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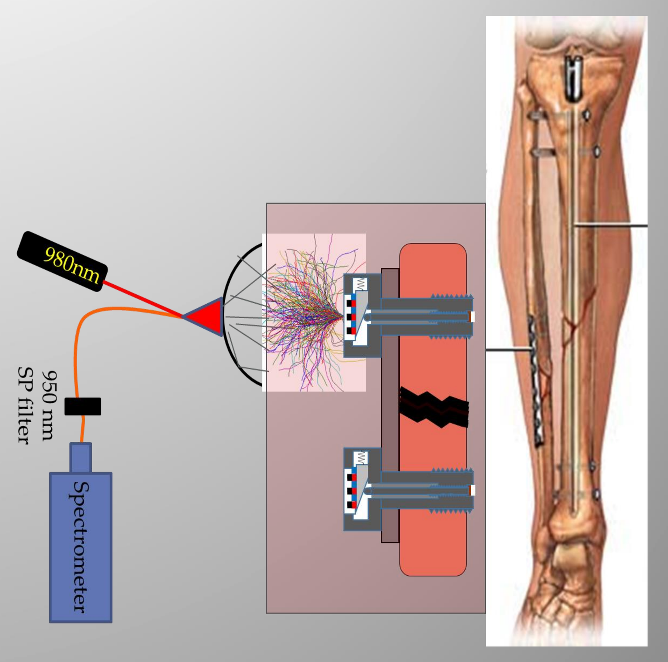
ABSTRACT

Fracture fixation usually involves a combination of mechanical fixation with rods, plates and/or screws which repair slowly and are susceptible to infection. Treatment of large osseous defects use allografts which have failure rates of up to 25%, and complication rates as high as 30-60%. Implant infection and loosening are serious concerns, but can currently only be measured through expensive instrumented implants, biopsy culture, or radiographs. None of these directly quantify implant loading and stability however. There is therefore a need for a simple, cost effective way to quantify implant loading and stability in patients. The purpose of our study is to design and evaluate an optically-based strain measuring orthopaedic screw to quantify the change in strain of the implant *in vivo* after surgery and monitor the load sharing between the bone and the implant. The screw head incorporates a spectral ruler based on Moiré effect which indicates strain. The screw system developed will be able to quantify clinically-relevant bone healing strains in the range of 10-3000μstrains, corresponding to 0.5-150μm change in length for a 5 cm gauge length. Through this work, we will be able to develop a unique portable tool for physicians to quantify bone healing rather than relying on less quantitative assessments based on pain and radiography.

INTRODUCTION

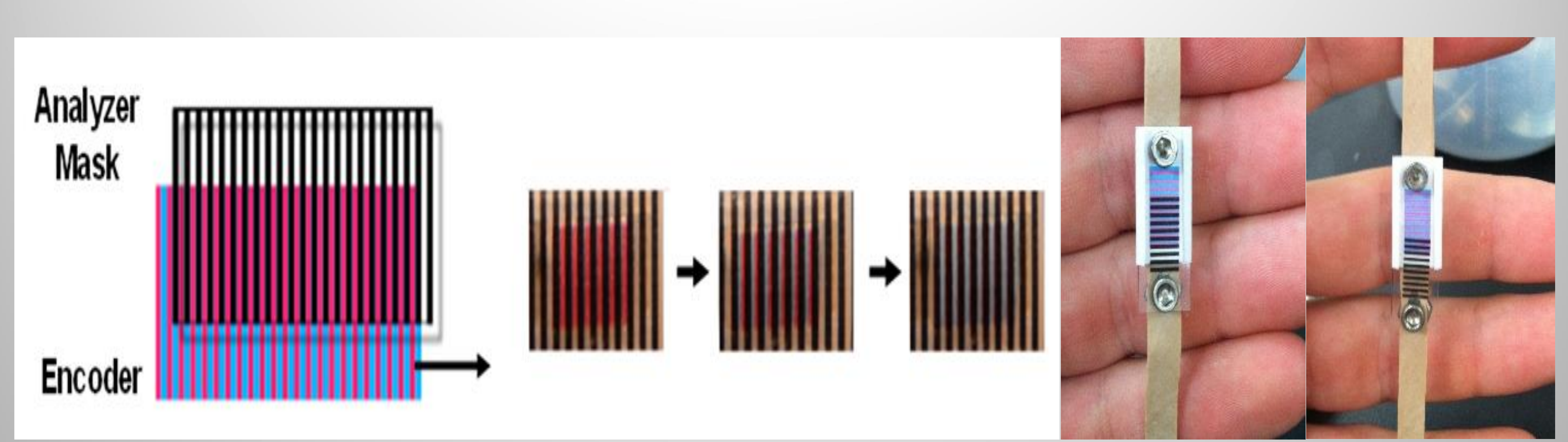
- Over 28 million musculoskeletal injuries are treated annually in the USA, including 2 million fracture fixation implant surgeries[1]
- Limb fractures with large segmental defects are especially challenging to treat and result in high rates of non-union and revision surgeries.
- Apart from bone alignment and stability, mechanical implants share the load with the bone, rather than entirely support the bone.
- Infections often lead to loosening of the implant can and result in failure.
- 5 – 10 % of the surgeries result in implant infection[1]

