

# Fiber Reinforced Adhesive Patch (FRAP): A New Technology for Minimal Invasive Treatments of Bone Fractures

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## Abstract

Instead of screws and metal plates we have developed a unique adhesive implant to stabilize the various types of bone fractures defined as the Fiber Reinforced Adhesive Patch (FRAP) technology. The new implant consists of an adhesive strengthened with fibers to form a composite patch. The FRAP technology is developed as a degradable adhesive facilitating a mechanically strong triazine system based on non-toxic allylic and thiol compounds. The thiolene cross linking strategy is highly desirable in a surgical environment as it can be performed via minimally invasive optical fibers and with excellent tolerance to oxygen. The number of layers and the size of the FRAP technology is chosen by the surgeon depending on the fracture characteristics and the anticipated load on the fracture. When at place, the tailor-made FRAP technology is photo-cured by UV light to a hard composite thereby bridging and stabilizing the fracture or the skull bone after neurosurgical operations. The experimental and numerical analysis on bovine bone fractures shows that the new FRAP technology should become an excellent alternative or complement to existing metal implants.

Keywords: Adhesive; Bone fracture; Finite element modelling

## Introduction

The global annual incidence of both acute and chronic types of various bone injuries is enormous and will increase with a growing elderly population within the next decades [1,2]. Existing surgical treatment of complicated fractures in the neurosurgical and orthopedic fields mostly rely on the application of screw-fixated metal implants. Due to their rigid design, the intervention requires open surgery and general anesthesia.

Adhesive fixation of bone fractures has been an area of interest since the middle of the 20<sup>th</sup> century as an alternative to conventional fixation with metal screws and plates [3-11]. Since adhesives do not demand drilling and can be distributed with minimal invasive surgery through an endoscope under local anaesthesia, it possesses some obvious advantages. So far no biocompatible adhesive has yet been proven to possess sufficient strength for bone fracture stabilization. A unique adhesive implant has been developed to stabilize the various types of bone fractures defined as the Fiber Reinforced Adhesive Patch (FRAP) technology. The new implant consists of an adhesive, strengthened with fibers to form a composite FRAP technology and developed as a degradable adhesive facilitating a mechanically strong two component triazine adhesive system based on non-toxic thiol and allylic compounds. The thiol-ene cross-linking strategy is highly desirable in a surgical environment as it can be performed via minimally invasive endoscopy. The intention is that the number of layers and size of the FRAP technology, implanted under local anaesthesiology, will be chosen by the surgeon depending on the fracture characteristics and the anticipated load on the fracture. However, it is unknown whether the strength of FRAP fixation is

mechanically sufficient to maintain stability during daily loading after surgery. In order to set requirements for the strength of the FRAP technology, numerical analysis is a strong complement to further evaluate experimental results before use in health care. The Finite Element (FE) method is the numerical method of choice for this application as data from experiments can be further analyzed and confirmed in complex geometry and materials.

The aim of the present experimental study and numerical analysis is

• to mechanically analyse the strength of the FRAP technology on induced bovine bone fractures and

• to analyse the mechanical results on the first and second cervical vertebrae by using an FE model developed for the human cervical spine.

## **Materials and Methods**

## Specimen preparation

Fresh bovine femur bones were collected and frozen to -30 degrees Celsius. A thin layer of soft tissue was left to prevent the bone from drying during freezing. On the day of testing, the bone was thawed at room temperature and cleaned of all remaining soft tissue, including bone marrow. The hollow pipe-shaped bones were then split into eight rod-like shapes and sawed into lengths of approximately 75 mm. Each of the rods were then wet sanded with a "120" sandpaper to achieve smooth and evenly shaped rods. To create a generic fracture, the rods were sawed into two pieces. The two pieces were then bonded with 2-6 lamina of a fiber reinforced adhesive to form a bonding patch, FRAP (Table 1). Specimens #1-18 were designed to induce a cohesive failure mode while specimens #19-24 were designed to fail adhesively. Citation: Pedersen K, Axel Nordberg A, Peter Halldin P, Holst HV, et al. (2014) Fiber Reinforced Adhesive Patch (FRAP): A New Technology for Minimal Invasive Treatments of Bone Fractures. J Trauma Treat S2: 007. doi:10.4172/2167-1222.S2-007

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Specimen	No. of lamina	Failure type	Bonding width	Patch thickness
1-6	2	Cohesive	12-13 mm	0.11 mm
7-12	3	Cohesive	12-13 mm	0.16 mm
13-18	4	Cohesive	12-13 mm	0.22 mm
19-24	6	Adhesive	12-13 mm	0.35 mm

