ORIGINAL ARTICLE

Determination of Shear Strength of Periosteum Attached to Bone With BioGlue Surgical Adhesive

Douglas M. Sidle, MD; Corey S. Maas, MD

Objective: To determine the shear strength of BioGlue Surgical Adhesive (Cryolife Inc, Kennesaw, Georgia) for use in periosteal fixation in endoscopic browplasty.

Methods: In a controlled design, the shear strength of periosteal attachment to native bone and that of dissected periosteum affixed to bone with BioGlue surgical adhesive was physiologically determined. Twenty-one periosteum and bone samples were harvested from 3 human cadavers. These samples were tested for maximum shear strength using an Instron Model 5500 universal materials testing machine. Native samples consisted of periosteum still attached to the bone surface, while BioGlue samples consisted of dissected periosteum reattached to the bone surface using BioGlue surgical adhesive. The maximum shear strength attained for each sample was recorded and used to determine if native samples differed from those using BioGlue surgical adhesive.

Results: The mean (SD) maximum shear strength values obtained during testing were 57.8 (31.7) kPa and 45.9 (27.4) kPa (589.4 [323.3] gram force [gf]/cm^2 and 468.0 [279.4] gf/cm^2) for native (n=8) and BioGlue (n=9) samples, respectively. There was no statistical difference between the native and BioGlue samples ($P>.05$) using analysis of variance.

Conclusion: This study demonstrates that the adhesive properties of BioGlue are similar to the strength of attachment of native periosteum to bone and supports the use of BioGlue as an alternative method of fixation for use in endoscopic brow-lifting.

Arch Facial Plast Surg. 2008;10(5):316-320

Author Affiliations: The Maas Clinic, San Francisco, California (Drs Sidle and Maas); Division of Facial Plastic Surgery, Department of Otolaryngology, Feinberg School of Medicine, Northwestern University, Chicago, Illinois (Dr Sidle); and Division of Facial Plastic Surgery, Department of Otolaryngology, University of California, San Francisco (Dr Maas).

ENDOSCOPIC BROWPLASTY HAS become an increasingly popular method for forehead rejuvenation since its introduction in the early 1990s. The ideal optical pocket for the endoscopic approach is subperiosteal because of reduced bleeding, ease of dissection, and identification of neurovascular landmarks. This less invasive approach to brow surgery is dependent on the complete release of periosteum from the underlying cortex and its effective repositioning to create a more youthful appearance. As such, the success of the procedure is dependent on adequate repositioning and fixation of the released periosteum back to the cortex of the frontal bone. A plethora of options have been described to achieve this fixation. The most common approaches, ie, external bolstering sutures, spanning fixation sutures, transcutaneous screws, cortical bone tunnels, and resorbable cleats, all have significant drawbacks.[1-10] The search for an ideal fixative for use in endoscopic browplasty continues.

BioGlue Surgical Adhesive (Cryolife Inc, Kennesaw, Georgia) is primarily a complex of purified serum albumin and glutaraldehyde and is approved by the Food and Drug Administration for tissue adhesion in select cardiovascular procedures.[11-15] It has recently been shown in a clinical study to be sufficient for achieving brow fixation when used as the only brow fixation method during endoscopic browplasty.[16] However, to our knowledge, no studies have been performed, either in vivo or in vitro, analyzing the adhesive properties of BioGlue when used to reattach periosteum to cortical human bone.

We investigated the use of BioGlue in the fixation of periosteum to human cortical bone in an effort to further validate its superiority as a primary method of brow fixation during endoscopic browplasty.

METHODS

Stress is defined simply as force per unit of area (stress=force/area). Shear stress is a state in which the shape of a material changes, usually by "sliding" forces, without a particular volume change. It is the components of the stress at a point that act parallel to the plane in which they lie. Shear strength is a structural engineering term used to

describe the stress needed to create a structural failure whereby a component fails by shearing when it splits into 2 parts that slide past each other. Calculations of maximum shear stress take into consideration the surface area of attached material (in this case, periosteum to bone): 1 Pa = 1 N/m^2.