- The purpose of our study is to quantify the change in strain of the implant *in vivo* after surgery and monitor the load sharing between the bone and the implant.
- This project aims to develop a screw and measurement technique to enable the quantification of clinically-relevant bone healing strains.
  - Spectral rulers based on Moiré effect allow for measurement through tissue to aid in detection of implant loosening.
  - Spectral rulers will be incorporated on to the head of the orthopedic screws.
  - The spectral rulers will enable accurate detection of position with high resolution by incorporation of X-ray Luminescence or Fluorescence.



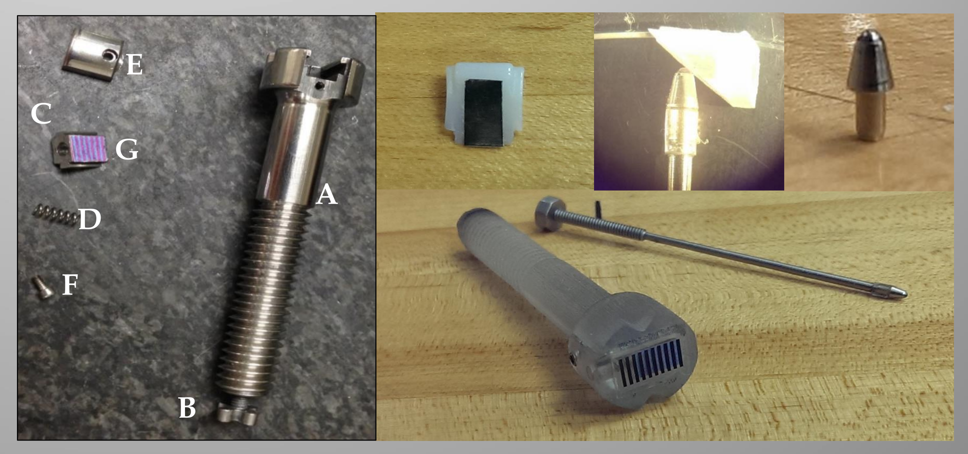
MATERIALS

- Spectral ruler patterns are prepared in Inkscape, a graphics program and printed with either an inkjet or laser printer. They are comprised of two substrates:



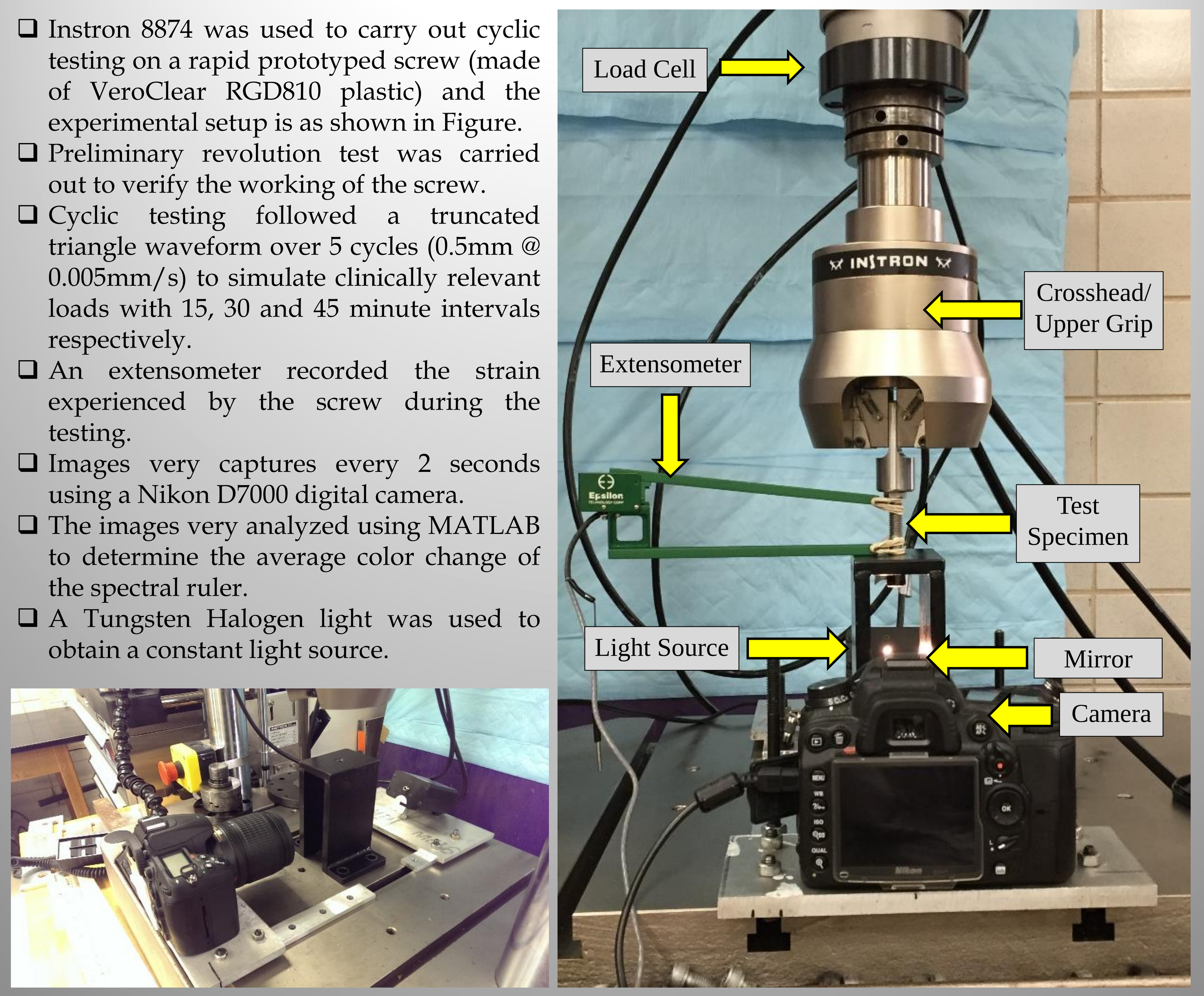
- Modified SS screws and Rapid prototyped screws (VeroClear RGD810 plastic) were used for testing. They are comprised of seven components:

