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Production of thin shell clavicle implants through Single Point Incremental Forming

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Abstract.

The expanding demand for discrete freeform parts in bio-medical applications emphasizes the need for flexible production processes like Single Point Incremental Forming. This paper presents the specific challenges encountered during the design and fabrication of clavicle implants using medical grade titanium sheets. The fracture fixation and bone aligning task of these implants call for specific accuracy distribution, while the distinct geometry and post forming heat treatment influence production accuracy. The design potential for these implants considering forming angles of titanium grade 2 and soft tissue interactions are discussed. A generic case for the design, forming, heat treatment and trimming of a Titanium clavicle fixation plate is presented.

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Keywords: SPIF; implant; clavicle; accuracy; design

1. Introduction

As a flexible sheet forming process, Single Point Incremental Forming (SPIF) has the potential to aid in the fabrication of patient specific bio-medical hardware. This process, using only generic tooling, is well-suited to meet the demand for unique part production. Trailing preliminary research on the manufacture of cranial implants [1] a number of research institutes have dived into the production of both cranial and maxilla facial implants [2,3]. Araújo et al. [4] investigated the forming limit curve of Ti grade 2 and correlated this to the strains required in the fabrication of facial implants surrounding the eye socket. While concerns on biocompatibility and surface quality of titanium were addressed by Fiorentino et al. [5], Hussain et al.[6] described a preprocess micro-arc oxidation combined with an in process lubrication using MoS_2 to obtain best surface quality while forming Ti grade 2 sheets.

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While incremental forming has shown potential as an alternative process to manufacture custom thin shell cranial and maxilla facial implants, other bone structures and medical procedures can benefit from these type of implants as well. Clavicle fractures are common among young active people with increasing number of fractures over the last years. Huttunen et al. [7] reported an increase from 2,480 Swedish clavicle fractures in 2001 to 4,525 in 2012, similar to the trend observed in Belgians leading medical institutes. Medical treatment for these fractures can be categorized as conservative or operative treatment, using respectively external immobilization bandages or surgical fixation devices. While thin shell implants are a proven technology for cranio-facial surgery, clavicle implants have thus far been generic bulk titanium bars, resulting in a necessary reoperation rate of up to 53%, as reported in [8]. Main reasons for operative removal are soft tissue irritations through poor geometric fit and thickness of the current fixation plates for such a superficial bone.

Clavicle fixation proves to be the next step in complexity after cranial implants because of increased load-bearing, increased soft tissue interaction and large uni-directional curvatures rapidly increasing the required forming angle.

In this article the authors present a novel treatment procedure from broken bone to manufactured implant, explaining the application and manufacturing specific design limitations. The accuracy results of a fist demonstrator case are presented.

2. Treatment of Clavicle Fractures

The clavicle, unlike the cranium, is littered with muscle attachments and other soft tissue. This with the understanding that the periosteum layer around the bone should be minimally affected and squeezed by the implant, makes the design and fabrication of patient specific implants necessary. As these implants will take up both fixation tasks as well as aligning tasks of the bone during the operation, the global accuracy of these parts is crucial. Moreover, the distinct accuracy specifications for this application lay in aiding the global orientation of the bone fragments for optimal shoulder function rather than absolute local fit to the bone.

The current treatment flow for patients consists of an X-ray followed by the operation using a generic set of fixation plates. These allow negligible patient tailored treatment, most often resulting in sub optimal aligning of the bone and irritation by the implant.

The novel proposed treatment flow is depicted in Fig 1 and includes:

- A low dose CT-scan that allows to determine the bone and fracture morphology (Fig 1a and b). Using these data, the bone can be digitally aligned and the initial position and fit shape of the implant can be established (Fig 1c).
- After determining the muscle attachment sites of the bone, the final potential implant area on the bone is defined (Fig 1d pink area) avoiding these muscle areas.
- Acknowledging the limited forming angle for Ti grade 2 using SPIF (47°) [9], an implant can be positioned and designed in the potential implant area (Fig 1e).
- Embedding the implant into a larger workpiece allows the fabrication starting from a flat sheet (Fig 1f).
- Subsequently the part will be formed, heat treat stress relieved and cut out.
- Finally the custom implant can be used during operation, fixating the bone and aiding in proper alignment of the bone fragments. (Fig 2.)

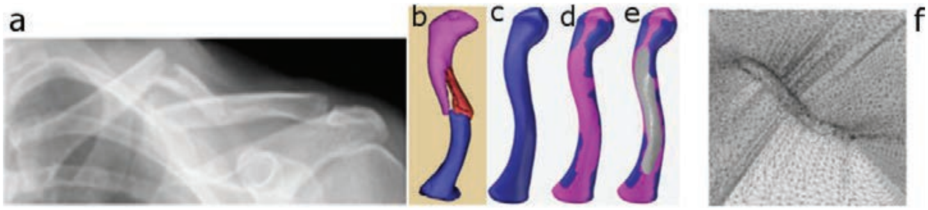

Fig. 1. From left to right: a) CTscan of clavicle; b) 3D reconstruction; c) reconstructed clavicle; d) clavicle with predicted muscle attachment sites (blue area); e) clavicle with designed implant; f) implant embedded in extension structure