Fresh human cadaver heads were acquired and used to harvest a set of frontal cortical bone pieces with attached periosteum (**Figure 1**). Specimens from donors who had connective tissue disease were excluded from the study.

From the harvested frontal bone, the shearing strength of a standard size of attached native periosteum, typically around 0.5 cm^2 to 2.0 cm^2, was determined as it was pulled from its underlying cortical bone. An Instron Model 5500 universal materials testing machine (Instron Corporation, Norwood, Massachusetts) was used to determine all forces (**Figure 2**). This instrument is maintained by its manufacturer by periodic evaluation and was in calibration at the time the measurements were recorded. Measurement of the surface area of the attached periosteum was performed using a Dura-Cal IP65 electronic caliper (Brown and Sharp, North Kingstown, Rhode Island). The results of this first set of tests established a baseline for normal cadaver frontal bone periosteal adherence strengths.

In a second set of experiments, the periosteum was elevated from the underlying cortical bone using a periosteal elevator, a technique that is typical of that used during endoscopic browplasty. The periosteum was then readhered to its original piece of cortex using BioGlue Surgical Adhesive in accordance with its typical use as a tissue sealant. The BioGlue samples were prepared in 1 of 2 ways—either by "placing" the periosteum onto the curing BioGlue or by "pressing" the periosteum into the curing BioGlue. Two minutes was allowed to pass to allow full polymerization and curing of the BioGlue. Again, approximately 0.5 cm^2 to 2.0 cm^2 of surface area was used to reattach the periosteum to bone. Once fixation was obtained, the limit of force that could be applied before the newly adhered periosteum was torn from the bone was again determined.

Samples were inserted into the Instron Model 5500 in a manner such that the glue plane was aligned in tension with the force axis of the Instron and then pulled at a rate of 10 mm/min until shear or tissue rupture occurred (Figure 2).

Data were compiled into a spreadsheet program (MS Excel; Microsoft Corp, Redmond, Washington). The maximum shear strength attained by each sample was recorded and used to determine if native samples differed from those using BioGlue surgical adhesive. These results can also be compared with the periosteal shearing strengths determined by other investigators.[17,18]

Figure 1. Photograph of harvested cadaveric frontal bone samples with attached native periosteum.

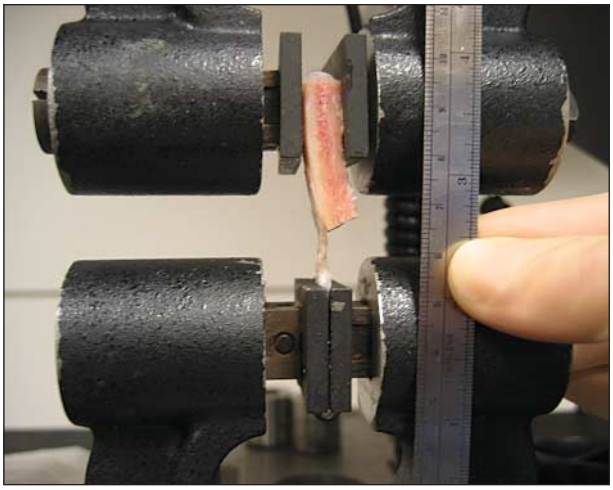

Figure 2. Bone and periosteum complex loaded into Instron Model 5500 (Instron Corporation, Norwood, Massachusetts).

RESULTS

Samples were collected from 3 different cadaver frontal bones. Native samples (n = 9) consisted of periosteum still attached to the bone surface, whereas BioGlue samples (n = 12) consisted of dissected periosteum reattached to the bone surface using BioGlue Surgical Adhesive. One native and 3 BioGlue samples sustained periosteum tissue rupture prior to shear occurring (the periosteum itself tore before being sheared from the bone; see "Tear" in Results column in the **Table**). Data from samples that ruptured were not used to compare shear strength values because shear did not occur. In the cases of periosteum rupture, the bond to be sheared—whether native or BioGlue—remained intact, indicating that the bond was stronger than the tensile strength of the periosteum tissue for these samples.

