Zprobe: Humeral Bone Quality Device

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PROBLEM STATEMENT

Orthopedic surgeons performing shoulder arthroplasty currently lack objective, intraoperative tools to assess bone quality, needed to guide implant selection.

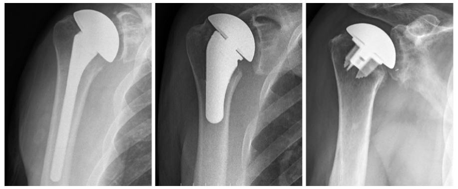


Fig. 1. Long, short, and stemless implants [1]

KEY FUNCTIONAL REQUIREMENTS

Requirement	Ideal Specification	Achieved?
Device must be hand-held	Weight ≤ 350g Grip diameter ≤ 25 mm Length ≤ 250 mm	☑
Device must be able to collect continuous measurements representative of bone quality	A continuous measurement that spans the entire spectrum of bone quality	☑
Device must be able to gather measurements in a reasonable time	Duration of single actuation ≤10 seconds	☑
Device must not damage the proximal humeral bone to any degree that impairs implant fixation	Extent of bone damage resulting from device use <1cm in diameter & depth	☑
Device must be reusable	Number of actuations before failure	☑

Table 1. Key Functional Requirements and Specifications

DESIGN RATIONALE

CURRENT PRACTICE

Fig. 2. Thumb Test

During surgery, bone quality is currently evaluated using the subjective "**thumb test**," in which surgeons press on the resected humeral head to estimate its mechanical integrity.

CLINICAL NEED

- The thumb test is a subjective method, dependent on surgeon judgment
- Outcomes vary based on:
  - Applied force
  - Location of assessment [2]
- Surgeons show limited accuracy in detecting poor bone quality at the proximal humerus when compared to objective metrics [2]

APPROACH: ELECTRICAL IMPEDANCE

- **Electrical impedance (Z):** resistance to alternating current
- Conductivity decreases linearly with bone density [Fig. 3]
- Therefore, impedance increases with bone density

More porous → Lower quality → Less Z

Less porous → Higher quality → More Z

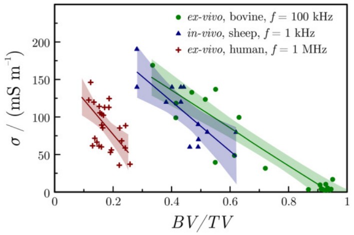
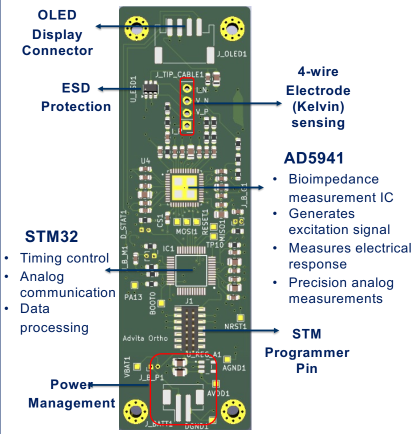


Fig. 3. Bone Conductivity (1/R) vs. Bone Density [3]

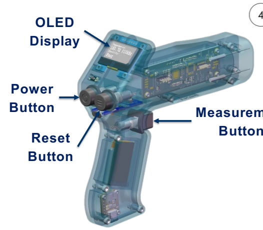
THE ZPROBE

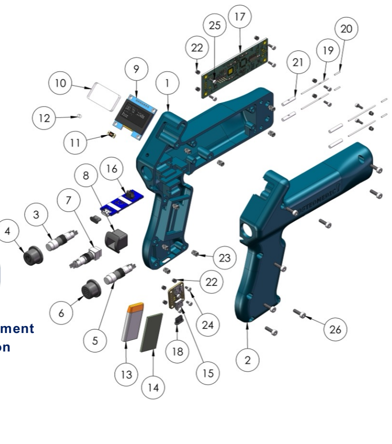
ELECTRONIC ARCHITECTURE



MECHANICAL ASSEMBLY

- Two-piece housing simplifies assembly and access to internal components
- PCB mounted in the main body with distributed internal components
- Components are secured using heat-set inserts and screws



