JABFM
eISSN 2280-8000

J Appl Biomater Funct Mater 2017; 15(4): e356-e361
DOI: 10.5301/jabfm.5000375

ORIGINAL RESEARCH ARTICLE

Load-bearing capacity and fracture behavior of glass fiber-reinforced composite cranioplasty implants

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ABSTRACT

Background: Glass fiber-reinforced composites (FRCs) have been adapted for routine clinical use in various dental restorations and are presently also used in cranial implants. The aim of this study was to measure the load-bearing capacity and failure type of glass FRC implants during static loading with and without interconnective bars and with different fixation modes.

Methods: Load-bearing capacities of 2 types of FRC implants with 4 different fixation modes were experimentally tested. The sandwich-like FRC implants were made of 2 sheets of woven FRC fabric, which consisted of silanized, woven E-glass fiber fabrics impregnated in BisGMA-TEGDMA monomer resin matrix. The space between the outer and inner surfaces was filled with glass particles. All FRC implants were tested up to a 10-mm deflection with load-bearing capacity determined at 6-mm deflection. The experimental groups were compared using non-parametric Kruskal-Wallis analysis with Steel-Dwass post hoc test.

Results: FRC implants underwent elastic and plastic deformation until 6-mm deflection. The loading test did not demonstrate any protrusions of glass fibers or cut fiber even at 10-mm deflection. An elastic and plastic deformation of the implant occurred until the FRC sheets were separated from each other. In the cases of the free-standing setup (no fixation) and the fixation with 6 screws, the FRC implants with 2 interconnective bars showed a significantly higher load-bearing capacity compared with the implant without interconnective bars.

Conclusions: FRC implants used in this study showed a load-bearing capacity which may provide protection for the brain after cranial bone defect reconstruction.

Keywords: Cranioplasty, Deflection, Failure mode, Fiber-reinforced composite, Fracture, FRC, Load-bearing

Introduction

In dentistry and medicine, fiber reinforcing of polymer matrices with different fibers (aramid, carbon/graphite, glass and polyethylene) started in the early 1960s, and since then, several fiber-reinforced materials have emerged (1-3) with both load-bearing and non-load-bearing clinical applications.

Glass fiber-reinforced composites (FRCs) have been adapted to routine clinical use in various dental restorations and are presently also used in cranial implants (4, 5). Attempts have been made to develop an application feasible for orthopedic use (6, 7).

Accepted: July 6, 2017
Published online: August 11, 2017

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In clinical studies investigating the reconstruction of skull bone defects, we have previously reported a successful application of FRC for use as a cranioplasty material (8-11). Cyclic loading of the masticatory system or the weight of the body during physical exercise presents different requirements – namely, fatigue strength for the material's mechanical properties, compared with non-load-bearing applications where a static load-bearing capacity is typically required. In cranioplasty implants, the function of the implant is to provide protection to the brain by offering anatomically shaped support for the soft tissues and by providing a microenvironment for bone regeneration. Structurally, bones of the cranium are sandwich structures where thin inner and outer layers of compact bone are bound together by cancellous bone. A structure of this kind is effective to resist damage by external forces. Development of FRC cranioplasty implants has led to a sandwich structure of resin-impregnated fiber glass sheets, which imitate the structure of compact bone. The free space between the sheets is normally loaded with loose particles of bioactive glass, which provide a microenvironment for bone growth. The particles of bioactive glass do not bind the sheets

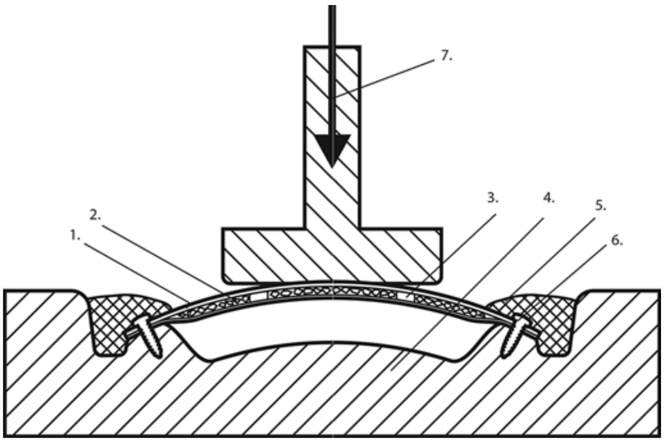

Fig. 1 - The test setup: 1 = outer glass fiber-reinforced composite (FRC) sheet, 2 = glass particles, 3 = interconnective bar, 4 = custom-made test jig, 5 = dental stone simulating bone growth, 6 = titanium fixation screw, 7 = direction of the load.