A) 2.5 inch 3/8-16 bolt
B) M3 x 0.5 threaded inner rod
C) Wedge
D) Spring
E) Containing wall
F) 0-80 bolt
G) Spectral ruler

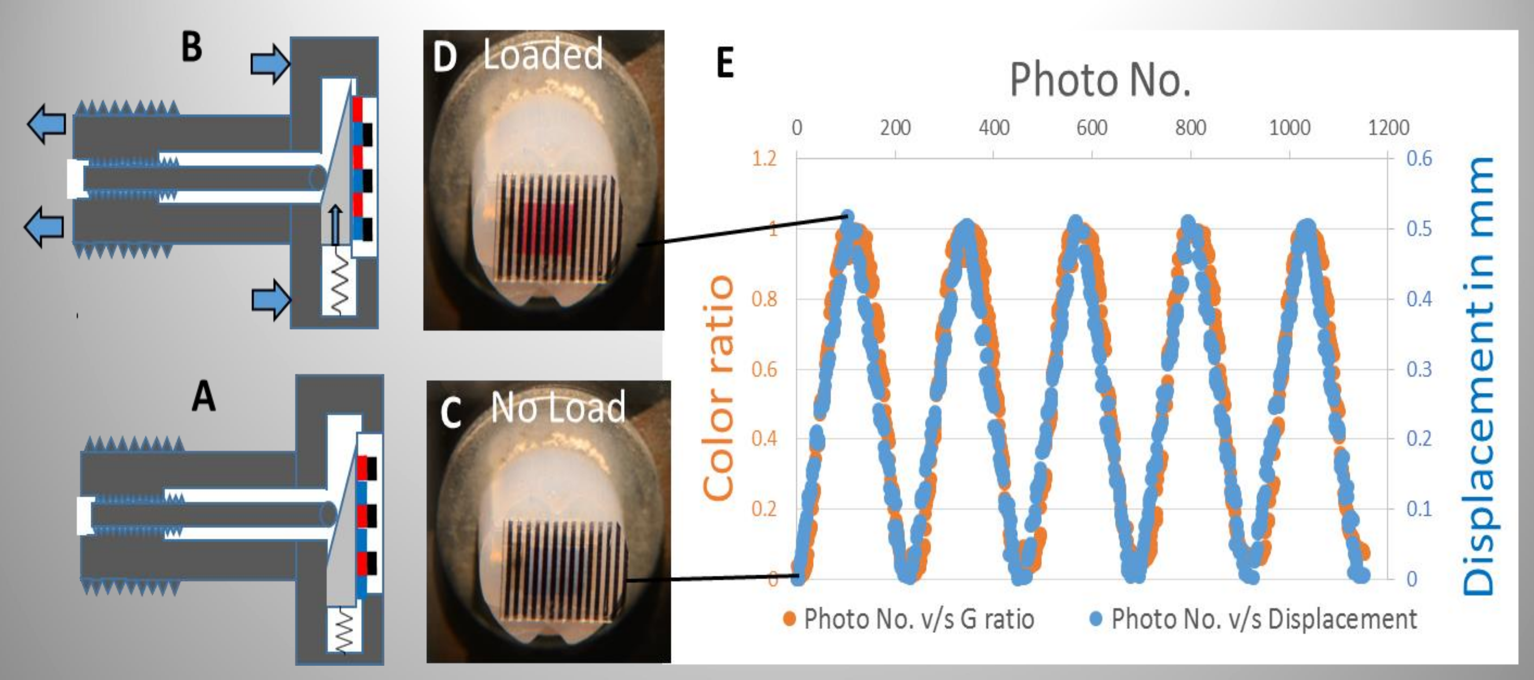


METHODS

- Instron 8874 was used to carry out cyclic testing on a rapid prototyped screw (made of VeroClear RGD810 plastic) and the experimental setup is as shown in Figure.
- Preliminary revolution test was carried out to verify the working of the screw.
- Cyclic testing followed a truncated triangle waveform over 5 cycles (0.5mm @ 0.005mm/s) to simulate clinically relevant loads with 15, 30 and 45 minute intervals respectively.
- An extensometer recorded the strain experienced by the screw during the testing.
- Images very captures every 2 seconds using a Nikon D7000 digital camera.
- The images very analyzed using MATLAB to determine the average color change of the spectral ruler.
- A Tungsten Halogen light was used to obtain a constant light source.



RESULTS



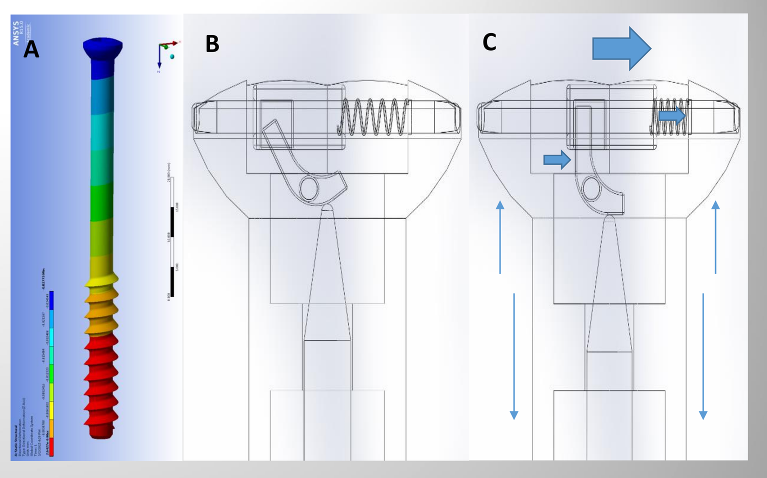
DISCUSSION

- Revolution test results showed that an average color change per 45° revolution was calculated to be approximately 15%.
- Cyclic testing results showed a 16% color change which is very close to the expected theoretical color change of 18%.
- With this approach we can provide a robust, angle independent measurement with a simple, and easily fabricated spectral ruler that can be manufactured with biocompatible materials. It also provides a sensitive, non-invasive, and highly versatile solution based on optical fringes.
