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## Revolutionizing Biomedical Manufacturing: The Transformative Potential of Incremental Sheet Metal Forming (ISMF)

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### ABSTRACT:

Incremental Sheet Metal Forming (ISMF) has emerged as a versatile and innovative method for deforming sheet metal, particularly advantageous for small batch production and rapid prototyping. This paper explores the application of ISMF in the manufacturing of custom-made biomedical implants, emphasizing its potential to revolutionize this field. Unlike traditional manufacturing processes that rely on expensive molds and complex setups, ISMF utilizes simple tools and fixtures, making it a cost-effective solution for producing intricate, asymmetrical components. This method is especially beneficial in the medical industry, where the demand for personalized implants is growing. The study delves into the specifics of Single Point Incremental Forming (SPIF), a subset of ISMF, which maintains the material's crystal structure while enabling precise deformation. Given the biocompatibility concerns with conventional Ti-6Al-4V alloys, which release toxic vanadium and aluminum ions, this research highlights alternative materials and methodologies to enhance safety and performance. Experimental results and finite element simulations demonstrate the improved forming limits and deformation capabilities of ISMF compared to traditional methods. The findings underscore ISMF's ability to produce complex shapes without the need for specialized molds, significantly reducing manufacturing costs and time. This paper also discusses the technological advancements in tool path generation and numerical simulations that have propelled ISMF to the forefront of rapid prototyping technologies. By showcasing successful applications in creating dental and orthopedic implants, this research confirms ISMF's transformative impact on biomedical manufacturing, paving the way for more efficient, customized, and patient-specific medical solutions.

**Keywords:** Incremental Sheet Metal Forming (ISMF), Biomedical Implants, Single Point Incremental Forming (SPIF), Rapid Prototyping, Custom-made Implants

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## 1. Introduction

The concept of ISMF dates back to 1967 when Leszak patented an apparatus and process for continuous local deformation. Despite the initial interest, significant research began in the 1990s, gaining momentum with the advent of 3-axis CNC milling centers in 2001. This period marked a shift from specialized CNC machines to more accessible universal milling centers. Prominent researchers in this field include Jeswiet, Hirt, Micari, Duflou, and Allwood [1-8]. Continuous local deformation shaping technology remains a hot research topic due to its application limitations, such as significant temperature generation, high surface roughness, and low productivity.

In recent years, the field of sheet metal deformation has seen the development of various innovative methods, among which Incremental Sheet Metal Forming (ISMF) has garnered significant attention. ISMF has emerged as a prominent technique due to its notable advantages in small batch production and rapid prototyping. This method is increasingly being recognized as a critical area of research and development (R&D) within the manufacturing industry [1]

ISMF employs a relatively simple setup, utilizing a ball-end cylindrical tool that lacks a cutting edge. The metal plate is securely clamped on a jig, allowing it to be incrementally deformed to conform to the shape of a mold cavity. One of the significant advantages of ISMF is the use of inexpensive mold materials, such as wood or plastic, which eliminates the need for costly specialized molds [2]

The process begins with the design of a 3-D CAD model of the finished part. This model is then transferred to a Computer-Aided Manufacturing (CAM) environment, where a reasonable tool path is simulated. The resulting tool path guides the deformation tool as it incrementally shapes the metal sheet. Depending on the complexity of the part being produced, the process may or may not require a supporting mold [3]

Incremental Sheet Metal Forming (ISMF) is a versatile and modern sheet metal forming process that does not necessitate dedicated dies or molds. Instead, it relies on generic, easily adjustable tooling to progressively shape the metal. The key component of ISMF is a hemispherical or ball-ended tool that follows a predefined path, incrementally deforming the metal sheet. This method provides significant design flexibility and can produce complex geometries that are challenging or impossible to achieve with traditional stamping processes [4]

The primary advantages of ISMF include its suitability for small batch production and rapid prototyping. Traditional manufacturing processes require substantial time and financial investment in creating specific molds and dies, which is impractical for small production runs or prototypes. ISMF mitigates these costs by using generic tooling and simple jigs, making it particularly attractive for industries that require customization and quick turnaround times, such as the biomedical sector [5]