TABLE I - Experimental groups for glass fiber-reinforced composite (FRC) implants

Experimental group	Type of fixation to the testing jig	Interconnective bars
1	Free-standing, no fixation	No
2	Free-standing, no fixation	Yes
3	6 screws	No
4	6 screws	Yes
5	6 screws + dental stone rim	No
6	6 screws + dental stone rim	Yes
7	6 screws + dental stone impregnation	No
8	6 screws + dental stone impregnation	Yes

TABLE II - Materials used in the study

Brand	Manufacturer	Lot.
BisGMA	Esschem Europe ltd.	751-42
TEGDMA	Esschem Europe ltd.	766-34-03
Camphorquinone	Esschem Europe ltd.	688-50
DMAEMA	Sigma-Aldrich Co. LLC	BCBF8391V
120 g/m^2 woven glass fiber fabric	Ahlstrom Glassfibre Oy	1100090947
250 g/m^2 woven glass fiber fabric	Ahlstrom Glassfibre Oy	0691140840
2,400 tex glass fiber roving	Ahlstrom Glassfibre Oy	07490101
Glass granules	Suomen lasinjalostus Oy	NA

BisGMA = bisphenol A glycidyl methacrylate; DMAEMA = N,N-dimethylaminoethyl methacrylate; TEGDMA = triethylene glycol dimethacrylate.

together, and therefore additional fiber reinforcements, also called interconnective bars, are added to the implants.

The influence of the interconnective bars and of the marginal fixation of the implant, on the load-bearing capacity of the implant structure remains unknown. Also, what kind of fracture mode exists in a catastrophic failure situation of the glass FRC cranial implant remains uncertain.

Here, we evaluated, firstly, the load-bearing capacity of the implant, and secondly, the type of failure presented by sandwich-type glass FRC implants bearing the mechanical loading with and without interconnective bars and with different fixation modes. The selected FRC structures simulated the FRC cranioplasty implants currently in clinical use. Our null hypothesis was that there would be no significant difference in load values among the groups of FRC implants.

Materials and methods

Two types of sandwich-like glass FRC implants were used in this study. These consisted of implants with and without FRC interconnective bars. The experimental setup for testing the load-bearing capacities of the 2 types of implants simulated the fixation of an actual glass FRC cranioplasty implant at the different stages of healing – i.e., primary fixation by titanium screws only, and later bone growth into the pores of the FRC implant. The experiment setup allowed the assessment of the effects of the reinforcing interconnective bars and different types of fixation of the glass FRC implant to the testing jig (Fig. 1). In total, there were 8 experimental groups. Each group contained 8 (n = 8) glass FRC implants. The experimental groups are listed in Table I.

Preparation of the glass FRC implants

The shell of the sandwich-like FRC implants was made of 2 sheets of woven FRC fabric. The materials used in the study are listed in Table II. The FRC implants were manufactured using 2 different types of silanized, woven E-glass fiber fabrics (120 g/m^2 and 250 g/m^2, respectively), which were impregnated with a monomer resin of 65:35 wt% bisphenol A glycidyl methacrylate (BisGMA)–triethylene glycol dimethacrylate (TEGDMA), including a photosensitive initiator system containing 0.8% camphorquinone and 0.8% N,N-dimethylaminoethyl methacrylate (DMAEMA). Resin impregnation left mesh-like holes in the implant surface, which in clinical conditions would allow blood absorption into the implant to occur.

One sheet of the FRC fabric was used on the outer surface of the FRC implant and the other sheet on the inner surface. The space between the outer and inner surfaces was filled with particles of glass (particle size: 500-1,250 µm. The glass particles simulated particles of bioactive glass with the same particle size in clinical implants. The total weight fraction of glass particles in the FRC implant was 35 wt%.