- Luminescent spectral rulers have a bromocresol purple patterned dye (encoder) which absorbs a portion of the X-ray scintillator film (analyzer mask) luminescence spectrum in a position-dependent manner to aid in strain measurement through tissue by monitoring color change captured by spectrometer.
- We hypothesize to be able to monitor fracture healing by quantifying the load sharing between the bone and the implant non-invasively with the help of luminescent spectral rulers.

EVOLUTION OF SCREW DESIGN

CONCLUSION AND FUTURE WORK

- It has been demonstrated that strain can be detected optically with our novel spectral rulers fabricated with inkjet and laser printers by monitoring color change captured by digital camera.
- To increase the sensitivity and measure up to 50 micron elongation inside the body, 100 and 50 micron spectral rulers will be used on SS screws.
- Our future work will include miniaturization of the spectral ruler and incorporation of our luminescent sensors in clinically used orthopedic screws for testing.
- The spectral rulers developed can be easily modified to investigate many different biomechanical problems including bone healing with intramedullary nails, orthopedic screw loosening, endodontic osteointegration, tendon repair, intrafragmentary gauges, and muscle atrophy.
- Finite Element Analysis of orthopaedic screws to plot a stress map.



- Prototype 4 design for orthopaedic screws to help obtain mechanical advantage of ~10 and thus improve sensitivity of the spectral rulers.

Through this work, we will be able to develop a unique portable tool for physicians to quantify bone healing rather than relying on less quantitative assessments based on pain and radiography.

ACKNOWLEDGEMENTS

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