Table 1: Specimens used in this study

## **FRAP** bonding

The FRAP bond used for fixation was made of a fiber reinforced adhesive. The adhesive used was Scotch bond XT (produced by 3M Espe), a commercially available dental adhesive, based on a light activated polymeric system. It consists mainly of BisGMA, HEMA, dimethacrylates, ethanol, water, photo initiator and a methacrylate, functional copolymer of polyacrylic and polyitaconic acids. The fibres used were woven 90/0 E-glass fibre mat from Porcher industries, style 106, 25 g/m<sup>2</sup>. The FRAP bond was applied on all fractured specimens. The FRAP consists of an inner layer of adhesive, followed by 2-6 layers of fibres, and lastly, one top coat of adhesive, all applied circumferentially around the fracture but not on the ends (Figure 1). Fibre layers were all oriented with major fibre direction along with

tensile direction of the specimen. Prior to applying the inner layer of adhesive, the bonding area was rinsed, etched using phosphoric acid from 3M Espe, and rinsed again. The inner layer adhesive was applied in a few consecutive layers with a gently rubbing motion. The fiber mat was then applied as strips, approximately 12-13 mm wide and lengthwise along the fracture ranging between 37 and 42 mm. The top coat of adhesive was applied until the fibers were completely saturated with adhesive. Curing was performed with curing light, Elipar 2500 from 3M, in 400-500 nm range, designed for dental adhesives. Curing speed was approximately 3-4 cm<sup>2</sup>/min. To allow complete polymerization, the specimens were kept at room temperature for 4 hours after bonding. The cortical bone was kept moist by regularly spraying it with saline.



Figure 1: Schematic presentation of the FRAP technology (left) applied on the induced bovine bone fracture (middle) before mechanically tested in the Instron machine (right)

## Specimen testing

All mechanical tests were performed in an Instron 5567 with a 5kN load cell, and with a crosshead speed of 2 mm/min. The tensile tests were performed by inserting two parallel pins through the bone with wire connections to the load cell. A Digital Speckle Photography (DSP) with Aramis software (produced by GOM GmbH) was used to measure strain vectors in the FRAP bond during tensile testing. All specimens were tested until complete failure was observed. The circumferential bonding length of the specimen was measured with a scanner using a resolution of 118 pixels per cm.

## Finite element analysis

Simulation of fracture stability was performed by modelling both fractures and fixating bonds in the KTH neck model [12,13] (Figure 2). All simulations were performed in the FE code LS-DYNA [14]. The KTH FE neck model includes a rigid head [15]. The seven vertebrae (C1-C7) are modelled with linear viscoelastic material models for the cortical and trabecular bone. The two uppermost thoracic vertebrae (T1-T2) are represented by rigid cubes and joints. The intervertebral

discs are modelled with membrane elements with orthotropic properties for the annulus fibres, viscoelastic solid elements for the ground substance, and solid elements with incompressible material properties for the nucleus pulpous. The facet joints are modelled as sliding contacts with friction representative of cartilage. All spinal ligaments are modelled as either non-linear tension-only springs or elastic membranes with contact definitions toward relevant tissues. The cervical musculature was included as spring elements representing the passive force of the musculature. The KTH neck model has been extensively compared to experimental data from volunteer, cadaver and specimen experiments. Relevant to this study is the good kinematic agreement of the cadaver specimen testing of the upper cervical spine in quasi-static flexion and extension. Furthermore, the KTH neck model compared well to dynamic compression-flexion experiments with human cervical spine and skull specimens performed by volunteer experiments by [12].

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Figure 2: Motions; a) Extension with used global coordinate system, b) flexion, c) lateral bending

One C1 arch fracture and two C2 dens fractures were induced in the model, (Figure 3). The fractures were induced as a 0.4 mm gap in the solid cortical bone, (Figure 3c). The C1 fracture was a double arch fracture, also known as a Jefferson fracture. The C2 fractures were a dens type 2 fracture and a dens type 3 fracture. The FRAP was modelled with 4-node shell elements around the induced fracture, 0.2 mm thick and 0.4 mm wide. An elastic isotropic material model was used with the young modulus of 15GPa, which was measured in the tensile experiment of the FRAP presented below). Circumferential length for the bonds were 17.1 + 30.0 mm for the double C1 fracture, 33.5 mm for the dens type 2 C2 fracture, and 33.4 mm for the dens type 3 C2 fracture. The muscles were given only passive properties.



Six different loads were applied in order to simulate a normal flexion, extension and lateral bending in two different loading speeds. The thorax cube was rigidly fixed and a pure moment of 5 Nm was applied to the skull. The global coordinate system used is defined in Figure 2. A local coordinate system is defined in Figure 3, where w is oriented in the tensile direction of the fixation bond. The moment was applied dynamically, as a half sinusoidal impulse, with durations of 500 ms and 100 ms. Forces were computed in w direction from the isotropic shells filling the gap in the C1 and C2 simulation a FRAP.