The FRC implants were prepared with and without interconnective FRC bars of continuous unidirectional E-glass fiber rovings. When 2 parallel interconnective FRC bars were added to the core of the implant, the space filled with glass granules was divided into 3 compartments. In experimental groups 2, 4, 6 and 8, 2 parallel interconnective bars (length 40 mm) were used to reinforce the FRC implants. The interconnective bars were made of a unidirectional silanized and BisGMA-TEGDMA monomer resin impregnated with E-glass fiber rovings. The distance between the 2 parallel interconnective bars was 42 mm. In experimental groups 1, 3, 5 and 7, the FRC implants were not reinforced with interconnective bars. The 2 sheets of woven FRC fabric were joined together and sealed in an area that stretched 8 mm from the edge of the FRC implant. Screw holes were made in this area alongside the contour of the edge of the FRC implant.

The design of the FRC implant, simulating a standard-sized implant (Glace, Temporal Large; Skulle Implants Corp., Turku, Finland), is available for clinical use (Fig. 1). The final thickness of the slightly convex sandwich-like FRC implants was 0.8 mm at the margins where the outer and inner implant surface joined together and 2.5 mm in the areas containing glass particles and interconnective bars. The geometry and thickness of the FRC implant was standardized by using a precisely machined mold during the fabrication. The implant size was 112 × 67 mm with 12 fixation holes (Ø 1.5 mm). The distance of the fixation holes from the edge of the implant was 5 mm, and the distance between holes was 25 mm. Alternate fixation holes were used during screw fixation with 6 screws.

The resin matrix was photocured in a specially constructed curing device with a light source that emitted 467-nm wavelength light.

Mechanical testing of the FRC implants

A non-standard bending test was performed. The test setup is illustrated in Figure 2. Computer-aided design (CAD) software (Rhinoceros 4; Robert McNeel & Associates, USA) was used to create the 3-dimensional geometry of the FRC implant and to design the supporting jig for the mechanical test. The supporting jig was then milled from a solid block of aluminum under computer control.

The FRC implants were stored in water at +37˚C for 1 week before the mechanical test. Water sorption is known to plasticize the resin matrix and cause a reduction of ca. 20% in E-glass FRCs (12, 13).

The FRC implants in groups 3 and 4 were fixed to the support jig with 6 titanium screws (4 mm, Glace; Skulle Implants Corp., Turku, Finland), using every second screw hole. A screwdriver with a 4-mm tip (Glace; Skulle Implants Corp.) was used. In groups 5 and 6, in addition to screw fixation, a dental stone (improved type 4 dental stone; GC Fujirock, GC Europe N.V., Leuven, Belgium) was cast with a vibrator (VIB 24; Silfradent, S. Sofia, Italy) on the 15-mm rim of the implant. A powder to liquid ratio of 5:1 was used as instructed by the manufacturer. In groups 7 and 8, screw fixation was used, and the FRC implants were impregnated with dental stone (see Tab. I for details). Dental stone was used to simulate properties of bone in contact with the implant, as described in earlier publications (14, 15).

The FRC implants were statically loaded at a constant speed of 1 mm/min in air. The load was applied at the central area of the implant where there were no interconnective bars, and thus the initial load was focused on the outer FRC sheet only. The plunger was rectangular in shape with dimensions of 17 × 55 mm (see Fig. 2 for details). A universal mechanical testing machine (LR30K; Lloyd Instruments Ltd., Fareham, UK) was employed. A load cell with a capacity of 2,500 N was chosen based on preliminary test values. The

