Biomechanical considerations of semi-anatomic glass fiber-reinforced (GFRC) composite implant for mandibular segmental defects: A technical note

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Abstract.

Objectives: The aim of this study was to investigate the selected biomechanical properties of semi-anatomic implant plate made of biostable glass fiber-reinforced composite (GFRC) for mandibular reconstruction. Two versions of GFRC plates were tested in in vitro loading conditions of a mandible segmental defect model, for determining the level of mechanical stress at the location of fixation screws, and in the body of the plate.

Methods: GFRC of bidirectional S3-glass fiber weaves with dimethacrylate resin matrix were used to fabricate semi-anatomic reconstruction plates of two GFRC laminate thicknesses. Lateral surface of the plate followed the contour of the resected part of the bone, and the medial surface was concave allowing for placement of a microvascular bone flap in the next stages of the research. Plates were fixed with screws to a plastic model of the mandible with a large segmental defect in the premolar-molar region. The mandible-plate system was loaded from incisal and molar locations with loads of 10, 50, and 100 N and stress (microstrain, με) at the location of fixation screws and the body of the plate was measured by strain gauges. In total the test set-up had four areas for measuring the stress of the plate.

Results: No signs of fractures or buckling failures of the plates were found during loading. Strain values at the region of the fixation screws were higher with thick plate, whereas thin plates demonstrated higher strain at the body of the plate. Vertical displacement of the mandible-plate system was proportional to the loading force and was higher with incisal than molar loading locations but no difference was found between thin and thick plates.

Conclusion: GFRC plates withstood the loading conditions up to 100 N even when loaded incisally. Thick plates concentrated the stress to the ramus mandibulae region of the fixation screws whereas the thin plates showed stress concentration in the angulus mandibulae region of the fixation and the plate itself. In general, thin plates caused a lower magnitude of stress to the fixation screw areas than thick plates, suggesting absorption of the loading energy to the body of the plate.

Keywords: Mandibular reconstruction, implant, fixation plate, free flap, fiber-reinforced composite, FRC

Biomechanical considerations of semi-anatomic glass fiber-reinforced (GFRC) composite implant for mandibular segmental defects: A technical note

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Introduction

Mandibular resection and osteosynthesis with implantable plates and screws is a challenging reconstructive surgery which is inevitable when continuity of the bony structure is lost. Malignant tumours such as oral squamous cell carcinomas are often the cause of bone structure loss. Other pathologies which may require radical treatment include for example resistant osteonecrosis of the jaw; medical or radiotherapy of origin and benign tumours or cysts; ameloblastoma and odontogenic ceratocyst. Marginal resection can be a treatment of choice when there is no invasion of superficial mandibular cortical bone in the case of a malignancy. It is widely accepted that autogenous bone-containing free bone flaps from *fibula* with plate fixation is a gold standard as a reconstructive method for segmental continuity defects of the mandible. It is of great importance to have adequate setting of the bone flap for functional rehabilitation in terms of masticatory function, this includes selecting a suitable plating and fixation system. Presently there are different types of osteosynthesis available in clinical situations demanding segmental mandibulectomy: conventional reconstruction plates which can be bent on pre-fabricated printed 3D skull model and computer assisted design and manufactured (CAD/CAM) patient specific implants (PSI) (Rendenbach et al., 2017). Treatment of choice does not only depend on patient specific factors but also a significant factor is the amount of time available. The material of choice for the plates has been undeniably titanium and its alloys although titanium may have some limitations. Although titanium has high strength, it interferes with radiotherapy, and causes lowered diagnostic image quality of computed tomography (CT) and magnetic resonance imaging (MRI) (Zou et al., 2015; Filli et al., 2015). Other limitations of titanium include the lack of iso-elasticity with bone and the potential for immunologic reactions caused by the corrosion of titanium products (Rendenbach et al., 2019; Gittens et al., 2011).

Resorbable plate and implant materials of polymers and magnesium alloys are still in early development and they do not yet have a reliable bone flap stabilizing effect. The release of acidic compounds by degradation of biopolymers and hydroxic gas formation from the corrosion and leaching of magnesium are also matters of concern.