The biomedical implant market is expanding rapidly, driven by an aging population and a growing demand for personalized medical solutions. Custom-made implants are especially beneficial as they can be tailored to the unique anatomical features of individual patients, leading to better integration and fewer complications. ISMF is highly suitable for this application due to its flexibility in producing complex and precise shapes without the need for expensive, specialized tooling [6]

Single Point Incremental Forming (SPIF), a variant of ISMF, has been effectively used to form intricate, asymmetrical components typical of biomedical implants. SPIF maintains the material's crystal structure by relying on stretching and bending processes, which is crucial for preserving the biocompatibility and mechanical properties of implant materials [7]

One commonly used material in biomedical implants is the Ti-6Al-4V alloy. However, concerns have been raised about the toxicity of vanadium and aluminum ions released from this alloy, which can cause severe health issues such as osteomalacia and Alzheimer's disease. Despite these concerns, the alloy's excellent mechanical properties and biocompatibility make it a popular choice, provided the release of toxic ions can be managed effectively through coating technologies or alternative alloy compositions [8]

ISMF represents a significant advancement in sheet metal forming, offering unique advantages for small batch production and rapid prototyping, especially in the biomedical sector. Its ability to produce customized implants quickly and cost-effectively makes it a promising technology for meeting the growing demand for personalized medical solutions. Continued research and development in ISMF techniques and materials will further enhance its capabilities and applications across various industries.

## 2. ISMF in Biomedical Implants

ISMF's adaptability makes it particularly suitable for the biomedical field. The method allows for the rapid prototyping of custom implants, significantly reducing the time from concept to final product. For example, researchers have used ISMF to create dental support plates and skull fragments from lightweight titanium. This technique is also being explored in the automotive industry for parts like radiator fins, headlight housings, and car model shells.

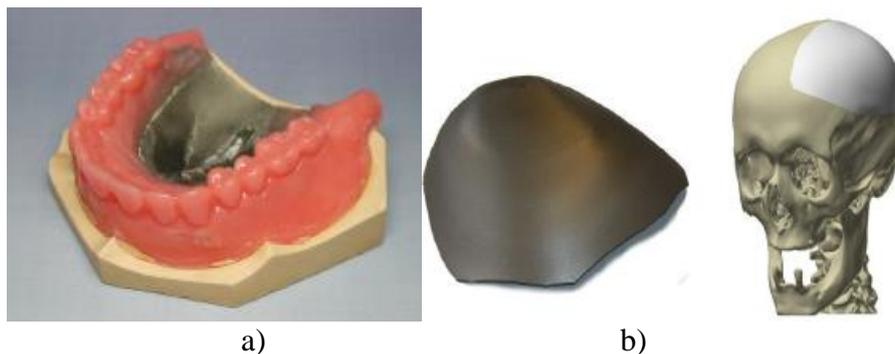


Figure 1: Rapid prototyping products from ISMF: a) Dental application  
b) Medical application

The market for implantable devices is vast and growing (Fig. 1). Traditionally, these products are manufactured using conventional processes, but for custom-made implants, Incremental Sheet Forming is an excellent alternative. Single Point Incremental Forming (SPIF), a specific ISMF method, is used to form intricate, asymmetrical components by stretching and bending the material while maintaining its crystal structure. SPIF can be performed on standard CNC milling machines, making it accessible and practical.

A commonly used material for implants is the Ti6Al4V alloy. However, the vanadium content in this alloy poses toxicity risks. Both vanadium and aluminum ions released from Ti-6Al-4V alloy have been linked to severe health problems, such as osteomalacia and Alzheimer's disease. This has driven the need for safer alternatives, highlighting the importance of innovative forming methods like ISMF, which can work with a variety of materials, including those better suited for biomedical applications.