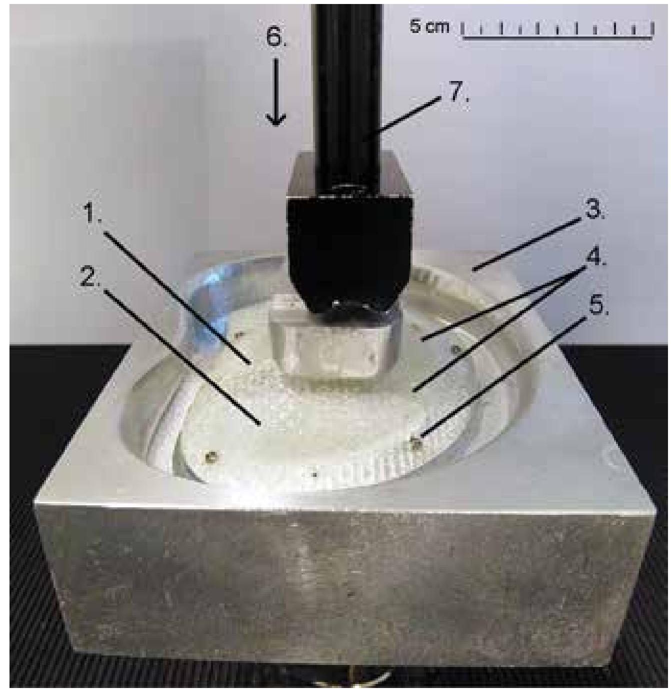

Fig. 2 - The glass fiber-reinforced composite (FRC) implants were supported by an aluminum jig. Four different fixation methods were used. A universal mechanical testing machine was used to apply static loading to implants at a speed of 1 mm/min. Flexural strength values were digitally recorded. Assessment of the fracture behavior of implants was based on visual and manual inspection. 1 = outer FRC sheet, 2 = glass particles, 3 = custom-made test jig, 4 = interconnective bars, 5 = a titanium fixation screw, 6 = direction of the load, 7 = the plunger.

load-bearing values were recorded with Nexygen Plus software (Lloyd Instruments Ltd.). All FRC implants were tested up to 10-mm magnitude of deflection, but the load-bearing capacity – i.e., load required for visual catastrophic failure – was determined at 6-mm magnitude of deflection. The load was released after the loading test.

Statistical analysis

Descriptive statistics were calculated including means, standard deviation, medians and minimum and maximum values. The Shapiro-Wilk test was used to evaluate the normality of the distributions of the data in the experimental groups. To compare the experimental groups, a nonparametric Kruskal-Wallis analysis was performed with Steel-Dwass post hoc test. The confidence level was set at 95% and the level of statistical significance was predefined at a p value <0.05. All analyses were performed using JMP for Mac, version 10.0 (SAS Institute Inc., Cary, NC, USA).

Results

Results of the mechanical tests are presented in Table III and in Figure 3. Typical load-deflection curves are presented in Figure 4 for deflection up to 10 mm. The Shapiro-Wilk test revealed that the experimental data did not conform to a normal

TABLE III - Descriptive statistics for maximum load-bearing capacities (in newtons) at 6-mm deflection

Group	Mean	SD	Minimum	Median	Maximum	Post hoc*
1	47.77	8.84	28.29	49.41	56.49	A
2	67.82	7.98	59.68	65.50	79.83	B
3	78.59	11.96	62.99	76.13	100.1	B
4	175.39	100.81	91.59	147.01	410.76	C
5	157.50	107.28	87.87	120.45	397.76	C
6	269.91	215.16	115.18	171.68	649.05	C
7	175.39	100.81	91.59	147.01	410.76	C
8	116.57	68.08	22.20	112.7	213.41	ABC

SD = standard deviation.
* Post hoc grouping: groups with a different letter were significantly different.

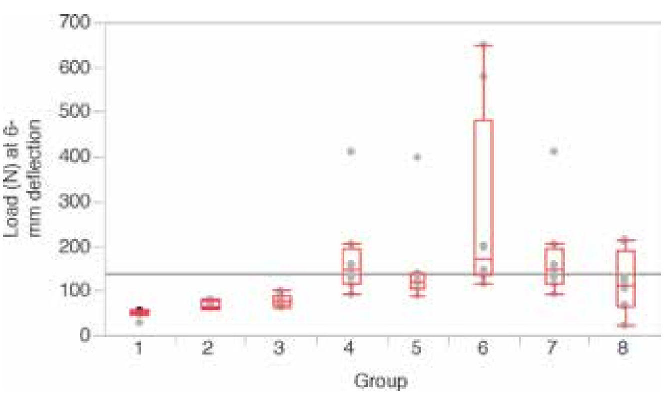

Fig. 3 - Statistical analysis of load data at 6 mm deflection of the glass fiber-reinforced composite (FRC) implants. Values in boxes are means with 95% confidence intervals; whiskers from minimum to maximum.

distribution and therefore nonparametric analysis methods were used. The statistical analysis revealed that, for the fixations not involving dental stone, the FRC implants reinforced with the interconnective bars were associated with significantly higher loads suffering failure, compared with implants without the interconnective bars. When the dental stone was employed (groups 5, 6, 7 and 8), the reinforcing effect of interconnective bars was no longer detectable. The groups with screw fixation only had significantly higher load values compared with the groups without any fixation. No significant differences were found between groups with fixations involving dental stone.