One non-resorbable and non-metallic material alternative for bone implants which has been studied *in vitro, in vivo* and clinically for cranial and orthopaedic use is glass fiber-reinforced composite (GFRC) laced with bioactive glass (Zhao et al., 2009; Nganga et al., 2012; Ylä-Soininmäki et al., 2013; Moritz et al., 2014; Kulkova et al., 2016; Piitulainen et al., 2017; Liesmaki et al., 2019; Posti et al., 2015; Piitulainen et al., 2019).

GFRC provides high strength and high fracture toughness with cortical bone like modulus of elasticity. Using computed tomography (CT) data, GFRC has been utilized to fabricate patient-specific implants (PSI) for cranial reconstructions through molding techniques (Piitulainen et al., 2015).

Although GFRC is visible in X-rays it does not cause artifacts in CT and MRI images, and does interfere with radiation therapy (Kuusisto et al., 2018a, 2018b; Rendenbach et al., 2018; Toivonen et al., 2019; Vallittu et al., 2017; Vallittu et al., 2020).

Early *in vitro* testing of GFRC plates for mandibular reconstruction utilizing a simple flat shaped design was developed for a titanium plate counterpart in the fixation of a free bone flap. The plate showed a somewhat higher interosteotomy movement of the bone flap compared to titanium plate of similar design. This was assumed to relate to the lower rigidity of the plate structure (Rendenbach et al., 2019).

It is well known that rigidity of the structure is related to the dimensions and cross-sectional geometry. Thus, the aim of this study was investigate the biomechanical properties of GFRC plate with two thickness dimensions, and semi-anatomic cross-sectional geometry, on the stability and magnitude of stress in the mandible-plate system especially at the screw fixation regions.

Materials and methods

The semi-anatomical GFRC plates were designed to mirror the anatomical shape of the mandible, and featured a concave medial surface to facilitate the positioning of a bone flap for future research and clinical applications.

Computer-aided design (CAD) software, Rhinoceros (Robert McNeel & Associates), was used to design the plate based on a three-dimensional (3D) CAD model of a human mandible. The design of the plate involved matching the anatomical contours of the mandible at the location of the segmental bone defect and incorporated a concave medial surface to facilitate the positioning of a bone flap, as well as designated areas for screw fixations to the bone. The CAD model of the mandible was then virtually resected to create a right-sided one segmental mandibular defect of region DD 45-47. The resected CAD model of the mandible was 3D-printed in polyurethane. Additionally, a mold for the fabrication of GFRC plates was designed using the same CAD software. The mold surfaces were designed with a thickness of 3 mm to permit blue light penetration, facilitating the light-curing process of the resin. The mold was 3D-printed in acrylonitrile butadiene styrene (ABS) thermoplastic polymer.

The GFRC plates were prepared by lamination of sheets of silanized glass weaves (250 g/m2) impregnated with light-curing bis-GMA-TEGDMA (65:35 wt%) resin with a camphorquinone-amine photoinitiator system (0.7 wt%) pressed together in the mold. The sheets of the GFRC fabric were oriented in a 45° angle to each other with the first layer oriented at a 45° angle to the long axis of the plate. The mold with the fiber weaves was then placed into a vacuum chamber with blue light (3M Espe Visio Beta Vario) to facilitate polymerization of the resin matrix and eliminate the presence of an oxygen-inhibited surface layer. Polymerization was followed by post-photocuring at elevated (95°C) temperature (Ivoclar Vivadent Targis Power) for 20 minutes. Finally, the polymerized preforms were separated from the mold and cut to the desired shape using a high-speed dental grinding disc. The edges of the implants were finished with grinding paper (SiC Paper #180, Stuers Aps). Thereafter, all the plates were stored in an incubator (37°C) for six months prior to testing.

Two groups of GFRC plates were prepared: the first group, 'thin GFRC plate' featured a uniform shell thickness of 1 mm and was prepared using three layers of fiber weaves. The second group, 'thick GFRC plate', had a uniform shell thickness of 2 mm and was made with six layers of fiber weaves.

For the biomechanical testing, the mandible-implant systems were created by fixing the GFRC plates to the 3D-printed mandibles with screws. To simulate titanium bicortical screw fixation, standard steel screws (diameter 3.0 mm) were used to fix the plates to the mandible. There were five screws at the distal end of the plate and three screws at the mesial end of the plate (Figure 1 a, b).

Using a molding technique, similar to the one described earlier (Rendenbach et al., 2019), The test set-up for quasi-static loading the mandible-implant system, illustrated in Figure 1 a and b, followed the set-up of the previous study (Rendenbach et al., 2019).