### 3. Advantages of ISMF

Although ISMF is slower compared to die-form stamping technologies, it is well-suited for single-piece and small-batch production due to the reduction in costs associated with expensive molds. Studies by Iseki and Kumon have demonstrated the creative limits of ISMF, showing that the forming limit curve (FLC) of ISMF is significantly higher than the limits predicted by traditional plastic fracture theories and verified through conventional methods. Unlike the V-shaped forming limits of traditional methods, ISMF produces larger deformation limits with an almost linear downward slope in the principal-secondary deformation coordinate system (Fig. 2)

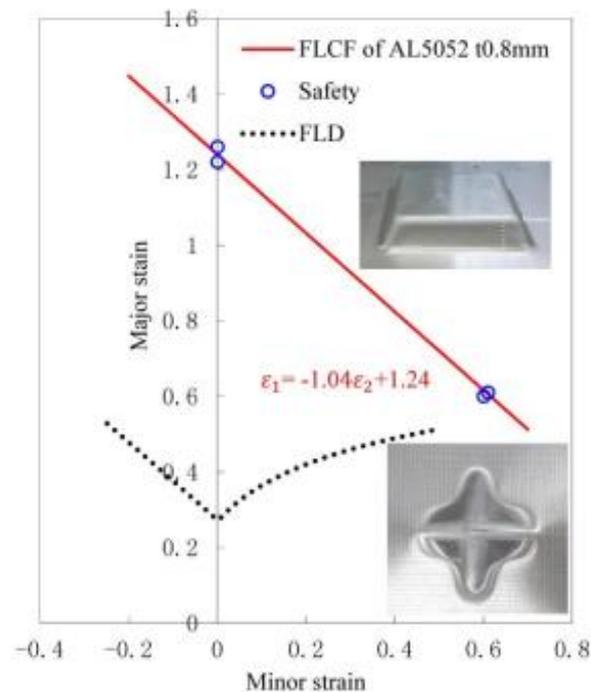


Figure 2: Forming limit curve (FLC) of ISMF

Comparative studies show that the forming limits in ISMF are significantly higher than those in traditional forming methods. The forming limit diagram (FLD) in ISMF is raised much higher than the limits calculated from plastic damage theory and obtained experimentally through traditional methods. The safety standards of Clift et al. provide a basis for calculating these forming limits, considering factors such as equivalent strain, equivalent stress, and the anisotropy coefficient.

The material forming limits in ISMF of metal sheets is bounded by the bending and stamping limit curve. Prior studies have shown that applying a combined load of bending and stamping increases the forming limit. The forming limit of ISMF method typically exhibits an almost straight downward shape in the major-minor deformation coordinate system. The points on this forming limit line are calculated based on the initial point at the Equibiaxial strain region, with subsequent points determined according to the relationship between principal and minor strain ratio, along with the equivalent strain function for the plane stress state as shown in Figure 2.

#### 4. Tool Path Generation and Numerical Simulation

ISMF is a continuous shaping process wherein plastic deformation occurs locally in a small area beneath the forming tool. The deformation tool moves in controlled paths to create three-dimensional profiles, directly modeling from 3-D CAD models into finished products without intermediate mold stages. The basic configurations used in ISMF involve shaping along concave or convex surfaces, depending on the part surface where the tool is moving. The key parameters affecting ISMF include the shaping tool radius, metal plate thickness, vertical feed rate, tilt angle after deformation, deformation rate, axial force, and horizontal bending force.

Generating tool paths in ISMF involves dividing the part into cutting layers, where each layer's profile matches the desired part shape. CAM software like CIMATRON, DELCAM, or MASTERCAM is used to simulate and generate these paths, typically following a spiral tool path from top to bottom.

