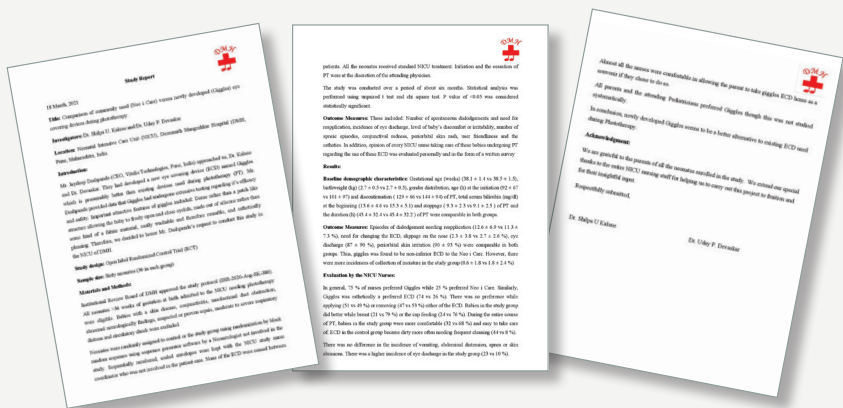


CLINICALLY PROVEN



REPORT: Randomised trial at Deenanath Mangeshkar Hospital, Pune, India

REPORT EXCERPTS

SCOPE

Study design: Open Label Randomized Control Trial (RCT)
Sample size: Sixty Neonates (30 in each group)
Materials and Methods: Institutional Review Board of DMH approved the study protocol (IHR-2020-Aug-SK-380). All neonates >36 weeks of gestation at birth admitted to the NICU needing phototherapy were eligible. Babies with a skin disease, conjunctivitis, nasolacrimal duct obstruction, abnormal neurologically findings, suspected or proven sepsis, moderate to severe respiratory distress and circulatory shock were excluded.

OPINION

Nurses: In general, 75 % of nurses preferred Giggles while 25 % preferred [redacted]. Similarly, Giggles was aesthetically a preferred ECD* (74 vs 26%). There was no preference while applying (51 vs 49 %) or removing (47 vs 53 %) either of the ECD. Babies in the study group did better while breast (21 vs 79 %) or the cup feeding (24 vs 76 %). **During the entire course of PT, babies in the study group were more comfortable (32 vs 68 %) and easy to take care of.** ECD in the control group became dirty more often needing frequent cleaning (44 vs 8 %). There was no difference in the incidence of vomiting, abdominal distension, apnea or skin abrasions. There was a higher incidence of eye discharge in the study group (23 vs 10 %).

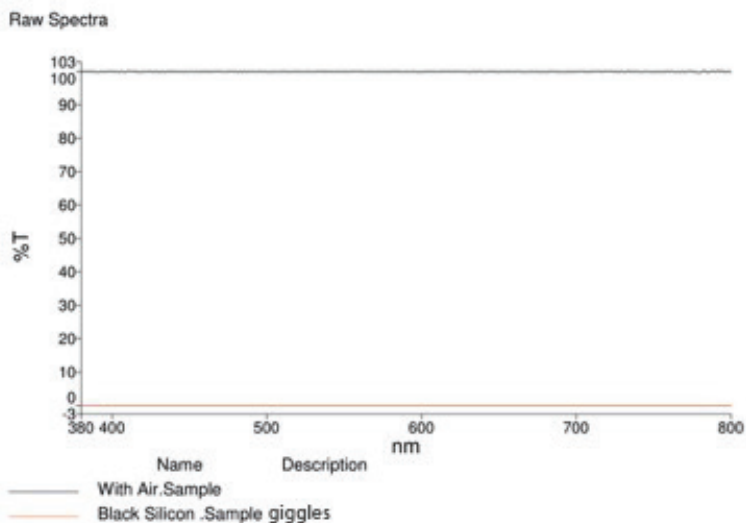
Pediatricians & Parents: All parents and the attending Pediatricians preferred Giggles though this was not studied systematically.

CONCLUSION

In conclusion, newly developed Giggles seems to be a better alternative to existing ECD used during Phototherapy.

*ECD: Eye Covering Device | Control Group: Existing ECD | Study Group: Giggles Neonatal Phototherapy Goggles

LAB TESTED



OPACITY TEST

Giggles shows **zero** transmittance of **blue-light**.

Successfully tested for blue-light opacity after five days of blue-light exposure.

Tested light ranges from 380 nm to 800 nm. This covers the blue-light phototherapy range. Giggles shows zero transmittance.