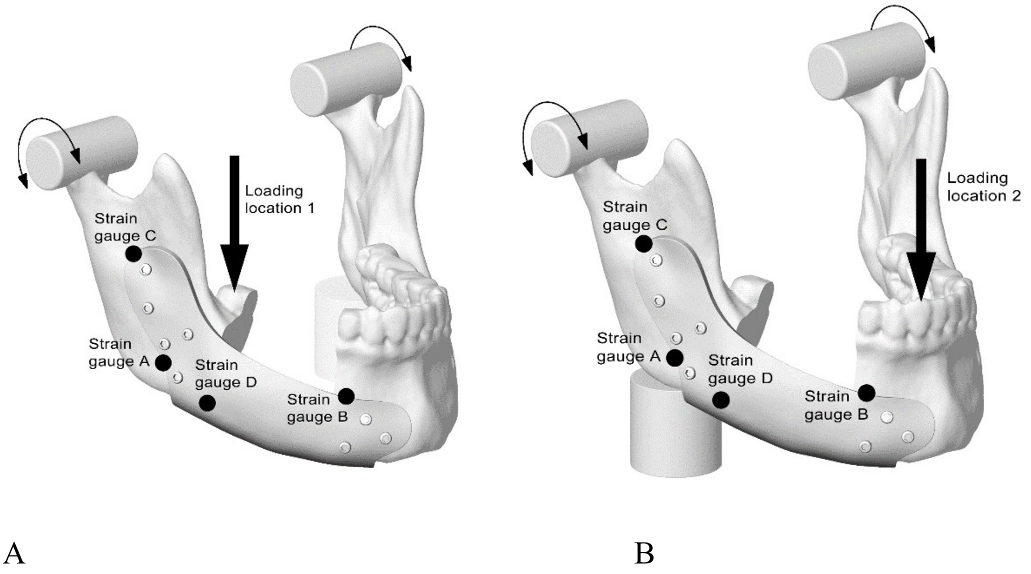


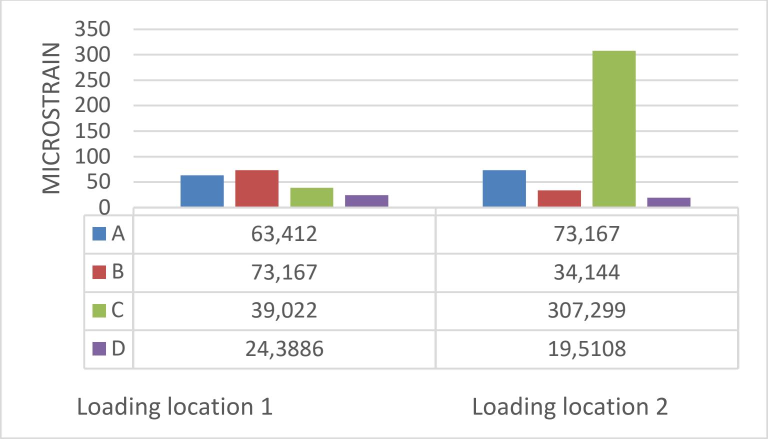
Figure 1. Schematic presentation of the plate, location of strain gauges and the set-up for a) molar and b) incisal loading (arrow).

A motorized universal material testing machine (Lloyd Instruments LR30k Plus, serial No. 107173) was employed to measure the loads. A customized jig made of steel was designed and fabricated to perform the experiment. Loading was done in 2 different occlusal locations: molar loading (1) and incisal loading (2). Using the customized jig, the condyle of each mandible was fixed and supported from the region of the *angulus mandibulae*. The plate was leaned against the bottom of the jig with the mandibular angle of one side only (contralateral to the loading region). This setup was designed to simulate the load to the plate during a masticatory cycle. All tested plates were loaded by applying force (load applied to one loading region; 1 or 2) until desired peak load (10 N, 50 N, 100 N) was reached. Prior actual loading event preload of 1N was used to adjust the mandibular-plate system on testing jig. Vertical movement (mm) of the of the loading tip was plotted against the load and it was used as an indicating unit of the deformation of the mandible-plate system.

