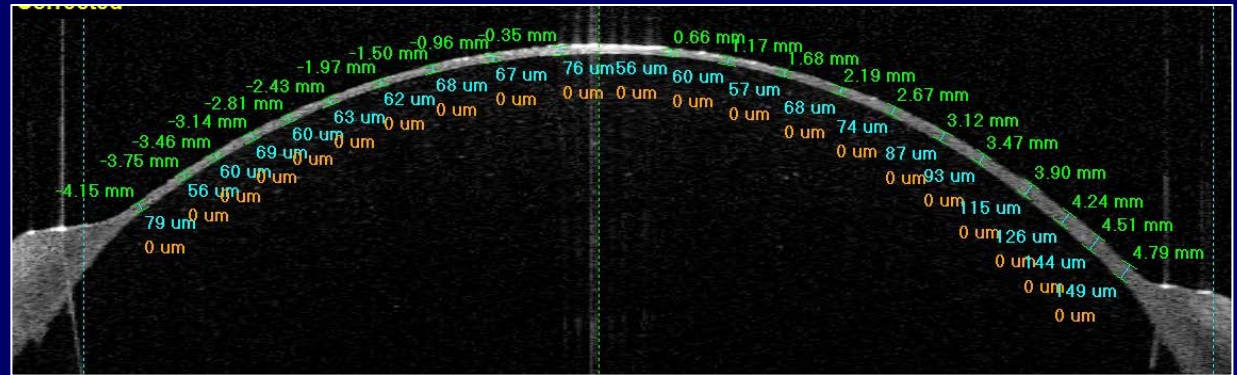


150 μm



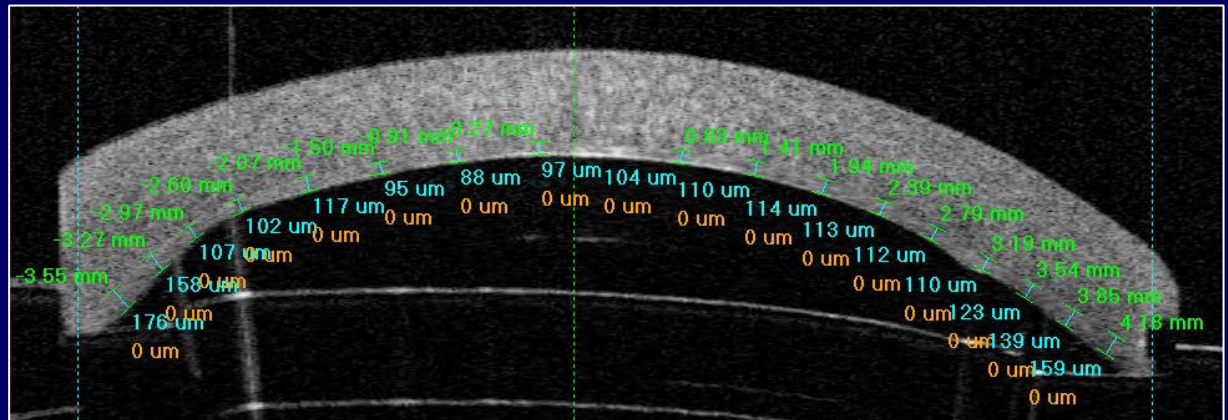
SUPPORTO STROMALE N. 10 lenticoli usati

POST-CUT



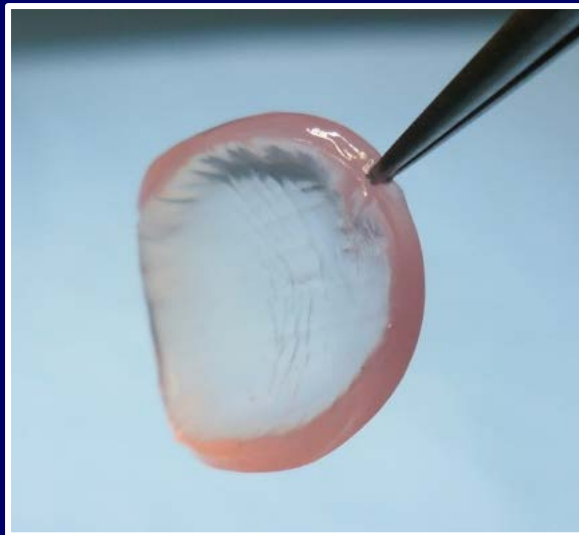
+ 18 ± 21 %

POST-Conservazione (7 giorni)



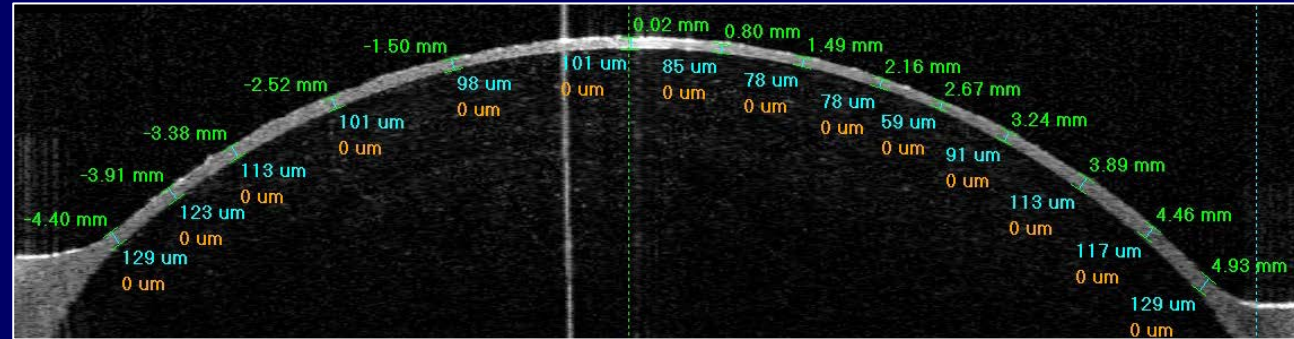
...difficoltà nella separazione dei lenticoli conservati con lo stroma anteriore.