To determine if the 2 BioGlue techniques used to produce samples resulted in different shear strengths, the data from 5 "placed" samples and 4 "pressed" samples were analyzed as separate groups. The mean (SD) shear values were 56.9 (30.7) kPa and 32.2 (17.1) kPa (580.2 [313.1] gram force [gf]/cm^2 and 328.3 [174.4] gf/cm^2) for the "placed" and "pressed" samples, respectively, with relative standard errors of the mean of 54.1% and 53.1%. The mean for the "placed" samples was skewed by an outlier. Analysis of variance showed that there was no statistical difference between the 2 techniques ($P = .20$), so all BioGlue samples were combined for further analysis.

The mean (SD) maximum shear strength values obtained during testing were 57.8 (31.7) kPa and 45.9 (27.4) kPa (589.4 [323.3] gf/cm^2 and 468.0 [279.4] gf/cm^2) for

Table. Raw Metric Data for 21 Periosteum and Bone Samples

Sample No.	Shear Area, mm²	Length of Sample Between Grips, mm	Max Force, N	Max Stress, kPa	Max Displacement, mm	Max Strain, %	Treatment[a]	Secondary Treatment	Result	Shear Interface[a]
1	371.85	28.00	9.84	26.47	7.62	27.21	Native	NA	Tear	NA
2	137.48	13.00	14.57	106.00	5.39	41.46	Native	NA	Shear	Periosteum and bone
3	117.52	42.00	3.06	26.10	4.00	9.52	BioGlue	Place	Shear	Periosteum and BioGlue
4	191.00	30.00	4.27	22.30	10.97	36.57	Native	NA	Shear	Periosteum and bone
5	103.29	20.00	4.52	44.00	3.90	19.50	Native	NA	Shear	Periosteum and bone
6	97.02	19.00	2.00	21.00	0.98	5.16	Native	NA	Shear	Periosteum and bone
7	147.90	25.00	5.26	35.60	2.08	8.32	BioGlue	Press	Shear	Periosteum and BioGlue
8	105.79	19.00	2.26	21.00	5.52	29.05	BioGlue	Press	Tear	NA
9	188.86	22.00	19.68	104.00	4.03	18.32	BioGlue	Place	Shear	Periosteum and BioGlue
10	80.06	17.00	3.59	45.00	6.95	40.88	Native	NA	Shear	Periosteum and bone
11	150.96	25.00	11.20	74.20	3.95	15.80	BioGlue	Place	Tear	NA
12	71.71	24.00	5.32	73.90	2.98	12.42	Native	NA	Shear	Periosteum and bone
13	102.85	26.00	8.32	80.80	3.23	12.42	BioGlue	Place	Tear	NA
14	97.11	11.00	2.77	28.50	2.70	24.54	BioGlue	Press	Shear	Periosteum and BioGlue
15	74.90	20.00	7.15	96.00	6.98	34.90	Native	NA	Shear	Periosteum and bone
16	84.56	15.00	4.52	53.00	1.73	11.53	BioGlue	Press	Shear	Periosteum and BioGlue
17	63.60	12.00	3.45	54.00	3.63	30.25	Native	NA	Shear	Periosteum and bone
18	88.11	21.00	5.24	59.40	7.23	34.43	BioGlue	Place	Shear	Both planes
19	77.36	16.00	0.91	11.70	5.37	33.56	BioGlue	Press	Shear	Periosteum and BioGlue
20	65.65	23.00	4.07	62.03	3.17	13.78	BioGlue	Place	Shear	Both planes
21	106.11	17.50	3.48	32.80	3.77	21.54	BioGlue	Place	Shear	Both planes

Abbreviations: Max, maximum; NA, not applicable.
[a] BioGlue Surgical Adhesive is manufactured by Cryolife Inc, Kennesaw, Georgia.

native (n=8) and BioGlue (n=9) samples, respectively (**Figure 3**), with relative standard errors of mean of 54.8% and 56.3%. Statistical analysis of these groups was completed using analysis of variance. There was no statistical difference between the native and BioGlue samples (P=.42).