Mechanical stress of the plates were measured with strain gauges (Kyowa KFGS 350Ω Biaxial, 0°/90°stacked rosette, LOTNO: Y4713M). Strain gauges were connected to the strain measurement device (Kyowa Electronic Instruments, PCD-300A) to record the strain data using data acquisition software (PCD-30A Ver.01.07). Strain gauge positions in the mandible-plate system were divided into 4 groups (A, B, C, D) (Figure 1 a, b) and magnitude of stress was expressed in microstrain units (με). Strain values were recorded at peak loads of 10 N, 50 N and 100 N. Net strain values of tensile and compression stress were calculated and used as indicative values of the stress at the strain gauge position.

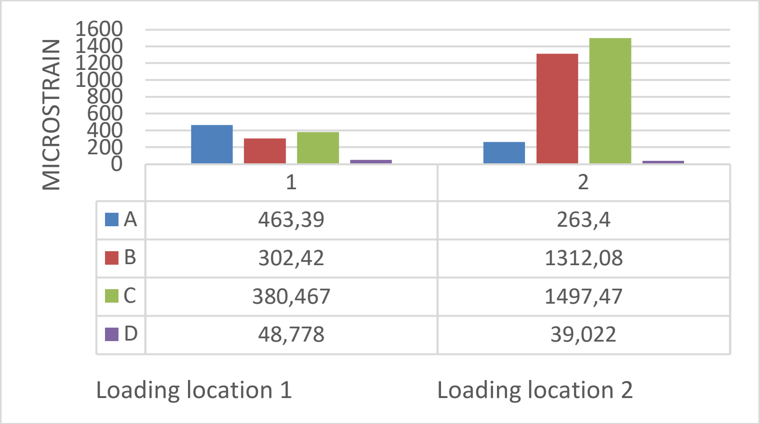
Results

Figure 2 a-c shows net strain values for thick plate at 10, 50 and 100 N loaded from positions of 1 and 2 and measured by strain gauges at locations A, B, C, D. Lowest strain values were recorded at strain gauge position D (78.0 με) which was located at the base of the plate. Highest strain values were recorded at the strain gauges at most distal and mesial the region of the plate-screw fixation (strain gauge locations B: 3282. 8 με and C: 2614.5 με). In general, increased loading values and incisal loading location increased the strain.



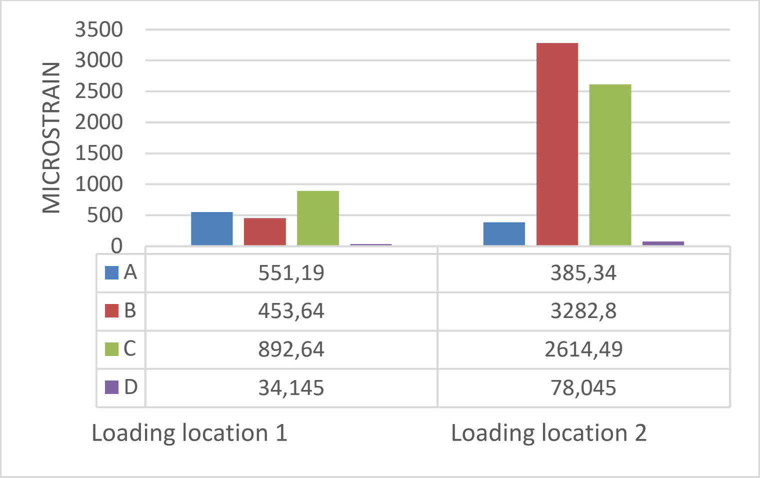
🟦 A	63,412	73,167
🟥 B	73,167	34,144
🟩 C	39,022	307,299
🟪 D	24,3886	19,5108