Test Item: Giggles-Phototherapy Goggle
Composition – FDA approved elastomer
Date of Receipt: 28 May 2020
Test Certificate Issue Date: 24 July 2020

Test Results

Study No.	Study Title	Test Item Name	Specification	Result
620/001	Skin irritation test in New Zealand White rabbits	Giggles-Phototherapy Goggle (Batch No: 001)	ISO 10993-10:2010 (E)	Non-Irritant
620/002	Skin Sensitization Test in Guinea Pigs (GPMT)	Giggles-Phototherapy Goggle (Batch No: 001)	ISO 10993-10:2010 (E)	Non-Sensitizer

Based on the test results, the test item “Giggles-Phototherapy Goggle” meets the requirement of above-mentioned ISO 10993 standard.

BIO-COMPATIBILITY TEST

Skin safety

Successfully tested for biocompatibility : skin irritation and skin sensitivity as per ISO-10993. Giggles is compatible for skin use.



THE ‘CARING’ GOGGLES



HIGH SAFETY • HIGH COMFORT
Special Bubble Design for Eye Opening



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Erandwane, Pune- 411004

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SETTING ‘NEW STANDARDS’ IN PHOTOTHERAPY EYE COVERS

FORCED EYE CLOSURE, A LONG-STANDING PROBLEM

Current ‘standard of care’ eye covers for neonatal phototherapy force neonates to shut their eyes during treatment. Forced eye closure comes with a series of problems in its wake. It is a known cause of irritation and crankiness as well as certain corneal infections in babies. This impacts the overall experience of phototherapy adversely.

SOLUTION CONCEPTUALISED BY A NEONATOLOGIST

The solution to the problem of ‘forced eye closure’ comes from a neonatologist with four decades of experience. He envisaged ‘an eye opening’ neonatal phototherapy eye cover. He added further value to this solution by visualising a robust non-fabric eye cover to ensure better hygiene and a good fit to prevent slipping of eye gear. Designed to the neonatologist’s specifications, Giggles Neonatal Phototherapy Goggles is replete with several features that enhance the neonate’s safety, hygiene and comfort.

GIGGLES: A LAB TESTED, CLINICALLY PROVEN SOLUTION

Giggles Neonatal Phototherapy Goggles has set in new standards for eye protection. It eliminates forced eye closure, resulting in a happier treatment period for the neonate. It enhances neonate’s comfort, safety and hygiene with novel design features and the use of FDA approved silicone in place of fabric or fabric akin material. It is lab tested for skin safety (bio-compatibility) and opacity. It has undergone randomised trial at the Deenanath Mangeshkar Hospital, Pune, which is a reputed and premier hospital in Western India.

HOSPITALS USING GIGGLES

- Launched in May 2021, Giggles is already in use at:
- Deenanath Mangeshkar Hospital, Pune
 - Sahyadri Hospital, Pune
 - Yash IVF, Pune
 - Mickey Mouse Hospital, Nasik
 - Varad NICU and Child Care Centre, Sholapur



Over 14 million babies undergo blue-light phototherapy globally every year.

DESIGNED FOR SAFETY & COMFORT



GIGGLES, THE CARING GOGGLES

Giggles cares for the neonate’s health, safety, hygiene, comfort and happiness through its unique features and skin-safe material.

FEATURES



EYE OPENING FACILITY

Special bubble design of Giggles provides comfortable space for eye opening. This is a unique feature introduced to enhance comfort and eliminate irritation and eye infections caused by forced eye closure.



BLUE-LIGHT SHIELD

Giggles is laboratory tested to ensure total opacity for a period of 5 days of exposure to blue-light; i.e. for the entire period of phototherapy of a baby. (5 days is usually the maximum period of phototherapy session of a baby.)



SKIN FRIENDLY MATERIAL

Giggles is made from soft, light weight FDA approved silicone. The silicone is tested for biocompatibility (skin friendliness) -ISO 10993. It is hypo allergic and non-irritant to the skin.



ADAPTIVE DESIGN

Giggles adapts to the facial contours of the neonate giving it a very soft and comfortable resting around the eyes. This also ensures that there are no passages left for blue-light entry around the eyes.



FIRM & COMFORTABLE FIT

The headband of Giggles has size adjustments based on head circumference of the baby. This ensures a perfect fit for any head size, which prevents slipping of Giggles to the nose. Slipping of eye gears is a common problem, and can, at times, lead to apnea due to nasal blockage.



HYGIENIC FOR REPEAT USE

Giggles can be used multiple times for the same baby. It is safe for use for full five days of phototherapy. Cleaning is simple. It can be cleaned with soap and water before a repeat use.