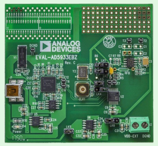


ITEM NO.	DESCRIPTION	QTY.
1	RIGHT HOUSING SHELL	1
2	LEFT HOUSING SHELL	1
3	ROUND MAINTAINED PUSH BUTTON SWITCH	1
4	POWER BUTTON COVER	1
5	ROUND MOMENTARY PUSH BUTTON SWITCH	1
6	RESET BUTTON COVER	1
7	SQUARE MOMENTARY PUSH BUTTON SWITCH	1
8	MEASUREMENT BUTTON COVER	1
9	OLED DISPLAY	1
10	OLED WINDOW	1
11	LED	1
12	LED WINDOW	1
13	3.7V BATTERY	1
14	SILICONE FOAM	1
15	BATTERY CHARGER	1
16	STLINK V3MINIE	1
17	PCB	1
18	USB-C COVER	2
19	ELECTRODE	4
20	POLYOLEFIN HEAT SHRINK TUBING	4
21	BUTT SPLICE	4
22	M2 HEAT-SET INSERT	12
23	M3 HEAT-SET INSERT	8
24	M2 4MM SCREW	4
25	M2 6MM SCREW	8
26	M3 10MM SCREW	8

TESTING

IMPEDANCE GAUGES

AD5933 Eval Board



Preconfigured impedance measurement board using the AD5933 chip

FNIRSI LC1020E LCR

LCR meter used to validate impedance readings

ANIMAL BONE TESTING

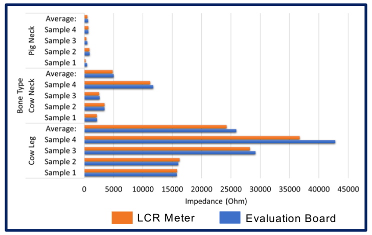


Fig. 5 Impedance comparison: Evaluation Board vs. LCR Meter

Bone Type	Avg. % Error
Cow Leg	5.31%
Cow Neck	2.61%
Pig Neck	36.90%

Table 2. Average Percent Error: Evaluation Board vs. LCR Reference

- Impedance measurements were consistently **higher in weight-bearing bone (cow leg) compared to neck samples**, reflecting expected differences in bone structure [4]
- Agreement between the evaluation board and LCR reference was **strongest in higher impedance ranges**
- Measurement error increased substantially in lower impedance samples, due to limitations with the AD5933

POROSITY TESTING

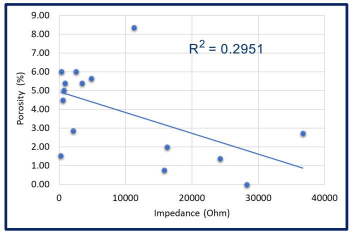


Fig. 6 Porosity vs. Impedance of Animal Bone Samples

$$Porosity = \frac{W_{dry\ bone} - W_{saturated\ bone}}{\rho_{water} * Volume_{bone}}$$

Eq. 1. Porosity Calculation

- Porosity showed a general **inverse relationship with impedance**
- Porosity calculated using mass difference between dry and saturated samples
- **Higher impedance samples corresponded to lower porosity values**
- Variability in porosity measurements may be influenced by residual fat or tissue

HUMAN FACTORS TESTING

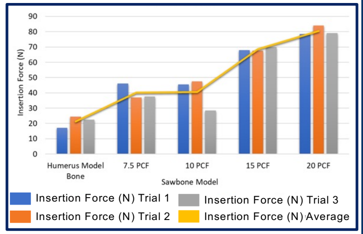


Fig. 7 Insertion Force vs. Bone Density (PCF Sawbone Models)

Metric	Value	Result
% Equipment Variation (Repeatability)	0.32%	Excellent
% Appraiser Variation (Reproducibility)	36.94%	Not Acceptable
%GRR	36.94%	Not Acceptable

Table 3. Gage R&R Metric Values and Analysis

- **Average insertion force increased with bone density**
- Low EV indicates a reliable measurement system, while high AV reflects operator-dependent variation
- Forces ranged from ~20–85 N; within a feasible clinical range [5]
- Probe failure occurred at 340 N (**~4× safety factor**)

FUTURE DESIGN ITERATIONS

- Expand testing across a wider range of bone qualities (including osteoporotic samples)
- Calibrate PCB using human humerus bones with known quality extremes
- Improve probe insertion consistency (depth, angle) via mechanical design (spring mechanism)
- Standardize testing conditions (probe location, temperature, controlled lab environment)
- Conduct further testing to validate the integration and performance of the PCB within the casing

ACKNOWLEDGMENTS

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REFERENCES