A



	1	2
🟦 A	463,39	263,4
🟥 B	302,42	1312,08
🟩 C	380,467	1497,47
🟪 D	48,778	39,022

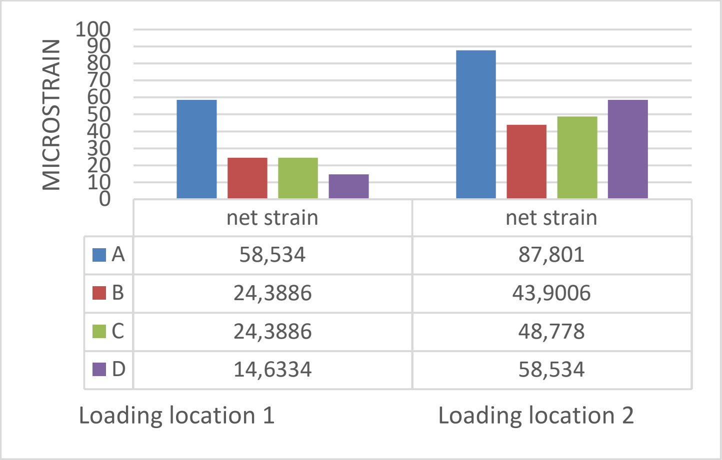
B



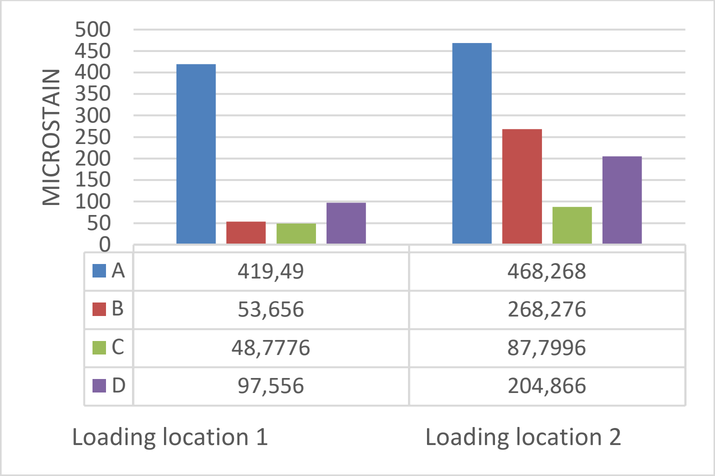
C

Figure 2. Microstrain (με) of the mandible-plate system of thick GFRC plate fixed and loaded with a) 10 N, b) 50 N and c) 100 N as illustrated in Figure 1.

Accordingly, Figure 3 a-c shows net strain values for thin plate at 10, 50 and 100 N loaded from positions 1 and 2 and measured by strain gauges at locations A, B, C, D. In contrast to thick plate, the lowest strain values were found at distal (location C: 24.4 με) strain gauge position and the highest strain values at the strain gauges were located in the screw fixation area at the *corpus mandibulae* area (location A: 780.5 με). Quite high values were also observed at the base of the plate (location D: 321.9 με) . Also with the thin plates, the highest strain values were recorded when the system was loaded incisally but the values as whole were at a lower level than with the thick plate.

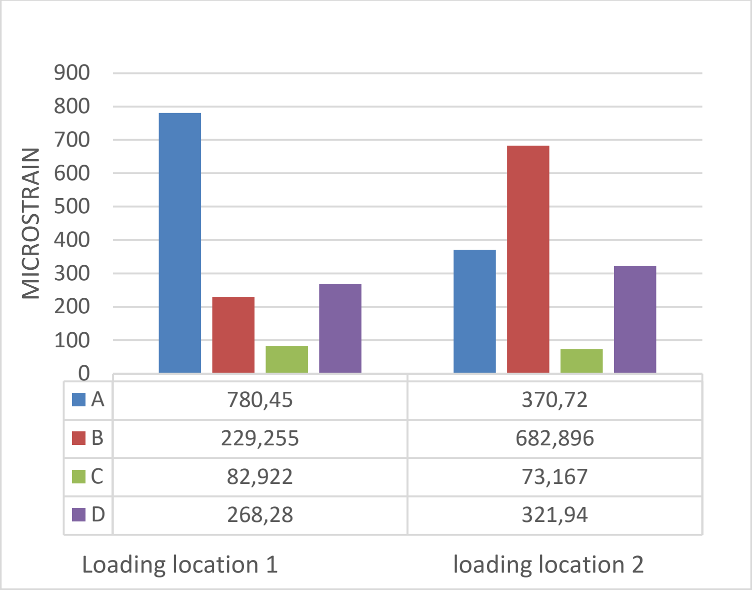


A



	Loading location 1	Loading location 2
🟦 A	419,49	468,268
🟥 B	53,656	268,276
🟩 C	48,7776	87,7996
🟪 D	97,556	204,866