In groups 1 through 6, the FRC implants underwent elastic and plastic deformation until 6-mm deflection. Breakage of the implant occurred by separation of FRC sheets that were joined together at the boundary of the implant and the interconnective bars. A loosening of the fixation was observed with higher magnitudes of deflection. Glass fibers were not cut or exposed during loading up to 10 mm magnitude of deflection, and once the load was released, the implants returned to almost their original shape.

Discussion

This study demonstrated the load-bearing capacity of glass FRC implants, which are used in cranial reconstructive surgery. The implants that were used in this study had a structure and material composition corresponding to those used clinically for use as patient-specific implants or as standard-shaped implants. However, not all of the parameters of the specimens used in this study were consistent with the implants in clinical use. In a clinical setting, the geometrical shape of the implant reflects the 3-dimensional architecture of the cranial bone defect. In a complex-shaped defect, an autograft or a patient-specific implant is needed for cranioplasty. However, standard procedures to open the skull bone are used. Thus, in many patients, a standard-shape implant may be used if their own bone flap is not viable. Clinically, the implants are primarily fixed with screws, and therefore this study put an emphasis on investigating also the effect of fixation on the load-bearing capacity of FRC implants.

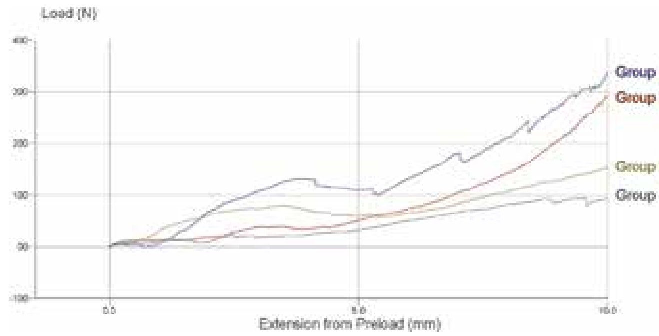

Fig. 4 - The load-deflection curves of glass fiber-reinforced composite (FRC) implant groups.

To the knowledge of authors, this is the first study to test the load-bearing capacity of sandwich-like glass FRC implants and to determine the effect of interconnective bars on these implants. We hypothesized that the interconnective bars would increase the load-bearing capacity of the FRC implant. Accordingly, the results of this study are in line with these expectations. However, the lack of statistical differences in the groups fixed with dental stone was unexpected. We expected that the effect of interconnective bars would not be associated with the fixation method. However, when a static load is applied to an osseointegrated FRC implant, the failure of this structure occurs in the bony tissue (16).

In this study, the fracture location of the implant was at the margin area where the FRC sheets were laminated together. However, before this breakage of the implant structure occurred, the fracture type was elastic and plastic deformation, which was present in the polymer matrix and not in the glass fibers. In the cases of free-standing setup (no fixation) and of fixation with 6 screws, the FRC implants with 2 interconnective bars showed significantly higher load-bearing capacity compared with the implant without interconnective bars. When the screw fixation of FRC structures was used, the load-bearing capacity until 6-mm deflection was markedly increased in comparison with that in the group with no fixation.

Load-deflection curves from testing the implants showed where the implants started to become internally damaged – i.e., upon breakage of fibers in the polymer matrix, then interconnective bar breakage, and finally the outer and inner FRC sheets were separated from each other. In fact, the first stage of loading was concentrated on the outer sheet only, which was deflected before the load was concentrated on the interconnective bars and the inner sheet and finally on the marginal fixation of the implant. A more detailed analysis of the fracture behavior with external forces of different velocities should be carried out in future investigations.

No statistical differences were observed among groups with dental stone fixation. This can be explained by the higher compressive strength of the dental stone compared with that of the FRC implants. The implications of these findings are that after the initial bone ingrowth into the porous FRC implant, the load-bearing capacity of the implant increases. Thus, the reinforcing effect of the interconnective bars is important in the initial healing stage, and this effect is diminished at a later healing stage by bone formation.