A convergence study was done by increasing the number of elements on C2 from 2368 shells and 4992 solids to 7056 shells and 39936 solids. This also meant that the number of elements on the modelled FRAP increased from 32 to 128. A 100N load was then applied in local u direction at the distal end of the dens and forces were computed in local w direction in the FRAP.

## Results

## Specimen testing

Tensile testing of bone specimen #1-24 showed maximum FRAP bond strength,  $\sigma$ m=155 MPa and maximum shear stress in the bonepatch interface,  $\tau$ m=6 MPa. Failure mode for specimen #1-18 was cohesive failure and for #19-24 adhesive failure. Young's modulus and strain to failure of the FRAP was calculated in the load direction, to E=13-15 GPa and  $\epsilon$ =2.5%. Figure 4 shows, for cohesively failed specimen #1-18, maximum load divided with circumferential bond length. The size independent strength ratio (N/mm) was calculated to 34 N/mm for the 4 lamina specimen, #13-18, 24 N/mm for the 3 lamina specimen, #7-12 and 17.7 N/mm for the 2 lamina specimen #1-6. Maximum load for the tested specimen lay between 600 and 1260 N, and the circumferential bonding length varied between 37 and 42 mm. FRAP thickness was measured to 0.11 mm for 2 lamina specimens, 0.16mm for 3 lamina specimens and 0.22 mm for 4 lamina specimens.



## Finite element analysis

From FE simulations only tensile forces in local w coordinate were considered. In order to compare the numerical results with experimental results, a dimensionless value was calculated. Measured stresses were multiplied with bonding thickness, 0.2 mm, around the fracture, N/mm. The highest force found in the bond, 21.1 N/mm, was in the anterior part of the C2 dens 3 fracture during extension, (Figure 5). Maximum measured force from experiment, 34 N/mm divided by the computed maximum force from the FE model (21 N/mm), yields a factor of 1.61. The negative tensile force indicates a compressive load, which is transferred mainly to the adjacent bone tissue. The tensile fracture forces were generally found to be greater for the C2 dens 3 fracture than for the C2 dens 2 fracture, and for extension neck motion compared to flexion. It was also seen that a shorter load pulse

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increased fracture forces. Lateral bending showed higher forces in the C1 Jefferson fracture than the C2 dens fractures. All results from the FE simulations are presented in Table 2. The convergence study showed that the internal energy in the FRAP technology increased by 2.51%, when increasing the number of elements in the FRAP technology from 32 to 128.

# Discussion

This study has shown that it is possible to stabilize cervical bone fractures on C1 and C2 with the FRAP technology. The bonded fractures can withstand forces higher than computed forces in an FE model of the human neck. When comparing FRAP bonded bone specimens with results from the FE simulations three and four lamina bondings were sufficient. The four lamina FRAP endured 61% higher forces than those found in the FE model while for the three lamina bond it was 14%. The two lamina bond would have failed during the conditions simulated in FE. With the knowledge gained from these results it would be desirable to use a four lamina fibre FRAP technology. Although this study shows promising results of bonding cervical fractures, there are limitations.





Fracture type	Extension 100 ms	Extension 500 ms	Flexion 100 ms	Flexion 500 ms	Lateral 100 ms	Lateral 500 ms
C2 dens type 2	15.7	13.0	2.8	2.1	12.5	9.9
C2 dens type 3	21.1	17.6	4.9	6.1	9.5	7.8
C1 Jefferson	6.5	4.1	5.7	5.6	15.0	13.1

Table 2: Maximum tensile force per length in bonded fractures from FE simulations (N/mm)

## **FRAP bonding**

Currently, the most practical method of using fiber reinforcement is the application of woven fiber patches, because of their ease of manipulation and positioning on the cortical bone. Well-designed woven fiber systems are also known to influence the stress distribution and, depending on its orientation and alignment, are effective in altering, stopping, and redirecting the propagation of cracks. In this study, bonding was performed circumferentially around the fracture. However, in surgery, a circumferential bond may be difficult to perform due to lack of accessibility or anatomical circumstances. It is, therefore, important to be able to leave parts of the fracture without treatment. This was not tested in this study. Leaving parts of the fracture untreated is also important to minimize possible interference with fracture healing. Since fracture healing, among other mechanisms, evokes callous formation on the outside of the bone, a minimum of interfering material along the fracture is desirable [16]. In this study fractures were obtained by simply sawing the bone specimen in two pieces. This method was chosen to increase reproducibility. However, realistic fractures found in health care are often more complex in its shape and can in many cases add a certain amount of mechanical support to the stabilized fracture.