B

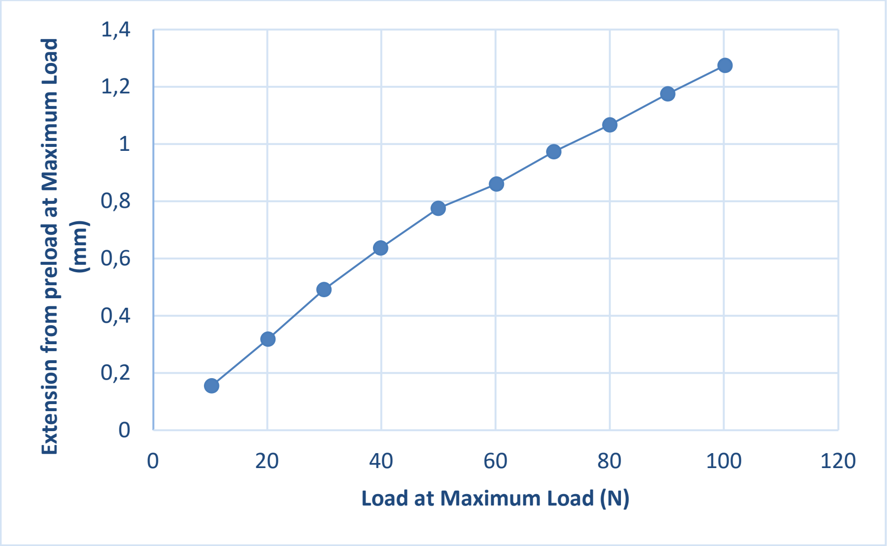


	Loading location 1	loading location 2
🟦 A	780,45	370,72
🟥 B	229,255	682,896
🟩 C	82,922	73,167
🟪 D	268,28	321,94

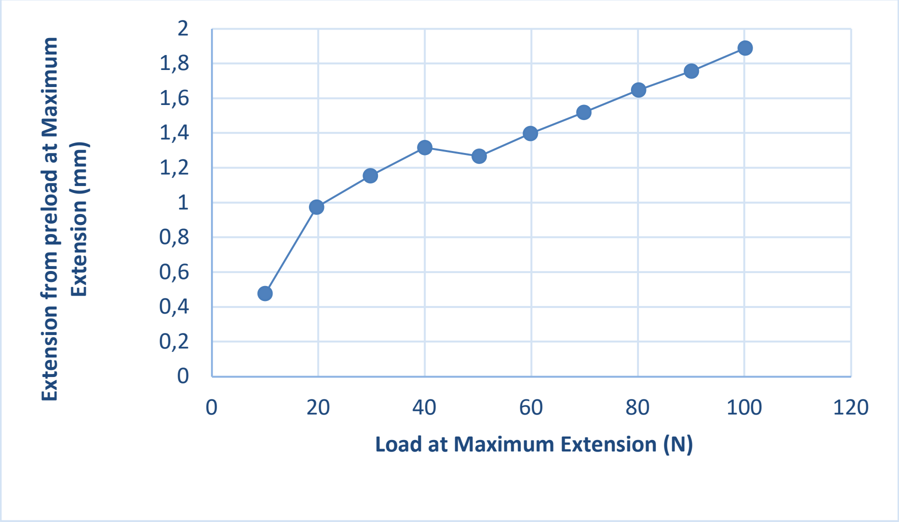
C

Figure 3. Microstrain (με) of the mandible-plate system of thin GFRC plate fixed and loaded with a) 10 N, b) 50 N and c) 100 N as illustrated in Figure 1.

