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Post-marketing surveillance of CustomBone™ implanted in children under 7 years old

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Introduction: CustomBone™ is a cranial biomimetic ceramic implant. Though contraindicated under 7 years old, it is used under this age threshold in daily practice. Finceramica performed a surveillance study to investigate the outcome in this age group.

Methods: 29 children under 7 years old received CustomBone™ from July 2006 to November 2012 in 17 international hospitals. Data of 25 children, 12 boys and 13 girls (age 3-7y), are available at least one year after implant.

Results: Sites of the cranial defect were frontal or parietal (20% each), parieto-temporal (16%), fronto-parietal or fronto-parieto-temporal or occipital (12% each), fronto-temporal (8%). Etiologies were trauma (64%), malformation (28%), tumor of the bone/skin and other (4% each). Reasons to use CustomBone™ were decompressive craniectomy for brain injury (52%), resorption of autologous bone flap (20%), malformation (12%), failure of other cranioplasty (8%), comminuted fracture or tumor of the bone/skin (4% each). Rupture of the implant occurred in one of the 29 children during the implant (3.44%); cranioplasty in this patient was successfully completed with the back-up device. Four adverse events were registered during the follow-up period consisting of 2 cases of fracture and 2 of infection, requiring in all cases the removal of the device.

Conclusion: Post-marketing surveillance revealed a 16% (4/25) failure rate in this age group. This rate is higher than reported in adults and children over 7 years old (mean 3.8%, ranging 0-8%). However, CustomBone™ may be considered a valid option under 7 years old since other materials are burdened by more significant rates of complications. Limits to its use in children younger than 7 years old remain the adequate thickness of bone edges of the defect and the size as well as the complexity of the defect. Thus, indication to CustomBone™ beyond age limit should be carefully evaluated by the surgeon on a case by case basis.

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