COMMENT

In the clinical setting, there are numerous anatomical and technical details that affect brow repositioning and fixation, such as extent of the forehead flap dissection in the subperiosteal plane, amount of dissection into the temporal region, and strength of the remaining brow depressor musculature to name a few. Tissue modifications such as myotomies, myectomies, neurectomies, and galeal scoring all influence the forces acting on repositioning maneuvers. However, it is still necessary to fixate the elevated flap back to the underlying cortical bone to achieve long-term brow respositioning.[1] It was our objective to determine the shear strength of BioGlue surgical adhesive as a tissue adhesive for use in periosteal fixation and to determine how its adhesive properties compare with that of native periosteum on bone. The results of this experiment may be of significant utility to the facial plastic surgeon who is considering which method of brow fixation to use during an endoscopic brow-lift.

Fixation of the brows during the critical period of periosteal readherence is especially important for the success of the endoscopic browplasty technique. While results from animal studies suggest that between 1 and 12 weeks are required for periosteal reattachment,[19-22] recent evidence suggests that at least 6 weeks of fixation may be necessary to allow the periosteum adequate time to readhere to its new location on the frontal bone cortex.[20,23] Numerous options exist to achieve this, many of which extend operative times because of complicated or labor intensive techniques. Some popular methods add substantial operative risk to the procedure and often result in palpable and even visible hardware in the scalp area that may persist for months beyond their desired beneficial effect.

As an alternative to these more invasive and involved fixation techniques, investigators have explored the use of tissue adhesives that can be easily and rapidly inserted into the optical cavity to secure the periosteum until physiologic reattachment has occurred. BioGlue is resorbed over 2 years, well beyond the critical 6 weeks needed to allow proper periosteal readherence. Moreover, it creates a bond strength of up to 1500 kPa, 1000% greater than the largely hemostatic fibrin glue–like products.[24] Still, the relationship between tensile strength and full resorption rate is not necessarily linear or proportionate. To our knowledge, there is currently no data demonstrating the material's strength at time points beyond initial application, and further studies delineating the duration of adhesive strength are needed. In the clinical situation, tissue surrounding the adhesive will be remodeling as time passes, and the adhesion of the periosteum will vary from one individual to the next.

In our recently reported clinical series of patients, surgical brow position, while using BioGlue as the primary method of fixation, was maintained during the critical period of periosteal reattachment and remained elevated over 12 months when compared with the preoperative state.[16] These objective results corroborated

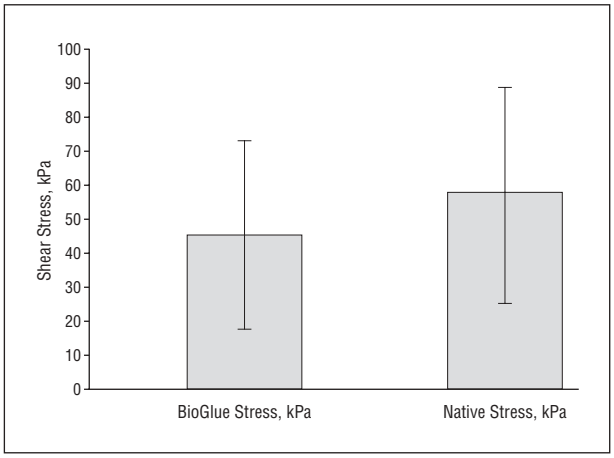

Figure 3. Comparison of shear strength values for native and BioGlue samples. The mean maximum shear strength values were obtained during testing for native and BioGlue Surgical Adhesive (Cryolife Inc, Kennesaw, Georgia) samples. There was no statistical difference between the native and BioGlue samples ($P > .05$). Error bars indicate standard deviation.

the subjective improvement in brow position by both the surgeons and, more importantly, the patients. Results were both efficacious and safe. We reported a very low complication rate, represented primarily by the finding of small palpable BioGlue nodules, which resolved with time.