Bonding was performed on moist specimens, which also showed the best results. It was subjectively found that too wet specimen wet diluted the adhesive and dry specimen provided suboptimal adhesion. Bovine bone was chosen to prioritize reproducibility, the higher density than human bone [17] was not believed to significantly influence the results for this study. The curing time of 3-4 cm/min was sufficient to fully cure even deeply located laminas. It could be seen that decreasing the time between curing and testing from 4 hours to 45 minutes, decreased tensile strength by roughly 22%. Extending the after-curing time to 12 hours, however, gave no significant increase in strength. A decrease in strength of 29% was also found when omitting the sanding preparation. The circumferential bonding width of 12-13mm was chosen primarily to evoke cohesive failure for 2,3 and 4 lamina bonds and adhesive failure for the six lamina bond. Optimal FRAP size and adhesive overlap can be estimated by L=t \* ( $\sigma$ m/ $\tau$ m), where: t=patch thickness,  $\sigma$ m=maximum stress in the patch,  $\tau$ m=shear stress in the patch-bone interface, (Figure 6).



Figure 6: Circumferential application of the FRAP technology strengthened with UV light

#### Finite element analysis

The KTH neck model was subjected to flexion, extension and lateral bending. Six load cases were chosen for this study, 100 ms and 500 ms dynamic loading of 5 Nm applied to the skull. Compared to mechanical tests on cervical segments found in the literature ranging between 2-4 Nm [18-20] this is slightly higher. However, it was believed to be a fairly accurate and conservative approximation of mild daily loading. The 500 ms dynamic loading can be considered to be representative of a patient sitting with a flexed, extended or laterally bent neck. The 100 ms dynamic simulations are more representative of a patient subjected to mild external violence inducing a rapid neck motion. To simulate a rapid neck motion governed wilfully it would have been necessary to simulate this with active tension in the muscle elements rather than by applying an external force. The forces from the FE simulation were obtained from the isotropic shell around the induced fracture. In this study it was found that all load cases induced a major stress axis in the local w coordinate. Therefore, the simplification of only considering tensile forces in the local w coordinate was performed although this does not take into account shear and bending of the fixation bond. Since a small fracture gap was left in the FE model compressive forces were observed. However, this is in reality taken up by the surrounding bone tissue. The convergence study showed a moderate 2.51% increase of internal energies when doubling the number of elements in the vertebrae indicating a sufficient resolution of the KTH head and neck model for this study. The KTH head and neck model used in this study has been validated for local and global neck kinematics but the model has not been validated for stress prediction in the vertebrae. However, as the model has detailed geometry and has all tissues modelled anatomically it is believed that the model provides a realistic indication.

## Biocompatibility

From a biocompatible point of view, Scotch bond XT is an approved dental adhesive, and thereby sufficiently biocompatible for dental use. However, for clinical use, it is unknown whether Scotch bond is non-toxic enough to ensure to not inhibit bone healing or cause any other adverse reactions. Szep et. al. [21] investigated a number of modern adhesives and found some of them to cause fibroblast apoptosis. Therefore, further studies with focus on cytotoxicity, long-term stability and amount of residual monomers, are suggested before in vivo studies are performed. Investigations regarding presence of non-polymerized, residual monomers after photo-polymerization were made by Tuusa et al. [22]. They used a bis-GMA. TEGDMA-PMMA resin and found that the presence of oxygen increases residual monomers but did not find the presence of bone to increase it significantly. The biocompatibility of E-glass fibres was tested in vitro by M. Väkiparta et al. [23] who found no signs of cytotoxicity. Regarding mechanical biocompatibility, the calculated Young's modulus of 13-15GPa of the FRAP is, compared with the stiffness of human bone 15-20GPa, similar and therefore less likely to cause local stress shielding, compared to relatively stiff metal plates.

Based on the present results it is tentative to suggest that the FRAP technology has the potential to improve the surgical treatment initially of low loading fractures and later of more loading fractures in the lower part of the body. Also, it is quite possible that the FRAP technology has the potential to replace the metal implants used for skull bone flaps including bone defects in the skull bone.

Since no similar implant systems have been tested for these indications in vivo, implant related complications are yet unknown. In this study focus was to investigate mechanical sufficiency i.e. to prevent mechanical failure. However, other aspects, such as biological complications, toxicity/growth disturbances/infections etc. needs to be tested for as well in future studies. It is also important to point out that mechanical stability most likely will decrease over time. Therefore additional mechanical in vitro/vivo studies needs to be made to study this.

## Conclusion

The mechanical tests with the FRAP technology was shown to exhibit sufficient strength for fixating the C1 and C2 vertebral fractures analyzed with the FE modelling. The results are encouraging and motivate further mechanical tests, FE simulations and biocompatibility tests before it is used in clinical practice.

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