Finite element simulation (FEM) plays a crucial role in ISMF, helping predict stress distribution, deformation, and plastic failure. Material properties, including elastic modulus, Poisson's coefficient, and density, are modeled alongside anisotropy models to describe plastic flow laws. The simulations use shell elements to balance accuracy and computational efficiency, considering factors like friction coefficients and material data (Fig. 3)

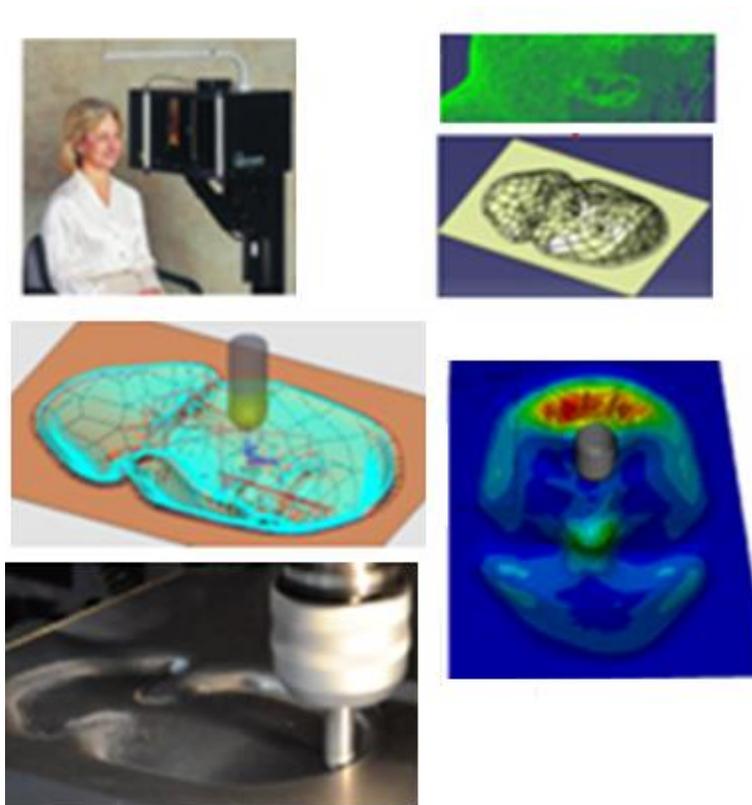


Figure 3: CAD/CAM Tool path, simulation and experiment

Simulations of square tower shapes with different angles have demonstrated ISMF's capability to predict forming heights and plastic failure points accurately. These simulations align well with experimental results, showcasing ISMF's potential for producing complex shapes without intermediate molds.

This study utilizes the commercial software ABAQUS for simulating the ISMF machining process. This software facilitates elastic and elastoplastic simulations of the metal forming process, enabling the analysis of characteristics such as stress distribution, deformation, and plastic failure. Before simulating the forming deformation process, it is imperative to establish the mechanical properties of the 3D model, geometric profiles of objects, and contact surfaces. The elastoplastic model is commonly selected for simulation, incorporating material properties like elastic modulus, Poisson coefficient, and material density. Furthermore, the material's tensile and compression curve equations, along with the anisotropy model, are applied to describe the plastic flow laws. The basic equations for forming dynamic analysis are outlined as follows:

The displacement amount, step time, velocity, and acceleration are calculated using Euler's algorithm, assuming constant acceleration and velocity at each individual point over time during an incremental step (Eq. (1))

$$\begin{aligned} \dot{u}^N_{\left(i+\frac{1}{2}\right)} &= \dot{u}^N_{\left(i-\frac{1}{2}\right)} + \frac{\Delta t_{(i+1)} + \Delta t_{(i)}}{2} \ddot{u}^N_{(i)} \\ u^N_{(i+1)} &= u^N_{(i)} + \Delta t_{(i+1)} \dot{u}^N_{\left(i+\frac{1}{2}\right)} \end{aligned} \tag{1}$$

The acceleration at the start of the increment is determined using diagonal mass matrices, where [M] represents the total mass diagonal matrix, {F} is the applied load vector, and {I} is the internal force vector (Eq. (2)):

$$\{\ddot{u}^N_{(i)}\} = [M]^{-1} \cdot (\{F_{(i)}\} - \{I_{(i)}\}) \tag{2}$$

The time increment limit is determined to satisfy the specified inequality (Eq. (3)):

$$\Delta t \leq \frac{2}{\omega_{\max}} \tag{3}$$

Equation (4 and 5): The characteristic element length (Le) and cd are calculated to determine the time increment limit.