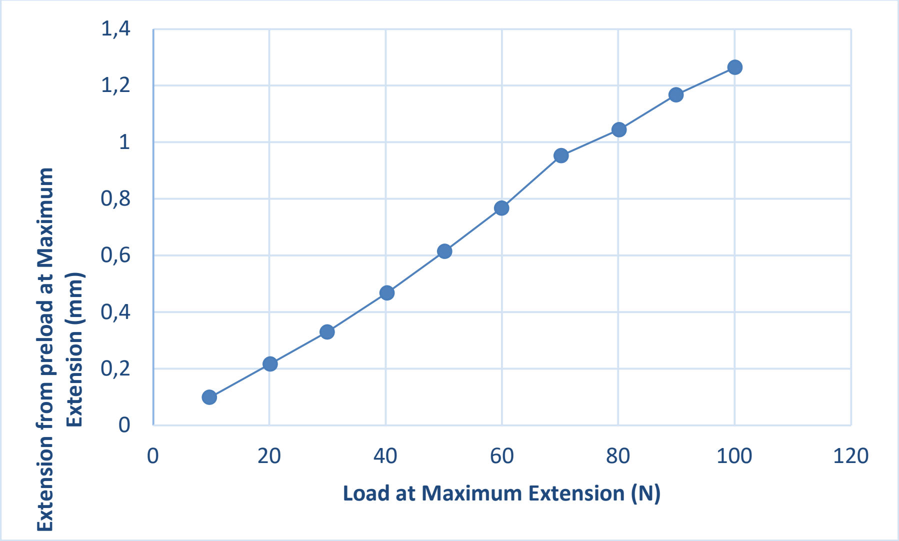
When vertical displacement of the loading tip, which indicates deformation and bending of the mandible-plate system is plotted against the loading force, loading location and thickness of the plate demonstrated a more linear relationship when the load was applied to the molar region than to the incisal region (Figure 4 a -d). The highest load (100 N) caused a ca. 1.9 mm vertical displacement to the incisal area and ca. 1.3 mm displacement to the molar area. No difference was found between the thick and thin plates. Neither thick or thin plates showed visible damage of the plate by fracturing or buckling during the loading event.


Extension from preload at Maximum Load (mm)
1,4
1,2
1
0,8
0,6
0,4
0,2
0
0
20
40
60
80
100
120
Load at Maximum Load (N)

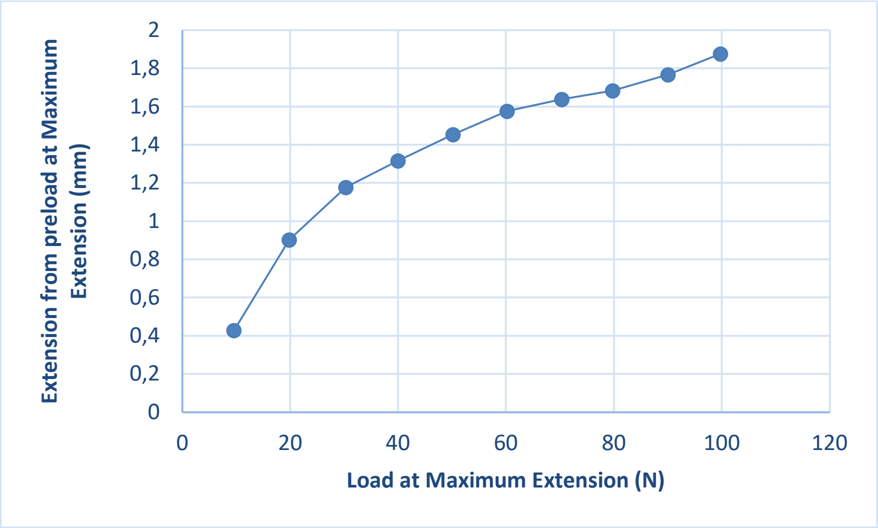
A


Extension from preload at Maximum Extension (mm)
2
1,8
1,6
1,4
1,2
1
0,8
0,6
0,4
0,2
0
0
20
40
60
80
100
120
Load at Maximum Extension (N)

B


Extension from preload at Maximum Extension (mm)
1,4
1,2
1
0,8
0,6
0,4
0,2
0
0
20
40
60
80
100
120
Load at Maximum Extension (N)

C



D

Figure 4. Vertical displacement (mm) of the mandible-plate system plotted against the loading force: a) thick plate loaded from molar area, b) thick plate loaded from incisal area, c) thin plate loaded from molar area, d) thin plate loaded from incisal area.