Mechanical properties of human nasal fascia and periosteum have been explored,[17] but there is a lack of data evaluating the periosteum of the human brow. Furthermore, to our knowledge, no studies have yet evaluated the attachment properties of periosteum to the human skull. In this regard, our study is novel. Although there were sufficient samples to conduct statistical analyses on these groups, the relatively large standard errors of the mean of equal size, even in the control group, suggest variability in the tissue composition and points to the need to conduct additional studies with a larger number of samples.

Indeed, there are a number of difficulties involved when using an animal model to simulate a clinical situation in humans.[18] Specifically, wounds in the clinical situation are closed under tension, whereas in animal models, they have not been.[21-23,25] Moreover, forces on the flap will be in a parallel direction, not perpendicular as was applied in one animal model.[20] Unfortunately, biological materials are never uniform. The spread of the data seen with the control samples speaks to this variance in the tissue and from one individual to the next. In this specific case, anatomic, age, or postharvest handling differences may have further contributed to the variance. Our model seeks, at least in part, to correct some of these deficiencies. After a 2-minute period to allow curing of the BioGlue, samples were inserted into the Instron in a manner such that the glue plane was aligned in tension with the force axis of the Instron (Figure 2). This more closely mimics the clinical situation. Forces were applied parallel to the axis of the periosteum-cortical bone plane.

Another concern is that samples with only 1 cm^2 of surface area are too small to replicate the clinical situation. That 1 cm^2 has much less adhesion than a whole sheet of periosteum is a valid point. However, our calculations of maximum stress take into consideration the surface area of attached periosteum: 1 Pa = 1 N/m^2. Too large a surface area of attached periosteum not only made measurements using the Instron cumbersome but risked premature rupture of the periosteum sample. Indeed, rupture occurred in 4 of our test samples. These samples were not, therefore, used in the calculations of periosteal adherence. These cases of periosteal tear or rupture, however, suggest something interesting. In the cases of periosteum rupture, the bond to be sheared—whether native or BioGlue—remained intact, indicating that the bond was stronger than the tensile strength of the periosteum tissue for these samples. This would seem to indicate that an attachment existed that was strong enough to resist the aforementioned forces adversely and downwardly acting on a newly repositioned brow.

In conclusion, our study demonstrates that BioGlue, used as a tissue adhesive to affix periosteum to bone, provided a shear strength bond statistically similar to that of native periosteum on bone. This suggests that the adhesive properties BioGlue as the primary method of brow fixation are similar to that of undisturbed periosteum. These results support the use of BioGlue as an alternative method of fixation in endoscopic brow-lifting. Furthermore, the results support the continued investigation of BioGlue as a tissue adhesive for use in facial plastic surgery procedures.

Accepted for Publication: September 11, 2007.
Correspondence: Douglas M. Sidle, MD, Northwestern Medical Faculty Foundation, 675 N St Clair St, Ste 15-200, Chicago, IL 60611 (drsidle@yahoo.com).
Author Contributions: Dr Sidle had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Sidle and Maas. *Acquisition of data:* Sidle. *Analysis and interpretation of data:* Sidle. *Drafting of the manuscript:* Sidle. *Critical revision of the manuscript for important intellectual content:* Sidle and Maas. *Statistical analysis:* Sidle. *Obtained funding:* Sidle and Maas. *Administrative, technical, and material support:* Sidle and Maas. *Study supervision:* Maas.
Financial Disclosure: Dr Maas has received a research grant from Cryolife Inc and has served as a consultant for and has stock in Bioform Inc.
Funding/Support: This research was supported through a travel grant and materials supplied by Cryolife Inc.
Previous Presentation: This manuscript was presented as a poster at the American Academy of Facial Plastic and Reconstructive Surgery fall meeting; September 22-25, 2005; Los Angeles, California.

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