$$\Delta t = \min\left(\frac{L^e}{c^d}\right) \tag{4}$$

$$c^d = \sqrt{\frac{\lambda + 2\mu}{\rho}} \tag{5}$$

Anisotropic models, such as Hill's inequality, can be incorporated into the simulation process (Eq. (6)):

$$\sigma_x^2 + \sigma_y^2 - \frac{2R_m}{1+R_m} \sigma_z \sigma_y + \frac{2(1+2R_m)}{1+R_m} \tau_{xy}^2 = \bar{\sigma}^2 \tag{6}$$

Figure 4 illustrates the outcomes achieved following the rapid prototyping of products featuring intricate surfaces under real conditions and corresponding FEM simulation

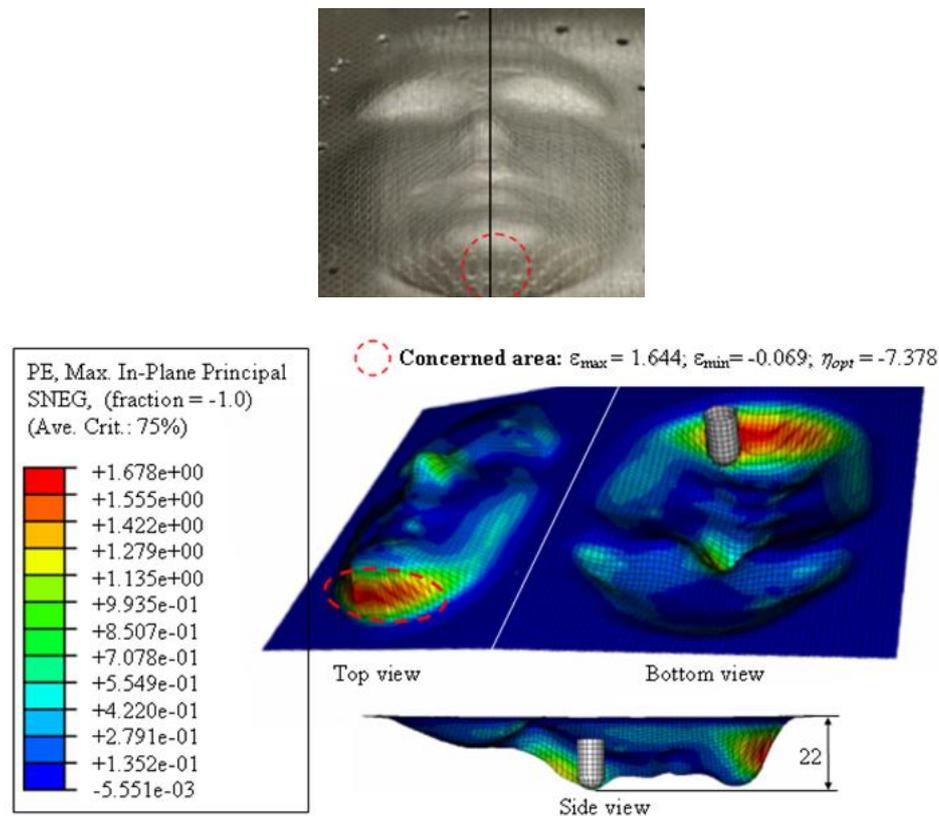


Figure 4: Final product and corresponding simulation.

## 5. Conclusion

ISMF is a promising technique for the rapid prototyping and small-batch production of biomedical implants. Its ability to create complex, custom shapes without the need for expensive molds makes it a viable alternative to traditional manufacturing methods. The continuous local plastic deformation method is an innovative approach that meets the needs of modern manufacturing, particularly in the biomedical field, where customization and rapid production are crucial. The integration of CAD/CAM technologies and numerical simulations further enhances ISMF's capabilities, making it a cutting-edge solution for future manufacturing challenges.

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