Discussion

Titanium remains a reliable material of choice in clinical practice. Nevertheless, while titanium plates are widely used in reconstructing segmental defects of the mandible, their use is not without challenges, including the risks of plate exposure, incomplete osseous union, and potential complications in diagnostic imaging. Consequently, the development of a semi-anatomical patient-specific GFRC plate presents an opportunity to enhance current surgical outcomes. With its L-shaped profile, our novel PSI is engineered to provide sufficient structural strength for mandibular reconstruction and includes a surface optimized for bone flap application, thereby augmenting the functional integration of the implant. This study adds to previous research on a non-metallic material alternative in the form of GFRC, which is clinically used in Europe for cranioplasty implants. It extends this use to cranio-maxillo facial surgery (Klieverik et al., 2023; Piitulainen et al., 2015). Some encouraging early positive results of using the GFRC in jaw bone reconstructions have been reported (Farook S et al., 2016) but mostly the studies have been in vitro studies including studies of GFRC dental implants (Abdulmajeed et al., 2011; Ballo et al., 2014; Farook et al., 2017). It is to be noted that resective surgery and rehabilitation of masticatory function are also concerns with implications for esthetic outcomes, which can have significant implications on life quality. In such clinical situations, the loss of soft and hard tissues can be significant. Having esthetically satisfying results, GFRC implants could offer symmetrical support against soft tissue instrusion to area with a defect. GFRC implants also have utility in the case of post operative radiotherapy, where metallic implants may be problematic .

It is known that biomechanical properties, especially modulus of elasticity of the plate material and structural rigidity of the plate, have an impact on the fusion of a fibula free bone flap used in the reconstruction of segmental defect of a mandible. Thus, the present study extends existing research involving GFRC plate with design modifications aimed at rectifying the shortcomings of previously studied plates. The test design was selected for it's ability to characterize the level of mechanical stress in the simulated situation of reconstructed segmental defect by primarily screw fixed semi-anatomic GFRC plate. The loading force for the test set-up was considerably lower than than that of human maximal biting forces of up to 847 N measured unilaterally, because of drastic reduction of the biting force with patients under treatment of mandible reconstruction with free bone flap (Curtis et al., 1997; Maurer et al., 2006; Waltimo and Könönen., 1993).

When the design of the presently tested semi-anatomic GFRC plate is compared to the previously studied GFRC plate which followed the form of bended titanium plate, it became obvious that cross-sectional geometry and dimensions provided higher structural rigidity, although the GFRC material has same modulus of elasticity. Location and number of fixation screws was selected according to the present understanding of stress distribution in the mandible-plate system. We did not find any signs of damage of the mandible-plate system in general or that which could relate to the location or number of the screws. However, some interesting findings were made when the magnitude of stress was analyzed at different parts of the mandible-plates system with two loading locations.

The results showed that strain values in the base of the plate (strain gauge D) were higher in thin plate compared to thick plate. Strain values at the region of plate-screw fixation (strain gauges B and C) however were higher in thick plate compared to thin plate. Thus, it seems that thicker and stiffer plate transfers strain into the plate-screw fixation region whereas thin plate bends and absorbs energy into the body of the plate. Increased strain at the plate-screw fixation region may cause micromovement at the screw-plate interface and may even result in debris formation from titanium or GFRC. Possible titanium debris derived from titanium screws might have cytotoxic effects, therefore causing complications such as loss of bone and plate loosening. Possible cytotoxic effect of titanium particles has been demonstrated in previous studies (Messous et al., 2021). Future studies should examine the influence of alternative screw fixation configurations to prevent unfavorable strain at the most distal and mesial regions of the plate-screw fixation. Potential failure mechanisms of GFRC plates with varied thicknesses should also be examined in the future. Increased energy absorption to the plate base in thin plate configurations may cause a buckling failure type whereas thick plate may result in plate loosening at the plate-screw interface due to potential micromovement.

Mechano-biologically ideal plate design should provide enough stiffness and fatigue strength to allow bone healing in a free flap situation. The ideal range of stiffness for mandibular bone healing however is unclear. Nevertheless, animal studies of long bone fracture healing indicate that axial intersegmental movement up to 1.0 mm, stimulates callus bone formation while axial movements above 2.0 mm impairs bone repair (Claes, 2017; Claes et al., 1998; Kenwright and

Goodship, 1989; Schell et al., 2008). Although presently studied GFRC plates showed relatively high vertical displacement at 100 N loading, due to reduced masticatory forces after mandibular reconstruction, GRFC plates might still provide sufficient stability for successful reconstruction of segmental defect of mandible.

Conclusions

GFRC plates withstood the loading condition up to 100 N even when loaded incisally. Thick plates concentrated the stress to the *ramus mandibulae* region of fixation screws whereas the thin plates showed stress concentration to the *angulus mandibulae* region of the fixation and the plate itself. In general, thin plates caused a lower magnitude of stress to the fixation screw areas compared to thick plates, suggesting absorption of the loading energy to the body of the plate.

Acknowledgements

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