LENTICOLO ANTERIORE



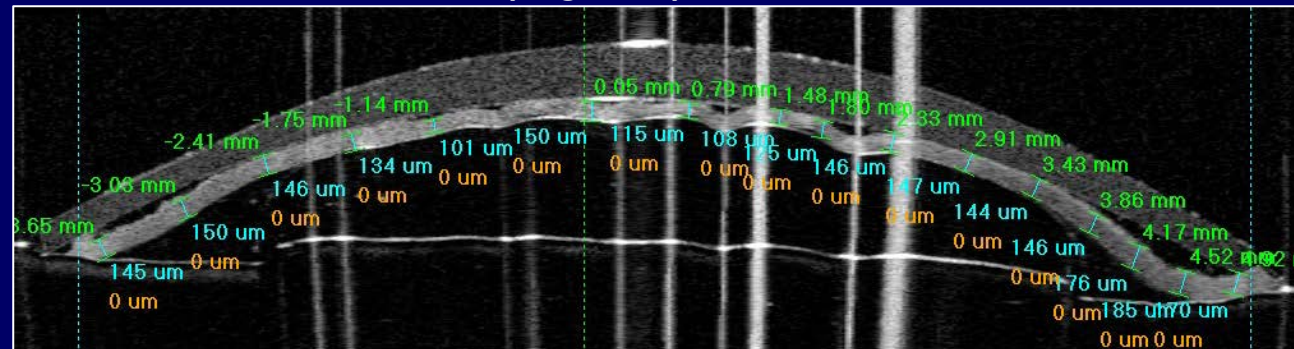
SUPPORTO STROMALE n. 10 lenticoli usati

POST-CUT



+ 42 ± 12 %

POST-Conservazione (7 giorni)



..con la lente a contatto c'è una maggiore scorrevolezza tra lenticolo e il suo supporto.

PREPARAZIONE LENTICOLO PRE-CARICATO

VALIDAZIONE CHIRURGICA

- 4 CHIRURGHI (Italia e Estero)
 - DSAEK e UT-DASEK (n=16)
 - Lembi con diversi diametri (8-8,75 mm)
 - Mini (2,5 mm) e Maxi (3,2 mm) Glide
 - Supporto: Lente a contatto e Lenticolo anteriore

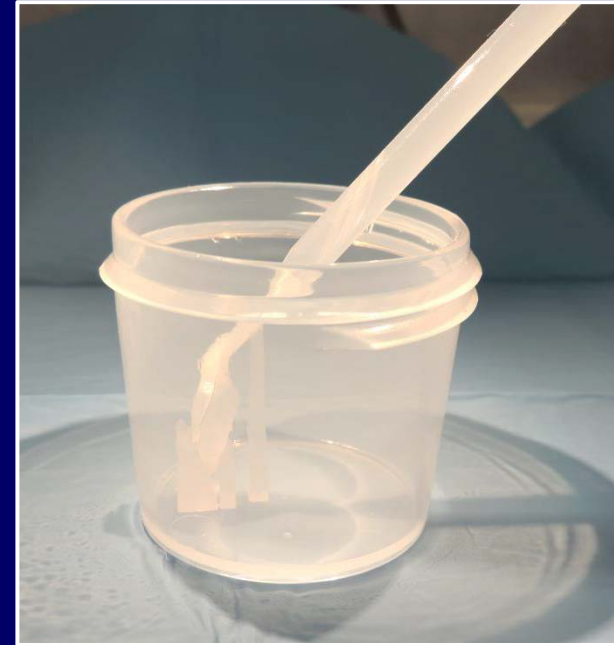
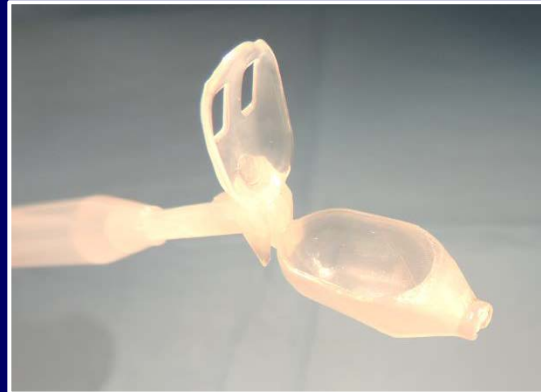
Esito della validazione chirurgica

➤ Questionario

- Valutazione sul device
 - Funzionalità, facilità di utilizzo, dimensioni, ecc.
- Dati POST-operatori
 - Spessore, visus, conta endoteliale

PRODUZIONE

- Preparazione stampi ad iniezione
- Plastica certificata
 - FDA e ISO 10993
- Stampaggio



CONCLUSIONI

- Il device facilita l'utilizzo dei lenticoli posteriori per DSAEK e UT-DSAEK, rendendo l'intervento più sicuro e veloce.
 - Brevetto USA e Europeo
 - Prototipizzazione
 - Validazione
 - Fase di produzione
 - Validazione finale