High mechanical loads are not generally applied on skull bone, and thus implants indicated for cranial bone defect reconstruction are considered as non-load-bearing devices. However, the mechanical properties of a cranioplasty material need to be superior to those of cranial bone. The mechanical properties of cranial bone are dependent on the anatomical location due to the variance of bone thickness and microstructure (17-20). We chose to report the load-bearing capacity up to 6-mm deflection, and from a clinical perspective, greater deformity of the implant would almost certainly be harmful. Cranial bone is a sandwich-like structure with 2 layers of cortical bone and a central trabecular layer, which increases the bending strength and stiffness of the whole bone structure. Based on clinical experience, the minimum requirement of an initial load-bearing capacity after cranial bone defect reconstruction was proposed to be around 200 N (21). The mechanical properties of human cranial and cortical bone are known (17, 19, 22), with a mean bending strength of 82 ± 25 MPa (832 ± 255 kg/cm^2) of adult cranial bone being reported. In another study, a compression test of pediatric skull bone was performed. Skull bone fracture was observed at a maximum load of 520 lb (236 kg), which is equal to 2,300 N (23).

The load-bearing capacity of the glass FRC decreases by ca. 20% during the first days of use when exposed to water or body fluids. After 4 weeks, the toughness of the FRC remains stable for 10 years (12, 13, 24). Therefore, in this study, the FRC implants were immersed in water for 1 week prior to the the bending test. In clinical conditions, the implants are inserted dry after sterilization, but the water in plasma starts to be absorbed into the polymer matrix between the glass fibers. We can assume that in a few weeks' time after implantation, the glass FRC implants will be saturated with water and have a load-bearing capacity corresponding to what was found in this study with water-saturated implants.

The main limitations of this study need to be considered. First, the force applied to the implant was steady, and the testing machine head moved at a quasi-static speed. These measurements may not accurately reflect the loading in a clinical situation with an external impact-type force applied to an implant. Second, in this study, we could not calculate the flexural strengths on each part of the complex geometry of the implant. Due to this limitation of the study, the results need to be construed as a composite of the mechanical properties and the geometrical shape of the implant. However, material properties of glass FRC with a corresponding composition are known (15, 25, 27-30). When the width and thickness of the construction are fixed, the geometry or convexity has little effect on the load-bearing capacity (26). However, with more complex shapes, locally applied pressure is concentrated, and a fracture may occur with a lower load than for an implant with a simpler shape (25). Third, there remains the possibility of an error in the accuracy of the visual analysis. However, during pilot testing, the observed fracture types of the nonfixated and screw-fixated implants correlated with the abrupt changes in the deflection curves. Fourth, the lack of statistical differences among the groups with dental stone fixation (groups 5-8) may be due to a small sample size. Another possible reason may be an error in the accuracy of the measurement, as there were some outliers in these groups (see Fig. 3).

The anisotropicity of FRC may be utilized to enhance the mechanical properties in the direction against an anticipated force. In this study, the adding of interconnective bars of continuous unidirectional glass fibers – i.e., anisotropic FRC to the implant – increased the load-bearing capacity. The load-bearing capacity of the FRC implant may be further increased by modifying the design – i.e., increasing the thickness and changing the geometry of the implant. Recently, nano-filled FRCs were proposed to be superior to conventional FRCs in terms of mechanical properties (31). However, further investigation is required in these areas.

We conclude that the FRC implants used in this study showed a load-bearing capacity that may offer protection to brain tissues after cranial bone defects are reconstructed. The loading test did not demonstrate any protrusions of glass fibers or cut fibers. An elastic and plastic deformation of the implant occurred until the FRC sheets were separated from each other.

Acknowledgements

Authors express their gratitude to the research team of the BioCity Turku Biomaterials Research Program (http://www.biomaterials.utu.fi) with the principal financing partners of the FRC implant research being the Finnish Agency for Technology and Innovation (TEKES), the Academy of Finland and the European Commission (grant: NEWBONE NMP3-CT-006-026279-2). Maiju Mutanen, Jutta Jokinen, Laura Kinnunen and Jari Madetoja are acknowledged for their help with the preparation of the FRC implants. Aura Professional English Consulting Ltd. (http://www.auraenglish.com) performed the language editing of this manuscript.

Disclosures

Financial support: J.M.P. received financial support in the form of a congress fee and travel expenses paid for by Skulle Implants Corp.
Conflicts of interest: P.K.V. is a board member and shareholder of Skulle Implants Corp., which aims to commercialize FRC implants.

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