


Central Fabrication and Manufacturing


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American Orthotic & Prosthetic Association

Overview
Why Use
Changes
Challenges
Opportunities

Central Fabrication




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Overview of C-Fab Landscape

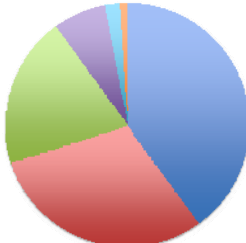
- 70 C-Fabs in US
- 12 ABC Accredited Facilities
- 99.9% of O&P Clinics utilize a C-Fab

Data calculated using information from AOPA, ABC, and O&P Business News, and PFA




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Overview of C-Fab Landscape



- Foot Orthotics
- AFOs
- P&O
- Spinal
- Cranial
- UE


Data calculated using information from AOPA, ABC, O&P Business News, and PFA



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Why Clinics use a C-Fab?


- Specialty fabrication
- Lack of time
- Lack of technicians/ability to train/hire
- Practitioner only practices
- More Cost Effective



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C-Fab Changes

- Scanners and Carvers
- New Materials
- New Techniques
- Electronic Alignment Systems
- 3D Printing



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C-Fab Challenges & Opportunities

- FDA/Government Regulations
- C-Fab Accreditation
- OTS reimbursement declining
- Custom Orthotic Documentation Requirements
- Risk v. Reward of being an early adopter



How to incorporate it into the process
Durability of 3D Printed products
Custom or Not

3D Printing



3D Printing: How to use it

- C-Fab
- R&D
- Finished Good



3D Printing: Durability

- How long will a 3D printed hand last?
- What is the expected durability?
- Is a 3D printed product safe as a definitive orthosis or prosthesis?



3D Printing: Custom or Not

- Are 3D printed hands custom?
- How would a 3D printed hand be billed?
- Does a 3D printed hand need to be FDA approved?
- FDA Registration/CE Mark
 - What is AOPA's position?
 - Should AOPA make a recommendation?



Overview
Trends
Challenges
Opportunities

Manufacturing



Manufacturing Overview

- ISO Quality Standards
- New Materials = New Equipment
- Automation



Manufacturing Trends

- Consolidation
- 3D Printing
- New ISO Foot Testing Standards
- Emphasis on prosthetics
- Emphasis on Rehab-Orthotics



Manufacturing Challenges

- Reimbursement
- Changing Regulatory Requirements
- Increasing Competition
- Small Quantities = Big Price
- Where to manufacture?



Manufacturing Opportunities

- Lower Cost Materials
- Look outside O&P
- Robotics
- Sustainable/Additive Manufacturing
- ERP Systems



Q&A

